Safety of baby diapers

ANSES revised opinion
Collective expert appraisal report
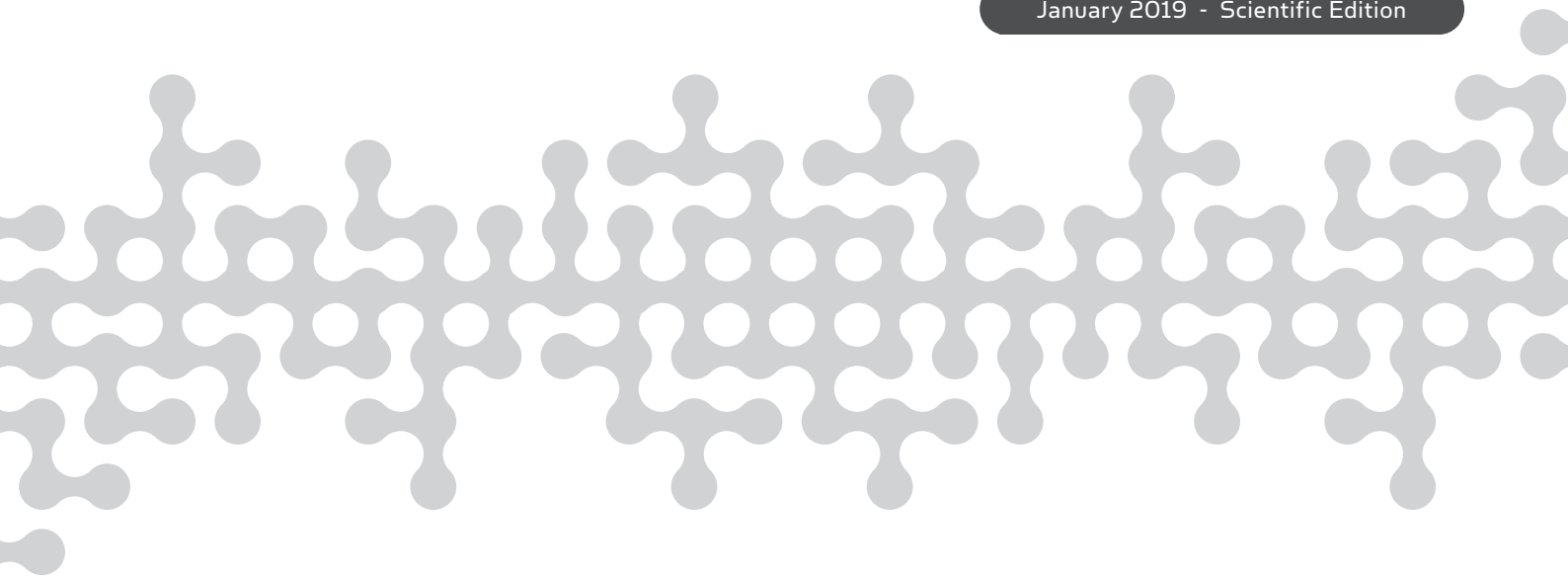
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Collective expert appraisal report

The Director General

Maisons-Alfort, 17 January 2019

Revised OPINION[1]
of the French Agency for Food, Environmental and Occupational Health & Safety

on the safety of baby diapers

ANSES undertakes independent and pluralistic scientific expert assessments.

ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.

It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are published on its website. This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 17 January 2019 shall prevail.

On 25 January 2017, ANSES received a formal request from the Directorate General for Health (DGS), the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) and the Directorate General for Risk Prevention (DGPR) to conduct an expert appraisal on the following issue: the safety of baby diapers.

1. BACKGROUND AND PURPOSE OF THE REQUEST

At European Union (EU) level, baby diapers are subject to the general safety requirement defined by European legislation relating to consumer goods, transposed in the French Consumer Code. There is no regulatory framework specific to baby diapers in France or in the EU. However, there are harmonised regulations applying to other types of products (cosmetic products, medical devices) used in the urogenital area (e.g. incontinence products) that lay down obligations in terms of safety assessments and the listing of ingredients.

In January 2017, a publication in a "popular" magazine relayed in the media reported levels of chemicals (pesticides, dioxins, furans, PAHs and volatile organic compounds) in baby diapers (60 Millions de Consommateurs, 2017).

At the same time, ANSES received a formal request to assess the safety of baby diapers in terms of the risk of infection, allergy or intolerance and/or the risks associated with chemical action via dermal contact and contact with the mucous membranes. ANSES's expert appraisal was requested with the following aims:

1. undertake a chemical risk analysis, especially in the event of exposure through contact in young children (a susceptible population group);

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[1] Cancels and replaces the Opinion of 6 December 2018 (see change history in Annex 1).

2. assess the relevance of defining thresholds for the presence of these substances in diapers, especially regarding hazards (with or without threshold effects) and the duration and mode of exposure;
3. where appropriate, issue recommendations to encourage better control of manufacturing methods, composition and consumer information, particularly at EU level.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

The expert appraisal fell within the sphere of competence of the Expert Committee (CES) on "Assessment of chemical risks of consumer items and products", which met from May 2016 to August 2017, and was then entrusted to the CES on "Assessment of chemical risks of consumer items and products 2". The methodological and scientific aspects of the work were presented to the CESs between May 2016 and November 2018. It was adopted by the CES at its meeting on 15 November 2018.

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.

The experts' declarations of interests are made public via the ANSES website (www.anses.fr).

To obtain the various stakeholders' opinions, a series of hearings took place between April and May 2017 with consumer groups (Federal Union of Consumers - UFC), companies and trade federations (Love & Green, Procter & Gamble, Federation of Trade and Retail Companies - FCD, National Association of the Medical Technology Industry - SNITEM, French grouping of manufacturers of single-use products for hygiene, health and wiping or Group'Hygiène, the EDANA[2] professional federation) and a public body (French National Consumer Institute - INC).

To conduct this expert appraisal, ANSES collected all of the available data from institutional reports and scientific publications relating to the composition and technical properties of materials and the diseases caused by diapers, including dermatitis. The literature search found only a few reports by public bodies and a scarcity of independent scientific publications. Publications written by authors employed by companies selling baby diapers are marked with an asterisk (*) in the expert appraisal report. ANSES also took non-scientific publications into account, including the results of comparative tests carried out by consumer groups, particularly those behind the formal request (60 Millions de Consommateurs, 2016). Lastly, the results of tests commissioned by the DGCCRF in 2017 and 2018 from the Joint Laboratory Service (SCL) wereincorporated into the expert appraisal.

ANSES also held an international consultation in order to collect information dealing with safety assessments of baby diapers, the regulations and public policies or recommendations, the composition of products, chemicals, and studies currently being undertaken on these products.

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[2] The European Disposables And Nonwovens Association or EDANA comprises companies in the nonwoven industry and provides recommendations that member companies undertake to follow.

3. ANALYSIS AND CONCLUSIONS OF THE CES

Since the 1990s, single-use diapers have been used by more than 90% of families in most of the European Union (EDANA, 2011). In France, disposable diapers have been worn by over 95% of babies for almost 20 years (Group'Hygiène, 2015). Estimates of the total number of disposable diapers used by a baby before the age of toilet training range from 3800 to 4800. These estimates vary depending on the age at which it is considered that children are fully toilet trained (between 2.5 and three years old).

The analysis and conclusions of the expert appraisal presented here deal with the following:

- The skin diseases caused by the wearing of diapers,
- The chemical risks:
    o Types of materials used in baby diapers,
    o Chemicals identified in baby diapers and chemical contamination,
    o Quantitative health risk assessment associated with chemicals detected or quantified in single-use baby diapers.

■ **Skin diseases caused by the wearing of diapers**

Diaper dermatitis (diaper rash) is the most common skin disease in infants. There are various forms of diaper dermatitis:

- Irritant dermatitis, the most common form, which can be caused by an increase in skin moisture, a high alkaline skin pH, the mixing of urine and stools, or the mechanical action of friction between the skin and diaper (Scheinfeld, 2005; Runeman, 2008*; Tüzün *et al.*, 2015; Atherton, 2016*; Bender and Faergemann, 2017*),
- Infectious dermatitis (Staphylococci, *Candida albicans)* (Šikić Pogačar *et al.,* 2017),
- Inflammatory dermatitis, a less common form that includes allergic contact dermatitis, which can be caused by certain components of the diaper (Roul *et al.,* 1998; Larralde *et al.,* 2001; Belhadjali *et al.*, 2001; Onken *et al.*, 2011; Jacob *et al.*, 2012; Chiriac *et al.*, 2017; Yu *et al.*, 2016 and 2017).

The prevalence of diaper dermatitis is estimated to be between 7% and 50%, depending on the country and hygiene practices, keeping in mind that many cases are not reported by doctors or parents and heal within a few days without any medical treatment (Klunk *et al.*, 2014). The frequency and severity of diaper dermatitis have decreased over time, primarily thanks to improvements in the performance and models of single-use diapers over the past 30 years. These cases of dermatitis most commonly occur between nine and 12 months of age.

■ **Chemical risks**

The CES first studied the possible chemical risks associated with the types of materials contained in single-use baby diapers. It then undertook a quantitative health risk assessment of the chemicals found in diapers.

    o **Types of materials used in baby diapers**
The data relating to the types of materials used in baby diapers came primarily from manufacturers and trade federations.

Regarding the **composition of baby diapers**, macromolecular materials can be broken down into two main categories:

- Products of natural origin, derived from wood cellulose, which all undergo chemical treatment (bleaching). The exact nature of these cellulose products, which influences their physicochemical properties, was not provided as part of this formal request.
- Synthetic products such as polyolefins (polyethylenes and polypropylenes) and superabsorbent polyacrylates (sodium polyacrylate or SAP-SuperAbsorbent Polymer). There are very different manufacturing processes that provide these polymers with specific properties, but these processes differ by the nature of the polymerisation initiators and/or catalysts, of which traces can be found in the finished material. SAP is contained in all single-use diapers.

It should be noted that the precise nature of the materials with which single-use baby diapers are made could not be determined through the hearings that were held. The same lack of information was noted for the description of processing aids such as glues, and for intentionally added substances (fragrances, inks, etc.).

Nonetheless, certain stages of the manufacturing processes appear to use silica, a percentage of which is in nanoparticle form. The CES reiterates that declaration in the national R-Nano registry is required for any substance with nanoparticle status, whether it is produced, imported or distributed in France, as is, contained in a mixture without being bound to it, or contained in a material intended to release it under normal conditions of use.

- o **Chemicals identified in baby diapers/Chemical contamination**

In 2016, 2017 and 2018, the French National Consumer Institute (INC) and the Joint Laboratory Service (SCL) conducted tests on shredded whole diapers and shredded diaper parts, in order to screen for the presence of chemicals. Solvent extraction was used to extract as many chemicals as possible from 23 products for the INC (2017, 2018) and SCL (2017). The tests were conducted with the best-selling commercial products on the French market, as well as with retailers' own brands and "eco-friendly" diapers.

The following classes of substances were screened for:

- By the INC: pesticides, PAHs, dioxins and furans, fragrances and volatile organic compounds (VOCs), heavy metals, nonylphenol, octylphenol and nonylphenol monoethoxylates,
- By the SCL: pesticides, PAHs, dioxins, furans and DL-PCBs ("dioxin-like" polychlorinated biphenyls), phthalates, organotins, VOCs, fragrances and azoic dyes.

The substances quantified or detected at least once via these tests in single-use baby diapers sold in France were:

- in shredded **whole diapers**:
    - o volatile organic compounds (naphthalene, styrene, toluene, dichlorobenzenes, p-isopropyltoluene, xylenes, chlorobenzene),
    - o pesticides (hexachlorobenzene, quintozene and its metabolite pentachloroaniline, glyphosate and its metabolite AMPA),
    - o formaldehyde,
    - o dioxins, furans and DL-PCBs,

- o fragrances (benzyl alcohol, benzyl salicylate, coumarin, hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyral®), butylphenyl methylpropional (Lilial®), limonene, linalool, alpha-isomethyl ionone);

- in shredded **diaper parts**[3]:
  - o dioxins, furans (in the outer layer, the inner layer and other parts, except the core),
  - o PAHs in the elastics (benzo[b]fluoranthene, benzo[a]anthracene, indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene).

The SCL also carried out **migration tests with whole diapers and shredded whole diapers for single use in a urine simulant**[4]. Dioxins, furans and DL-PCBs, PAHs and formaldehyde were quantified or detected.

Regardless of the test, the detected and/or quantified chemicals were the same overall. However, due to the use of analytical methods of varying precision, for the same diaper product, the same substance could be detected in one test and quantified or not detected in another.

It should be noted that, of the pesticides found in these products, the majority are currently prohibited in the EU (lindane and quintozene since 2000, hexachlorobenzene since 2004), with the exception of glyphosate which is authorised in France and the EU.

According to the data from the literature and the information provided during the hearings, the chemicals detected or quantified in diapers by the SCL or INC are not intentionally added by the manufacturers, with the exception of fragrances. The majority of the chemicals detected or quantified in diapers can either be the result of raw-material contamination (e.g. pesticides) or be formed during manufacturing processes such as bleaching or bonding (e.g. DL-PCBs, furans and dioxins). Today, the cellulose used in these products is no longer bleached by elemental chlorine. However, processes using chlorinated agents such as chlorine dioxide, for example, are used and can be responsible for the formation of dioxins and furans. Regarding the presence of PAHs in single-use diapers, the experts do not rule out PAH formation during the manufacture of these diapers due to the use of high temperatures for certain manufacturing processes (Abdel-Shafy and Mansour, 2016).

Contaminants were found both in "eco-friendly" diaper products and in other diaper products.

- o **Quantitative health risk assessment of substances detected or quantified in single-use baby diapers**

A quantitative health risk assessment (QHRA) was undertaken for the chemicals detected or quantified in baby diapers. The CES used the QHRA approach formalised in 1983 by the US National Research Council (NRC, 1983). This approach is divided into four separate steps: identification of hazards, description of the dose-response relationship, assessment of exposure, and characterisation of risks.

An analysis of uncertainties was carried out during the expert appraisal. It focused on:
- the context and formulation of the question,
- the body of knowledge,

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[3] A diaper part refers to a component considered separately, such as the elastic bands, inner layer, absorbent pad, etc.

[4] The urine simulant consisted of urea, creatinine, ammonium citrate, NaCl, KCl, $KHSO_4$, $MgSO_4$, $KH2PO_4$ and $KHCO_3$ in water (Colon *et al.*, 2015).

- the method of assessing health risks via the identification of hazards, choice of toxicity reference values (TRVs), estimation of exposure and characterisation of risks.

The QHRA was based on the various analyses undertaken by the SCL and the INC:
- Solvent extractions in shredded whole diapers or diaper parts (SCL, 2017; INC, 2017 and 2018; Group'Hygiène, 2018[5]),
- Extractions with a urine simulant in shredded whole diapers (SCL, 2017),
- Extractions with various urine simulants in whole diapers (SCL, 2018; Group'Hygiène, 2018[6]).

The QHRA was first undertaken using a "worst-case" scenario in order to rapidly eliminate substances posing no health risks. In cases when the TRV was exceeded, a "realistic" approach (a scenario whose parameters intend to replicate the actual conditions of use commonly encountered) was implemented.

▪ **Hazard identification**

As part of its hazard identification approach, the CES investigated whether the substances found in diapers were covered by harmonised classifications according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) and according to the carcinogenicity classification of the International Agency for Research on Cancer (IARC).
In light of the proximity of these products to the reproductive organs, the CES also consulted classifications and databases with the aim of identifying potential endocrine-disrupting (ED) effects[7].

▪ **Description of the dose-response relationship**

A toxicity reference value (TRV) is a toxicological index that, when compared with exposure, is used to qualify or quantify a risk to human health. A distinction is made between "threshold" TRVs, used for substances that, above a certain dose, cause damage whose severity is proportional to the absorbed dose (direct non-genotoxic carcinogenic and non-carcinogenic effects); and "no-threshold" TRVs, or excess risk per unit (ERU), used for substances for which direct genotoxic or carcinogenic effects can appear irrespective of the dose received and the likelihood of their occurrence. These TRVs are defined as an increase in the likelihood, compared to an unexposed subject, of an individual developing the disease if he/she is exposed over his/her entire lifetime to a unit dose of the substance.

At first, for each chemical, the TRVs established by national, European and international agencies were identified, with a focus on those developed for a chronic duration of exposure (repeated and/or long-term exposure, generally associated with low or moderate dose levels), the parameter regarded as most relevant in view of the context of the formal request. Considering the close contact of baby diapers with the buttocks, the use of dermal TRVs seemed the most appropriate. However, since no TRVs were available for this route of exposure, a search for TRVs by the oral route was carried out.

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[5] Confidential tests

[6] Confidential tests

[7] Classifications of the European Commission (BKH, 2000 and 2002; DHI, 2007), the US EPA and the Illinois EPA and inclusion on the TEDX (The Endocrine Disruption Exchange Inc) and SIN (Substitute It Now) lists.

For PAHs and dioxins and furans, only the TRVs for the reference compound[8] were identified, namely benzo[a]pyrene and 2,3,7,8-tetrachlorodibenzo-para-dioxin or TCDD (the most toxic congener). The toxicity of other compounds in the same class was estimated from toxic equivalency factors (TEFs) used to express the toxicity of all congeners with the same toxicological mechanism of action compared to that of the leader.

When there was no TRV (p-isopropyltoluene, benzyl salicylate, butylphenyl methylpropional or Lilial®, hydroxyisohexyl 3-cyclohexene carboxaldehyde or Lyral®, alpha-isomethyl ionone), the critical doses selected by national, European and international agencies were identified and a critical dose was selected.

The experts considered that the TRVs apply to the entire population regardless of age, including children. If there are data showing that children are more susceptible than adults to the effects of certain substances, these must be taken into account in the establishment of the TRV (ANSES, 2017). First using a worst-case approach, the CES considered, by default, that the TRVs applied to children between 0 and 36 months of age, and the most disadvantageous TRV was used regardless of how it had been established.

Then, whenever the risk analysis undertaken according to the "worst-case" scenario found the TRV to have been exceeded, the experts decided to conduct a more detailed analysis of the TRV considering the relevance of the choices made (critical effect, key study, critical dose, uncertainty factors) and the transparency of the manner in which it had been established (Annex 2).

The experts discussed the applicability of the selected TRVs to the population of children aged 0 to 36 months, who can be particularly susceptible to certain chemicals. The CES thus chose the approach used for the infant Total Diet Study (iTDS, 0-36 months) (ANSES, 2016b) and the QHRA on the mouthing of plastic toys containing phthalate substitutes (ANSES, 2016). The CES therefore reviewed the toxicological data specific to children taken into account in the establishment of each of these TRVs (studies of perinatal and postnatal toxicity, studies of developmental toxicity, reproductive studies conducted with several generations, etc.).

- **Exposure assessment**

Refined exposure scenarios were developed in order to characterise the exposure of children between 0 and 36 months of age inclusive to the chemicals previously identified in baby diapers. The dermal route of exposure was the one taken into account in this assessment, and more specifically exposure via the buttocks.

The daily exposure dose (DED, expressed in mg/kg/day) was calculated using a deterministic approach according to the following formula:

For solvent extractions (shredded whole diapers or diaper parts)
$$DED = (C_{shredded\ material} \times W \times F \times T \times Abs) / BW \text{ [scenario 1]}$$

For extractions in shredded diapers with a urine simulant:
$$DED = (C_{shredded\text{-}material\ simulant} \times W \times F \times R \times Abs) / BW \text{ [scenario 2.1]}$$

For extractions in whole diapers with a urine simulant:
$$DED = (C_{diaper\ simulant} \times W \times F \times Abs) / BW \text{ [scenario 2.2]}$$

Where DED: daily exposure dose (mg/kg/day)

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[8] Reference congeners with the highest toxicity.

$C_{shredded\ material}$: concentration of the chemical extracted with a solvent from shredded whole diapers and diaper parts (mg/kg of diaper)

$C_{shredded\text{-}material\ simulant}$: concentration of the chemical extracted with a urine simulant from shredded whole diapers (mg/kg of diaper)

$C_{diaper\ simulant}$: concentration of the chemical extracted with a urine simulant from a whole diaper, in relation to the weight of the diaper taking into account the extracted simulant volume (mg/kg of diaper)

W: average weight of a diaper or of the diaper part (kg)

F: frequency of use (number/day)

T: transfer to skin (%)

R: reflux ratio (%[9])

Abs: fraction absorbed by the skin (%)

BW: body weight of a child (kg)

It should be noted that the DED that seemed the most realistic from these various analyses was that calculated from the extractions in whole diapers with a urine simulant (scenario 2.2), since:
- the capacity to extract substances from diapers to urine was not modelled but was observed during the experiment. This avoided the need to use the default skin transfer value T of 7%;
- quantities of substances were only measured in urine actually coming out of the diapers after pressing, which avoided the need to use the modelled reflux ratio R parameter.

The CES used the following values for each exposure parameter to calculate the DED according to a "worst-case" scenario and subsequently using a "refined" approach (Table 1).

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[9] The reflux ratio corresponds to the transfer of the substance into body fluids by extraction or solubilisation, followed by migration to the surface layer and release onto the skin under pressure.

Table 1: Summary of the parameters used to assess exposure according to the worst-case scenario and the refined scenario

Parameter	Worst-case scenario	Refined scenario		
Concentration (mg/kg)	For quantified substances: highest concentration in each diaper For detected substances: LoQ (SCL, 2016 and 2018; INC, 2016 and 2018)	For quantified substances: highest concentration in each diaper For detected substances: LoQ/2 (SCL, 2016 and 2018; INC, 2016 and 2018)		
Weight of a diaper (W) (g)	24 g (size 1) (Krause *et al.,* 2006*; Rai *et al.,* 2009)	0-6 months exclusive	24 g	Krause *et al.* (2006)* Rai *et al.* (2009)*
		6-12 months inclusive	33 g	
		13-18 months inclusive	33 g	
		19-24 months inclusive	40 g	
		25-30 months inclusive	40 g	
		31-36 months inclusive	45 g	
Frequency of use (F) (number of diapers per 24 hrs)	12/day (Ishii *et al.*, 2015)	0-6 months exclusive	7.98	UK Environment Agency, 2005 (average daytime frequency + one diaper/night)
		6-12 months inclusive	6.66	
		13-18 months inclusive	6.75	
		19-24 months inclusive	5.95	
		25-30 months inclusive	5.85	
		31-36 months inclusive	4.7	
Transfer of the substance to the skin (T)	100%	7% (Odio *et al.,* 2000)*		
Dermal absorption (Abs)	100% (ANSM, 2010)			
Reflux ratio (R)	100%	1.32% (Dey *et al.,* 2016)* for scenario 2.1		
Body weight (BW) (kg)	2.6 kg (SFAE, 2013)	0-6 months exclusive	3.9 kg	(SFAE, 2013)
		6-12 months inclusive	7 kg	
		13-18 months inclusive	8.4 kg	
		19-24 months	9.2 kg	
		25-30 months inclusive	10 kg	
		31-36 months inclusive	11.4 kg	

For the refined scenarios, the experts underline that for the skin transfer and reflux ratio parameters, the only available data were those published in the literature by manufacturers.

Regarding dermal absorption, the experts chose to retain the value used for the worst-case scenario (100%), considering that diaper dermatitis could not be reasonably excluded and that it was likely to impact the dermal absorption of the chemicals.

Characterisation of risks (see Annex 3)

Regarding risk characterisation, depending on the type of effect:
- a hazard quotient (HQ) was calculated for substances with a threshold effect,
- an Individual Excess Risk (IER) was calculated for substances with a no-threshold effect (carcinogenic effect). In this study, the acceptable risk was set at 10^{-6}, the most conservative value.

Threshold effects	HQ < 0.1	0.1 < HQ < 1	HQ > 1
	No toxic effects are expected in the exposed population.	It is necessary to ensure that there are no other concomitant sources of exposure, to not risk exceeding the TRV by combining intakes from all the sources of exposure to these substances.	The occurrence of a risk cannot be ruled out, although it is not possible to predict its likelihood of occurrence in the exposed population.
No-threshold effects	IER < 10^{-7}	10^{-7} < IER < 10^{-6}	IER > 10^{-6}
	The number of expected cancer cases is less than one out of 10 million exposed people.	The number of expected cancer cases is between one out of one million and one out of 10 million exposed people.	The number of expected cancer cases is greater than one out of one million exposed people.

For substances for which no TRV could be identified, the CES calculated a margin of exposure (MOE[10]).

Regarding the substances measured by **solvent extraction in shredded whole diapers (scenario 1)**, a risk calculation was undertaken using a refined scenario for all fragrances, dioxins, furans and DL-PCBs and their sums, as well as for three VOCs[11] and hexachlorobenzene.
It showed cases in which the health threshold was exceeded for infants aged 0-12 months inclusive, for two fragrances (hydroxyisohexyl 3-cyclohexene carboxaldehyde or Lyral® and butylphenyl methylpropional or Lilial®) detected in one of the diaper products out of the 19 analysed.

Regarding the substances quantified by **solvent extraction in certain diaper parts**[12] **(scenario 1)**, no cases of the health threshold being exceeded were found for PAHs or for 2,3,4,6,7,8 HxCDF, for children aged 0 to 36 months.

Regarding dioxins, furans and DL-PCBs and their sums found by **extraction with a urine simulant in shredded whole diapers (scenario 2.1)**, a risk calculation was undertaken according to a refined scenario. It did not show any cases of the health threshold being exceeded for children aged 0 to 36 months.

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[10] The MOE was calculated as the ratio of the No Observed Adverse Effect Level in animals to the value of the daily exposure dose: MOE = Critical dose / DED
[11] 1,2,3-trichlorobenzene; 1,2,4-trichlorobenzene; 1,3,5-trimethylbenzene
[12] Plastic parts and outer layer

Regarding the substances found by **extraction with a urine simulant in whole diapers (scenario 2.2)**, a risk calculation was undertaken according to a refined scenario for 10 detected PAHs[13], formaldehyde, PCB-126, the sum of dioxins and furans, the sum of DL-PCBs and the sum of dioxins, furans and DL-PCBs[14], which were quantified. It highlighted the following, for children aged 0 to 36 months:

- cases in which the risk indicator (no-threshold carcinogenic effects) was exceeded for the 10 PAHs (benzo[g,h,i]perylene, benzo[b]fluoranthene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene);
- cases in which the health threshold[15] (threshold effects) was exceeded for six PAHs (benzo[b]fluoranthene, cyclopenta[c,d]pyrene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[a]pyrene, dibenzo[a,h]anthracene) and for PCB-126, the sum of DL-PCBs, and the sum of dioxins, furans and DL-PCBs.

The results of the above exposure calculations were limited to exposure related to baby diapers, excluding other possible exposure sources (environmental, dietary, consumer products). The possibility of cumulative exposure through various exposure routes leading to an increase in the estimated risks could not be ruled out, especially for substances found in baby diapers whose HQ was between 0.1 and 1 or whose IER was around 10^{-7} (orange column), such as:
- dioxins,
- furans,
- DL-PCBs,
- PAHs (benzo[g,h,i]perylene, chrysene, 5-methylchrysene, benzo[e]pyrene),
- some VOCs (1,2,4 trichlorobenzene and 1,2,3 trichlorobenzene),
- hexachlorobenzene,
- fragrances (coumarin, limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyral®), butylphenyl methylpropional (Lilial®), benzyl salicylate),
- formaldehyde.

Dioxins, furans, DL-PCBs and PAHs are ubiquitous substances that can be found, for example, in food and particularly in breast milk.

The risk calculations performed did not take endocrine-disrupting or skin-sensitising effects into account. However, a number of the substances are possible EDs[16] or are classified as known or suspected skin sensitisers[17]. These skin-sensitising effects were confirmed by data from the literature.

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[13] For detected substances, the concentration used in the risk calculations was the value LQ/2.

[14] Classifications of these substances and sector-specific regulations are available in Annex 5.

[15] TRVs established based on developmental effects for PAHs and reprotoxic and developmental effects for dioxins, furans and DL-PCBs (Annex 1)

[16] Naphthalene, styrene, toluene, 1,4-and 1,3-dichlorobenzene, m-xylene + p-xylene, hexachlorobenzene, quintozene, glyphosate, benzyl salicylate, Lilial, PAHs, dioxins, furans and DL-PCBs (BKH, DHI, SIN List, TEDX List); note that these classifications were not analysed by ANSES as part of this expert appraisal.

[17] BaP, formaldehyde, quintozene, linalool, limonene and Lyral® classified as skin sensitisers according to the CLP Regulation; 1,2,3 trichlorobenzene, Lilial®, alpha-isomethyl ionone, benzyl salicylate and coumarin self-classified under the REACh Regulation

■ **Conclusions**

There are no epidemiological data demonstrating an association between health effects and the wearing of diapers. However, hazardous chemicals have been found in these diapers. Based on the results of the INC and SCL tests and the literature data, a quantitative health risk assessment was undertaken for single-use baby diapers according to refined scenarios considered to be realistic. This QHRA showed cases of the health thresholds being exceeded for several substances. Therefore, to date and in the current state of knowledge, it is not possible to rule out a health risk associated with the wearing of single-use diapers.

■ **Recommendations**

On the basis of the above conclusions, the CES is issuing the following recommendations:

Recommendations for the public authorities:

- Regarding the regulatory framework

The existing regulatory system governing the composition, use and manufacture of single-use diapers as defined in the General Product Safety Directive is insufficient, due to the presence of hazardous chemicals in these products. The CES recommends developing a more stringent regulatory framework to limit the presence of these substances. This regulatory framework could involve a restriction procedure for each type of product according to the REACh Regulation (Annex XVII). The substances quantified or detected in this expert appraisal could be used as a basis for a list of substances to be included in this regulatory measure.

- Regarding the monitoring of hazardous chemicals in single-use diapers

The CES recommends pursuing measurement campaigns for all products on the market, according to the protocol used by the SCL in 2018 (extraction with a urine simulant from a whole single-use diaper), in order to ensure that the conclusions and recommendations of this Opinion intended for manufacturers and companies marketing products are taken into account.

Recommendations for manufacturers and companies marketing products regarding the composition of single-use diapers and the chemical risks:

- Since the health thresholds were observed to be exceeded in this study, the CES recommends eliminating the use of all fragrances, especially those likely to have skin-sensitising effects.

- The CES recommends better controlling the origin of natural raw materials that can become contaminated even before manufacture (need to develop and enforce more stringent specifications, for example).

- The CES recommends improving diaper manufacturing processes in order to reduce as far as possible the presence of hazardous chemicals, such as dioxins, furans, DL-PCBs, formaldehyde and PAHs, in the materials used in single-use baby diapers. To limit chlorinated dioxins and furans, the bleaching phases for materials could be undertaken without any chlorinated agents (such as chlorine dioxide, sodium or calcium hypochlorite, etc.). Techniques are available to achieve this, such as the use of dioxygen and hydrogen peroxide.

- Pending changes to the regulations, the CES recommends setting a maximum concentration not to be exceeded for each chlorinated dioxin and furan and DL-PCB congener that would be of the same order of magnitude as the limit of quantification. Initially, the lowest LQ used in this expert appraisal (around 0.02 ng/kg) could be proposed. This value is not a health threshold.

Recommendations regarding the acquisition of knowledge:

In order to be capable of assessing the risks posed by hazardous substances intentionally added by manufacturers and those associated with contaminants found in these products, the CES recommends:

- conducting studies to obtain substantiated scientific information on the transfer of substances from the material to the skin/mucous membranes;

- developing TRVs for the mucocutaneous route, which currently does not have any;

- developing more realistic experimental protocols conducted with the urine of babies wearing single-use diapers.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

This expert appraisal sought to assess the safety of baby diapers in terms of the risk of infection, allergy or intolerance and/or the risks associated with chemical action via dermal contact and contact with the mucous membranes. To do so, ANSES undertook a four-phase study:

- study of the composition of these products,

- identification of the regulated or non-regulated chemicals of concern liable to be present in baby diapers,

- review of knowledge on the hazards presented by these substances,

- quantitative health risk assessment (QHRA) for these substances.

The French Agency for Food, Environmental and Occupational Health & Safety endorses the CES's conclusions and recommendations.

Analyses and tests involving 23 single-use baby diaper products available on the market were undertaken by the Joint Laboratories Service (SCL) and the French National Consumer Institute (INC). The analysis results highlighted the presence of chemicals, including some intentionally added substances such as fragrances that can have a skin-sensitising effect. Other substances detected or quantified in diapers seem to be due to contamination of the raw materials or manufacturing processes. The most notable of these are undesirable substances including PAHs, dioxins, furans and DL-PCBs, pesticides, formaldehyde and volatile organic compounds (VOCs).

Based on the results of the analyses and the various test protocols, ANSES undertook a quantitative health risk assessment of dermal exposure and concluded that a risk could not be ruled out for the following undesirable substances in baby diapers: two fragrances (butylphenyl methylpropional or Lilial®, hydroxyisohexyl 3-cyclohexene carboxaldehyde or Lyral®), certain PAHs, PCB-126 and the sum of dioxins, furans and DL-PCBs. No cases of the health thresholds being exceeded were observed for other fragrances, prohibited pesticides, glyphosate or its metabolite, VOCs or formaldehyde (Annex 5).

The quantitative risk assessment undertaken was supplemented by an analysis of the sources of uncertainty and their impact on the results, and the Agency considers that all of the assumptions have reasonably amplifying effects.

Moreover, ANSES underlines that there are other potential sources of exposure to these substances in children aged 0 to 36 months; the presence of some of these has been documented, in the infant Total Diet Study in particular (ANSES, 2016). The possibility of cumulative exposure via various routes leading to an increase in the risks assessed in this expert appraisal therefore cannot be ruled out, especially for dioxins, furans, DL-PCBs, PAHs, VOCs, certain pesticides, and formaldehyde.

As a result, ANSES recommends eliminating or reducing as much as possible the presence of these various undesirable substances and classes of substances in baby diapers by applying the ALARA[18] principle.

To that end, ANSES recommends, especially in the short term, using regulatory tools (changes in the French and European regulatory frameworks via the REACh Regulation) to limit the presence of these various undesirable substances and classes of substances in baby diapers. ANSES also recommends conducting campaigns to monitor these undesirable substances and classes of substances in all of the disposable baby diapers available on the market in order to ensure that the conclusions and recommendations of this Opinion are taken into account by manufacturers and companies marketing products.

In addition, ANSES underlines the need to develop studies to better characterise the skin transfer and absorption of chemicals to achieve more robust results.

Dr Roger Genet

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[18] As Low As Reasonably Achievable

ANNEE 1 : REVISED ANNEX FOLLOW UP

Date	Page(s)	Modification Description
08/01/2019		Typology, layout and spelling
08/01/2019	9	Table 1 : addition of acronyms for each parameter and removal of « 100% for scenario 1 » regarding the reflux ration in refined scenario
08/01/2019	11	Changes of wording between de « exceedances of the health threshold related to non-threshold effects (carcinogenic effects) in "cases in which the risk indicator (no-threshold carcinogenic effects) was exceeded »
08/01/2019	11	Footnote 16 , addition of « these classifications were not analysed by ANSES as part of this expert appraisal »
08/01/2019	14	ALARA definition added in footnote

ANNEXE 2 : TRV WITH OR WITHOUT THRESHOLD AND CRITICAL DOSES SYNTHESIS TAKEN INTO ACCOUNT FOR THE QRA BASED ON A REALISTIC SCENARIO

Threshol TRVs and critical doses synthesis used in the QRA bases on a realistic scenario

Chemicals	TRVs	Organism (year)	TRV or NOAEL	Target organ/Critical effect
VOC				
1,2,3 trichlorobenzene	Chronic	RIVM (2001)	8.10^{-3} mg/kg/d	↑ significant relative liver weight and mild to moderate histopathological changes in the liver, kidneys and thyroid
1,2,4 trichlorobenzene	Chronic	ATSDR (2014)	0.1 mg/kg/d	Hepatocellular hypertrophy in males
1,3,5 trimethylbenzene	Chronic	US EPA (2016)	0.01mg/kg/d	neurotoxicity
Pesticides				
Hexachlorobenzene	Chronic	ASTDR (2015)	7.10^{-5} mg/kg/d	Hepatotoxicity
Dioxins andFurans + DL- PCB-				
2,3,7,8 TCDD → TEF applied for dioxins,furans and DL-PCB	Chronic	US EPA (2012)	0.7 pg/kg/d	Reprotoxicity and developmental toxicity
PAH				
Benzo[a]pyren → TEF applied for PAH	Chronic	US EPA (2017)	3.10^{-4} mg/kg/d	Developmental toxicity
Formaldehyde				
Formaldehyde	Chronic	OMS-IPCS (2005)	0.15 mg/kg/d	Stomach irritations and nephrotoxicity
Fragrances				
Benzyl alcohol	Chronic	EFSA (2011)	≤ 5 mg/kg/d	No reprotoxicity, teratogenicity and cancerogenicity
Coumarin	Chronic	EFSA (2008)	< 0.1 mg/kg	Hepatotoxicity
Limonen	Chronic	EFSA (2012)	0.1 mg/kg/d	Hepatotoxicity
Linalol	Chronic	JECFA (1998)	< 5 mg/kg/d	No effect
Butylphenyl methyl propional (lilial®)	Chronic	SCCS (2016)	NOAEL = 5 mg/kg/d	Systemic effects and maternal toxicity
Hydroxyisohexyl 3-cyclohexene carboxaldéhyd (lyral®)	Chronic	SCCS (2011)	NOAEL = 15 mg/kg/d	Hepatotoxicity
Alpha-isomethyl ionone	Chronic	Belsito *et al.* (2007)	NOAEL = 50 mg/kg/d	Systemic effects
Benzyl salicylate	Chronic	US EPA (2010)	NOAEL = 50 mg/kg/d	Hepatotoxicity (Dog) and bone effects (rat)

No-threshold TRV synthesis used for QRA based on a realistic scenario

Chemicals	Organism (year)	Value	Target organ/critical effect
1,2,4 trichlorobenzene	OEHHA (1999)	$3.6.10^{-3}$ (mg/kg/d)$^{-1}$	Hepatocellular carcinoma
Pesticides			
Hexachlorobenzene	OEHHA (2011)	1.8 mg (mg/kg/d)$^{-1}$	Liver tumor
PAH			
Benzo[a]pyrene → TEF applied for PAH	US EPA (2017)	1 (mg/kg/d)$^{-1}$	Gastrointestinal tumor

ANNEXE 3 : QRA RESULTS SYNTHESIS BASED ON A REALISTIC APPROACH ACCORDING TO THE VARIOUS ANALYSIS

Threshold effects	HQ < 0,1	0,1 < HQ < 1	HQ >1
No threshold effect	IER < 10^{-7}	10^{-7} < IER < 10^{-6}	IER > 10^{-6}

Scenarios		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	Ages	Solvent extraction					Urine simulant			
		Whole diaper shredded		Diaper parts shredded			Whole diaper shredded		Whole diaper	
		INC, 2017 et 2018 ; SCL, 2017		INC, 2017 ; SCL, 2017			SCL, 2017		SCL, 2018	
		HQ	IER	Part	HQ	IER	HQ	IER	HQ	IER
Pesticides										
Hexachlorobenzene	0-6 months exclusive	$9.82.10^{-2}$	$8.84.10^{-8}$							
	6-12 months inclusive	$6.28.10^{-2}$	$1.13.10^{-7}$							
	13-18 months inclusive	$5.30.10^{-2}$	$1,43.10^{-7}$							
	19-24 months inclusive	$5.17.10^{-2}$	$1.86.10^{-7}$							
	25-30 months inclusive	$4.68.10^{-2}$	$2.,11.10^{-7}$							
	31-36 months inclusive	$3.71.10^{-2}$	$2.00.10^{-7}$							
Formaldehyde										
Formaldehyde	0-6 months exclusive	$2.57.10^{-2}$					Threshold carcinogen		0.9	
	6-12 months inclusive	$1.64.10^{-2}$							0.58	
	13-18 months inclusive	$1.39.10^{-2}$							0.49	
	19-24 months inclusive	$1.35.10^{-2}$							0.47	
	25-30 months inclusive	$1.23.10^{-2}$							0.43	
	31-36 months inclusive	$9.71.10^{-3}$							0.34	

HQ : Hazard quotient; IER : Indivial Excess Risk; MOEref/MOE : reference marge of exposure/marge of exposure

Scenarios		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	Ages	Solvent extraction					Urine simulant			
		Whole diaper shredded		Diaper parts shredded			Whole diaper shredded		Whole diaper	
		INC, 2017 et 2018 ; SCL, 2017		INC, 2017 ; SCL, 2017			SCL, 2017		SCL, 2018	
		HQ	IER	Parts	HQ	IER	HQ	IER	HQ	IER
PAH										
Benzo[g,h,i]perylene	0-6 months exclusive				$2.86.10^{-7}$	$6.14.10^{-12}$			0.68	$1.47.10^{-5}$
	6-12 months inclusive				$1.83.10^{-6}$	$7.85.10^{-11}$			0.44	$1.87.10^{-5}$
	13-18 months inclusive				$1.55.10^{-6}$	$9.94.10^{-11}$			0.37	$2.38.10^{-5}$
	19-24 months inclusive				$1.51.10^{-6}$	$1.29.10^{-10}$			0.36	$3.09.10^{-5}$
	25-30 months inclusive				$1.37.10^{-6}$	$1.26.10^{-10}$			0.33	$3.00.10^{-5}$
	31-36 months inclusive				$1.08.10^{-6}$	$6.63.10^{-10}$			0.26	$2.55.10^{-5}$
Benzo[b]fluoranthene	0-6 months exclusive				$2.86.10^{-6}$	$6.14.10^{-11}$			6.24	$1.34.10^{-4}$
	6-12 months inclusive				$1.83.10^{-5}$	$7.85.10^{-10}$			3.99	$1.71.10^{-4}$
	13-18 months inclusive				$1.55.10^{-5}$	$9.94.10^{-10}$			3.37	$2.17.10^{-4}$
	19-24 months inclusive				$1.51.10^{-5}$	$1.29.10^{-9}$			3.29	$2.82.10^{-4}$
	25-30 months inclusive				$1.37.10^{-5}$	$1.26.10^{-9}$			2.97	$2.74.10^{-4}$
	31-36 months inclusive			Elastic parts	$1.08.10^{-5}$	$1.07.10^{-9}$			2.36	$2.32.10^{-4}$
Benzo[a]anthracene	0-6 months exclusive				$2.86.10^{-5}$	$6.14.10^{-11}$				
	6-12 months inclusive				$1.83.10^{-4}$	$7.85.10^{-10}$				
	13-18 months inclusive				$1.55.10^{-4}$	$9.94.10^{-10}$				
	19-24 months inclusive				$1.51.10^{-4}$	$1.29.10^{-9}$				
	25-30 months inclusive				$1.37.10^{-4}$	$1.26.10^{-9}$				
	31-36 months inclusive				$6.88.10^{-5}$	$1.07.10^{-9}$				
Indeno[1,2,3-c,d]pyrene	0-6 months exclusive				$4.40.10^{-4}$	$1.47.10^{-9}$				
	6-12 months inclusive				$3.71.10^{-4}$	$1.88.10^{-8}$				
	13-18 months inclusive				$3.62.10^{-4}$	$2.39.10^{-8}$				
	19-24 months inclusive				$3.28.10^{-4}$	$3.10.10^{-8}$				
	25-30 months inclusive				$2.60.10^{-4}$	$3.02.10^{-8}$				
	31-36 months inclusive				$6.88.10^{-5}$	$2.56.10^{-8}$				
Cyclopenta[c,d]pyrene	0-6 months exclusive								5.10	$1.09.10^{-4}$
	6-12 months inclusive								3.26	$1.40.10^{-4}$
	13-18 months inclusive								2.75	$1.77.10^{-4}$
	19-24 months inclusive								2.69	$2.30.10^{-4}$
	25-30 months inclusive								2.43	$2.24.10^{-4}$
	31-36 months inclusive								1.93	$1.90.10^{-4}$

Scenarios		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	Ages	Solvent extraction					Urine simulant			
		Whole diaper shredded		Diaper parts shredded			Whole diaper shredded		Whole diaper	
		INC, 2017 et 2018 ; SCL, 2017		INC, 2017 ; SCL, 2017			SCL, 2017		SCL, 2018	
		HQ	IER	Part	HQ	IER	HQ	IER	HQ	IER
Chrysene	0-6 months exclusive								0.41	$8.75.10^{-6}$
	6-12 months inclusive								0.26	$1.12.10^{-5}$
	13-18 months inclusive								20.22	$1.42.10^{-5}$
	19-24 months inclusive								0.22	$1.84.10^{-5}$
	25-30 months inclusive								0.19	$1.79.10^{-5}$
	31-36 months inclusive								0.15	$1.52.10^{-5}$
5-methyl chrysene	0-6 months exclusive								0.51	$1.09.10^{-5}$
	6-12 months inclusive								0.33	$1.40.10^{-5}$
	13-18 months inclusive								0.28	$1.77.10^{-5}$
	19-24 months inclusive								0.27	$2.30.10^{-5}$
	25-30 months inclusive								0.24	$2.24.10^{-5}$
	31-36 months inclusive								0.19	$1.90.10^{-5}$
Benzo[k]fluoranthene	0-6 months exclusive								6.03	$1.29.10^{-4}$
	6-12 months inclusive								3.86	$1.65.10^{-4}$
	13-18 months inclusive								3.26	$2.09.10^{-4}$
	19-24 months inclusive								3.18	$2.72.10^{-4}$
	25-30 months inclusive								2.87	$2.65.10^{-4}$
	31-36 months inclusive								2.28	$2.25.10^{-4}$
Benzo[j]fluoranthene	0-6 months exclusive								6.03	$1.29.10^{-4}$
	6-12 months inclusive								3.86	$1.65.10^{-4}$
	13-18 months inclusive								3.26	$2.09.10^{-4}$
	19-24 months inclusive								3.18	$2.72.10^{-4}$
	25-30 months inclusive								2.87	$2.65.10^{-4}$
	31-36 months inclusive								2.28	$2.25.10^{-4}$
Benzo[e]pyrene	0-6 months exclusive								0.98	$2.10.10^{-5}$
	6-12 months inclusive								0.63	$2.68.10^{-5}$
	13-18 months inclusive								0.53	$3.40.10^{-5}$
	19-24 months inclusive								0.52	$4.42.10^{-5}$
	25-30 months inclusive								0.47	$4.30.10^{-5}$
	31-36 months inclusive								0.37	$3.64.10^{-5}$

Scenarios		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	Ages	Solvent extraction					Urine simulant			
		Whole diaper shredded		Diaper parts shredded			Whole diaper shredded		Whole diaper	
		INC, 2017 et 2018 ; SCL, 2017		INC, 2017 ; SCL, 2017			SCL, 2017		SCL, 2018	
		HQ	IER	Part	HQ	IER	HQ	IER	HQ	IER
Benzo[a]pyrene	0-6 months exclusive								66.3	$1.42.10^{-3}$
	6-12 months inclusive								42.4	$1.82.10^{-3}$
	13-18 months inclusive								35.8	$2.30.10^{-3}$
	19-24 months inclusive								34.9	$2.99.10^{-3}$
	25-30 months inclusive								31.6	$2.91.10^{-3}$
	31-36 months inclusive								25.1	$2.47.10^{-3}$
Dibenzo[a,h]anthracene	0-6 months exclusive								51	$1.09.10^{-3}$
	6-12 months inclusive								32.6	$1.40.10^{-3}$
	13-18 months inclusive								27.5	$1.77.10^{-3}$
	19-24 months inclusive								26.9	$2.30.10^{-3}$
	25-30 months inclusive								24.3	$2.24.10^{-3}$
	31-36 months inclusive								19.3	$1,90.10^{-3}$
VOC										
1,2,3-trichlorobenzene	0-6 months exclusive	0.11								
	6-12 months inclusive	$6.87.10^{-2}$								
	13-18 months inclusive	$5.80.10^{-2}$								
	19-24 months inclusive	$5.66.10^{-2}$								
	25-30 months inclusive	$5.12.10^{-2}$								
	31-36 months inclusive	$4.06.10^{-2}$								
1,2,4-trichlorobenzene	0-6 months exclusive	$2.38.10^{-2}$	$6.13.10^{-8}$							
	6-12 months inclusive	$1.52.10^{-2}$	$7.83.10^{-8}$							
	13-18 months inclusive	$1.29.10^{-2}$	$9.92.10^{-8}$							
	19-24 months inclusive	$1.25.10^{-2}$	$1.29.10^{-7}$							
	25-30 months inclusive	$1.14.10^{-2}$	$1.46.10^{-7}$							
	31-36 months inclusive	$9.00.10^{-3}$	$1.39.10^{-7}$							
1,3,5-trimethylbenzene	0-6 months exclusive	$4.13.10^{-2}$								
	6-12 months inclusive	$2.64.10^{-2}$								
	13-18 months inclusive	$2.23.10^{-2}$								
	19-24 months inclusive	$2.17.10^{-2}$								
	25-30 months inclusive	$1.97.10^{-2}$								
	31-36 months inclusive	$1.56.10^{-2}$								

Scenarios		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	**Ages**	Solvent extraction					Urine Simulant			
		Whole diaper shredded		Diaper parts shredded			Whole diaper shredded		Whole diaper	
		INC, 2017 et 2018 ; SCL, 2017		INC, 2017 ; SCL, 2017			SCL, 2017		SCL, 2018	
		HQ	IER	Part	HQ	IER	HQ	IER	HQ	IER
Fragrances										
Benzyl alcohol	0-6 months exclusive	$1.72.10^{-2}$								
	6-12 months inclusive	$1.10.10^{-2}$								
	13-18 months inclusive	$9.28.10^{-3}$								
	19-24 months inclusive	$9.05.10^{-3}$								
	25-30 months inclusive	$8.19.10^{-3}$								
	31-36 months inclusive	$6.49.10^{-3}$								
Coumarin	0-6 months exclusive	0.86								
	6-12 months inclusive	0.55								
	13-18 months inclusive	0.46								
	19-24 months inclusive	0.45								
	25-30 months inclusive	0.41								
	31-36 months inclusive	0.33								
Limonen	0-6 months exclusive	0.86								
	6-12 months inclusive	0.55								
	13-18 months inclusive	0.46								
	19-24 months inclusive	0.45								
	25-30 months inclusive	0.41								
	31-36 months inclusive	0.33								
Linalol	0-6 months exclusive	$1.72.10^{-2}$								
	6-12 months inclusive	$1.1.10^{-2}$								
	13-18 months inclusive	$9.28.10^{-3}$								
	19-24 months inclusive	$9.05.10^{-3}$								
	25-30 months inclusive	$8.19.10^{-3}$								
	31-36 months inclusive	$6.49.10^{-3}$								

Scenarios		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	Ages	Solvent extraction					Urine simulant			
		Whole diaper shredded		Diaper parts shredded			Whole diaper shredded		Whole diaper	
		INC, 2017 et 2018 ; SCL, 2017		INC, 2017 ; SCL, 2017			SCL, 2017		SCL, 2018	
		MOEref/MOE	IER	Part	HQ	IER	HQ	IER	HQ	IER
Benzyl salicylate	0-6 months exclusive	0.17								
	6-12 months inclusive	0.11								
	13-18 months inclusive	$9.28.10^{-2}$								
	19-24 months inclusive	$9.05.10^{-2}$								
	25-30 months inclusive	$8.19.10^{-2}$								
	31-36 months inclusive	$6.49.10^{-3}$								
Hydroxyisohexyl 3-cyclohexene carboxaldehyde (lyral®)	0-6 months exclusive	1.72								
	6-12 months inclusive	1.1								
	13-18 months inclusive	0.93								
	19-24 months inclusive	0.91								
	25-30 months inclusive	0.82								
	31-36 months inclusive	0.65								
Butylphenyl methyl propional (lilial®)	0-6 months exclusive	1.72								
	6-12 months inclusive	1.1								
	13-18 months inclusive	0.93								
	19-24 months inclusive	0.91								
	25-30 months inclusive	0.82								
	31-36 months inclusive	0.65								
alpha-isomethyl ionone	0-6 months exclusive	0.17								
	6-12 months inclusive	0.11								
	13-18 months inclusive	$9.28.10^{-2}$								
	19-24 months inclusive	$9.05.10^{-2}$								
	25-30 months inclusive	$8.19.10^{-2}$								
	31-36 months inclusive	$6.49.10^{-2}$								

Scenarios	Ages	Scenario 1			Scenario 2.1	Scenario 2.2
		Solvent extraction			Urine Simulant	
		Whole diaper shredded INC, 2017 et 2018 ; SCL, 2017	Diaper parts shredded INC, 2017 ; SCL, 2017		Whole diaper shredded SCL, 2017	Whole diaper SCL, 2018
Chemicals		HQ	Part	HQ	HQ	HQ
Dioxins, furans and DL PCB						
1,2,3,6,7,8 HxCDD	0-6 months exclusive	$6.48.10^{-2}$				
	6-12 months inclusive	$4.14.10^{-2}$				
	13-18 months inclusive	$3.50.10^{-2}$				
	19-24 months inclusive	$3.41.10^{-2}$				
	25-30 months inclusive	$3.09.10^{-2}$				
	31-36 months inclusive	$2.45.10^{-2}$				
1,2,3,4,6,7,8 HpCDD	0-6 months exclusive	$5.06.10^{-2}$			$2.24.10^{-3}$	
	6-12 months inclusive	$3.23.10^{-2}$			$1.43.10^{-3}$	
	13-18 months inclusive	$2.73.10^{-2}$			$1.21.10^{-3}$	
	19-24 months inclusive	$2.66.10^{-2}$			$1.18.10^{-3}$	
	25-30 months inclusive	$2.41.10^{-2}$			$1.07.10^{-3}$	
	31-36 months inclusive	$1.91.10^{-2}$			$8.47.10^{-4}$	
2,3,7,8 TCDF	0-6 months exclusive				$9.63.10^{-4}$	
	6-12 months inclusive				$6.16.10^{-4}$	
	13-18 months inclusive				$5.20.10^{-4}$	
	19-24 months inclusive				$5.07.10^{-4}$	
	25-30 months inclusive				$4.59.10^{-4}$	
	31-36 months inclusive				$3.64.10^{-4}$	
2,3,4,7,8 PeCDF	0-6 months exclusive				$7.25.10^{-3}$	
	6-12 months inclusive				$4.64.10^{-3}$	
	13-18 months inclusive				$3.92.10^{-3}$	
	19-24 months inclusive				$3.82.10^{-3}$	
	25-30 months inclusive				$3.46.10^{-3}$	
	31-36 months inclusive				$2.74.10^{-3}$	
1,2,3,4,7,8 HxCDF	0-6 months exclusive				$1.04.10^{-3}$	
	6-12 months inclusive				$6.63.10^{-4}$	
	13-18 months inclusive				$5.60.10^{-4}$	
	19-24 months inclusive				$5.46.10^{-4}$	
	25-30 months inclusive				$4.94.10^{-4}$	
	31-36 months inclusive				$3.92.10^{-4}$	

Scenarios		Scenario 1			Scenario 2.1	Scenario 2.2
Chemicals	Ages	Solvent extraction			urine simulant	
		Whole diaper shredded	Diaper parts shredded		Whole diaper shredded	Whole diaper
		INC, 2017 et 2018 ; SCL, 2017	INC, 2017 ; SCL, 2017		SCL, 2017	SCL, 2018
		HQ	Part	HQ	HQ	HQ
2,3,4,6,7,8 HxCDF	0-6 months exclusive	$5.25.10^{-2}$	backsheet	$3.69.10^{-3}$		
	6-12 months inclusive	$3.36.10^{-2}$		$2.36.10^{-3}$		
	13-18 months inclusive	$2.84.10^{-2}$		$1.99.10^{-3}$		
	19-24 months inclusive	$2.77.10^{-2}$		$1.94.10^{-3}$		
	25-30 months inclusive	$2.50.10^{-2}$		$1.76.10^{-3}$		
	31-36 months inclusive	$1.99.10^{-2}$		$1.39.10^{-3}$		
1,2,3,4,6,7,8 HpCDF	0-6 months exclusive	$7.56.10^{-2}$			$1.51.10^{-3}$	
	6-12 months inclusive	$4.84.10^{-2}$			$9.65.10^{-4}$	
	13-18 months inclusive	$4.08.10^{-2}$			$8.15.10^{-4}$	
	19-24 months inclusive	$3.98.10^{-2}$			$7.95.10^{-4}$	
	25-30 months inclusive	$3.60.10^{-2}$			$7.19.10^{-4}$	
	31-36 months inclusive	$2.86.10^{-2}$			$5.70.10^{-4}$	
OCDF	0-6 months exclusive				$5.86.10^{-4}$	
	6-12 months inclusive				$3.75.10^{-4}$	
	13-18 months inclusive				$3.17.10^{-4}$	
	19-24 months inclusive				$3.09.10^{-4}$	
	25-30 months inclusive				$2.79.10^{-4}$	
	31-36 months inclusive				$2.21.10^{-4}$	
Sum of dioxins and furans quantified	0-6 months exclusive	0.2			$8.52.10^{-3}$	0.62
	6-12 months inclusive	0.13			$5.45.10^{-3}$	0.4
	13-18 months inclusive	0.11			$4.60.10^{-3}$	0.34
	19-24 months inclusive	0.1			$4.49.10^{-3}$	0.33
	25-30 months inclusive	$9.31.10^{-2}$			$4.06.10^{-3}$	0.3
	31-36 months inclusive	$7.38.10^{-2}$			$3.22.10^{-3}$	0.23
PCB 126	0-6 months exclusive					4.16
	6-12 months inclusive					2.66
	13-18 months inclusive					2.25
	19-24 months inclusive					2.19
	25-30 months inclusive					1.98
	31-36 months inclusive					1.57

Scenarios		Scenario 1			Scenario 2.1	Scenario 2.2
Chemicals	**Ages**	**Solvent extraction**			**Urine simulant**	
		Whole diaper shredded	**Diaper parts shredded**		**Whole diaper shredded**	**Whole diaper**
		INC, 2017 et 2018 ; SCL, 2017	INC, 2017 ; SCL, 2017		SCL, 2017	SCL, 2018
		HQ	Part	HQ	HQ	HQ
PCB 118	0-6 months exclusive	0.11				
	6-12 months inclusive	$7.15.10^{-2}$				
	13-18 months inclusive	$6.04.10^{-2}$				
	19-24 months inclusive	$5.89.10^{-2}$				
	25-30 months inclusive	$5.33.10^{-2}$				
	31-36 months inclusive	$4.22.10^{-2}$				
PCB 105	0-6 months exclusive	$6.35.10^{-2}$				
	6-12 months inclusive	$4.06.10^{-2}$				
	13-18 months inclusive	$3.43.10^{-2}$				
	19-24 months inclusive	$3.34.10^{-2}$				
	25-30 months inclusive	$3.03.10^{-2}$				
	31-36 months inclusive	$2.40.10^{-2}$				
Somme quantified DL PCB	0-6 months exclusive	0.21			$6.99.10^{-4}$	4.46
	6-12 months inclusive	0.14			$4.47.10^{-4}$	2.85
	13-18 months inclusive	0.12			$3.78.10^{-4}$	2.41
	19-24 months inclusive	0.11			$3.68.10^{-4}$	2.35
	25-30 months inclusive	0.1			$3.33.10^{-4}$	2.13
	31-36 months inclusive	$8.05.10^{-2}$			$2.64.10^{-4}$	1.69
Sum of Dioxins + furans + DL PCB	0-6 months exclusive	0.29			$8.62.10^{-3}$	4.58
	6-12 months inclusive	0.19			$5.51.10^{-3}$	2.93
	13-18 months inclusive	0.16			$4.66.10^{-3}$	2.48
	19-24 months inclusive	0.15			$4.54.10^{-3}$	2.41
	25-30 months inclusive	0.14			$4.11.10^{-3}$	2.18
	31-36 months inclusive	0.11			$3.26.10^{-3}$	1.73

ANNEXE 4 : REGULATION FOR CHEMICALS WITH EXCEEDED HEALTH THRESHOLDS

Chemicals	CAS Number	Harmonised classification (CLP regulation	Self classification	REACH Restriction (Annex XVII)	Cosmetic Product Regulation
PAH					
benzo[g,h,i]perylene	191-24-2	Not Classified	-	-	-
benzo[b]fluoranthene	205-99-2	Carc 1B – H350	-	0.5 mg/kg by weight of this component in toys and childcare articles	Forbidden in cosmetic products
cyclopenta[c,d]pyrene	27208-37-3	Not Classified	-	-	-
chrysene	218-01-9	Muta 2 – H341 Carc. 1B – H350	-	0.5 mg/kg by weight of this component in toys and childcare articles	Forbidden in cosmetic products
5-methyl chrysene	3697-24-3	-	Acute tox. 4 – H302 Eye Dam. 1 – H318 Carc. 2 ou 1B – H351/350 Not classified	-	-
benzo[k]fluoranthene	207-08-9	Carc. 1B – H350	-	0.5 mg/kg by weight of this component in toys and childcare articles	Forbidden in cosmetic products
benzo[j]fluoranthene	205-82-3	Carc. 1B – H350	-		
benzo[e]pyrene	192-97-2	Carc. 1B – H350	-		
benzo[a]pyrene	50-32-8	Skin Sens. 1 – H317 Muta. 1B – H340 Carc. 1B – H350 Repr. 1B – H360FD	-		
dibenzo[a,h]anthracene	53-70-3	Carc. 1B – H350	-		
DL PCB					
PCB 126	57465-28-8	-	STOT RE 2 – H373 Not classified	-	-
Fragrances					
Hydroxyisohexyl 3-cyclohexene carboxaldehyde (lyral®)	31906-04-4	Skin Sens 1	-	-	0.001% in leave-on products and 0.01% in rince-off products
Butylphenyl methyl propional (Lilial®)	80-54-6	-	Acute Tox 4 H302 Repr 2 H 361 ou Repr 1 H 360 Skin Irrit 2 H 315 Skin Sens 1B H 317		

ANNEXE 5 : REGULATION FOR CHEMICALS WITH NO EXCEEDED HEALTH THRESHOLDS

Chemicals	CAS Number	Harmonised classification (CLP regulation	Self classification
Fragrances			
Benzyl alchool	100-51-6	Acute Tox 4*- H302 Acute Tox 4* - H332	-
Linalol	78-70-6	Skin Sens. 1B – H317	
Benzyl salicylate	118-58-1	-	Skin Sens 1B ou 1 – H317 Eye Irrit 2 – H319 Skin Irrit 2 – H315 STOT SE 3 ou 2 –H335 ou H371
Coumarin	91-64-5		Acute Tox 4 – H302 Skin Sens 1 ou 1B – H317 Acute Tox 3 – H301, 311 et 331 STOT RE 2 – H373 Carc 2 – H351 Acute Tox 1 – H300
Limonen	5989-27-5	Flam Liq 3 – H226 Skin Irrit 2 – H315 Skin Sens 1 – H317	-
Linalool	78-70-6	Skin Sens. 1B – H317	-
Alpha-isomethyl-ionone	1271-51-5	-	Skin Irrit 2 – H315 Skin Sens 1B ou 1 – H317 Eye Irrit 2 –H319
VOC			
Naphtalene	91-20-3	Acute Tox 4 – H302 Carc 2 – H351	-
Styrene	100-42-5	Flam. Liq 3 – H226 Skin Irrit 2 – H315 Eye Irrit 2 – H319 Acute Tox 4* – H332 STOT RE 1 – H372 Repr. 2 – H361d	-
Toluene	108-88-3	Flam. Liq 2 – H225 Skin Irrit 2 – H315 Asp.Tox 1 – H304 STOT SE 3 – H373 STOT RE 2* - H373 Repr. 2 – H361d	-
1,4-dichlorobenzene	106-46-7	Eye Irrit 2 – H319 Carc.2 – H351	-
1,3-dichlorobenzene	541-73-1	Acute Tox 4* - H302	-
p-isopropyltoluene	99-87-6	Flam. Liq. 3, H226 Acute Tox. 3, H331 Asp. Tox. 1, H304	_
o-xylene	95-47-6	Flam liq 3 – H226 Acute Tox 4* – H312 Skin Irrit 2 – H315 Acute Tox 4* - H332	-
m-xylene + p-xylene	1330-20-7	Flam Liq 3 – H226 Acute Tox 4 – H312 Skin Irrit 2 – H315 Acute Tox 4 – H332	-
chlorobenzène	108-90-7	Flam Liq 3 – H226 Skin irrit 2 – H315 Acute Tox 4 – H332	-
n-propylbenzene	103-65-1	Flam Liq 3 Asp Tox 1 STOT SE 3	-
1,2,3 trichlorobenzene	87-61-6	-	Acute Tox 4

			Skin Sens 1
1,2,4 trichlorobenzene	120-82-1	Acute Tox 4 Skin Irrit 2	-
1,3,5 trimethylbenzene	108-67-8	Flam Liq 3 STOT SE 3	-
Forbidden pesticides			
Hexachlorobenzene	118-74-1	Carc 1B – H350 STOT RE 1 – H372	-
Pentachloroaniline (quintozene metabolite)	527-20-8	-	Acute Tox 3 – H301, H311, H331 STOT RE 2 – H373
Quintozene	82-68-8	Skin Sens 1 – H317	-
phytopharmaceutical chemicals			
Glyphosate	1071-83-6	Eye Dam. 1 – H318	-
AMPA (glyphosate metabolite)	1066-51-9	-	Not classified Skin Corr 1A – H314 Acute Tox 4 – H302, 314, 332 Skin Irrit 2 – H315 Eye Irrit 2 – H319
Dioxins/furans			
1,2,3,6,7,8 HxCDD	57653-85-7	-	Acute Tox 3 – H301 Eye irrit 2 – H319
1,2,3,4,6,7,8 HpCDD	35822-46-9	-	Eye Irrit 2 H 319 STOT SE 3 H 335 Muta 2 H 341
2,3,4,6,7,8 HxCDF	60851-34-5	-	Acute Tox 3 – H301 Eye Irrit 2 – H319
1,2,3,4,6,7,8 HpCDF	67562-39-4	-	Acute Tox 3 - H301 Eye Irrit 2 – H319
2,3,7,8 TCDF	51207-31-9	-	Acute Tox 1 – H300
2,3,4,7,8 PeCDF	57117-31-4	-	Acute Tox 1 – H300 Eye Irrit 2 – H319 STOT SE 3 – H335 Carc 1A – H350 STOT RE 2 – H373
1,2,3,4,7,8 HxCDF	70648-26-9	-	Acute Tox 3 – H301 Eye Irrit 2 – H319
OCDF	39001-02-0	-	Acute Tox 1 – H300
DL PCB			
PCB 81	70362-50-4	-	STOT RE 2 – H373
PCB 77	32598-13-3	-	STOT RE 2 – H373
PCB 123	65510-44-3	-	STOT RE 2 – H373 Not classified
PCB 118	31508-00-6	-	STOT RE 2 – H373
PCB 114	74472-37-0	-	STOT RE 2 – H373 Not classified
PCB 105	32598-14-4	-	Acute Tox 4 – H302 STOT RE 2 – H373
PCB 167	52663-72-6	-	STOT RE 2 – H373 Not classified
PCB 156	38380-08-4	-	STOT RE 2 – H373 Not classified
PCB 157	69782-90-7	-	STOT RE 2 – H373 Not classified
PCB 169	32774-16-6	-	STOT RE 2 – H373 Not classified
PCB 189	39635-31-9	-	STOT RE 2 – H373 Not classified
PAH			
Benzo[a]anthracene	56-55-3	Carc 1B – H350	-

Indeno[1,2,3-c,d]pyrene	193-39-5	-	Carc 2 – H351
Formaldehyde			
Formaldehyde	50-00-0	Acute Tox 3* - H301, 311 et 331 Skin Corr 1B - H314 Skin sens 1 – H317 Muta 2 – H341 Carc 1B – H350	-

Safety of baby diapers

Request No 2017-SA-0019
Related Request No 2016-SA-0108

Collective
expert appraisal REPORT

Expert Committee (CES) on "Assessment of chemical risks of consumer items and products"

November 2018

Mots clés

Couche, culotte d'apprentissage, bébé, jetable, substances chimiques, évaluation quantitative de risques sanitaires, EQRS

Keywords

Diaper, nappy, training pants, baby, disposable, chemicals, quantitative health risk assessment, QHRA

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"Méthodologie détaillée des essais sur les couches pour bébé" (Detailed testing methodology for baby diapers) (2016); French National Consumer Institute (INC) – **Confidential document**

"Résultats des essais détaillés sur les couches culottes" (Results of detailed tests on training pants) (2016); French National Consumer Institute (INC) – **Confidential document**

"Sécurité des couches pour bébés et couches pour incontinence adulte. TN 35 JB" (Safety of baby diapers and diapers for adult incontinence) (2017); Joint Laboratories Service (SCL) – **Confidential data**

"Étude prospective interne à la CCRF en parallèle de la TN 35 JB portant sur la sécurité des couches pour bébés et couches pour incontinence adulte" (Prospective CCRF in-house study in parallel with TN 35 JB dealing with the safety of baby diapers and diapers for adult incontinence) (2017); Joint Laboratories Service (SCL) – **Confidential data**

"Étude de recherche de substances chimiques dans des couches pour bébé par extraction avec solvant d'une part et/ou relargage dans l'urine artificielle d'autre part" (Study on

screening for chemicals in baby diapers by solvent extraction on the one hand and/or release into artificial urine on the other hand) (2018); Group'Hygiène – **Confidential data**

"Évaluation des extractibles et des relargables dans des couches pour bébé. Évaluation des risques des relargables" (Assessment of extractables and leachables in baby diapers. Risk assessment of leachables" (2018); Group'Hygiène – **Confidential data**

"Résultats des essais" (Test results) (2018); Joint Laboratories Service (SCL) – **Confidential data**

"Résultats des essais détaillés sur les couches culottes" (Results of detailed tests on training pants) (2018); French National Consumer Institute (INC) – **Confidential document**

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Acronyms and abbreviations

ADAF: age-dependent adjustment factor
ADEME: *Agence de l'environnement et de la maîtrise de l'énergie* (French Environment and Energy Management Agency)
AFNOR: *Association Française de Normalisation* (French Standardisation Association)
ALAT: alanine aminotransferase
AMPA: aminomethylphosphonic acid
ANSES: *Agence nationale de sécurité sanitaire alimentation, environnement, travail* (French Agency for Food, Environmental and Occupational Health & Safety)
ANSM: *Agence nationale de sécurité du médicament et des produits de santé* (French Health Products Safety Agency)
APEO: alkylphenol ethoxylate
AOX: adsorbable organic halogen
ASF: age-sensitivity factor
ATSDR: US Agency for Toxic Substances and Disease Registry
BBP: benzyl butyl phthalate
BfR: *Bundesinstitut für Risikobewertung* (German Federal Institute for Risk Assessment)
BIT: benzisothiazolinone
BMD: benchmark dose
BTEX: benzene, toluene, ethylbenzene and xylene
CES: Expert Committee
CFPA: Chlorine Free Products Association
CI$_{95\%}$: 95% confidence interval
CLP: Classification, Labelling and Packaging
CMR: Carcinogenic, Mutagenic and Reprotoxic
COLIPA: European Cosmetic and Perfumery Association
Danish EPA: Danish Environmental Protection Agency
DBP: dibutyl phthalate
DDPP: Departmental Directorate for the Protection of Populations
DEHP: di(2-ethylhexyl)phthalate
DIBP: diisobutyl phthalate
DIDP: diisodecyl phthalate
DINP: diisononyl phthalate
DED: daily exposure dose
DGCCRF: Directorate General for Competition, Consumer Affairs and Fraud Control
DGPR: Directorate General for Risk Prevention
DGS: Directorate General for Health
DL-PCB: dioxin-like polychlorinated biphenyl
DMP: dimethyl phthalate
DNOP: di-n-octyl phthalate
EC: European Commission
ECF: elemental chlorine free
ECHA: European Chemicals Agency
EDANA: European Disposables and Nonwovens Association
EECF: enhanced elemental chlorine free
EFSA: European Food Safety Authority
ERU: excess risk per unit
EVA: ethylene-vinyl acetate

FCD: *Fédération du commerce et de la distribution* (French Trade and Retail Federation)

FSC: Forest Stewardship Council

HpCDD: heptachlorodibenzodioxin

HQ: hazard quotient

HxCDD: hexachlorodibenzodioxin

IARC: International Agency for Research on Cancer

ICPHSO: International Consumer Product Health and Safety Organization

ICRT: International Consumer Research and Testing

IEPA: Illinois Environmental Protection Agency

IER: individual excess risk

IFRA: International Fragrance Association

INC: *Institut national de la consommation* (French National Consumer Institute)

IPCS: International Programme on Chemical Safety

JECFA: Joint FAO/WHO Expert Committee on Food Additives

JMPR: Joint FAO/WHO Meeting on Pesticide Residues

KEMI: *Kemikalieinspektionen* (Swedish Chemicals Agency)

LD: limit of detection

LDPE: low-density polyethylene

LFGB: German Food and Feed Code

LOAEL: lowest observed adverse effect level

LQ: limit of quantification

MBT: mercaptobenzothiazole

MIT: methyliosthiazolinone

MOE: margin of exposure

MOEref: reference margin of exposure

MOS: margin of safety

NAS: National Academy of Sciences (USA)

ND: not detected

NICNAS: National Industrial Chemicals Notification and Assessment Scheme

NIH: National Institutes of Health

NOAEL: no observed adverse effect level

NRC: US National Research Council

OCDD: octachlorodibenzo-p-dioxin

OCDF: octachlorodibenzofuran

OECD: Organisation for Economic Co-operation and Development

OEHHA: Office of Environmental Health Hazard Assessment (within Cal-EPA: California Environmental Protection Agency)

OR: odds ratio

PAH: polycyclic aromatic hydrocarbon

PBT: Persistent, Bioaccumulative and Toxic

PCDD: polychlorinated dibenzo-p-dioxin

PCDF: polychlorinated dibenzofuran

PCF: processed chlorine free

PE: polyethylene

PeCDD: 1,2,3,7,8-pentachlorodibenzo-p-dioxin

PeCDF: pentachlorodibenzofuran

PERMID: Prolonged Exposure Rewet Method In Diapers

PET: polyethylene terephthalate

PFOA: perfluorooctanoic acid

PLA: polylactic acid

PP: polypropylene
PTMI: Provisional Tolerable Monthly Intake
PUL: polyurethane laminate
PVC: polyvinyl chloride
QHRA: quantitative health risk assessment
RAPEX: Rapid Alert System for dangerous non-food products
REACh: Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM: *Rijksinstituut voor Volksgezondheid en Milieu* (Netherlands National Institute for Public Health and the Environment)
SAP: SuperAbsorbent Polymer
SCCS: Scientific Committee on Consumer Safety
SCL: *Service commun des laboratoires* (Joint Laboratory Service)
SI: Sustainability Index
SVHC: Substance of Very High Concern
TBT: tributyltin
TCDD: 2,3,7,8-tetrachlorodibenzo-p-dioxin
TCDF: tetrachlorodibenzofuran
TCF: total chlorine free
TDEX: The Endocrine Disruption Exchange, Inc.
TEF: toxic equivalency factor
TEQ: toxic equivalent quantity
TEWL: transepidermal water loss
TNPP: tris(4-nonylphenyl) phosphite
TRV: toxicity reference value
TTC: Threshold of Toxicological Concern
UF: uncertainty factor
UF_A: inter-species uncertainty factor
UF_D: database uncertainty factor
UF_H: inter-individual uncertainty factor
$UF_{B/L}$: uncertainty factor related to the use of a LOAEL or BMD
UF_S: uncertainty factor related to subchronic to chronic transposition
UFC: *Union Fédérale des Consommateurs* (Federal Union of Consumers)
US EPA: United States Environmental Protection Agency
US CDC: United States Centers for Disease Control and Prevention
US CPSC: United States Consumer Product Safety Commission
US FDA: United States Food and Drug Administration
US NAS: United States National Academy of Sciences
VOC: volatile organic compound
vPvB: very Persistent, very Bioaccumulative
WHO: World Health Organization

List of tables

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1 Background, purpose and procedure for carrying out the expert appraisal

1.1 Background

At European Union (EU) level, baby diapers are subject to the sole general safety requirement defined by European legislation relating to consumer goods, transposed in the French Consumer Code. There is no other regulatory framework specific to baby diapers in France or in the EU. However, there are harmonised regulations applying to other types of products (cosmetic products, medical devices) used in the urogenital area (e.g. incontinence products) that lay down obligations in terms of safety assessments and the transmission of lists of ingredients to the competent authorities.

At the end of 2016, an article in the French newspaper "Le Parisien" reported the presence of polycyclic aromatic hydrocarbons (PAHs) in single-use baby diapers. Further to its publication, a petition entitled "Pour que Pampers supprime définitivement les substances cancérigènes de ses couches !"[1], calling on Pampers to permanently remove carcinogenic substances from its diapers, was launched by a Ms Durand-Thonon in France. As of 13 November 2018, 76,045 people had signed this petition intended for the Minister of Social Affairs and Health and four managers from Procter & Gamble.

In January 2017, a publication in a "popular" magazine relayed in the media reported levels of chemicals (pesticides, dioxins, furans, PAHs and volatile organic compounds) in baby diapers (60 Millions de Consommateurs, 2017).

1.2 Purpose of the request

On 29 April 2016, ANSES received a formal request from the Directorate General for Health (DGS) and the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) to assess the safety of feminine hygiene products in terms of the risk of infection, allergy or intolerance and/or related to chemical action via dermal contact and contact with the mucous membranes (Annex 1).
ANSES's expert appraisal was requested with the following aims:
1. study the typical composition of feminine hygiene products;
2. identify regulated or non-regulated chemicals of concern liable to be present in these hygiene products, possibly in trace amounts;
3. conduct a review of knowledge on the hazards presented by these chemicals, in particular through contact with the vaginal mucosa;
4. assess the relevance of defining thresholds for the presence of these chemicals in feminine hygiene products, especially in view of the duration and mode of exposure;

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[1] https://www.change.org/p/alan-george-lafley-pour-que-pampers-supprime-définitivement-les-substances-cancérigènes-de-ses-couches-aglafleyfan-alanlafley-duronc2?source_location=minibar

5. where appropriate, issue recommendations to encourage better control of manufacturing methods, composition and consumer information, particularly at EU level.

ANSES broadened points 1, 2 and 3 of the formal request to include baby diapers since these products are subject to the same general safety requirement (French Consumer Code) as feminine hygiene products, are made by the same manufacturers and may have similar ingredients.

On 25 January 2017, ANSES again received a formal request from the DGS, the Directorate General for Risk Prevention (DGPR) and the DGCCRF, to assess the safety of baby diapers (Annex 2). ANSES's expert appraisal was requested with the following aims:

1. undertake a chemical risk analysis, especially in the event of exposure through contact in young children (a susceptible population group);
2. assess the relevance of defining thresholds for the presence of these chemicals in diapers, especially regarding hazards (with or without threshold effects) and the duration and mode of exposure;
3. where appropriate, issue recommendations to encourage better control of manufacturing methods, composition and consumer information, particularly at EU level.

This report will not address the environmental impact of baby diapers. Several life-cycle analysis studies dealing with baby diapers have been undertaken and published over the last few years, including the study by Cordella *et al.* (Cordella *et al.*, 2015). In 2005, the UK Environment Agency carried out a life-cycle analysis (updated in 2008) enabling the environmental impacts associated with the use of single-use and reusable diapers to be assessed over a period of two and a half years (UK Environment Agency, 2005 and 2008). Similar work was undertaken by the French Environment and Energy Management Agency (ADEME) in 2012 (ADEME, 2012).

1.3 Procedure: means implemented and organisation

ANSES entrusted the examination of this formal request to the Expert Committee (CES) on "Assessment of chemical risks of consumer items and products", which met from May 2016 to August 2017, and then to the CES on "Assessment of chemical risks of consumer items and products 2".
The methodological and scientific aspects of the rapporteurs' expert appraisal work were regularly submitted to the CESs. This report takes into account the comments and additional information provided by the CES members. The work was adopted by the CES on "Assessment of risks of consumer items and products 2" at its meeting on 15 November 2018.

This work was therefore conducted by a group of experts with complementary skills.
The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".
To obtain the various stakeholders' opinions, a series of hearings took place between April and May 2017 with:
-   the French National Consumer Institute (INC) on 4 May 2017,
-   Love & Green on 21 April 2017,

- European Disposables and Nonwovens Association (EDANA)[2] and Group'Hygiène[3] on 28 April 2017,
- Procter & Gamble on 3 April 2017,
- the French Trade and Retail Federation (FCD) on 4 April 2017,
- the French consumer group UFC Que Choisir on 27 April 2017.

An international consultation washeld between 15 November and 31 December 2016 to collect information dealing with:
- safety assessments of feminine hygiene products and baby diapers;
- the regulations and public policies or recommendations;
- the composition of these products;
- chemicals (and their properties justifying use in these products);
- studies currently being undertaken on these products.

Table 1 lists the various organisations contacted as part of the international consultation.

Table 1: Organisations contacted as part of the international consultation

Institution	Country
World Health Organization (WHO)	International
Consumers International	International
International Consumer Product Health and Safety Organization (ICPHSO)	International
International Consumer Research & Testing (ICRT)	International
OECD - Global Recalls portal[4]	International
European Consumer Organisation (BEUC)	European Union
RAPEX (Rapid Alert System for dangerous non-food products) contact points[5]	European Union
Bundesintitut für Risikobewertung (BfR)	Germany
Danish EPA	Denmark
Kemikalieinspektionen (KEMI, Swedish Chemicals Agency)	Sweden
Health Canada	Canada
National Institutes of Health (NIH) - National Institute of Allergy and Infectious Diseases (NIAID)	USA
US Centers for Disease Control and Prevention (US CDC)	USA
US Food and Drug Administration (US FDA) ─ Center for Devices and Radiological Health (CDRH)	USA
US Consumer Products Safety Commission (US CPSC)	USA

Six organisations responded to this consultation. The consultation results are detailed in Annex 3.

To conduct this expert appraisal, ANSES collected all of the available data from institutional reports and scientific publications relating to the composition and technical properties of materials and the diseases caused by diapers (dermatitis). The literature

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[2] EDANA is an international association serving the nonwovens industry. www.edana.org

[3] Group'Hygiène is a professional association of producers of single-use products for hygiene, health and wiping sold on the French market. www.grouphygiene.org

[4] https://globalrecalls.oecd.org

[5] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

search found only a few reports by public bodies and a scarcity of independent scientific publications. Publications written by authors employed by companies selling baby diapers are marked with an asterisk (*) in this report. ANSES also took non-scientific or "grey" publications into account, including the results of comparative tests carried out by consumer groups, particularly those behind the formal request (60 Millions de Consommateurs, 2016). Lastly, the results of tests commissioned by the DGCCRF in 2017 and 2018 from the Joint Laboratory Service (SCL) were incorporated into the expert appraisal.

1.4   Prevention of risks of conflicts of interest

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.

The experts' declarations of interests are made public via the ANSES website (www.anses.fr).

2 Definition of the products studied

Ever since they were invented in the early 1930s, single-use baby diapers have continuously evolved to meet the expectations of modern life. They have become more compact, more absorbent and easier to use. According to EDANA, since 1987, baby diapers have become 50% lighter due to the use of fewer raw materials.

Group'Hygiène affirms that in France, the basic rudiments of disposable diapers appeared in the late 1950s in the form of rolls of multi-layer cellulose wadding. Disposable diapers gradually replaced reusable diapers. They quickly took the form of individual rectangular pads placed in the pants of babies.
It was during the 1973-1974 period that the first diaper pants appeared on the market, evolving into the products that exist today. First sold in pharmacies, single-use baby diapers have since become "consumer" products mainly found in supermarkets and hypermarkets. They are also used in the maternity and paediatric departments of hospitals and clinics.

Diapers are products made of several materials whose objectives are to absorb and retain the child's urine and faeces while keeping his/her skin clean and dry.

There are several types of diapers:
- Disposable diapers: These are single-use diapers. Depending on the child's age and body weight, various sizes and ranges of diapers are available (for newborns, for children who are becoming mobile, etc.). There are several models of disposable diapers with different characteristics:
  o Traditional diapers,
  o Diaper pants or training pants for toilet-training the child,
  o Swimming diapers, used when babies/children are engaging in water activities. These diapers are made of an absorbent material that does not swell up in water,
  o Night diapers, intended for children over three years of age, in order to help them with toilet training at night.

- Reusable diapers: Unlike disposable diapers, reusable diapers can be reused. There are three types of reusable diapers[6]:
  o Flat diapers: large squares of absorbent fabric that are folded several times and then placed in a suitable diaper cover (with or without a pocket). When the diaper needs to be changed, you can easily unfold it for machine-washing. The diaper cover can be used several times. There are also prefold diapers, a variation on flat diapers, which are easier to use.
  o Fitted diapers, which look more like disposable diapers on account of their anatomical shape. They consist of a diaper, an absorbent sheet and a waterproof diaper cover. You simply place the absorbent sheet inside the diaper

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[6] www.les-couches-lavables.fr

and add the diaper cover. When the diaper needs to be changed, you dispose of the absorbent part and wash the diaper, keeping the diaper cover for reuse.

o   Pocket diapers: these all-in-one multipurpose diapers are waterproof and absorbent and do not require a cover. When they are dirty, you empty them and put them directly in a washing machine.

3 Regulations and voluntary certification schemes

3.1 French and European regulations

In France and in the EU, baby diapers are not covered by any specific regulations, whether for their composition, manufacture or marketing.

The General Product Safety Directive (2001/95/EC) is the only regulation to which these products are subject; the obligations it imposes on companies include the duty to market safe products for use under reasonably foreseeable conditions by consumers, to undertake a risk assessment, to have at their disposal the corresponding dossier, to provide consumers with information about risks, to ensure the traceability of products, and to have a procedure for withdrawing products from the market.

During the hearings, manufacturers of such products wishing to include certain chemicals in their products claimed to also comply with the following regulations:

- Regulation (EC) No 1223/2009 on cosmetic products, in particular regarding the substances used in lotions. This regulation lays down a positive list of substances that manufacturers can use in cosmetics,
- Regulation (EC) No 1907/2006 (REACh Regulation) and Regulation (EC) No 1272/2008 (CLP Regulation). According to the REACh Regulation, baby diapers are considered as articles containing substances that may be released (e.g. lotion).
- as well as the advice provided in the EDANA and Group'Hygiène guides.

Germany:

In Germany, baby diapers are considered as commodities and are regulated by the German Food and Feed Code (LFGB). There are no regulations specific to diapers. However, the BfR has issued recommendations related to the materials used for the manufacture of baby diapers, in particular regarding:

- the materials used,

- maximum concentrations for acrylic acid,

- the use of scented oils and conditioning agents,

- the use of chemicals, plastic materials and dyes.

Voluntary certification schemes There are several certification schemes pertaining to baby diapers but they rely on voluntary participation by manufacturers. These schemes provide guidance for consumers and companies but are not subject to enforceable regulations.

At EU level, since 24 October 2014, there has been an **Ecolabel** certification scheme for single-use absorbent hygiene products (feminine sanitary towels, tampons, nursing pads, baby diapers) (EC, 2014). This EU Ecolabel enables consumers to identify good-quality products meeting high environmental standards. It guarantees a reduced environmental impact throughout the product life cycle, minimal use of hazardous substances, and the implementation of quality and performance tests. The EU Ecolabel is the only official European environmental certification scheme that can be used in all European Union Member States.

Figure 1: EU Ecolabel logo

In general, some manufacturers draw inspiration, among other things, from the EU Ecolabel's list of substances and migration limits to assess the safety of their products (Annex 4).

The Nordic Swan Ecolabel, the official ecolabel of the Nordic countries (Iceland, Sweden, Norway, Denmark, Finland), was created in 1978 (Nordic Ecolabel, 2011). It is a seal of approval intended to help consumers choose the most eco-friendly products, within 63 product groups (cleaning products, paper towels, textiles, etc.). Companies using the logo undertake, among other things, to limit certain chemicals that are hazardous to human health, limit greenhouse gas emissions when manufacturing their products, use renewable raw materials, organic cotton, wood from sustainably managed forests, etc. The criteria that diapers have to meet to obtain the Nordic Swan Ecolabel can be found in Annex 4.

Figure 2: Nordic Swan Ecolabel logo

The **FSC** (Forest Stewardship Council) **certification scheme** is an international environmental certification scheme that ensures that products are sourced from sustainably managed forests, that there is a procedure for tracking timber from the forest to the finished product, and that forestry practices limit environmental impacts on the fauna, flora, natural environment and local populations. There are three different types of FSC certification scheme depending on the composition of the FSC-certified product:
   - the FSC 100% certification scheme: the product contains 100% (by weight) FSC-certified virgin fibre;
   - the FSC Mix certification scheme: the product contains FSC-certified fibre, recycled fibre and controlled wood;
   - the FSC Recycled certification scheme: the product contains 100% (by weight) FSC-certified recycled fibre.
FSC is an international non-profit organisation created in 1993 and based in Bonn (Germany).

Figure 3: FSC (Forest Stewardship Council) logo

The **TCF (Totally Chlorine Free), PCF (Processed Chlorine Free)** and **SI (Sustainability Index) certification schemes** are proposed by the Chlorine Free Products Association (CFPA)[7]. They certify that a product has been manufactured and bleached without any use of chlorine.

The **OK Biobased - Vinçotte certification scheme** certifies products based on their concentration of renewable raw materials.

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[7] An independent not-for-profit accreditation and standard-setting organisation, located in the state of Illinois, United States

4　Use of baby diapers

Since the 1990s, single-use diapers have been used by more than 90% of families in most European countries (EDANA, 2011). **In France**, **disposable diapers have been worn by over 95% of babies** for almost 20 years (Group'Hygiène, 2015). Nonetheless, some parents choose to use reusable diapers. The choice of diaper type is influenced by family members as well as by income disparity and methods of access to information (Thaman and Eichenfield, 2014*).

In 1990, Shanon *et al.* published the results of a questionnaire-based study on diaper choices in 600 parents of young children under two years of age seen in a clinic or by paediatricians in Ottawa (Shanon *et al.*, 1990). Single-use diapers were used by 82.3% of the parents. Only 2.7% of the parents exclusively used reusable cloth diapers. The choice was driven by convenience for disposable diapers, rash prevention for disposable and reusable diapers, cost for diapers washed at home, and convenience for diapers washed by a diaper cleaning service.

In 2004, a study on diaper use (types of diapers used, number of diaper changes per day, age when children stop using diapers) was undertaken in the United Kingdom. Eight thousand households were surveyed between June 2002 and February 2003. Only those with a child who was in diapers or had worn diapers in the recent past (children under the age of 10) were interviewed (n=2096). Of these families, 94.1% used only single-use diapers, 1.5% only reusable diapers, 2.4% both types of diapers but primarily disposable diapers, and 2% both types of diapers but primarily reusable diapers (UK Environment Agency, 2005b). The people preferring reusable diapers considered they were more eco-friendly and less expensive and contained fewer chemicals. In some cases, they had also been recommended by friends or family members or donated by a family that no longer needed them.

In Belgium, a pilot programme was implemented in 2002 and then in 2005 to encourage parents to use reusable diapers for a period of 13 weeks. The parents were recruited in a maternity department. Seventy percent of the 436 women invited to take part in this programme declined. Only 23 participants (in 2002 or 2005) said they intended to continue using reusable diapers at the end of the 13 weeks, i.e. 5% of the women invited to participate. The main reasons for not wanting to continue were leakage, difficulty of use, extra work and cost (EDANA, 2010). Several other initiatives have been taken in France to promote reusable diapers (ADEME, 2012).

Diapering habits vary according to country, income level, family practices and cultural norms. Single-use diapers are used in most countries except for example in India and China, where reusable diapers are widely used. Diaper changing practices differ depending on the country. In Japan, for example, babies are changed while standing up rather than while lying on their back, which has resulted in babies in Japan frequently wearing training pants before they start toilet training. However, in Western Europe and North America, training pants are almost exclusively limited to the toilet-training period (Figure 4) (Thaman and Eichenfield, 2014*).
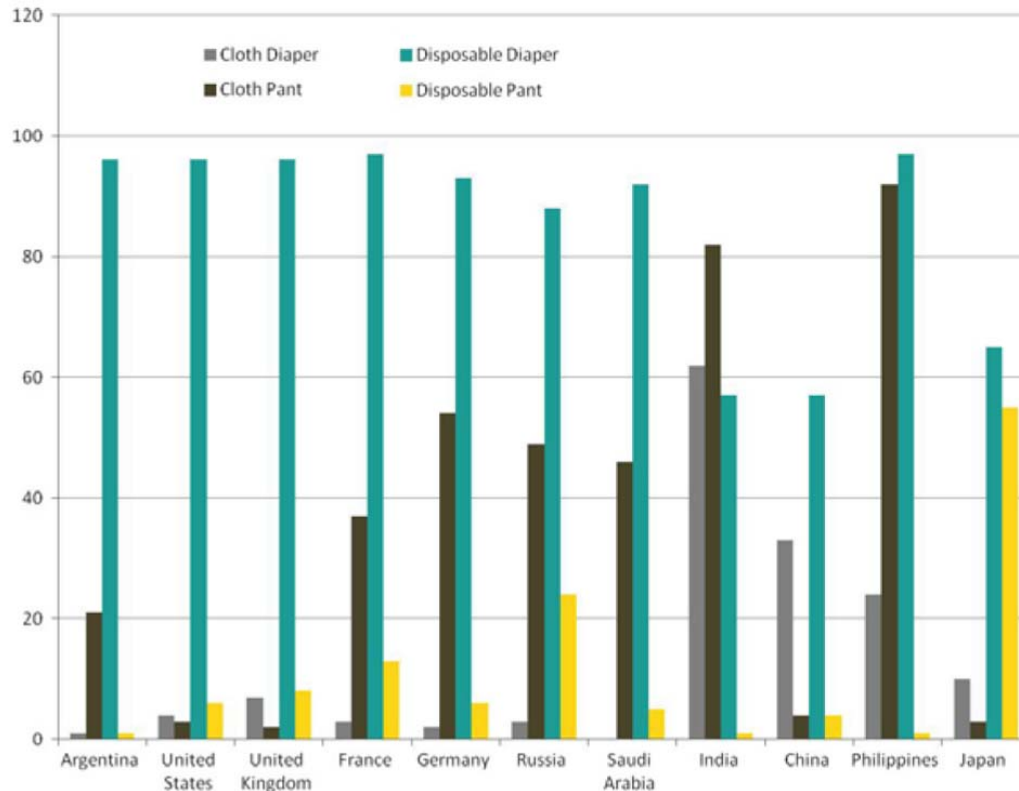
Figure 4: Use of the various types of diapers according to country in children between the ages of zero and 24 months (%) (Thaman and Eichenfield, 2014*)

Group'Hygiène underlined the key role of single-use diapers in the **quality of life** of babies and parents (Group'Hygiène, 2015). Dryness, leakage, skin health, comfort and hygiene were found to be the characteristics of disposable diapers having the greatest impact on quality of life. In a study undertaken by the industry in France, Germany and the United Kingdom in 2007, 87% of the 350 women with children under the age of nine years who were interviewed considered the use of disposable baby diapers as having a positive impact (Figure 5) (EDANA, 2010).
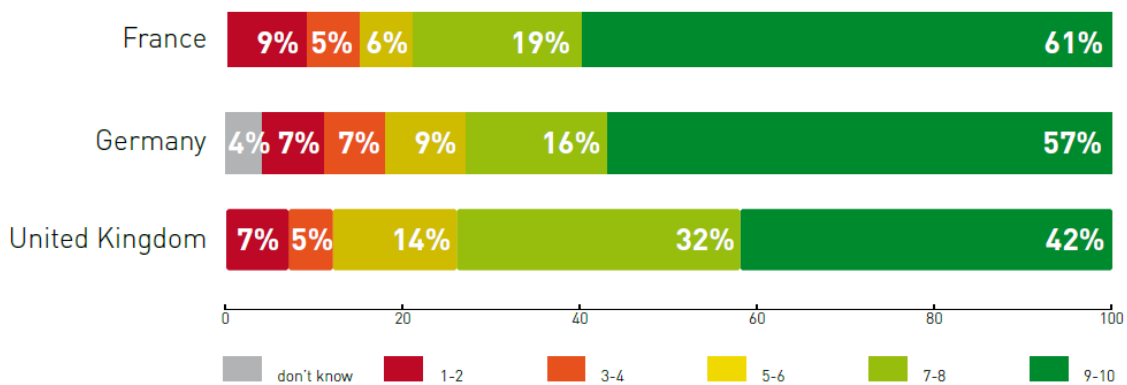
Rating of the positive impact of single-use diapers on the daily quality of life of a mother on a scale from one (no impact) to 10 (high impact).

Figure 5: Use of baby diapers and their impact on the quality of life of parents in 2007 (EDANA, 2010)

- **Number of diapers used before toilet training**

Estimates of the number of disposable diapers used by a baby before toilet training range from 3800 to 4800 (see §8.3.4.2.3). These estimates vary depending on the age at which it is considered that children are fully toilet trained (between 2.5 and three years old) (see §8.1).

- **Diaper wearing time**

Younger babies are changed more frequently than older babies (10 times/day versus 4-5 times/day). The average diaper wearing time for an older baby is four hours during the day and 10 to 12 hours at night (Thaman and Eichenfield, 2014*). Indeed, as they reach one year of age, babies sleep an average of 14 to 15 hours per day, with most of their sleep occurring overnight (~10-12 hours) (see §8.3.4.2.3).

- **Urinary output in infants**

Reference values for daily urinary excretion in various age groups are given in Table 2.

Table 2: Reference values for urinary output (Guide pratique des analyses médicales, 4ᵗʰ edition)

Age group	Urinary output (ml/24 hrs)
Newborn	15-60
Two weeks	100-300
One to two months	250-450
Two to 12 months	400-600
Two to four years	500-800
Four to eight years	600-1000
Adolescent	700-1400
Adult	1000-1600

5 Market of baby diapers

Various observations can be made regarding the market of baby diapers in France and in some cases in the EU. They are primarily based on information from industry players. During the various hearings organised by ANSES, the issue of sales volumes for single-use baby diapers and training pants was addressed. It appeared that these figures were confidential and could not be used.

ANSES collected information from Group'Hygiène. According to this source, 3.2 billion diapers (accounting for 87% of sales volume) and diaper pants (13%) were sold in 2015 in metropolitan France. According to the same source, these figures have been stable since 2011 (Figure 6).
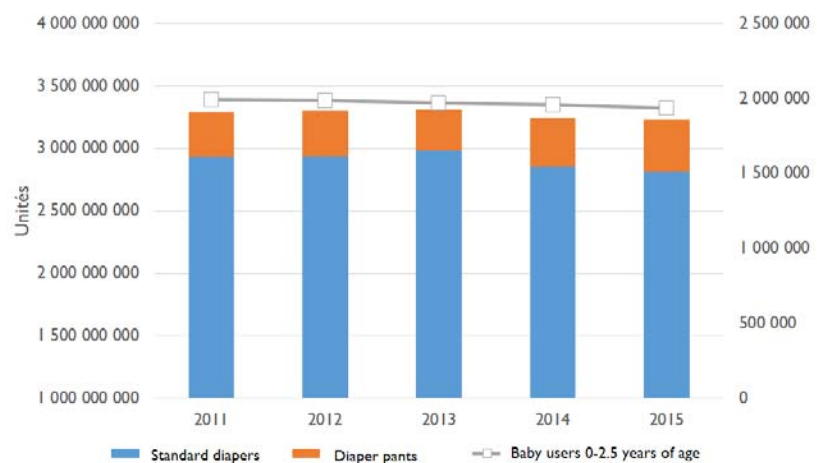
Figure 6: Sales volumes for diapers and diaper pants in metropolitan France (Group'Hygiène hearing, 2017)

According to EDANA, around 30 billion diapers and diaper pants are sold in the European Union (2015 figures) (Figure 7).
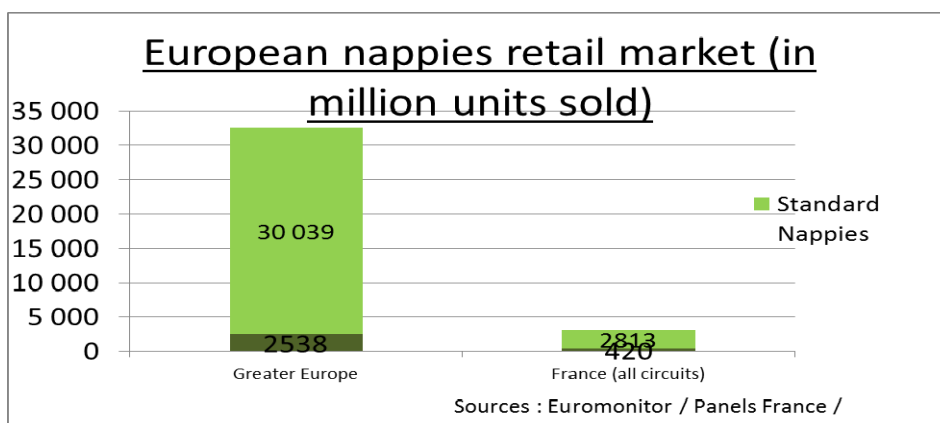
Figure 7: Sales volumes for baby diapers (EDANA hearing, 2015 figures-Euromonitor)

In the United Kingdom, single-use and reusable diapers represent around 2.47 billion units sold (UK Environment Agency, 2005).

6 Composition, manufacturing processes and assessment of raw materials and finished products

6.1 Composition

6.1.1 Disposable diapers

Disposable baby diapers consist of several superimposed layers (EDANA, 2015; Group'Hygiène[8], Karlberg and Magnusson, 1996; Kosemund *et al.*, 2009*; Dey *et al.*, 2014*; Dey *et al.*, 2016a and b*; Pampers website; Love and Green website[9]; Gupta *et al.*, 2009; Yu *et al.*, 2016; Counts *et al.*, 2017*):

- A **topsheet** in contact with the baby's skin. It captures urine and enables it to be transferred to the core of the inner layer while limiting moisture in contact with the buttocks in addition to leakage. The polyolefin topsheet is a porous nonwoven[10]. The hydrophobic nature of the polyolefins is primarily what enables the absorbent material to rapidly absorb urine. Lotion may be added to the topsheet. It acts as a barrier against moisture and as a skin conditioning agent helping reduce skin irritation and prevent skin problems.

- An **acquisition layer** is sometimes added to absorb liquid and transfer it to the core.

- A **core**, which captures, absorbs and retains urine, is made of wood cellulose fibres (fluff pulp[11]) and superabsorbent polymer (SAP or sodium polyacrylate). The cellulose fibres are intended to absorb urine and distribute it through the core, while SAP is intended to trap liquids. For certain diapers, the core takes the form of absorbent channels that help distribute urine (Figure 8).

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[8] http://couche-bebe.org/composants/la-technologie-au-service-de-mon-bebe-avec-la-couche-jetable/
[9]   http://www.loveandgreen.fr/nos-couches/?gclid=Cj0KEQiAzsvEBRDEluzk96e4rgABEiQAezEOoNEfNskDZTglCkGn1LZ4xuSi8TPtk32wlqMu3L9UacQaAkSz8P8HAQ
[10] According to EDANA, a nonwoven is a manufactured sheet, web or batt of directionally or randomly orientated fibres, bonded by friction, cohesion or adhesion.
[11] Chemical pulp made from long-fibre wood

Figure 8: Various forms of cores (Pampers website)

- A system for retaining urine and faeces inside the diaper, consisting of:
  - o An impermeable **backsheet**, serving as a leakproof barrier for the diaper. It traps moisture within the material. It is usually made of polyolefins. This backsheet can have various designs (textile, print designs, etc.). It can be made breathable to maintain the skin in good condition. Small inclusions in the polyethylene film create holes that are small enough to allow movements of water vapour and air while retaining urine within the diaper (Counts *et al.*, 2014* and 2017) (Figure 9).
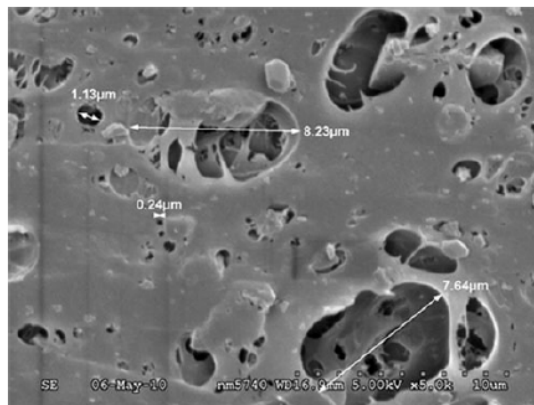
Figure 9: Detailed view of the micropores of a breathable backsheet (Counts *et al.*, 2014*)

  - o **Leak guards** that provide added protection against urine and faecal leakage. They are made of a hydrophobic nonwoven.

  - o **Elastics** that provide added protection against leakage by adapting to the baby's shape.

- The fastening system, which can be opened and closed several times. There are two different systems: adhesive and self-fastening systems.

  - o **Ear tabs** enabling the diaper to be fitted to the baby's waist by adjusting the position of the fasteners.

  - o **Fasteners** that attach to the ear tabs to close the diaper. The adhesive materials used are made of thermoplastic polymers. They are covered so as to never come into contact with the baby's skin.
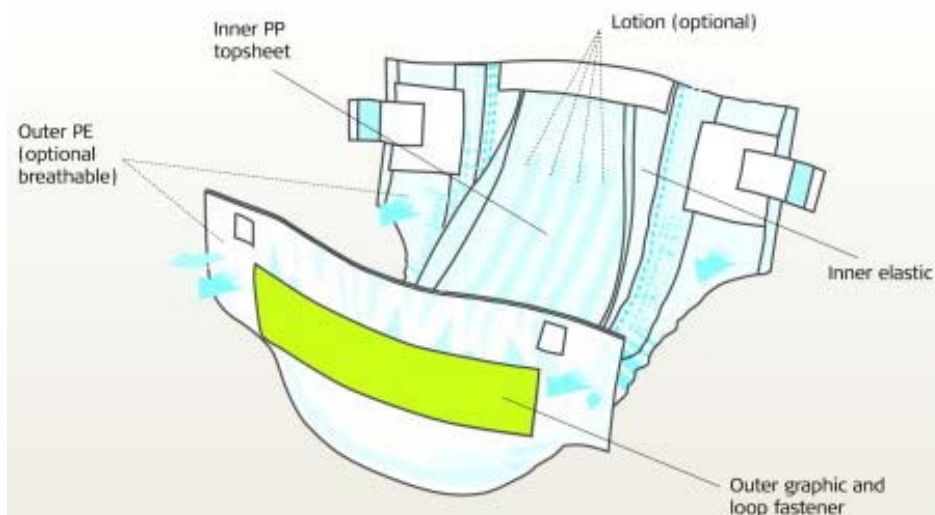
Figure 10: Diagram of a disposable diaper (EDANA)

Some diapers feature a **wetness indicator** that changes colour when exposed to urine. This indicator contains a pH-activated component.

Table 3: Summary of the composition of disposable baby diapers

External protective parts	Composition
Topsheet	Nonwoven produced from synthetic fibres (usually polypropylene, otherwise polyethylene or polyester) or bioplastics derived from corn starch and sugar cane +/- lotion
Acquisition layer (optional)	PET (polyethylene terephthalate) or cellulose and polyester fibres
Core	Superabsorbent polymer (SAP) encapsulated in wood cellulose fibres
Backsheet	Low-density polyethylene (LDPE) or a mixture of nonwoven with a film (LDPE) or nonwoven produced from synthetic fibres (polyethylene and polypropylene) or bioplastic fibre film produced from lactic acid (PLA) or a mixture of polyethylene and starch (Master-Bi) or corn starch or nonwoven made of natural viscose or polyurethane
Leak guard	Hydrophobic polypropylene nonwoven
Elastics	Thermoplastic polymers Lycra (polyurethane)
Ear tabs	Polyamide and polyethylene
Fasteners	Polyamide and polyethylene
Glue (for gluing the various sheets of the diaper)	Hot-melt adhesive* Or copolymer rubber and starch
Lotion (optional)	Pharmaceutical-grade purified petrolatum (= Vaseline), stearyl alcohol, paraffinum liquidum, aloe barbadensis extract (aloe vera)
Pigments	No disperse dye Soy-based dyes (eco-friendly diapers)
Fragrances (optional)	No information
Packaging	Polyethylene

* thermoplastic adhesive in solid form, designed to be melted by a heating element to provide it with adhesion properties. The main resins used in hot-melt adhesives are ethylene-vinyl acetate copolymer, polyamides, polyolefins (mainly polyethylene) and polyesters.

Some parts of a diaper may be **dyed**. Most major manufacturers of disposable diapers use pigments they consider "safe" for use in baby diapers, with no disperse dyes (Dey *et al.*, 2016b*; Pampers website). Local skin effects such as irritation and sensitisation are also

assessed for the pigments used in baby diapers, by undertaking patch tests on adult skin self-evaluated as sensitive. No cases of skin irritation or sensitisation have been found. Although manufacturers consider the use of these pigments to be safe, they try to limit exposure and transfer to babies' skin. Interior pigments are incorporated into the polymer resin, thus minimising their release. Exterior colours adhere to the backsheet and are covered by a layer of polypropylene fibres to minimise skin contact (Dey *et al.*, 2016b*; Counts *et al.,* 2017*). It should be noted that these dyes serve no technical purpose in diapers and are added only for aesthetic reasons.

Fragrances are sometimes added (Kosemund *et al.*, 2009*; Counts *et al.*, 2017*). When this is the case, very small amounts are added beneath the core. These fragrances must comply with the Code of Practice of the International Fragrance Association (IFRA) and have been assessed to ensure they are not sensitising or allergenic (Counts *et al.*, 2017*).

SAP is a sodium polyacrylate with varying degrees of cross-linking. To the naked eye, superabsorbent polymers appear as a white powder (100 to 800 μm in diameter) (low cross-linking) or very small beads (high cross-linking). In the presence of water, they absorb fluids and turn into a soft and deformable gel. They are prepared by inverse suspension polymerisation which requires the presence of hydrocarbon solvents and surfactants. SAP's absorption capacity is influenced by several parameters:
-   the charge density along the polymer chains,
-   the cross-linking density: the more cross-linked SAP is, the less it swells up and the less deformable the gel,
-   the ionic strength of the liquid: an SAP absorbs up to 500 times its weight in pure water but only 60 times its weight in saline solution (Gourmand and Corpart, 1999). According to EDANA, SAP absorbs up to 300 times its weight in water without releasing it (EDANA, 2015).

SAP was produced in the early 1970s in Japan and in the United States and was introduced into baby diapers in the early 1980s. By the early 1990s, SAP was widely used in disposable diapers and incontinence products (EDANA[12]) and its use in these products has continued to grow.

In certain diapers, **lotions** are intentionally added to help protect babies' skin. According to the Pampers website[13] and Counts *et al.* (2017*), the lotion in their diapers contains the following ingredients: a very small quantity (less than 0.10 g in a diaper for newborns) of pharmaceutical-grade purified petrolatum (a protective barrier, commonly called Vaseline), stearyl alcohol (an emollient commonly used for its moisturising properties), paraffinum liquidum (a protective barrier), and aloe barbadensis extract (aloe vera, for softness).

According to EDANA, no contaminants such as **dioxins, furans, DL-PCBs, pesticides, herbicides** or **halogens** are intentionally used in or added to baby diapers.

Changes in composition
The composition of disposable baby diapers has evolved over time: they are now thinner and more absorbent than their "ancestors", more comfortable to wear for babies, and more

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[12] http://www.edana.org/discover-nonwovens/how-they're-made/superabsorbents

[13]   https://www.pampers.co.uk/safety-and-commitment/quality-and-safety/article/what-is-a-pampers-diaper-pant-or-wipe-made-of

convenient for parents (Figure 11). The average weight of a disposable diaper decreased from 64.6 g in the late 1980s to 33.3 g in 2013, i.e. an almost 50% reduction over a 25-year period (EDANA, 2005, 2011 and 2015; Group'Hygiène, 2015). In the late 1980s, disposable diapers were made primarily of fluff pulp (52.8 g/diaper). The quantity of fluff pulp decreased, reaching 9.1 g/diaper in 2013, while the quantity of SAP sharply increased between the late 1980s and 2013, rising from 0.7 g/diaper to 12.6 g/diaper, thus explaining the decrease in weight.

In 2004

Adhesive 3%
Elastics 1%
Polypropylene 15%
Polyethylene 7%
Other 4%
Superabsorber 27%
Fluff pulp 43%

In 2011

Fluff Pulp 36.6%
SAP 30.7%
LDPE 6.2%
PP 16.0%
Tape 1.3%
Elastic 0.4%
Adhesives 2.8%
Elastic back ear 3.2%
Frontal tape 1.4%
Various synthetic polymers 1.4%

In 2013

Superabsorbant polyacrylate (SAP) (33%)
Fluff pulp (24%)
Nonwovens (21%)
Elastic & adhesive tape (13%)
Polyethylene (PE) film (5%)
Adhesive (3%)
Other (1%)

Figure 11: Typical composition of a disposable baby diaper in 2004, 2011 and 2013 (EDANA, 2005, 2011 and 2015)

6.1.2 Reusable diapers

Reusable diapers are made of:
- an **absorbent part** trapping liquids (urine and faeces);
- an **impermeable diaper cover** to avoid risks of leakage;
- **elastic** back, leg and stomach openings;
- a **fastening system** (Velcro, snaps).

Depending on the model, these components may be separate or sewn together.

A **protective sheet** is placed at the bottom of the diaper to collect faeces. It may be disposable or reusable (made of polar fleece, for example).

The following can also be added:
- One or more **inserts** for greater effectiveness. These are absorbent parts that are placed in the pocket of the diaper and removed once it is soiled. Several inserts can be combined in a diaper for better absorption;

- A **doubler (or booster)** that provides additional protection to improve the absorbency of reusable diapers. It is placed directly in contact with the baby's skin, inside the diaper. Doublers are particularly recommended at night.

Table 4: Summary of the composition of reusable baby diapers

External protective parts	Composition
Protective sheet	Wood (or corn) cellulose, sometimes with binders or polar fleece
Absorbent part	Natural absorbent materials: organic or non-organic cotton, hemp, bamboo, Tencel® or Lyocell®, microfibre, Stay-dry®, polar fleece, suede cloth, wool, silk, polyester, etc.
Insert, booster	Cellulose, polypropylene, polar fleece or silk
Diaper cover	PUL, wool, polar fleece, nylon, PVC, EVA, polyester, cotton, wool, hemp, etc.

PUL: polyurethane laminate, PVC: polyvinyl chloride, EVA: ethylene-vinyl acetate

Merchant websites for reusable diapers give the following washing recommendations: wash at 40°C and two or three times a month at 60°C, preferably with eco-friendly detergent. There is no mention of washing diapers before using them for the first time.

6.1.3 Substances with nanoparticle status

During the NanoRESP forum on 4 October 2017, a silica manufacturer indicated the presence of colloidal nano-silica (12-50 nm) in sanitary towels and diapers (NanoRESP, 2017). The presence of nano-silica in superabsorbent polymer has also been identified in patents (for example, the Hoechst (1991) patent for a new superabsorbent powder containing 55% to 99% cross-linked polymer with free acrylic acid, partially or totally salified by sodium or potassium, in combination with 1-45% colloidal nano-silica in non-agglomerated form with an average diameter of 9-50 nm). Indeed, nano-silica is used in inverse suspension, which is one of the methods for preparing SAP.

In order to corroborate the presence of nano-silica in baby diapers, R-Nano, the national registry of substances with nanoparticle status, was queried with the aim of determining whether substances with nanoparticle status could be found in baby diapers. Various types of searches were therefore performed in this registry, especially for data from the 2016 reporting year. These searches were conducted by:
- names of identified entities (reporting companies or clients of reporting companies),
- chemical names of substances,
- types of use.

The results confirmed that nano-silica is used for its "superabsorbent" properties. It is sold in particular to companies involved in the manufacture of diapers. The queries in the R-Nano database thus partly corroborated the data from the literature.

The addition of nanoparticles with antimicrobial properties was claimed by a start-up that filed a patent to use jellyfish flesh as an absorbent material in absorbent products (sanitary towels, tampons, baby diapers, incontinence diapers, bandages, sponges) instead of SAP.

6.2 Manufacturing processes for disposable diapers

The information available about manufacturing processes comes from EDANA, Group'Hygiène and reports of the UK Environment Agency.

Diaper manufacturers assemble raw materials received from their suppliers to manufacture baby diapers. Once received, the raw materials are stored in a temperature- and humidity-controlled environment.

The fully automated, continuous and mechanical manufacturing process is broken down into three main stages:
- Fiberisation of the fluff pulp, addition of SAP, and formation of the core,
- Lamination with films, nonwoven materials and elastic elements in order to form the disposable diaper,
- Shaping, cutting, folding and packaging.

The different materials are glued together with polymer-based adhesives (UK Environment Agency, 2005a).

The cellulose is bleached to remove lignin and other coloured impurities and to make it more absorbent. Before the 1990s, elemental chlorine was used. In the late 1980s, bleaching processes began to change due to high concentrations of polychlorinated dibenzo-p-dioxins (PCDDs) in wood pulp bleached using chlorine dioxide (Scialli *et al.*, 2001). Bleaching with elemental chlorine was gradually eliminated from the pulp industry. Today, various bleaching methods are used:
- the ECF (elemental chlorine free) method, which uses chlorine dioxide;
- the EECF (enhanced elemental chlorine free) method, which uses oxygen and/or slow heating;
- the TCF (total chlorine free) method, which uses hydrogen peroxide, oxygen or ozone (Counts *et al.*, 2017*).

ECF is the most widely used method. It should be specified that ECF processes with chlorine dioxide reduce the quantity of chlorinated products but do not eliminate them. It is therefore necessary to undertake assays on cellulose derivatives.

6.3   Assessment of raw materials and finished products

In order to comply with the European General Product Safety Directive, companies indicate that the following tests are undertaken at all levels of production for disposable baby diapers:
- when choosing the raw materials, in order to verify their safety and good tolerance with baby skin (sensitisation tests assessing hypoallergenicity, primary skin irritation tests, etc.);
- during manufacturing, in order to verify compliance with good manufacturing processes in terms of hygiene, cleanliness and suitability for the intended purpose;
- with finished products via microbiological and consumer tests;
- quality is then monitored once the diaper has been placed on the market, and consumer feedback is collected and studied.

EDANA has prepared guidelines for the testing of baby diapers, developed by a group of baby diaper manufacturers and testing institutes with expertise relating to these products (EDANA, 2016b).
EDANA's member companies have an ethical obligation to comply with the recommendations and guides to good practice developed within the organisation. Nonetheless, this is based on a voluntary approach. EDANA is not authorised to conduct audits.

- **Raw materials**

Several published studies undertaken by companies describe the steps of safety assessments for materials and raw materials (Kosemund *et al.*, 2009*; Dey *et al.*, 2014* and 2016b*):

- The first step consists in obtaining the complete composition of each material proposed for the manufacture of baby diapers;
- The safety of each material is assessed via a quantitative health risk assessment (QHRA) undertaken according to the principles of the United States National Academy of Sciences (US NAS) and the World Health Organization (WHO) (Dey *et al.,* 2014* and 2016b*). Thus, potential hazards associated with the ingredients are assessed, as are dose-response relationships. These are followed by an assessment of potential exposure and a characterisation of the risks. This QHRA is taken into account to determine a "safe" quantity of use in diapers for each ingredient (see §7.1.2). No ingredients are incorporated into diapers until their safety has been confirmed.
- Once the QHRA has been undertaken, compatibility assessments are carried out in addition to clinical tests to assess skin irritation. The skin's pH and moisture level as well as the lack of rash and mechanical irritation are some of the relevant parameters to be considered. Patch testing is conducted on adult skin to quantify potential skin irritation and sensitisation.
- Clinical confirmation tests are then undertaken for chemicals to confirm the results under real-life conditions.

- **During manufacturing**

According to EDANA's recommendations, various tests should be conducted with samples and the finished product in the manufacturing phase to ensure their quality and safety (EDANA, 2008).

- **Finished products**

EDANA recommends, for absorbent hygiene products including disposable baby diapers, adhering to the BfR Guidelines for the Evaluation of Personal Sanitary Products (BfR, 1996; EDANA, 2016a). In particular:

- Azo dyes that may produce any of the amines listed in Annex 1 of the German Commodities Regulation[14] may not be used;
- Cellulose, wood pulp, plastics and dyes should comply, by analogy, with the BfR recommendations on food contact materials;
- Any fragrances used should comply with the Code of Practice of the International Fragrance Association (IFRA).

However, considering that these guidelines are over 20 years old, companies can deviate from them provided that they justify compliance with safety requirements (EDANA, 2016a).

- **Post-marketing monitoring**

Manufacturers have departments that deal with consumer claims involving their products (there is usually a phone number on the packaging). Depending on the company, in the event of medical complaints, investigations may be launched and appropriate actions taken (EDANA, 2005; Kosemund *et al.*, 2009*).

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14 http://www.gesetze-im-internet.de/bedggstv/anlage_1.html, Annex I, No. 7, §3

Lastly, manufacturers have procedures for recalling products in event of an incident. In its 2005 guide, EDANA stated that no product recalls for single-use baby diapers had been necessary for products manufactured by EDANA members (EDANA, 2005; Kosemund *et al.*, 2009*).

7 Summary of the literature

7.1   Chemical risks

7.1.1   Chemicals in baby diapers

- **Composition**

In 2009, the Danish Environmental Protection Agency **(Danish EPA)** published a report on the assessment of exposure of two-year-olds to chemical substances in consumer products (Danish EPA, 2009). The agency selected several consumer products including baby diapers. Five single-use diapers from various sources were analysed (range of prices, popular brands, organic/non-organic brands). Several diaper parts were studied. Aliphatic hydrocarbons and polymers were found but not identified. All of the five tested diapers contained antioxidants. Limonene, used as a fragrance, was detected in three diapers and in particular in a diaper whose packaging said it was fragrance-free. Similarly, very low levels of formaldehyde were detected but not quantified in three diapers and more specifically in the printed backsheet and the acquisition layer. For all of the diapers, the table in Annex 5 summarises the chemicals detected, semi-quantified or quantified and the part of the diaper in which each chemical was found.

The Belgian Federal Public Service (VITO, 2018) screened four baby diapers in order to identify all of the compounds that could be extracted from a diaper. Levels of esters, heavy alcohol, alkanes and siloxanes were observed, but with "no risks to health".

In a second phase, 20 baby diapers of big-name brands, "store" brands and "bio" brands were analysed in order to screen for 17 PAHs, glyphosate and AMPA (aminomethylphosphonic acid), pesticides, phthalates (DEHP, DBP, DMP, DINP), parabens, isothiazolinones, phenolic compounds, PFOA, BTEX and dioxins and furans. Only the inner surface in contact with babies' skin was analysed after shredding. SAP was removed before extraction. The concentrations of most of the detected chemicals were below the limit of quantification. Some chemicals were quantified but at concentrations below 1 mg/kg with the exception of nonylphenol in a few diapers and BIT in one diaper:

- Nonylphenol in 17 products (0.038-4.4 mg/kg),
- Isothiazolinones in three products (MIT: 0.019-0.44 mg/kg; BIT: 1.6 mg/kg),
- Glyphosate (0.072-0.13 mg/kg) and AMPA (0.18 mg/kg) in two products,
- 6-caprolactam (0.029-0.59 mg/kg) in 10 products,
- Phthalates in one product (DEHP: 0.4 mg/kg; DBP: 0.18 mg/kg).

Dioxins and furans (2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDF) were quantified in eight products. Toxic equivalent quantity (TEQ) values for the sum of dioxins and furans ranged from 0.16 to 0.61 ng $_{TEQ}$/kg.

The most frequently quantified chemicals were nonylphenol and caprolactam. Possible sources of caprolactam include nylon threads and poly(ether-amide) elastomers. This chemical causes skin irritation. However, VITO considers it to be safe in baby diapers since the concentrations found are low. Nonylphenol is an endocrine disruptor, whose presence probably originates from the use of nonylphenolethoxylates (surfactants used for

cleaning, surface treatment, emulsification, solubilisation, etc.). Another source may be antioxidants (TNPP: tris(4-nonylphenyl) phosphite). The presence of nonylphenol should be further investigated and measures should be taken to reduce levels of this chemical in baby diapers.

In 2018, the Swiss Federal Food Safety and Veterinary Office (FSVO), in collaboration with the Fédération Romande des Consommateurs (FRC), a Swiss consumer association, also carried out tests with 21 single-use diapers available on the Swiss market. One hundred and fourteen chemicals were screened for in shredded diapers: dioxins and furans, PAHs, perfluorinated substances, glyphosate and AMPA, phthalates, volatile organic compounds (VOCs) and solvent residues. Dioxins and furans (1,2,3,4,6,7,8-HpCDD, OCDD and 1,2,3,4,6,7,8-HpCDF) were quantified in one product. PAHs (naphthalene, anthracene and pyrene) were quantified in 17 out of 19 diapers. Lastly, DIBP was quantified in one product. The FSVO concluded that baby diapers do not contain chemicals likely to pose health risks for infants or toddlers (FSVO, 2018; FRC, 2018). It should be noted that these conclusions were drawn without conducting a QHRA.

As part of tests undertaken by a company, polycyclic aromatic hydrocarbons (**PAHs**) were screened for in several parts of three diapers of two different brands (LQ = 0.1 mg/kg). Benzo[a]anthracene (0.11-0.194 mg/kg) and chrysene (0.0182-0.104 mg/kg) were quantified in two diapers, more particularly in the elastics for the first diaper and in the front and rear parts for the second diaper (industrial study, 2016).

In the **scientific literature**, some studies have screened for the presence of **dioxins and furans** in disposable and reusable baby diapers (Wiberg *et al.,* 1989; Schecter *et al.,* 1998; DeVito and Schecter, 2002; Shin *et al.*, 2005). TEQs were calculated in these various studies, primarily using the WHO's toxic equivalency factors (TEFs), in order to express the overall toxicity of dioxin mixtures. This is because dioxins are generally found in mixtures containing several types of dioxins and dioxin-like compounds, each with a specific degree of toxicity.

In 1989, Wiberg *et al.* measured levels of polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) in baby diapers on the Swedish market that had or had not been bleached without chlorine (Table 5). These authors also presented results for cloth diapers. The packaging of the diapers included the statement "chlorine-free" or "dioxin-free".

Table 5: Levels of PCDDs and PCDFs in baby diapers (Wiberg *et al.,* 1989)

	TCDD equivalent*	2,3,7,8-TCDF	2,3,7,8-TCDD	2,3,4,7,8-PeCDF	1,2,3,7,8-PeCDD
Disposable diapers	1.0 pg/g	2.7 pg/g	0.54 pg/g	<0.2 pg/g	<0.3 pg/g
Cloth diapers (unwashed)**	<0.2 pg/g	<0.2 pg/g	<0.1 pg/g	<0.1 pg/g	<0.1 pg/g

* calculated using "Nordic toxic equivalency factors" (1988)
** 1,2,3,7,8-PeCDF, 1,2,3,4,6,7,8-HpCDF, OCDF and OCDD were detected.

In 1998, Schecter *et al.* conducted a preliminary study on sanitary products including baby diapers of four different brands. Three of these were disposable diapers and one was a reusable cotton diaper. The authors quantified PCDDs and PCDFs (Table 6). The lowest concentrations were found in the cotton diaper.

Table 6: Concentrations of dioxins and furans in baby diapers (Schecter _et al.,_ 1998)

Diapers	Measured levels (ppt)			Dioxin TEQ (ppt)		
	PCDDs	PCDFs	Sum	PCDDs	PCDFs	Sum
Disposable - Brand E	3.9	1.8	5.6	0.005	0.064	0.069
Disposable - Brand F	2.2	0.5	2.7	0.005	0.010	0.015
Disposable - Brand G	1.8	0.5	2.3	0.004	0.010	0.014
Reusable diaper	2.6	0.2	2.7	0.005	0.001	0.006

De Vito and Schecter (2002) analysed four baby diapers, including three disposable diapers and one cotton diaper, all purchased in San Francisco. They screened for 17 PCDDs and PCDFs. Only five of the 17 dioxins were detected in the diapers (LD = 0.1 - 0.2 ppt). There were similar concentrations in the disposable and reusable diapers. Total PCDD/F concentrations in the diapers ranged from 1.8 to 3.7 pg/g, i.e. from 0.0042 pg TEQ/g (cotton diaper) to 0.023 pg TEQ/g (disposable diaper).

In a Korean study, Shin _et al._ (2005) screened for PCDDs and PCDFs in disposable diapers purchased in Korea, Japan, the United States and Germany (Shin _et al._, 2005 – abstract; article in Korean). OCDD was quantified in four diapers (two Korean and two Japanese), with concentrations ranging from 0.0013 to 0.0058 pg TEQ/g, and HpCDD in one Korean diaper (0.0163 pg TEQ/g). HpCDD ($5.6 \cdot 10^{-3}$ pg TEQ/g) and OCDD ($6\text{-}9 \cdot 10^{-4}$ pg TEQ/g) were quantified in three diapers (two purchased in the USA and one in Germany) after six hours of extraction whereas HxCDD (10^{-4} pg TEQ/g), OCDD ($4\text{-}6 \cdot 10^{-4}$ pg TEQ/g) and OCDF ($9 \cdot 10^{-4}$ pg TEQ/g) were found in four diapers (three American and one Japanese) after 24 hours of extraction.

Ishii _et al._ (2015) screened for seven **phthalates** (DEPH, DBP, BBP, DINP, DIDP, DNOP, DIBP) in the topsheet of five single-use diapers sold in Japan (two tests per product) (Ishii _et al._, 2015). DEHP and DBP were quantified in the topsheet, respectively in the concentration ranges of 0.1 to 0.6 µg/g and 0.1 to 0.2 µg/g (LQ = 0.1 µg/g). The other phthalates were not quantified.

Karlberg and Magnusson analysed the topsheet (including the glue) and core of the most common disposable baby diapers on the Swedish market to screen for **rosin components**:
- Abietic acid and dehydroabietic acid, which are the main allergens,
- 7-oxodehydroabietic acid, since it is a stable and easily analysable compound.

These rosin components were detected in all the diapers, essentially in the topsheet. No rosin components were found in the topsheet before gluing with cellulose for one diaper product tested in 1995. According to the producer, no rosin components should be present in the glue used for diapers. However, according to the authors, modified rosin is commonly used in glues.

Rosin is a known skin sensitiser. However, due to a lack of studies investigating the sensitising effects of low concentrations of rosin, the authors could not say whether the amounts detected in diapers were sufficient to cause sensitisation. Thus, the risk of inducing sensitisation to the rosin allergens contained in diapers can be considered low. However, the presence of rosin allergens in diapers poses a real risk of eliciting dermatitis in sensitised individuals, especially since penetration is enhanced by occlusion and irritation, potentially increasing this risk (Karlberg and Magnusson, 1996).

Moreover, the only available data on **tributyltin (TBT)** residues come from the **grey literature.** The CES could not determine the scientific quality of these data, in particular

due to the absence of precise descriptions of the analytical protocols used. Analyses undertaken by Greenpeace (2000) highlighted traces of TBT in disposable diapers sold in Germany (4.2 µg/kg in a first diaper, 4.7 µg/kg in a second, and 8.6 µg/kg in a third). A new analysis was carried out with several diaper parts. Higher concentrations of up to 38.4 µg/kg were found. TBT was found in both the inner and outer parts of the diaper, with the highest concentrations observed in the belt section. Other organotins (dibutyltin and monobutyltin) were also found.

Several articles on baby diapers have been published in the **grey literature** (UFC Que Choisir, 2015 and 2018; 60 Millions de Consommateurs, 2016 and 2018; Test-Achats, 2015; Anàlisis, 2015; Stiftungwarentest, 2005).

In 2015, the consumer group UFC Que Choisir published a study on the chemical contamination of products intended for young children (UFC Que Choisir, 2015). Sixty-eight products were analysed, including 11 diapers. Several of these 11 diapers had a "slightly high pH" while four "contained small quantities of one or two PAHs".
In 2018, UFC Que Choisir analysed 12 disposable diapers (size 4) to screen for 26 allergens listed by the EU, 18 PAHs and glyphosate, AMPA and glufosinate (in shredded material, by solvent extraction). Glyphosate was quantified in the central part of one diaper. However, the Hauts-de-Seine Departmental Directorate for the Protection of Populations (DDPP) did not identify any contamination for this same diaper. In another diaper, naphthalene was quantified in the elastics (0.24 mg/kg). No allergens were detected.

In 2017, 60 Millions de Consommateurs published the results of a comparative test on baby diapers. Twelve disposable diapers (size 3) were tested: four brand-name diapers, four own-brand diapers and four diapers with environmental claims. The objective was to "verify whether industrial diaper manufacturing processes or treatments generate residues with toxic risks". The following chemicals were screened for in each shredded diaper: pesticides including glyphosate, PAHs, dioxins and furans, allergens and VOCs. When necessary, additional analyses were undertaken with various diaper parts. The tests highlighted "residual" levels of pesticides, PAHs, dioxin traces and VOCs.
In 2018, 60 Millions de Consommateurs published a new comparative study involving 12 disposable baby diapers (four brand-name diapers, four own-brand diapers and four diapers with environmental claims). With the exception of four new products, the same diapers that had been tested in the 2017 study were analysed. The objective was to verify changes in industrial diaper manufacturing processes and whether the various treatments used generated any residues with toxic risks compared to the 2017 tests. The following chemicals were screened for in each shredded diaper: pesticides including glyphosate and AMPA, allergens, PAHs, VOCs, heavy metals, dioxins and furans, and nonylphenols, octylphenols and nonylphenolmonoethoxylate. These tests revealed the presence of VOCs and pesticides including AMPA.

In 2015, the Belgian association Test-Achats (Test-Achats, 2015) tested 12 different diapers and found PAHs in two of them.

Moreover, in 2015, the Spanish magazine Anàlisis published a study undertaken with 13 diapers whose objective was, among other things, to verify the presence of certain chemicals (Anàlisis, 2015). PAHs were found in two diapers; they included phenanthrene

and naphthalene in an eco-friendly diaper and naphthalene at concentrations below 1 mg/kg in another diaper.

Also in Spain in 2015, the journal OCU Salud (OCU Salud, 2015) analysed 11 diapers and detected anthracene and naphthalene in four of them. The magazine indicated that certain diapers had a non-neutral pH that was nonetheless within the limits recommended by the Oeko Tex certification scheme.

Lastly, in 2005, Stiftung Warentest (Stiftung Warentest, 2005) tested 21 diapers and screened for the presence of azo dyes, disperse dyes, heavy metals, formaldehyde, organotins and chlorophenol. Stiftung Warentest did not detect traces of these chemicals in any of the 21 diapers.

- **Emissions**

Only one experimental study was identified examining **emissions** from baby diapers (three disposable and one reusable) and their acute pulmonary effects (Anderson and Anderson, 1999). Male Swiss-Webster mice (n=4/group) were exposed from one to three times (t0, t6h and/or t24h), for 60 minutes, to emissions from four diapers placed in an emission chamber heated to 37°C. The chamber was continuously ventilated for 15 minutes before and after exposure. Total (VOC) concentrations ranged from 10 to 340 ppm after one hour of exposure (equilibrium) and were constant. An analysis of the chemicals emitted in the chamber identified around half of the peaks and showed the presence of several chemicals.

Table 7: Substances emitted from disposable diapers (Anderson and Anderson, 1999)

Diaper	Disposable				Cloth
	A	**B**	**C**		
Total VOCs (ppm)	340	200	35	190	10
Emitted chemicals	m-xylene p-anisaldehyde ethylbenzene styrene isopropylbenzene (cumene) dipentene m-methoxybenzaldehyde methyl cinnamate	toluene 1,3,5-trimethylbenzene trichloroethene 1-methylcyclopentylamine 1,2,3-trimethylcyclopentane dipentene	/	/	/

The mice exposed to diapers A and B showed sensory and pulmonary irritation and reduced airflow. The majority of the effects were larger with repeated exposure for brands A and B. Brand C caused increases in respiratory rate, tidal volume and mid-expiratory airflow velocity. Emissions from the reusable diaper only caused slight sensory and pulmonary irritation. Following two periods of exposure to diaper A, the histological analyses detected neutrophils, lymphocytes and oedema in the lungs. The authors considered these observations to be consistent with the slight inflammation of the alveolar walls. The bronchial mucosa and sub-mucosa were normal.

Thus, at least two diapers emitted VOC mixtures capable of causing adverse respiratory effects in mice. According to the authors, sensory irritation can be extrapolated from mice to humans, as it is the result of trigeminal nerve activation. Substances causing a sensory irritation reflex in mice induce a sensation of stinging, burning or pain in the eyes, nose, throat and/or face in humans. Regarding pulmonary irritation, Swiss-Webster mice seem

less sensitive to several atmospheric irritants than humans. The authors conclude that disposable baby diapers should be considered as one of the factors that may cause or exacerbate asthma. The CES expressed reservations regarding the scientific validity of this study, both in terms of the methodology used and the conclusions drawn.

7.1.2 Residue analyses and migration tests

7.1.2.1 Residue analyses in shredded whole diapers and diaper parts (by solvent extraction)

7.1.2.1.1 SCL (2017)

In the context of various controversies surrounding the use of feminine hygiene products (tampons and sanitary towels), the DGCCRF decided to include baby diapers and incontinence products in the laboratory testing campaign on all products placed on the market with the aim of verifying their composition and safety.

The DGCCRF thus collected samples from 19 of the best-selling brand-name and own-brand diapers in France. Samples were only taken from single-use diapers.

The following tests were undertaken:
- Composition analysis,
- Analyses of pesticide residues (362 compounds), glyphosate and its metabolite AMPA (aminomethylphosphonic acid),
- Analyses of phthalate residues (16 compounds),
- Analyses of organotin residues (tributyltin and dioctyltin),
- Analyses of PAHs (17 compounds in whole diapers and elastic diaper parts),
- Analyses of VOC levels (41 compounds),
- Analyses of odoriferous substances and preservatives (24 compounds),
- Analyses of dioxins, furans and dioxin-like polychlorinated biphenyls (DL-PCBs),
- Analyses of adsorbable organic halogens (AOX),
- Formaldehyde analyses,
- Analyses of 22 azo dyes, only in the backsheet (for three diapers having a coloured backsheet).

The tests were conducted with shredded whole diapers and/or shredded elastic parts (for PAHs only), in accordance with the SCL's internal protocols or with standards specific to each tested class of substance when such standards were available.

In light of the results (Table 8 and Table 9), the following observations can be made for the shredded whole diapers and elastic parts:
- No phthalates were detected,
- No pesticides (including glyphosate and AMPA) were detected,
- No organotins were detected,
- No azo dyes were detected,
- DL-PCBs were quantified in all the diapers at concentrations ranging from 16.98 to 1404.98 ng/kg of diaper,
- VOCs were quantified in all the diapers. Naphthalene and toluene were the two compounds found in most of the samples,
- PAHs were detected in the elastic parts (indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene, benzo[b]fluoranthene, benzo[a]anthracene) but at concentrations below the limits of quantification,

- Dioxins were quantified in 17 of the 19 analysed samples,
- Furans were quantified in 14 of the 19 analysed samples,
- Fragrances were detected but not quantified in only one sample,
- Formaldehyde was quantified in all the analysed samples (n=19).

Table 8: Chemicals quantified in shredded whole diapers (SCL, 2017)

Anonymised products	Chemicals (LD/LQ)								
	p-isopropyltoluene	m-xylene + p-xylene	o-xylene + styrene	Chlorobenzene	Naphthalene	Toluene	Total dioxins + furans (TEQ)	Total PCBs (TEQ)	Formaldehyde
	0.3 / 1 µg/kg						/	/	0.11 / 0.35 mg/kg
1	2 ± 1 µg/kg	2 ± 1 µg/kg	-	7 ± 2 µg/kg	-	9 ± 3 µg/kg	0.1 ng/kg	0.045 ng/kg	2.74 mg/kg
2	2 ± 1 µg/kg	-	-	-	-	5 ± 2 µg/kg	0.2 ng/kg	0.08 ng/kg	1.91 mg/kg
3	1 ± 0.9 µg/kg	-	3 ± 1 µg/kg	-	-	6 ± 2 µg/kg	0.1 ng/kg	0.101 ng/kg	37.4 mg/kg
4	-	-	-	-	9 ± 3 µg/kg	9 ± 3 µg/kg	0.1 ng/kg	0.101 ng/kg	1.89 mg/kg
5	-	3 ± 2 µg/kg	1 ± 0.9 µg/kg	-	-	-	0.1 ng/kg	0.032 ng/kg	2.29 mg/kg
6	-	2 ± 1 µg/kg	-	-	-	13 ± 4 µg/kg	0.3 ng/kg	0.146 ng/kg	1.75 mg/kg
7	3 ± 2 µg/kg	5 ± 2 µg/kg	4 ± 2 µg/kg	8 ± 2 µg/kg	1 ± 0.9 µg/kg	-	0.2 ng/kg	0.126 ng/kg	1.48 mg/kg
8	2 ± 1µg/kg	-	-	-	11 ± 3 µg/kg	-	0.1 ng/kg	0.157 ng/kg	1.55 mg/kg
9	5 ± 2 µg/kg	10 ± 3 µg/kg	5 ± 2 µg/kg	-	2 ± 1 µg/kg	2 ± 1 µg/kg	0.2 ng/kg	0.069 ng/kg	3.70 mg/kg
10	-	2 ± 1 µg/kg	2 ± 1 µg/kg	-	-	16 ± 5 µg/kg	0.3 ng/kg	0.161 ng/kg	2.8 mg/kg
11	2 ± 1 µg/kg	7 ± 2 µg/kg	-	-	13 ± 4 µg/kg	11 ± 3 µg/kg	0.1 ng/kg	0.186 ng/kg	2.28 mg/kg
12	-	-	-	2 ± 1 µg/kg	-	10 ± 3 µg/kg	0.3 ng/kg	0.099 ng/kg	1.51 mg/kg
13	2 ± 1 µg/kg	-	-	-	-	14 ± 4 µg/kg	0.1 ng/kg	0.089 ng/kg	2.14 mg/kg
14	5 ± 2 µg/kg	7 ± 2 µg/kg	2 ± 1 µg/kg	2 ± 1 µg/kg	2 ± 1 µg/kg	13 ± 4 µg/kg	0.1 ng/kg	0.119 ng/kg	3.15 mg/kg
15	13 ± 4 µg/kg	-	-	11 ± 3 µg/kg	12 ± 4 µg/kg	12 ± 4 µg/kg	0.1 ng/kg	0.048 ng/kg	2.17 mg/kg
16	1 ± 0.9 µg/kg	-	4 ± 1 µg/kg	-	-	5 ± 2 µg/kg	0.2 ng/kg	0.096 ng/kg	2.91 mg/kg
17	2 ± 1 µg/kg	-	-	-	6 ± 2 µg/kg	-	0.1 ng/kg	0.083 ng/kg	1.84 mg/kg
18	-	1 ± 0.9 µg/kg	2 ± 1 µg/kg	-	1 ± 0.9 µg/kg	36 ± 11 µg/kg	0.1 ng/kg	0.223 ng/kg	2.04 mg/kg
19	3 ± 1 µg/kg	2 ± 1 µg/kg	-	-	-	10 ± 3 µg/kg	0.2 ng/kg	0.122ng/kg	1.74 mg/kg

Table 9: Chemicals detected in shredded whole diapers or elastic parts (SCL, 2017)

Anonymised products	LD	Part	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Benzo[b]fluoranthene	0.03 mg/kg	Elastic part	-	-	-	-	-	-	x	-	-	-	-	-	-	x	-	-	-	-	-
Benzo[a]anthracene			-	-	-	-	-	-	-	-	-	-	-	-	-	x	-	-	-	-	-
Indeno[1,2,3-c,d]pyrene			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	x	-
Benzo[g,h,i]perylene			-	-	-	-	x	-	-	-	-	-	-	-	-	-	-	-	-	x	-
Naphthalene	0.3 µg/kg	Whole diaper	-	x	-	-	-	x	-	-	-	-	-	-	x	-	-	x	-	-	x
1,4-dichlorobenzene			x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
p-isopropyltoluene			-	-	-	-	x	x	-	-	-	-	-	x	-	-	-	-	-	x	-
1,3-dichlorobenzene			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	x	-
m-xylene + p-xylene			-	-	-	-	-	-	-	-	-	-	-	x	x	-	-	x	x	-	-
o-xylene + styrene			-	-	-	-	-	-	-	-	-	-	-	-	-	-	x	-	-	-	x
Chlorobenzene			-	-	x	x	-	x	-	-	-	x	x	-	x	-	-	-	-	x	-
Benzyl alcohol	0.0003%		x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Benzyl salicylate			x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Coumarin	0.001%		x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	0.0004%		x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3-(4-tert-butylphenyl)-2-methylpropanal	0.0003%		x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Limonene			x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Linalool			x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Alpha-isomethyl ionone			x	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

7.1.2.1.2 Group'Hygiène (2017)

The tests undertaken by Group'Hygiène are described in Annex 6, along with their results (CONFIDENTIAL).

7.1.2.2 Residue analyses in whole diapers or shredded whole diapers: migration tests in a urine simulant

7.1.2.2.1 With shredded whole diapers (SCL, 2017)

The DGCCRF carried out an initial exploratory study in order to measure the migration to a urine simulant of the chemicals detected or quantified in shredded whole diapers. Thus, only fragrances, VOCs, dioxins, furans and DL-PCBs were screened for in the 19 diapers analysed in the tests described above (see §7.1.2.1.1). The tests were undertaken by immersing 1 g of shredded diaper in 100 ml of urine simulant.

The composition of the urine simulant used was based on the publication by Colón *et al.* (2015) (Table 10).

Table 10: Composition of the urine simulant used (Colón *et al.*, 2015)

Compound	Concentration obtained
Urea	9.3 g·L^{-1}
Creatinine	2 g·L^{-1}
Ammonium citrate	1 g·L^{-1}
NaCl	8 g·L^{-1}
KCl	1.65 g·L^{-1}
KHSO$_4$	0.5 g·L^{-1}
MgSO$_4$	0.2 g·L^{-1}
KH$_2$PO$_4$	1.75 g·L^{-1}
KHCO$_3$	0.5 g·L^{-1}

Each shredded diaper was brought into contact with the urine simulant in an oven at 37°C (+/- 3°C) for four hours (+/- 10 mins) under stirring.

In light of the results (Table 11), it can be noted that:
- No fragrances were detected in the urine simulant,
- VOCs were not detected in the urine simulant,
- The dioxins, furans and DL-PCBs that had been quantified in the composition tests with the shredded diapers were found at concentrations of the same order of magnitude in the urine simulant.

Table 11: Quantified chemicals in TEQ (ng $_{TEQ}$/kg of diaper) extracted by the urine simulant from a shredded diaper with the first exploratory study (SCL, 2017)

Anonymised products	Total dioxins + furans	Total DL-PCBs
1	$7.62 \cdot 10^{-4}$	$5.69 \cdot 10^{-3}$
2	$9.40 \cdot 10^{-3}$	$1.37 \cdot 10^{-3}$
3	$3.02 \cdot 10^{-3}$	$1.48 \cdot 10^{-3}$
4	$2.29 \cdot 10^{-2}$	$5.56 \cdot 10^{-3}$
5	$5.19 \cdot 10^{-3}$	$1.43 \cdot 10^{-3}$
6	$9.20 \cdot 10^{-2}$	$1.14 \cdot 10^{-3}$
7	$1.11 \cdot 10^{-4}$	$7.55 \cdot 10^{-3}$
8	$2.01 \cdot 10^{-3}$	$6.52 \cdot 10^{-4}$
9	$3.23 \cdot 10^{-3}$	$1.26 \cdot 10^{-3}$
10	$1.88 \cdot 10^{-2}$	$2.37 \cdot 10^{-3}$
11	$1.66 \cdot 10^{-3}$	$4.83 \cdot 10^{-4}$
12	$4.29 \cdot 10^{-2}$	$2.90 \cdot 10^{-3}$
13	$3.08 \cdot 10^{-2}$	$2.85 \cdot 10^{-3}$
14	$6.34 \cdot 10^{-4}$	$8.65 \cdot 10^{-4}$
15	$8.36 \cdot 10^{-3}$	$7.42 \cdot 10^{-3}$
16	$1.65 \cdot 10^{-2}$	$1.46 \cdot 10^{-3}$
17	$1.64 \cdot 10^{-4}$	$6.21 \cdot 10^{-4}$
18	$2.44 \cdot 10^{-2}$	$1.15 \cdot 10^{-3}$
19	$7.90 \cdot 10^{-3}$	$1.36 \cdot 10^{-3}$

7.1.2.2.2　With whole diapers

- Group'Hygiène (2017)

The tests undertaken by Group'Hygiène are described in Annex 6, along with their results (CONFIDENTIAL).

- SCL (2018) – Second exploratory study

In 2018, the DGCCRF undertook a second exploratory study in order to measure the chemicals detected in the same 19 baby diapers, with the same urine simulant (Table 10) (Colón *et al*., 2015). In this study, the analyses were carried out with whole diapers soaked with urine simulant and then placed in an oven at 37°C for 16 hours. 200 ml of simulant were added to the diaper three times, with a 30-minute rest period between each addition. The tested simulant was extracted by pressing (recovery of 220 to 250 ml). The majority of the 600 ml of urine simulant remained trapped in the SAP. According to the CES, this was the test most closely replicating actual conditions of exposure in children, both in terms of the transfer of substances to the urine simulant and the composition of the simulant.

In light of the results described in Table 12, it can be noted that:
- No analysed fragrances were detected in the extracted urine simulant,
- No analysed VOCs were detected in the extracted urine simulant,
- Dioxins, furans and DL-PCBs were quantified in the extracted urine simulant with all the diapers,
- Formaldehyde was quantified or detected in the urine simulant extracted from 14 diapers,
- PAHs were detected but not quantified in the urine simulant extracted from 16 diapers (benzo[e]pyrene; benzo[a]pyrene; benzo[b]fluoranthene; dibenzo[a,h]anthracene; 5-methylchrysene; chrysene; benzo[g,h,i]perylene; benzo[k]fluoranthene; benzo[j]fluoranthene).

Table 12: Quantities of chemicals contained in the diapers and extracted by the urine simulant in relation to diaper weight. Second exploratory study (SCL, 2018)

Anony mised produc ts	Formal-dehyde (mg/kg)	Total DL-PCBs (ng/kg)	Total dioxins + furans (ng/kg)	Benzo[e] pyrene (mg/kg)	Benzo[a] pyrene (mg/kg)	Benzo[b] fluoranthene (mg/kg)	Dibenzo [a,h] anthracene (mg/kg)	5-methyl chrysene (mg/kg)	Chrysene (mg/kg)	Benzo[g,h,i] perylene (mg/kg)	Benzo[k] fluoranthen e (mg/kg)	Benzo[j] fluoranth ene (mg/kg)
1	3.57	35.67	0.43	-	-	-	-	-	-	-	-	-
2	1.86	30.80	0.3	< LQ = 2	-	-	-	-	-	-	-	-
3	-	34.03	0.67	-	< LQ = 2.21	-	-	-	-	-	-	-
4	1.66	13.76	0.09	-	-	< LQ = 1.82	< LQ = 0.54	-	-	-	-	-
5	-	6.04	0.13	< LQ = 1.58	-	-	-	-	-	-	-	-
6	1.23	11.44	0.06	-	-	-	-	< LQ = 1.7	-	-	-	-
7	2.91	34.84	0.83	< LQ = 2.2	-	-	-	-	-	-	-	-
8	-	7.39	0.84	< LQ = 1.93	-	< LQ = 1.93	-	-	-	-	-	-
9	1.99	379.6	1.36	< LQ = 3.26	-	-	-	-	-	-	-	-
10	1.15	43.40	0.16	< LQ = 1.36	-	-	-	-	< LQ = 1.36	< LQ = 1.36	-	-
11	1.62	36.94	0.36	-	< LQ = 1.92	-	-	-	-	-	-	-
12	4.98	29.94	0.64	< LQ = 1.72	-	< LQ = 1.72	-	-	-	< LQ = 1.72	-	-
13	7.18	20.38	0.30	< LQ = 1.71	-	< LQ = 1.71	-	-	-	-	-	-
14	4.66	27.24	0.25	-	-	-	-	-	-	-	-	-
15	7.5	25.71	0.12	< LQ = 2.28	-	-	-	-	-	< LQ = 2.28	-	-
16	-	20.73	0.04	-	-	< LQ = 2.08	-	-	-	< LQ = 2.08	-	-
17	-	12.13	0.07	< LQ = 2.01	-	< LQ = 2.01	-	-	-	< LQ = 2.01	< LQ = 2.01	< LQ = 2.01
18	ND (LQ = 1.07)	12.48	0.06		< LQ = 1.77							
19	1.10	8.76	0.06	-	-	-	-	-	-	-	-	-

ND: not detected; * The results in the table correspond to the concentrations extracted in the urine simulant without taking into account the volume recovered (220-250 ml).

7.1.3 Exposure calculations and risk assessments for single-use diapers

Rai *et al.* and Kosemund *et al.* (both Procter & Gamble) explain how risks are assessed for single-use diapers (Rai *et al.*, 2009*; Kosemund *et al.*, 2009*). Assessments adhere to the quantitative health risk assessment (QHRA) approach divided into four separate steps: hazard identification, description of dose-response relationships as part of hazard characterisation, exposure assessment, and health risk characterisation. According to the authors, the polymer materials in single-use diapers are of little concern since they are large and generally inert polymers not absorbed by the skin. However, special attention is paid to the remaining substances: non-polymer substances such as processing aids, aesthetic ingredients such as fragrances and dyes, and monomers, solvents and additives used during polymerisation.

Initially, physico-chemical parameters are analysed to determine whether substances can migrate outside of the diaper and whether they are bioavailable.

During the hazard identification step, available human and animal data are used. **The relevant effects to be considered in this context are systemic (acute, subchronic and chronic toxicity, reproductive and developmental toxicity, genotoxicity, carcinogenicity, neurotoxicity) and local (skin irritation, allergic contact dermatitis) effects.**

The exposure assessment takes into consideration the body weight and age of babies and the number of diapers used per day. Further details regarding exposure can be obtained by undertaking migration studies or permeation tests for example.

Rai *et al.* (2009*) and Dey *et al.* (2016a*) proposed two examples of QHRAs, involving citral, a raw material in fragrances, and acrylic acid, a residual monomer of SAP.

For citral, the authors followed the recommendations of the European Cosmetic and Perfumery Association (COLIPA) and IFRA to carry out the quantitative risk assessment for sensitisers, i.e. they adopted a margin of safety (MOS) approach. Exposure was calculated as follows:

$$(M \times C \times f \times T) / S$$

where: M: mass of raw material in the diaper (g/diaper) (e.g. quantity of fragrance per diaper)

C: concentration of the substance in the raw material (%)

f: frequency of use (number of diapers used per day). The number of diapers used varies depending on the baby's age (six per day for newborns and three for toddlers in Japan). For simplification purposes, an average frequency was used: five diapers/day

T: transfer of fluid to the skin from the inner parts of the diaper: 0.25% of the absorbed fluid

S: exposed surface area of skin (cm²): 1186 cm² (smallest diaper)

Rai *et al.* (2009*) concluded there was no risk of sensitisation for citral with an MOS of 1,000,000.

SAP is produced via the polymerisation of acrylic acid in an aqueous solution. However, since the polymerisation process is not 100% effective, there can be small residual

quantities of acrylic acid in SAP, primarily in salt form (sodium acrylate). Exposure was assessed using the following formula:

$$DED \ (mg/kg/day) = (M \times C \times f \times T \times A) / BW$$

where: M: mass of SAP in the diaper (g/diaper): not mentioned in Rai *et al.*, 15 g according to Dey *et al.*;
  C: concentration of the substance in the raw material (ppm): not mentioned in Rai *et al.*, 500 ppm according to Dey *et al.*;
  f: frequency of use (number of diapers used per day): five diapers/day in Rai *et al.*, six diapers/day according to Dey *et al.* (average: 4.4; 90th percentile: 6; and 95th percentile: 7);
  T: transfer of fluid to the skin from the inner parts of the diaper: 0.25% of the absorbed fluid (default factor) in Rai *et al.*, 0.19% of the absorbed fluid measured using the PERMID[15] method) according to Dey *et al.*;
  A: dermal absorption: 100%
  BW: body weight. This varies during the diaper-wearing period: 3.5 to 4 kg for a newborn, 10 kg on average at 12 months and 18 to 25 kg for toddlers. A body weight of 8 kg was used.

Rai *et al.* (2009*) and Dey *et al.* (2016a*) concluded there was no systemic risk for acrylic acid (MOS > 1). The MOS calculated by Dey *et al.* was 45, considering the TRV of the US EPA of 0.5 mg/kg/day and the DED of 0.011 mg/kg/day.

When no data are available for a chemical, it is recommended to undertake an assessment using the Threshold of Toxicological Concern (TTC) approach. This approach provides a conservative estimate of acceptable chronic exposure in the absence of data. This approach developed by the US FDA for food additives has been extended to include fragrances and other materials used in personal care products such as baby diapers. An example of implementation with the TTC method was proposed for an adhesive contaminant not specified in the publication (Rai *et al.*, 2009*).

Group'Hygiène affirms that the presence of **superabsorbents** is "without risk for babies". "These polymers have been used for around 20 years in baby diapers, as well as in products for adult incontinence and sanitary towels. The characteristics of these polymers are known. In particular, they are not sensitising for the skin or mucous membranes and their potential for irritation is low. The good tolerance of single-use baby diapers has been demonstrated by product safety tests and by clinical studies published in the scientific literature" (Journal of Diseases of Children). More than 400 studies have been conducted with **SAP**, concluding it has no systemic or local effects including skin irritation and sensitisation (Kosemund *et al.*, 2009*; Dey *et al.*, 2016b*). SAP does not cause irritation or allergies in the rare event that it escapes from the diaper, and it is not genotoxic or mutagenic. Note that if accidentally swallowed and absorbed by the gastrointestinal tract, SAP can have effects other than diarrhoea (study in rats: Lindenschmidt *et al.*, 1991 cited in Dey *et al.*, 2014*).

In 2002, De Vito and Schecter calculated dermal exposure to **dioxins and furans** via baby diapers and compared this exposure with the levels found in food. Two exposure calculations were performed: a first considering a worst-case scenario (equation 1) and a second considering that only the dioxins contained in urine are bioavailable and that urine is in contact with the skin (equation 2).

$$DED = (Cd * Md * Nd * Abs)/ BW \ [Equation \ 1]$$

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$$DED = (Dd * Nd * Abs) / BW \text{ [Equation 2]}$$

where DED: daily exposure dose via diapers (pg/kg bw/day)

Cd: concentration of dioxins and furans in the diaper in dioxin equivalent (pg $_{TEQ}$/g) (WHO toxic equivalency factors (TEFs))

Md: average weight of a diaper (g) = 40 g (hypothesis)

Nd: number of diapers used per day = 10 diapers/day for babies aged zero to six months, six diapers/day for babies aged six to 24 months (hypothesis)

Abs: dermal absorption

Dioxins are bound to the wood pulp fibres and are not readily available. There are no studies describing dermal absorption of dioxins bound to wood pulp products. The dermal absorption of TCDDs from soil has been estimated at 0.1% to 3% depending on the organic content of the soil. Between <0.1% and 3% of the dioxins contained in polyester or cotton fabrics are transferred to human skin within 72 hours (Klasmeier *et al.*, 1999 cited in De Vito and Schecter, 2002). Since pulp is a mixture of organic fibres, it is likely that dioxins are closely bound to these fibres and are not readily available. However, due to uncertainties, an absorption value of 3%, based on an estimate of dermal absorption from soil with low organic content (US EPA, 1992 cited in De Vito and Schecter, 2002), was used in the first calculation.

In the second calculation, an absorption value of 28% was estimated based on *in vivo* and *in vitro* experimental data, considering the dermal absorption of dioxins in aqueous solutions (US EPA, 2000 cited in De Vito and Schecter, 2002).

BW: body weight = 6.75 kg for babies aged zero to six months (hypothesis) and 11 kg for babies aged six to 24 months (adapted from Fleisher and Ludwig, 1993 cited in De Vito and Schecter, 2002)

Dd: mass of dioxins distributed in urine from a single diaper:

$$DJE = \frac{\left(\dfrac{Cd \times Md}{Md \dfrac{Kp}{UI}} \right) \times Nd \times Abs}{PC}$$

UI: urine load in a diaper = 45 g/diaper

Kp: pulp-synthetic urine partition coefficient for TDCF = 5.340 (calculated)

DJE	DED
PC	BW

The authors considered values of daily dietary exposure to dioxins of 145 pg $_{TEQ}$/kg/day for babies aged zero to six months (via breast milk only) and of 3.6 pg $_{TEQ}$/kg/day for babies aged six to 24 months (US EPA cited in De Vito and Schecter, 2002). Assuming 100% bioavailability (equation 1), deemed unlikely by the authors, dietary exposure was 3498 to 19,374 times greater than exposure via diapers for babies aged zero to six months, and 283 and 1568 times greater for babies aged six to 24 months. Assuming that only the dioxins contained in urine are bioavailable (equation 2), dietary exposure was 30,000 to 2,200,000 times greater than exposure via diapers. The authors concluded that exposure to dioxins via baby diapers does not significantly contribute to total dioxin exposure.

In 2015, Ishii *et al.* calculated dermal exposure to seven **phthalates** via the topsheet of single-use diapers and assessed the risk for each phthalate as well as the cumulative risk. The daily exposure dose was calculated using the following equation:

$$DED = (C \times Md \times Mig \times Nd \times Abs) / BW$$

where DED: daily exposure dose via the topsheet (mg/kg/day)

C: concentration of phthalate in the topsheet (mg/g), i.e. the highest concentration for DEHP and DBP and 0.1 µg/g for undetected phthalates

Md: weight of the topsheet of a diaper (g)

Mig: eluted rate of phthalates into artificial sweat and into a urine simulant.' Ishii *et al.* used the eluted rates in the sweat simulant, considering that the surface in contact with the topsheet is always in the presence of sweat. Thus, the eluted rates of DEHP, DBP, BBP, DINP, DIDP and DNOP were, respectively, 0.012%; 2.4%; 1.4%; 0.0011%; 0.0007%; and 0.0006%. For DIBP, the eluted rate of DBP was used due to the structural similarity of these two phthalates.

Nd: number of diapers used per day: 12/day (JHPIA, 2015 cited in Ishii *et al.*, 2015)

Abs: transdermal absorption. The authors used the absorption rates indicated in the European Union Risk Assessment Reports (EU-RARs), i.e. 5% for DEHP, BBP and DNOP (structural similarity with DEHP), 10% for DBP and DIBP (structural similarity with DBP) and 0.5% for DINP and DIDP.

BW: average body weight of a newborn = 2.9 kg (JMHLW, 2015 cited in Ishii *et al.*, 2015)

Based on these parameters, the DED was calculated and then compared with the critical doses selected in order to calculate the risk for each phthalate as well as a cumulative risk. The authors did not identify any risks, whether for the phthalates assessed separately or when calculating the cumulative risk ($6.7 \cdot 10^4 > 1000$).

7.2 Diseases

7.2.1 Diaper dermatitis

Diaper dermatitis is the most common skin disease in infants.

There are various forms of diaper dermatitis:
- Irritative dermatitis,
- Infectious dermatitis,
- Inflammatory dermatitis (psoriasis, eczema, seborrhoeic dermatitis, allergic contact dermatitis, etc.),
- Dermatitis associated with a systemic disease (Scheinfeld, 2005; Tüzün *et al.*, 2015; Lagier *et al.*, 2015; Cohen, 2017).

Only certain forms of dermatitis are related to the wearing of baby diapers. They are described below.

7.2.1.1 Irritative dermatitis

Irritative dermatitis is the most common form. Until a child is toilet trained, the diaper area is an occlusive, warm and moist environment due to prolonged contact between the baby's buttocks and faeces and/or urine. The available studies have shown that an increase in skin moisture, a high alkaline skin pH, the mixing of urine and faeces and the mechanical action of friction between the skin and diaper can cause irritative dermatitis to develop (Scheinfeld, 2005; Runeman, 2008*; Tüzün *et al.*, 2015; Atherton, 2016*; Bender and Faergemann, 2017*). This prolonged contact impairs skin barrier function. A decline in stratum corneum integrity leaves the skin permeable to chemicals, infectious agents and the enzymes found in urine and faeces. Urine increases the skin's moisture level and supplies urea. Due to faecal urease activity, urea is converted into ammonia, increasing the skin pH and promoting the activity of other faecal enzymes (lipases, proteases) contributing to the deterioration of the stratum corneum (Odio *et al.*, 2014*; Lagier *et al.*, 2015; Felter *et al.*, 2017*; Bender and Faergemann, 2017*).

Other factors promote the occurrence of irritative dermatitis and can aggravate its symptoms; these include gastrointestinal diseases (e.g. diarrhoea), low diaper-changing frequency, the use of low-absorbency diapers (Counts *et al.*, 2014*; Helmes *et al.,* 2014*), inadequate cleansing, the administration of antibiotics that can disrupt the equilibrium of the intestinal flora, teething, the presence of micro-organisms on the epidermis, the use of unsuitable care products for this location, allergies to chemicals, etc. (Tüzün *et al.*, 2015; Atherton, 2016*).

Some studies, undertaken by companies, indicate that the presence of lotion in the topsheet helps facilitate the restoration of skin barrier function and reduce the severity of irritation and diaper dermatitis (Odio *et al.*, 2000*; Odio and Friedlander, 2000*; Erasala *et al.*, 2007*; Counts *et al.*, 2014*).

There have been reports of cases of irritative dermatitis related to the wearing of reusable diapers that disappeared with the use of single-use diapers (Harfmann *et al.*, 2017; Maruani *et al.,* 2013).

7.2.1.2 Allergic contact dermatitis

Much less common, allergic contact dermatitis can be caused by certain components in a diaper (Roul *et al.,* 1998; Larralde *et al.,* 2001; Belhadjali *et al.*, 2001; Onken *et al.*, 2011; Jacob *et al.*, 2012; Chiriac *et al.*, 2017; Yu *et al.*, 2016 and 2017). The main chemicals identified as causing allergic contact dermatitis are as follows:
- mercaptobenzothiazole (MBT), found in the rubber used in the elastics (Roul *et al.,* 1998; Onken *et al.*, 2011),
- cyclohexylthiophthalimide, used as a vulcanisation retarder in rubber (Belhadjali *et al.*, 2001),
- p-tert-butylphenol formaldehyde resin, found in glues (Belhadjali *et al.*, 2001),
- disperse dyes (Alberta *et al.*, 2005).

However, Evans *et al.* indicate that the colouring agents used are pigments and not disperse dyes (Evans *et al.*, 2014*).

7.2.1.3 Infectious dermatitis

Secondary infections, due primarily to bacteria (Staphylococci) or *Candida albicans*, are common when the skin of the diaper area has lesions (Šikić Pogačar *et al.,* 2017). Cases of severe diaper dermatitis, including confirmed *Candida albicans* infections, have been reduced by 50% in children wearing breathable diapers. A controlled microbiological study showed an inhibiting effect of breathable diapers containing SAP on the survival of *Candida albicans* (Figure 12) (EDANA).
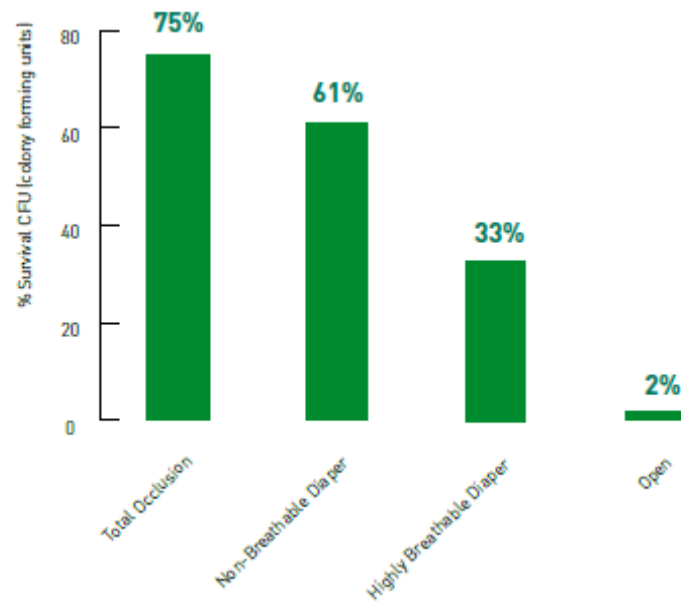
Figure 12: Survival of *Candida albicans* on human skin in various situations (EDANA, 2010)

7.2.1.4 Change over time

The prevalence of diaper dermatitis is estimated to be between 7% and 50%, depending on the country and hygiene practices, keeping in mind that many cases are not reported by doctors or parents and heal within a few days without any medical treatment. Its incidence peaks between the ages of nine and 12 months (Joran *et al.*, 1986 cited in Blume-Peytavi *et al.*, 2014*; Klunk *et al.*, 2014; Felter *et al.*, 2017*). In a study of 13,902 mothers (87% response rate) undertaken in the United Kingdom, the prevalence of diaper dermatitis in the first four weeks of life was around 25% (Philipp *et al.,* 1997). However, the frequency and severity of diaper dermatitis have decreased over time, primarily thanks to improvements in the performance and design of single-use diapers over the past 30 years. The number and severity of cases of diaper dermatitis have sharply decreased with the emergence of disposable diapers and the use of superabsorbent polymers keeping the buttocks dry. In a meta-analysis of four clinical studies undertaken by a company between 2004 and 2006, 96% of the 281 children wearing single-use diapers had only mild to moderate diaper rash at most, 4% had moderate to moderate/severe diaper rash, and none had severe diaper rash (Felter *et al.*, 2017*). Another international clinical study of around 800 children wearing single-use diapers showed very few cases of moderate or severe diaper rash (Carr *et al.*, 2017* cited in Felter *et al.*, 2017*).
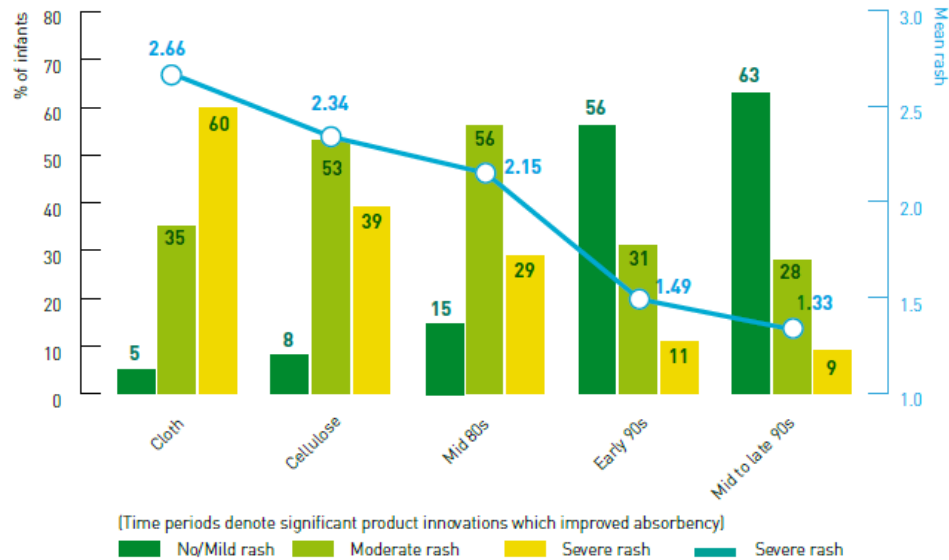
Figure 13: Change in cases of diaper dermatitis since the introduction of single-use baby diapers (Group'Hygiène, 2015; EDANA, 2010)

7.2.2 Urinary tract infections

In a prospective case-control study, *Nuutinen et al.* (1996) did not find any association between the type of diaper used and the risk of developing a urinary tract infection (disposable with SAP: OR = 0.95; $CI_{95\%}$ = 0.62 – 1.46; without SAP: OR = 1.04; $CI_{95\%}$ = 0.69 – 1.57; reusable cotton: OR = 1.00; $CI_{95\%}$ = 0.46 – 2.16). Conversely, in a case-control study of 59 girls under the age of two years with a urinary tract infection and 59 controls matched for age, Fahimzad *et al.* observed that the use of diapers with SAP was significantly higher in the individuals with urinary tract infections (cases) than in the control individuals (62.71% vs 35.59%; OR = 3.29; p = 0.005) (Fahimzad *et al.*, 2010).

Sugimura *et al.* studied the association between daily diaper-changing frequency and urinary tract infections in 128 infants with a temperature of ≤ 38°C, including 32 with a urinary tract infection. Diaper-changing frequency was significantly lower in the children with a urinary tract infection compared to the others. The main bacteria isolated from the urine samples of the children with a urinary tract infection were *Escherichia coli* followed by *Klebsiella pneumonia* (Sugimura *et al.*, 2009).

8 Health risk assessment for single-use diapers

The quantitative health risk assessment (QHRA) approach was formalised in 1983 by the US National Research Council (NRC, 1983), which defined it as "the use of a factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations". This methodological approach is divided into four separate steps: identification of hazards, description of dose-response relationships as part of hazard characterisation, assessment of exposure, and characterisation of health risks.

It enables the expected risk in a population to be quantified, taking into account exposure to and the toxicity of the substance in question. The assessment undertaken thus directly depends on the data available on the toxicity of products and on the habits of the population exposed to these products.

Based on the WHO/IPCS method proposing a step-by-step approach to health risk assessment (WHO-IPCS, 2010), the CES decided to first undertake a risk assessment using a worst-case approach in order to rapidly eliminate substances posing no health risks. In the event that potential risks were identified for certain chemicals using the worst-case approach, the CES refined the choices of toxicity reference values (TRVs) and exposure parameters with assumptions that were as realistic as possible ("refined" scenario).

8.1 Study population

The age at which children are toilet trained varies considerably depending on the individual. By two and a half years of age, approximately 90% of girls and 75% of boys have complete bladder control (Stoppard, 1990 cited in UK Environment Agency, 2005a). The average child will stay dry at night at the age of 33 months (normal range from 18 months to eight years) (Green, 1998 cited in UK Environment Agency, 2005a).
In 2004, the UK Environment Agency undertook a study on the use of disposable and reusable diapers. It showed that the average age out of diapers was 26.17 months (1553 respondents). By the age of two and a half years, 95% of children are out of disposable diapers (UK Environment Agency, 2005b). However, some children continue wearing training pants and/or diapers at night for varying lengths of time.

Table 13: Percentage of children wearing disposable diapers (all types) (UK Environment Agency, 2005b)

Age of child	Children wearing nappies (%)	Children not wearing nappies (%)
up to 6 months	100.0%	0.0%
6 to 12 months	95.7%	4.3%
12 to 18 months	82.8%	17.2%
18 to 24 months	45.6%	54.4%
24 to 30 months	17.6%	82.4%
30 to 36 months	4.8%	95.2%
36 to 42 months	1.8%	98.2%
42 to 48 months	0.4%	99.6%
48 to 54 months	0.1%	99.9%
54 to 60 months	0.1%	99.9%
60 to 66 months	0.1%	99.9%

In this expert appraisal, the health risk assessment was undertaken for children aged zero to 36 months inclusive.

8.2   Selection of chemicals

In 2016, 2017 and 2018, the INC and SCL conducted composition tests using solvent extraction with single-use baby diapers purchased in France (whole diapers and diaper parts). In parallel, in 2017 and 2018, the SCL carried out tests to measure chemicals in a urine simulant, extracted respectively from shredded diapers and from whole diapers.

Lastly, in 2017, Group'Hygiène undertook a study of 13 baby diapers representative of the French market:
- screening for chemicals under extreme conditions (solvent extraction from shredded diapers);
- screening for chemicals under conditions more representative of the product's use, on the basis of professional expertise (extraction with a urine simulant in whole diapers).

The results of this Group'Hygiène study are confidential (Annex 6).

The chemicals detected and quantified in these various tests, as well as the available limits of detection and/or quantification, are listed in Table 14 and 15.

Regardless of the test, the detected and/or quantified chemicals were the same. However, due to the use of different analytical methods (with different LDs and LQs), for the same diaper product, the same chemical could be detected in one test and quantified or not detected in another.

An additional literature search was conducted in the PubMed database to identify concentrations of the substances of interest in baby diapers (see §7.1.1).

These tests produced consistent results as to the presence of dioxins and furans, both in shredded whole diapers and diaper parts and in urine simulants, and were confirmed by the literature search. DL-PCBs (12 congeners) were only screened for by the SCL (shredded material or urine simulant) and nine of them were quantified in shredded whole diapers after solvent extraction and in a urine simulant. Twelve congeners were quantified in urine simulant (whole diapers).

The SCL and INC also observed the presence of VOCs in shredded whole diapers after solvent extraction.

In the tests undertaken with shredded diapers, solvent extraction enabled the SCL to detect four PAHs in the elastic part of the diapers while the INC quantified only one of these PAHs in the plastic part of the diapers. Ten PAHs, two of which were quantified in shredded diapers, were detected in urine simulant from whole diapers.

The SCL detected several fragrances only in shredded whole diapers using solvent extraction.

Glyphosate and AMPA were quantified by the INC and detected by the SCL in shredded whole diapers using solvent extraction. Some other pesticides (quintozene and its metabolite pentachloroaniline, hexachlorobenzene) were quantified by the INC in one diaper (shredded whole diaper, solvent extraction).

The majority of the chemicals detected or quantified in diapers can either be the result of raw-material contamination (e.g. pesticides) or be formed during manufacturing processes such as bleaching or gluing (e.g. DL-PCBs, furans and dioxins). Today, the cellulose used in these products is no longer bleached by elemental chlorine. However, processes using chlorinated agents such as chlorine dioxide, for example, are used and can be responsible for the formation of dioxins and furans.
Regarding the presence of PAHs in single-use diapers, the experts do not rule out PAH formation during the manufacture of these diapers due to the use of high temperatures for certain manufacturing processes (Abdel-Shafy and Mansour, 2016).

Table 14: Summary of results for the tests undertaken by the INC and SCL with shredded whole diapers and diaper parts using solvent extraction (only detected or quantified chemicals)***

Chemicals	CAS No.	INC (2018) Concentration range	INC (2017) Concentration range	SCL (2017) Concentration range	LD / LQ
PAHs (mg/kg of diaper)				**Elastic parts**	
Benzo[g,h,i]perylene	191-24-2	< LD	< LD	< LD - < LQ	0.03 / 0.1
Benzo[b]fluoranthene	207-08-9				
Benzo[a]anthracene	56-55-3				
Indeno[1,2,3-c,d]pyrene	193-39-5		**Plastic parts:** 1.2		
VOCs (mg/kg of diaper)					
Naphthalene	91-20-3	< LD	< LD - 0.07	< LD - $1.3·10^{-2} ± 4·10^{-3}$	$3·10^{-4}/10^{-3}$
1,4-dichlorobenzene	106-46-7		< LD	< LD - < LQ	
p-isopropyltoluene	99-87-6			< LD - $1.3·10^{-2} ± 4·10^{-3}$	
1,3-dichlorobenzene	541-73-1			< LD - < LQ	
Styrene	100-42-5	< LQ - 0.05	< LD - 0.03	NT	
o-xylene + styrene	95-47-6 + 100-42-5	< LD	NT	< LD - $5·10^{-3} ± 2·10^{-3}$	
m-xylene + p-xylene	1330-20-7		< LD	< LD - $10^{-2} ± 3·10^{-3}$	
Chlorobenzene	108-90-7			< LD - $1.1·10^{-2} ± 3·10^{-3}$	
Toluene	108-88-3		< LD - 0.04	< LD - $3.6·10^{-2} ± 1.1·10^{-2}$	
n-propylbenzene	103-65-1	< LQ - $5.03·10^{-2}$	< LD	< LD	
1,2,3-trichlorobenzene	87-61-6	< LQ - 0.25			
1,2,4-trichlorobenzene	120-82-1	< LQ - $6.93·10^{-2}$			
1,3,5-trimethylbenzene**	108-67-8	< LQ - 0.12			
Fragrances (mg/kg of diaper)					
Benzyl alcohol	100-51-6	< LD	< LD	< LD - < LQ	3 / 50
Benzyl salicylate	118-58-1				10 / 50
Coumarin	91-64-5				
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	31906-04-4				4 / 50
Butylphenyl methylpropional	80-54-6				
Limonene	5989-27-5				3 / 50
Linalool	78-70-6				
Alpha-isomethyl ionone	127-51-5				

Chemicals	CAS No.	INC (2018) Concentration range	INC (2017) Concentration range	SCL (2017) Concentration range	LD / LQ
Dioxins and furans (ng/kg of diaper)					**LQ***
1,2,3,6,7,8-HxCDD	57653-85-7		< LD	ND - 0.13	0.05 - 0.2
1,2,3,4,6,7,8-HpCDD	35822-46-9		**Topsheet: < LD -** 0.609	ND - 1.03	0.05 - 0.23
OCDD	3268-87-9		**Topsheet: < LD -** 2.69	ND - 2.15	0.03 - 0.2
Dioxins	/		/	ND - 3.18	/
1,2,3,6,7,8-HxCDF	57117-44-9		< LD	ND - 0.04	0.02 - 0.15
2,3,4,6,7,8-HxCDF	60851-34-5	< LQ	**Backsheet: < LD -** 0.501	ND - 0.11	0.02 - 0.18
1,2,3,4,6,7,8-HpCDF	67562-39-4		**Other parts excluding core and top- and backsheets: < LD -** 0.193	ND - 1.54	0.03 - 0.09
1,2,3,4,7,8,9-HpCDF	55673-89-7		< LD	ND - 0.26	0.03 - 0.15
OCDF	39001-02-0		**Whole diaper: < LD -** 1.78 **Outer layer: < LD -** 7.08 **Topsheet: < LD -** 0.351 **Other parts excluding core and top- and backsheets: < LD -** 2.59	ND - 13.02	0.08 - 0.53
Furans	/		/	ND - 14.68	/
Sum of dioxins + furans (TEQ WHO 2005)	/		/	$0 - 3.98 \cdot 10^{-2}$	/
Dioxin-like PCBs (ng/kg of diaper)					**LQ***
PCB-81	70362-50-4			ND - 1.77	0.21 - 0.94
PCB-77	32598-13-3			ND - 21.33	1.0
PCB-123	65510-44-3	NT	NT	0.26 - 11.74	/
PCB-118	31508-00-6			9.74 - 758.6	/
PCB-114	74472-37-0			ND - 31.67	0.17 - 0.57
PCB-105	32598-14-4			4.43 - 431.71	/
PCB-167	52663-72-6			< LD - 38.84	0.31 - 3.2
PCB-156	38380-08-4			< LD - 92.08	0.33 - 1.73
PCB-157	69782-90-7			< LD - 28.03	0.28 - 1.83
Total	/			16.98 - 1404.98	/
Total PCBs (TEQ WHO 2005)	/		/	$6.7 \cdot 10^{-4} - 4.3 \cdot 10^{-2}$	/

Chemicals	CAS No.	INC (2018)	INC (2017)	SCL (2017)	
		Concentration range	Concentration range	Concentration range	LD / LQ
Formaldehyde (mg/kg of diaper)					
Formaldehyde	50-00-0	< LD	< LD	1.48 - 37.4	0.11 / 0.35
Glyphosate and AMPA (mg/kg of diaper)					
Glyphosate	1071-83-6	< LQ	< LD - 0.02	ND	- / 0.05
AMPA	1066-51-9	< LQ - 0.045	< LD - 0.04		
Pesticides (mg/kg of diaper)					LQ
Hexachlorobenzene	118-74-1	< LQ	< LD - $2 \cdot 10^{-3}$	ND	0.01
Quintozene	82-68-8	< LQ - 0.013	< LD - $3 \cdot 10^{-3}$		
Pentachloroaniline	527-20-8	< LQ - 0.012			

NT: not tested; ND: not detected; * for the test sample; **: 1,3,5-trimethylbenzene + 4-chlorotoluene; ***: unspecified, the results are expressed for shredded whole diapers

Table 15: Summary of results for the tests undertaken by the SCL with shredded baby diapers or whole diapers using a urine simulant (only detected or quantified chemicals)

Chemicals	CAS No.	SCL			
		2017 tests with shredded diapers		2018 tests with whole diapers, "realistic" scenario	
		Concentrations	LD / LQ	Concentrations	LD* / LQ*
PAHs (mg/kg of diaper)					
Benzo[g,h,i]perylene	191-24-2	NT	-	< LD - < LQ	0.17 - 0.7/0.836
Benzo[b]fluoranthene	205-99-2				0.15 - 0.36/0.763
Cyclopenta[c,d]pyrene	27208-37-3				0.15 - 0.36/0.623
Chrysene	218-01-9				0.17 - 0.36/0.499
5-methylchrysene	3697-24-3				0.15 - 0.36/0.623
Benzo[k]fluoranthene	207-08-9				0.15 - 0.36/0.737
Benzo[j]fluoranthene	205-82-3				0.15 - 0.36/0.737
Benzo[e]pyrene	192-97-2				0.19 - 0.26/1.195
Benzo[a]pyrene	50-32-8				0.15 - 0.36/0.810
Dibenzo[a,h]anthracene	53-70-3				0.17 - 0.8/0.623
VOCs (mg/kg of diaper)					
Naphthalene	91-20-3	< LD	$3.7 \cdot 10^{-4}$/0.01	< LD	$1.5 \cdot 10^{-3}$ - $3.59 \cdot 10^{-3}$
1,4-dichlorobenzene	106-46-7				
p-isopropyltoluene	99-87-6				
1,3-dichlorobenzene	541-73-1				
Styrene	100-42-5				
o-xylene + styrene	95-47-6 + 100-42-5				
m-xylene + p-xylene	1330-20-7				
Chlorobenzene	108-90-7				
Toluene	108-88-3				
Dioxins and furans (ng/kg of diaper)			LQ*		LQ*
1,2,3,6,7,8-HxCDD	57653-85-7	ND	0.0288 - 0.15	ND - $5.5 \cdot 10^{-3}$	$1.4 \cdot 10^{-4}$ - $7 \cdot 10^{-3}$
1,2,3,4,6,7,8-HpCDD	35822-46-9	ND - 2.42	0.0347 - 0.1033	$3.3 \cdot 10^{-3}$ - $6.1 \cdot 10^{-3}$	**
OCDD	3268-87-9	ND - 3.22	0.1389 - 0.3556	ND - 0.18	$2.5 \cdot 10^{-2}$
Dioxins	/	ND - 5.64	/	$1.5 \cdot 10^{-2}$ - 0.25	/
2,3,7,8-TCDF	51207-31-9	ND - 0.1	0.0076 - 0.0422	ND - $3.7 \cdot 10^{-3}$	
1,2,3,7,8-PeCDF	57117-41-6	ND	0.0083 - 0.0541	ND	$3.66 \cdot 10^{-4}$ - 0.01
2,3,4,7,8-PeCDF	57117-31-4	ND - 0.26	0.0085 - 0.0571	ND - $1.5 \cdot 10^{-2}$	
1,2,3,4,7,8-HxCDF	70648-26-9	ND - 0.11	0.0237 - 0.089	ND - $4.4 \cdot 10^{-3}$	$3.66 \cdot 10^{-04}$ - 0.025
1,2,3,6,7,8-HxCDF	57117-44-9	ND - 0.05	0.0223 - 0.0827	ND - $8.4 \cdot 10^{-4}$	$3.66 \cdot 10^{-04}$ - 0.024
2,3,4,6,7,8-HxCDF	60851-34-5	ND - 0.04	0.0277 - 0.1127	ND - $1.9 \cdot 10^{-2}$	$7.3 \cdot 10^{-4}$ - 0.026

Chemicals	CAS No.	SCL			
		2017 tests with shredded diapers		2018 tests with whole diapers, "realistic" scenario	
		Concentrations	LQ*	Concentrations	LQ*
1,2,3,4,6,7,8-HpCDF	67562-39-4	ND – 1.6	$0.023 - 4.7 \cdot 10^{-2}$	ND - 0.1	$7 \cdot 10^{-4} - 5.87 \cdot 10^{-3}$
1,2,3,4,7,8,9-HpCDF	55673-89-7	ND - 0.12	$0.015 - 2.02 \cdot 10^{-1}$	$ND - 8.1 \cdot 10^{-3}$	$7.3 \cdot 10^{-4} - 0.06$
OCDF	39001-02-0	ND - 21.07	$5.37 \cdot 10^{-1} - 2.78 \cdot 10^{-1}$	ND - 0.15	0.01
Furans	/	ND - 22.92	/	ND - 0.25	/
Total dioxins + furans	/	0.06 - 23.97	/	2.22 - 139.2	/
Dioxin-like PCBs (ng/kg)			LQ*		
PCB-81	70362-50-4	ND	0.16 - 0.764	ND - 0.22	0.012 - 0.31
PCB-77	32598-13-3	ND - 3.76	0.17 - 0.59	ND - 1.03	$4.9 \cdot 10^{-3} - 1.4 \cdot 10^{-2}$
PCB-123	65510-44-3	ND - 1.38	0.20 - 1.044	ND - 0.58	$5.5 \cdot 10^{-2} - 1.6 \cdot 10^{-1}$
PCB-118	31508-00-6	10.56 - 142.81	**	1.58 - 72.16	**
PCB-114	74472-37-0	ND - 3.16	0.14 - 1.20	ND - 2.29	$31 \cdot 10^{-2} - 1.8 \cdot 10^{-1}$
PCB-105	32598-14-4	5.55 - 63.23	**	0.65 - 29.30	**
PCB-126	57465-28-8	ND	0.12 - 0.65	ND - 0.59	$1.1 \cdot 10^{-2} - 0.08$
PCB-167	52663-72-6	ND - 13.45	0.29 - 0.884	ND - 8.99	$1.2 \cdot 10^{-2} - 1.43 \cdot 10^{-2}$
PCB-156	38380-08-4	ND - 19.65	0.27 - 0.91	018 - 17.92	**
PCB-157	69782-90-7	ND - 7.35	0.19 - 0.87	ND - 2.34	$1.2 \cdot 10^{-2} - 7.6 \cdot 10^{-2}$
PCB-169	32774-16-6	ND	0.19 - 1.40	ND - 0.06	$1.1 \cdot 10^{-2} - 8.58 \cdot 10^{-2}$
PCB-189	39635-31-9	ND - 3.48	0.15 - 4.054	ND - 3.7	$1.3 \cdot 10^{-2} - 5.7 \cdot 10^{-2}$
Total PCBs	/	16.11 - 244.67	/		/
Formaldehyde (mg/kg)			LD*		LD*
Formaldehyde	50-00-0	NR	-	< LD - 2.75	0.12

ND: not detected

* for the test sample

** the chemical was quantified in all the tested products

In light of these results, the CES decided to conduct the QHRA for all of the chemicals quantified or detected (using solvent extraction) in shredded diapers or parts of baby diapers sold in France via the tests undertaken by the INC and SCL in 2017 and 2018:

- **Volatile organic compounds**
  - Naphthalene,
  - Styrene,
  - Toluene,
  - 1,4-dichlorobenzene,
  - 1,3-dichlorobenzene,
  - p-isopropyltoluene,
  - o-xylene + styrene,
  - m-xylene + p-xylene,
  - Chlorobenzene,
  - n-propylbenzene,
  - 1,2,3-trichlorobenzene,
  - 1,2,4-trichlorobenzene,
  - 1,2,5-trimethylbenzene
- **Pesticides**
  - Hexachlorobenzene,
  - Pentachloroaniline,
  - Quintozene,
  - Glyphosate and its metabolite, AMPA
- **Dioxins and furans (eight congeners)**
- **Dioxin-like PCBs (nine congeners)**
- **PAHs (benzo[g,h,i]perylene, benzo[b]fluoranthene, benzo[a]anthracene, indeno[1,2,3-c,d]pyrene)**
- **Formaldehyde**
- **Fragrances**
  - Benzyl alcohol,
  - Benzyl salicylate,
  - Coumarin,
  - Hydroxyisohexyl 3-cyclohexene carboxaldehyde,
  - Butylphenyl methylpropional or BMHCA,
  - Limonene,
  - Linalool,
  - Alpha-isomethyl ionone.

The CES also decided to conduct the QHRA for the chemicals detected or quantified in urine simulant via the tests undertaken by the SCL in 2017 and 2018 and by Group'Hygiène in 2017:

- **VOCs**
  - Naphthalene,
  - 1,4-dichlorobenzene,
  - p-isopropyltoluene,
  - 1,3-dichlorobenzene,
  - Styrene,
  - o-xylene + styrene,
  - m-xylene + p-xylene,
  - Chlorobenzene,

- o **Toluene,**
- **PAHs (benzo[g,h,i]perylene, benzo[b]fluoranthene, benzo[a]anthracene, indeno[1,2,3-c,d]pyrene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[a]pyrene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, dibenzo[a,h]anthracene, anthracene),**
- **Dioxins and furans (12 congeners),**
- **DL-PCBs (12 congeners),**
- **Formaldehyde.**

8.3 QHRA method

8.3.1 Identification of chemicals and physico-chemical properties

All of the physico-chemical properties of the substances of interest are available in Annex 7.

8.3.2 Hazard identification

The CES's experts decided to not produce full toxicological profiles for the different chemicals detected or quantified in baby diapers but rather to investigate whether they were covered by classifications. Thus, harmonised classifications according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) and carcinogenicity classifications of the International Agency for Research on Cancer (IARC) were investigated. In the absence of CLP classifications, self-classifications assigned by companies have been provided.

In view of the proximity of these products to the genital organs, the following classifications or databases enabling potential endocrine-disrupting (ED) effects to be identified were also consulted:
- European Commission
    - o BKH classification. The Dutch company BKH Consulting Engineers was commissioned by the European Commission's DG Environment to prepare two study reports in 2000 and 2002. The 2000 report focused on synthetic chemicals used primarily in industry, agriculture and consumer goods (553 substances), while the 2002 report dealt with 435 substances with insufficient data. The assessment of ED effects in humans and wildlife was based on the following selection criteria: persistence, production data, consumption/use, environmental concentrations, assessment of ED effects taking into consideration the relevance of the effects, test reliability, dose-response relationships, ED potential, structure-activity relationships, comparison with systemic toxicity, and human and wildlife exposure assessment.
    - o DHI classification. The Danish company DHI Water & Environment produced a report in 2007 on "low production volume chemicals" (LPVCs), not covered in the BKH reports (107 chemicals). ED effects were assessed using the same selection criteria as BKH.
- The Endocrine Disruption Exchange, Inc. (TEDX): Inclusion on the TEDX list. The aim of this list is to present chemicals for which at least one study has been published showing an effect on the endocrine system in order to improve information for scientists, managers and consumers. In June 2015, almost 1000 chemicals were included on the TEDEX list as EDs.

- <u>The NGO ChemSec</u>[16]: Inclusion on the SIN (Substitute It Now) list. ChemSec has identified substances meeting the criteria of Substances of Very High Concern (SVHCs) as defined in the REACh Regulation. Three categories of substances are included: CMR substances, Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances, and substances of equivalent concern including EDs (last updated: February 2017). The inclusion of a substance as an ED on the SIN list is based on a set of converging arguments (*in vivo* and/or *in vitro* toxicology and/or ecotoxicology studies, the substance's EU classification, etc.)[17].

- <u>US EPA</u>: Conclusion of the US EPA regarding the ED potential of the substances listed in the "Endocrine Disruptor Screening Program Tier 1 Assessments" (US EPA-EDSP). The inclusion of pesticides (52 active or inert substances) on this list is based on exposure potential rather than on evidence of endocrine disruption. Tests were undertaken for these substances to study their potential ED properties (oestrogen, androgen and/or thyroid activity via the implementation of five *in vitro* and six *in vivo* tests). The US EPA then conducted a weight-of-evidence assessment for each substance. It indicated whether there were ED effects with oestrogen, androgen or thyroid pathways according to toxicological or ecotoxicological studies. If there were several levels of evidence, only the highest was used.

- <u>IEPA</u> (Illinois Environmental Protection Agency): The IEPA classification presented in the "Endocrine Disruptors Strategy" report (1997). IEPA published a preliminary list of chemicals having ED effects *in vitro* or in animals and humans, classified into three categories: "known", "probable" and "suspect". These chemicals were identified based on a review of the available literature.

The classifications of the substances of interest are given in the table below.

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[16] A non-profit organisation founded in 2002 by four environmental organisations to advocate the principles of precaution, substitution, polluter pays and right-to-know

[17] The reason for including a substance must be specified in the Excel file in the "Reasons for inclusion on the SIN List" column (available for downloading at http://sinlist.chemsec.org/)

Table 16: Classifications of the substances of interest

Chemicals	CAS No.	Harmonised classification (CLP Regulation)[18]	Self-classification	IARC (year)	Endocrine disruption				
					BKH or DHI	TEDX list	SIN list	US EPA	IEPA
VOCs									
Naphthalene	91-20-3	Acute Tox. 4 – H302 Carc. 2 – H351	-	2B (2002)	-	Yes	Yes	-	-
Styrene	100-42-5	Flam. Liq. 3 – H226 Skin Irrit. 2 – H315 Eye Irrit. 2 – H319 Acute Tox. 4* – H332 STOT RE 1 – H372 Repr. 2 – H361d	-	2B (2002)	1 (1 for human health, 3 for wildlife)	Yes	Yes	-	Probable
Toluene	108-88-3	Flam. Liq. 2 – H225 Skin Irrit. 2 – H315 Asp. Tox. 1 – H304 STOT SE 3 – H373 STOT RE 2* – H373 Repr. 2 – H361d	-	3 (1999)	-	Yes	-	-	-
1,4-dichlorobenzene	106-46-7	Eye Irrit. 2 – H319 Carc. 2 – H351	-	2B (1999)	-	Yes	-	-	-
1,3-dichlorobenzene	541-73-1	Acute Tox. 4* – H302	-	3 (1999)	-	Yes	-	-	-
p-isopropyltoluene[19]	99-87-6	Flam. Liq. 3 – H226 Acute Tox. 3 – H331 Asp. Tox. 1 – H304	-	-	-	-	-	-	-
o-xylene	95-47-6	Flam. Liq. 3 – H226 Acute Tox. 4* – H312 Skin Irrit. 2 – H315 Acute Tox. 4* – H332	-	-	-	-	-	-	-
m-xylene + p-xylene	1330-20-7	Flam. Liq. 3 – H226 Acute Tox. 4 – H312 Skin Irrit. 2 – H315 Acute Tox. 4 – H332	-	3 (1999)	-	Yes	-	-	-
Chlorobenzene	108-90-7	Flam. Liq. 3 – H226 Skin Irrit. 2 – H315 Acute Tox. 4 – H332	-	-	-	-	-	-	-

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[18] Classifications and self-classifications related to an environmental effect are not shown in this table.

[19] Proposed classification, currently under discussion

Chemicals	CAS No.	Harmonised classification (CLP Regulation)	Self-classification	IARC (year)	Endocrine disruption				
					BKH or DHI	TEDX list	SIN list	US EPA	IEPA
n-propylbenzene	103-65-1	Flam. Liq. 3 Asp. Tox. 1 STOT SE 3	-	-	-	-	-	-	
1,2,3-trichlorobenzene	87-61-6	-	Acute Tox. 4 Skin Sens. 1	-	-	-	-	-	
1,2,4-trichlorobenzene	120-82-1	Acute Tox. 4 Skin Irrit. 2	-	-	-	-	-	-	
1,3,5-trimethylbenzene	108-67-8	Flam. Liq. 3 STOT SE 3	-	-	-	-	-	-	
Pesticides									
Hexachlorobenzene	118-74-1	Carc. 1B – H350 STOT RE 1 – H372	-	2B (2001)	1 (3 for human health, 1 for wildlife)	Yes	-	-	Probable
Pentachloroaniline	527-20-8	-	Acute Tox. 3 – H301, H311, H331 STOT RE 2 – H373	-	-	-	-	-	-
Quintozene	82-68-8	Skin Sens. 1 – H317	-	3 (1987)	3b	Yes	-	Possible interaction with oestrogen pathway in wildlife and thyroid pathway in mammals	-
Glyphosate	1071-83-6	Eye Dam. 1 – H318	-	2A (2017)	-	Yes	-	No evidence of ED activity	-
AMPA	1066-51-9	-	Not classified Skin Corr. 1A – H314 Acute Tox. 4 – H302, 314, 332 Skin Irrit. 2 – H315 Eye Irrit. 2 – H319	-	-	-	-	-	-

Chemicals	CAS No.	Harmonised classification (CLP Regulation)	Self-classification	IARC (year)	Endocrine disruption				
					BKH or DHI	**TEDX list**	**SIN list**	**US EPA**	**IEPA**
Formaldehyde									
Formaldehyde	50-00-0	Acute Tox. 3* – H301, 311 and 331 Skin Corr. 1B – H314 Skin Sens. 1 – H317 Muta. 2 – H341 Carc. 1B – H350	-	1 (2012)	-	-	-	-	-
PAHs									
Benzo[a]pyrene	50-32-8	Skin Sens. 1 – H317 Muta. 1B – H340 Carc. 1B – H350 Repr. 1B – H360FD	-	1 (2012)	1 (1 for human health, 2 for wildlife)	Yes	-	-	-
Anthracene	120-12-7	-	Not classified Eye Irrit. 2 – H319 Skin Irrit. 2 – H315 Skin Sens. 1 – H317 STOT SE 3 – H335 Carc. 2 – H351	3 (2010)	-	Yes	-	-	-
Benzo[g,h,i]perylene	191-24-2	-	Not classified	3 (2010)	-	-	-	-	-
Benzo[b]fluoranthene	205-99-2	Carc. 1B – H350	-	2B (2010)	-	Yes	Yes	-	-
Benzo[a]anthracene	56-55-3	Carc. 1B – H350	-	2B (2010)	2 (human health and wildlife)	Yes	Yes	-	-
Indeno[1,2,3-c,d]pyrene	193-39-5	-	Carc. 2 – H351	2B (2012)	-	Yes	-	-	-
Cyclopenta[c,d]pyrene	27208-37-3	-	-	2A (2010)	-	Yes	-	-	-
Chrysene	218-01-9	Muta. 2 – H341 Carc. 1B – H350	-	2B (2010)	-	Yes	-	-	-
5-methylchrysene	3697-24-3	-	Acute Tox. 4 – H302 Eye Dam. 1 – H318 Carc. 2 or 1B – H351/350 Not classified	2B (2010)	-	Yes	-	-	-
Benzo[k]fluoranthene	207-08-9	Carc. 1B – H350	-	2B (2010)	-	Yes	-	-	-
Benzo[j]fluoranthene	205-82-3	Carc. 1B – H350	-	2B (2010)	-	Yes	-	-	-

Chemicals	CAS No.	Harmonised classification (CLP Regulation)	Self-classification	IARC (year)	Endocrine disruption				
					BKH or DHI	TEDX list	SIN list	US EPA	IEPA
Benzo[e]pyrene	192-97-2	Carc. 1B – H350	-	3 (2010)	-	Yes	-	-	-
Dibenzo[a,h]anthracene	53-70-3	Carc. 1B – H350	-	2A (2010)	-	Yes	-	-	-
Fragrances									
Benzyl alcohol	100-51-6	Acute Tox. 4* – H302 Acute Tox. 4* – H332	-	-	-	-	-	-	-
Benzyl salicylate	118-58-1	-	Skin Sens. 1B or 1 – H317 Eye Irrit. 2 – H319 Skin Irrit. 2 – H315 STOT SE 3 or 2 – H335 or H371	-	-	Yes	-	-	-
Coumarin	91-64-5	-	Acute Tox. 4 – H302 Skin Sens. 1 or 1B – H317 Acute Tox. 3 – H301, 311 and 331 STOT RE 2 – H373 Carc. 2 – H351 Acute Tox. 1 – H300	3 (2000)	-	-	-	-	-
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	31906-04-4	Skin Sens. 1A – H317	-	-	-	-	-	-	-
BMHCA	80-54-6	-	Acute Tox. 4 – H302 Skin Irrit. 2 – H315 Skin Sens. 1B – H317 Repr. 2 – H361 or Repr. 1B – H360	-	-	Yes	-	-	-
Limonene	5989-27-5	Flam. Liq. 3 – H226 Skin Irrit. 2 – H315 Skin Sens. 1 – H317	-	3 (1999)	-	-	-	-	-
Linalool	78-70-6	Skin Sens. 1B – H317	-	-	-	-	-	-	-
Alpha-isomethyl ionone	127-51-5	-	Skin Irrit. 2 – H315 Skin Sens. 1B or 1 – H317 Eye Irrit. 2 – H319	-	-	-	-	-	-

Chemicals	CAS No.	Harmonised classification (CLP Regulation)	Self-classification	IARC (year)	Endocrine disruption				
					BKH or DHI	TEDX list	SIN list	US EPA	IEPA
Dioxins and furans									
Dibenzo-p-dioxins	262-12-4	-	Acute Tox. 4 – H302	3 (1997)	-	-	-	-	-
2,3,7,8-TCDD	1746-01-6	-	Acute Tox. 1 – H300 Eye Irrit. 2 – H319	1 (2012)	1 (human health)	Yes	-	-	Known
1,2,3,6,7,8-HxCDD	57653-85-7	-	Acute Tox. 3 – H301 Eye Irrit. 2 – H319	3 (1997)	-	-	-	-	-
1,2,3,4,7,8-HpCDD	35822-46-9	-	Eye Irrit. 2 – H319 STOT SE 3 – H335 Muta. 2 – H341	3 (1997)	-	-	-	-	-
OCDD	3268-87-9	-	Acute Tox. 1 – H300	3 (1997)	-	-	-	-	-
2,3,7,8-TCDF	51207-31-9	-	Acute Tox. 1 – H300	3 (1997)	-	Yes	-	-	Known
1,2,3,7,8-PeCDF	57117-41-6	-	Acute Tox. 3 – H301 Eye Irrit. 2 – H319 STOT SE 3 – H335 Muta. 2 – H341	3 (1997)	-	Yes	-	-	-
2,3,4,7,8-PeCDF	57117-31-4	-	Acute Tox. 1 – H300 Eye Irrit. 2 – H319 STOT SE 3 – H335 Carc. 1A – H350 STOT RE 2 – H373	1 (2012)	1 (human health)	Yes	-	-	-
1,2,3,4,7,8-HxCDF	70648-26-9	-	Acute Tox. 3 – H301 Eye Irrit. 2 – H319	3 (1997)	-	Yes	-	-	-
1,2,3,6,7,8-HxCDF	57117-44-9	-	Acute Tox. 1 – H300	3 (1997)	-	Yes	-	-	-
2,3,4,6,7,8-HxCDF	60851-34-5	-	Acute Tox. 3 – H301 Eye Irrit. 2 – H319	3 (1997)	-	Yes	-	-	-
1,2,3,4,6,7,8-HpCDF	67562-39-4	-	Acute Tox. 3 – H301 Eye Irrit. 2 – H319	3 (1997)	-	-	-	-	-
1,2,3,4,7,8,9-HpCDF	55673-89-7	-	Acute Tox. 1 – H300	3 (1997)	-	-	-	-	-
OCDF	39001-02-0	-	Acute Tox. 1 – H300	3 (1997)	-	-	-	-	-

Chemicals	CAS No.	Harmonised classification (CLP Regulation)	Self-classification	IARC (year)	Endocrine disruption				IEPA
					BKH or DHI	TEDX list	SIN list	US EPA	
Dioxin-like PCBs									
PCBs	1336-36-3	STOT RE 2 ─ H373	-	1 (2016)	-	-	-	-	Known (PCBs)
PCB-81	70362-50-4	-	STOT RE 2 – H373	1 (2016)	-	Yes	-	-	
PCB-77	32598-13-3	-	STOT RE 2 – H373	1 (2016)	1 (human health)	Yes	-	-	
PCB-123	65510-44-3	-	STOT RE 2 – H373 Not classified	1 (2016)	-	Yes	-	-	
PCB-118	31508-00-6	-	STOT RE 2 – H373	1 (2016)	1 (human and animal health)	Yes	-	-	
PCB-114	74472-37-0	-	STOT RE 2 – H373 Not classified	1 (2016)	-	Yes	-	-	
PCB-105	32598-14-4	-	Acute Tox. 4 – H302 STOT RE 2 – H373	1 (2016)	-	Yes	-	-	
PCB-126	57465-28-8	-	STOT RE 2 – H373 Not classified	1 (2012)	-	Yes	-	-	
PCB-167	52663-72-6	-	STOT RE 2 – H373 Not classified	1 (2016)	-	-	-	-	
PCB-156	38380-08-4	-	STOT RE 2 – H373 Not classified	1 (2016)	2 (human health)	Yes	-	-	
PCB-157	69782-90-7	-	STOT RE 2 – H373 Not classified	1 (2016)	-	-	-	-	
PCB-169	32774-16-6	-	STOT RE 2 – H373 Not classified	1 (2016)	1 (human health)	Yes	-	-	
PCB-189	39635-31-9	-	STOT RE 2 – H373 Not classified	1 (2016)	-	-	-	-	

8.3.3   Dose-response relationships

The second step of a QHRA consists, in practice, in choosing toxicity reference values (TRVs).

A TRV is a generic term encompassing all of the types of toxicological indicators that are used to establish a relationship between a dose and an effect (toxic with a threshold) or between a dose and a likelihood of effect (toxic without a threshold). TRVs are established by international (WHO, etc.) or European (EFSA) organisations or by national structures (US EPA, RIVM, Health Canada, ANSES, etc.). They enable the potential health effects of exposure to chemicals to be assessed.

By definition, a TRV is established for the most sensitive toxic effect transposable to humans, thus protecting against all of the toxic effects observed in the available studies.

TRVs are specific to a substance, duration and route of exposure. They apply to the entire population, including susceptible groups (ANSES, 2017a).

For each chemical, the TRVs established by national (ANSES, US EPA, ATSDR, OEHHA, Health Canada, RIVM), European (EFSA, JECFA) and international (WHO) organisations were identified, focusing on those developed for a chronic duration of exposure, the duration regarded as most relevant in view of the context of the formal request. **Considering the close contact of diapers with the buttocks, the use of dermal TRVs seemed appropriate. However, since no TRVs were available for this route of exposure, a search for TRVs by the oral route was carried out.**

Initially, using a worst-case approach, the most disadvantageous TRV was selected regardless of how it had been established. If the TRV was found to have been exceeded, the available TRVs were analysed, considering the relevance of the choices made (critical effect, key study, critical dose, uncertainty factors) and the transparency of the way in which these TRVs had been established.

For PAHs, only the TRVs of the reference compound, benzo[a]pyrene (BaP), were identified. Indeed, the toxicity of only a limited number of PAHs is currently known. Some PAHs, primarily those with a low molecular weight, induce systemic non-carcinogenic threshold effects (mainly kidney, liver and blood disorders) for which TRVs have been established. Other PAHs, in particular those with a high molecular weight, appear to be carcinogenic and genotoxic. BaP was considered as a marker of PAH exposure and effects (WHO-IPCS, 1998).

For dioxins, furans and DL-PCBs, only the TRVs of the reference compound, 2,3,7,8-tetrachlorodibenzo-para-dioxin or TCDD (the most toxic congener), and those for total dioxins and furans were analysed. The toxicity of other compounds in this class was estimated based on toxic equivalency factors (TEFs) used to express the toxicity of all congeners with the same mechanism of toxicological action compared to that of the reference compound.

When there were no TRVs, the critical doses selected by national, European and international organisations were identified using the same criteria.

For this health risk assessment, only children between the ages of zero and three years were specifically targeted. The issue of the applicability of the identified TRVs to the population under three years of age was discussed. This is because these are generally established for the general population and for lifetime exposure. Applying them to this

specific age group could therefore lead to uncertainties in terms of hazards when establishing the TRVs and also when calculating risks in comparison with exposure levels. ANSES considered that the TRVs apply to the entire population regardless of age, including children. If there are data showing that children are more susceptible than adults to the effects of certain substances, these must be taken into account in the establishment of the TRV. If these data cannot be used to establish the TRV, an additional factor can be applied on a case-by-case basis to protect susceptible population groups. In the absence of data showing that children are particularly susceptible, ANSES considered that the default intra-species uncertainty factor UF_H of 10 was sufficient to protect the entire population (ANSES, 2017a).

Thus, using an initial worst-case approach, the CES considered, by default, that the TRVs applied to children between zero and three years of age.

Then, whenever the TRV was found to have been exceeded, a more detailed analysis of the TRVs was conducted, considering the relevance of the choices made (critical effect, key study, critical dose, uncertainty factors) and the transparency of the way in which the TRV had been established. Moreover, the experts determined whether the selected TRVs could be applied to the population of children between zero and three years of age, who can be particularly susceptible to certain chemicals. To do so, the CES followed the approach used for the infant Total Diet Study (iTDS, 0-3 years) (ANSES, 2016a) and the QHRA on the mouthing of plastic toys containing phthalate substitutes (ANSES, 2016b). The CES therefore reviewed the toxicological data specific to children taken into account in the establishment of each of these TRVs (perinatal and postnatal toxicity studies, developmental toxicity studies, reproductive toxicity studies conducted with several generations, etc.).

8.3.4 Exposure assessment

The assessment of exposure relies on the calculation of a daily exposure dose (DED), which is the quantity of a substance to which a population (children between zero and three years of age here) is exposed on a daily basis. The DED is expressed in mg/kg/day. The calculation of this DED requires the development of exposure scenarios reflecting the population's habits and the selection of exposure variables from the available data or from hypotheses when the necessary data are not available. The experts decided to use a deterministic approach.

The **dermal route of exposure was the one taken into account in this assessment, and more specifically exposure in the diaper area.** Until a child is toilet trained, this area is a warm, occlusive and moist environment with ideal kinetic conditions facilitating the percutaneous absorption of substances (ANSM, 2010; SCCS, 2016a).

In this expert appraisal, the **establishment of exposure scenarios** aimed to characterise the exposure of children, from birth to the completion of toilet training, to chemicals previously identified in baby diapers.
Various scenarios were considered based on the available data sets (Figure 14):
- Scenario 1: The analyses were undertaken by shredding diapers and using solvent extraction. They enabled concentration levels of certain chemicalsto be estimated in diapers to evaluate their contamination. Only a percentage of these chemicals contained in the materials can really come into contact with the skin. To estimate the quantity of a chemical potentially in contact with a child's skin, a transfer parameter T

= X (%) was used. This scenario enabled the direct transfer of pollutants from diaper materials to a child's skin to be estimated without any need for solubilisation in urine.

- Scenarios 2.1 and 2.2: Two types of analyses were undertaken:
  - o Firstly, whole diapers were shredded and solubilised in synthetic urine (Scenario 2.1). This scenario enabled chemicals potentially solubilised in urine to be more clearly identified, but shredding is only marginally representative of the mechanism of exposure of children urinating in a diaper. The internal doses calculated with Scenario 2.1 were deemed less realistic than those obtained with Scenario 2.2.
  - o Secondly, synthetic urine was added to the diapers before being pressed out. The urine thus released from the diapers was then analysed (Scenario 2.2). The experts considered that Scenario 2.2 was a test providing realistic estimates of the capacity of urine to extract a number of chemicals from diapers. The doses contained in the urine recovered after pressing enabled quantities of chemicals in contact with a child's skin to be estimated. Taking into account the capacity of these chemicals to penetrate the skin (Abs = fraction absorbed by the skin), the experts were able to estimate more realistic internal exposure doses than in Scenario 2.1.
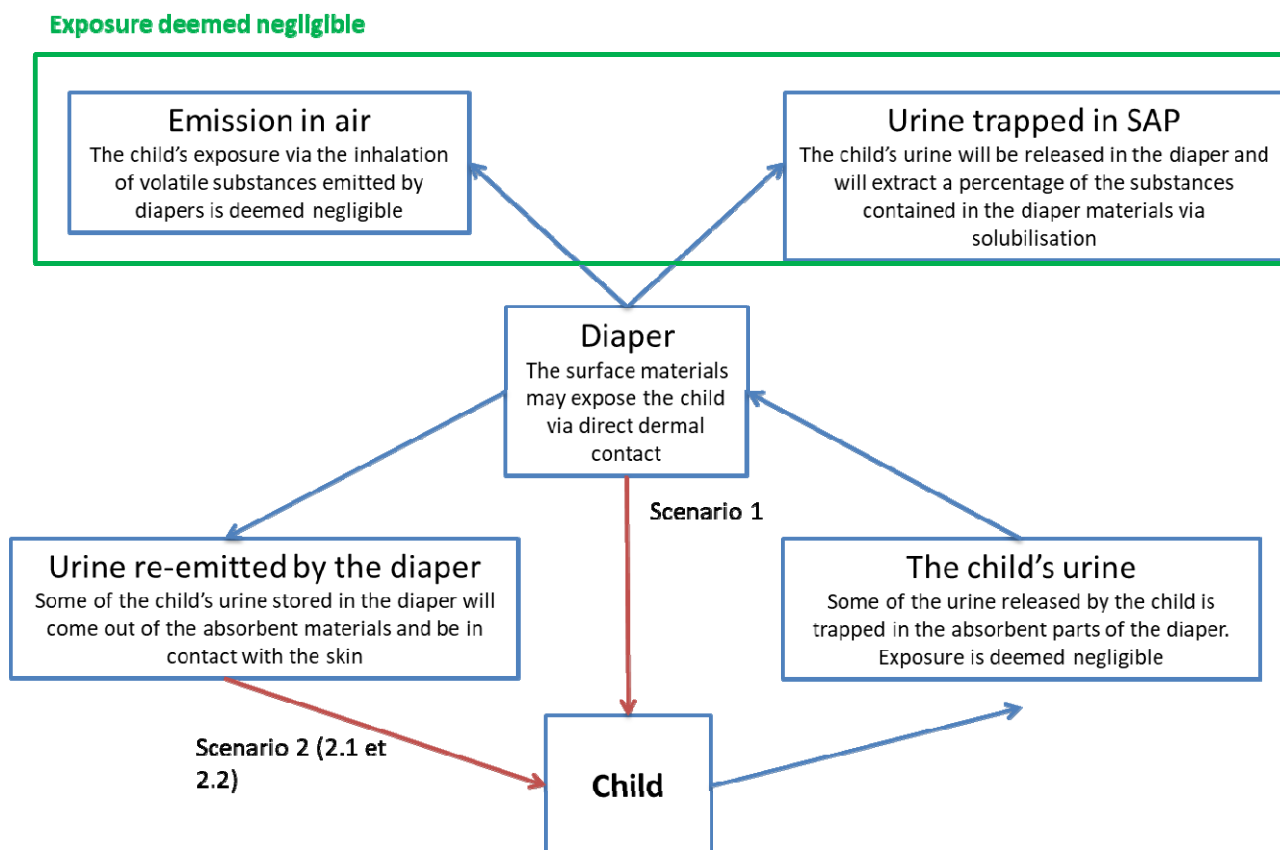
Figure 14: Diagram of child exposure to the chemicals contained in diapers

8.3.4.1 Daily exposure dose

A review of the exposure calculations performed in the various published studies was conducted and is available in Annex 9.

The CES considered that averaging lifetime exposure was not conservative enough. For certain effects, such as reprotoxicity and certain forms of endocrine disruption, there can be short exposure windows during which the risk of inducing harmful effects is high. It is therefore necessary to ensure that the TRV is complied with every day and not just on average, to avoid exposure peaks that may occur during these susceptibility windows. Therefore, the calculated DED corresponds to the daily exposure of a baby using disposable diapers.

A DED was calculated for each chemical individually, using the following equations:

For solvent extractions (shredded whole diapers or diaper parts)
$$\text{DED} = (C_{\text{shredded material}} \times W \times F \times T \times Abs) / BW \text{ [scenario 1]}$$

For extractions in shredded diapers with a urine simulant:
$$\text{DED} = (C_{\text{shredded-material simulant}} \times W \times F \times R \times Abs) / BW \text{ [scenario 2.1]}$$

For extractions in whole diapers with a urine simulant:
$$\text{DED} = (C_{\text{diaper simulant}} \times W \times F \times Abs) / BW \text{ [scenario 2.2]}$$

where   DED: daily exposure dose (mg/kg/day)
$C_{\text{shredded material}}$: concentration of the chemical extracted with a solvent from shredded whole diapers or diaper parts (mg/kg of diaper)
$C_{\text{shredded-material simulant}}$: concentration of the chemical extracted with a urine simulant from shredded whole diapers (mg/kg of diaper)
$C_{\text{diaper simulant}}$: concentration of the chemical extracted with a urine simulant from a whole diaper, in relation to the weight of the diaper taking into account the extracted simulant volume (mg/kg of diaper)
W: average weight of a diaper or of the diaper part (kg)
F: frequency of use (number/day)
T: transfer to skin (%)
R: reflux ratio (%)
Abs: fraction absorbed by the skin (%)
BW: body weight of a child (kg)

It should be noted that the DED that seemed the most realistic from these various analyses was that calculated from the extractions in whole diapers with a urine simulant (Scenario 2.2), since:
- the capacity to extract substances from diapers to urine was not modelled but was observed during the experiment. This avoided the need to use the default skin transfer value T of 7%;
- quantities of substances were only measured in urine actually coming out of the diapers after pressing, which avoided the need to use the modelled reflux ratio R parameter.

For dioxins, furans and DL-PCBs and PAHs, exposure and risks were assessed for each congener taken individually. Cumulative exposure was taken into account for each class of substances. For dioxins, furans and DL-PCBs, exposure was assessed using toxic equivalency factors (TEFs) indicating the toxicity of all congeners having the same mechanism of toxicological action as the "Seveso" dioxin (TCDD), considered the most toxic. Exposure was therefore expressed in toxic equivalent quantities (TEQs). The TEFs

were defined in 1998 and revised in 2005 by the WHO (Van den Berg *et al.,* 2006) (Figure 15).

	Isomer or homologue series (IUPAC number for PCB isomers)	TEF (WHO, 1998)	TEF (WHO, 2005)
PCDDs	2,3,7,8-tetraCDD	1	1
	1,2,3,7,8-pentaCDD		1
	1,2,3,4,7,8-hexaCDD	0.1	0.1
	1,2,3,6,7,8-hexaCDD	0.1	0.1
	1,2,3,7,8,9-hexaCDD	0.1	0.1
	1,2,3,4,6,7,8-heptaCDD	0.01	0.001
	OCDD	0.0001	**0.0003**
PCDFs	2,3,7,8-TCDF	0.1	0.1
	1,2,3,7,8-pentaCDF	0.05	0.03
	2,3,4,7,8-pentaCDF	0.5	0.3
	1,2,3,4,7,8-hexaCDF	0.1	0.1
	1,2,3,6,7,8-hexaCDF	0.1	0.1
	1,2,3,7,8,9-hexaCDF	0.1	0.1
	2,3,4,6,7,8-hexaCDF	0.1	0.1
	1,2,3,4,6,7,8-heptaCDF	0.01	0.01
	1,2,3,4,7,8,9-heptaCDF	0.01	0.01
	OCDF	0.0001	**0.0003**
Non-ortho PCBs	3,3',4,4'-TCB(77)	0.0001	0.0001
	3,3',4,5-TCB(81)	0.0001	**0.0003**
	3,3',4,4',5-PeCB(126)	0.1	0.1
	3,3',4,4',5,5'-HxCB(169)	0.01	**0.03**
Mono-ortho PCBs	2,3,3',4,44-PeCB(105)	0.0001	**0.00003**
	2,3,4,4',5-PeCB(114)	0.0005	**0.00003**
	2,3',4,44,5-PeCB(118)	0.0001	**0.00003**
	2',3,4,4',5-PeCB(123)	0.0001	**0.00003**
	2,3,3',4,4',5-HxCB(156)	0.0005	**0.00003**
	2,3,3',4,4',5-HxCB(157)	0.0005	**0.00003**
	2,3',4,4',5,5'-HxCB(167)	0.00001	**0.00003**
	2,3,3',4,4',5,5'-HpCB(189)	0.0001	**0.00003**

The values in bold indicate a change in the TEF value.

Figure 15: Toxic equivalency factors proposed by the WHO (1998 and 2005) for dioxins, furans and PCBs

For PAHs, exposure was also assessed using TEFs, considering BaP as the reference compound.

Table 17: TEFs proposed by various organisations for PAHs

	OEHHA, 1993 revised in 2015	INERIS, 2003	AFSSA, 2003	DFG, 2008 cited in BfR, 2009b	US EPA, 2010 (draft)**	TEFs considered in this expert appraisal
5-methylchrysene	1	0.01	/	/	/	0.01
Anthracene	/	0.01	0.01	/	0	0.01
Benzo[a]pyrene	**1**	**1**	**1**	**1**	**1**	**1**
Benzo[a]anthracene	0.1	0.1	0.1	0.1	0.2	0.1
Cyclopenta[c,d]pyrene	/	0.1	/	0.1	0.4	0.1
Chrysene	0.01	0.01	0.01	0.01	0.1	0.01
Benzo[b]fluoranthene	0.1	0.1	0.1	0.1	0.8	0.1
Benzo[j]fluoranthene	0.1	/	0.1	0.1	0.3	0.1
Benzo[k]fluoranthene	0.1	0.1	0.1	0.1	0.03	0.1
Benzo[e]pyrene	/	/	/	/	/	0.01*
Dibenzo[a,h]anthracene	/	1	1	1	10	1
Indeno[1,2,3-c,d]pyrene	0.1	0.1	0.1	0.1	0.07	0.1
Benzo[g,h,i]perylene	/	0.01	0.01	/	0.009	0.01
Naphthalene	/	0.001	0.001	0.001	/	0.001

* INERIS (2003) conducted a review of the various TEF tables. The following TEFs for benzo[e]pyrene were proposed in four studies: 0.004 (Krewski *et al.,* 1989), 0.01 (Malcom and Dobson, 1994), 0 (Muller et al., 1995a, b) and 0.002 (Larsen and Larsen, 1992). The CES selected the TEF from the study by Malcom and Dobson (1994). ** Arithmetic average

8.3.4.2 Selection of exposure variables

8.3.4.2.1 *Concentrations of chemicals in baby diapers*

The CES decided to use data from the SCL and INC to calculate the DED. The concentrations found in single-use baby diapers sold in France are summarised in Table 14 and 15 (INC, 2017 and 2018; SCL, 2017 and 2018; Group'Hygiène, 2018).

The SCL and INC results only cover a limited number of products and are therefore not representative of all of the baby diapers available on the French market (12 products for the INC and 19 for the SCL). The SCL tested the majority of the products analysed by the INC as well as some additional products but did not find the same chemicals or the same concentrations. This was partly due to the use of different analytical methods and limits of detection and/or quantification. It is important to note that the tests undertaken by the INC and SCL were performed with shredded samples possibly causing the chemicals to be diluted. Additional tests were conducted with specific diaper parts (e.g. PAHs in elastic parts for the SCL).

Tests undertaken with shredded diapers are not representative of real conditions since they lead to the extraction of chemicals contained in diaper parts regardless of whether these are in contact with the skin. In addition, if a chemical is contained only in one diaper part, there is a risk of underestimating exposure. For tests conducted in a urine simulant, there is a very low level of migration of lipophilic chemicals to this urine simulant but they can still be absorbed by the skin.

8.3.4.2.2 Average weight of a diaper

The average weight of a disposable diaper decreased from 64.6 g in the late 1980s to 40 g in 2010 and 33.3 g in 2013, i.e. an almost 50% reduction over a 25-year period (Figure 16) (EDANA, 2005, 2011 and 2015; Group'Hygiène, 2015).
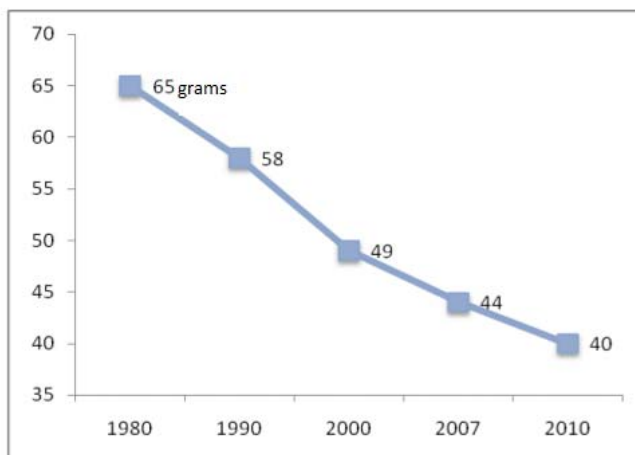
Figure 16: Change in the average weight of a single-use diaper between 1980 and 2010 (Group'Hygiène, 2015)

The literature data available for this parameter are summarised in the table below.

Table 18: Average weight of a single-use diaper

Reference	Weight (g)	Comment
De Vito and Schecter, 2002	Average = 40	Hypothesis
Krause *et al.* (2006)* Rai *et al.* (2009)*	50 Size 1 (2-5 kg): 24 Size 2 (3-6 kg): 25 Size 3 (4-9 kg): 33 Size 4 (7-20 kg): 40 Size 5 (11-25 kg): 45	P&G internal consumer usage data
Gupta *et al.* (2009)	30.1 to 50.7	Test with seven diapers
UK Environment Agency (2005)	42.77	Average UK data, 2001-2002
UK Environment Agency (2008)	38.6	Average
Group'Hygiène (2015)*	40	2010
EDANA (2015)*	33.3	2013

It should be noted that the weight of a diaper depends on its size. The INC undertook tests with size-3 diapers and the SCL with size-3 to -5 diapers depending on the model.

8.3.4.2.3 Frequency of use

The number of diapers used per day is influenced by the age of the child, the size of the diaper, the type of diaper used, the country and cultural habits.

The average number of daytime diaper changes decreases from seven per day at birth to five per day at the age of 2.5 years (
Table 19). When children no longer in diapers are not included, the average number of diapers used per day (daytime and nighttime, considering one diaper per night) by children between the ages of zero and 2.5 years ranges from 4.05 to 4.4.

Table 19: Daytime use of disposable diapers by age group in the United Kingdom (UK Environment Agency, 2005b)

Age band	Frequency	mean	SD	Changes per day	% still in nappies
up to 6 months	90	6.98	2.15	6.98	100.0%
6 to 12 months	168	5.66	1.64	5.66	95.7%
12 to 18 months	48	5.75	1.80	5.75	82.8%
18 to 24 months	120	4.95	1.49	4.95	45.6%
24 to 30 months	39	4.85	1.41	4.85	17.6%
30 to 36 months	20	3.70	1.66		4.8%
36 to 42 months	6	2.50	1.22		1.8%
42 to 48 months	7	4.00	1.29		0.4%
48 to 54 months	0	0	0		0.1%
54 to 60 months	2	2.50	2.12		0.1%
60 to 66 months					0.1%
66 to 72 months					0.0%

The UK Environment Agency concluded that 3796 disposable diapers are used by the average child between birth and the age of 2.5 years, i.e. 4.16 per day, based on 96.4% market penetration. This figure took into consideration the fact that some children are out of diapers before the age of 2.5 years (UK Environment Agency, 2005a, 2005b and 2008). It was adopted by Group'Hygiène and is used as a benchmark at the European and international levels.

Depending on the child's age and body weight, different sizes of diapers are used. Dey *et al.* (2016a) and Rai *et al.* (2009) studied diaper-changing frequency according to diaper size (Table 20).

Table 20: Diaper frequency of use by size in the USA (Dey *et al.*, 2016a*)

Diaper size (BW range)	No. of participants	Diaper use per day				Data reported in Rai et al., 2009
		Mean ± SD	75th percentile	90th percentile	95th percentile	Average change frequency
Size 1 (4–6 kg)	Not done	–	–	–	–	6
Size 2 (5–8 kg)	200	5.6 ± 2.1	7	8	9	5–6
Size 3 (7–13 kg)	150	4.7 ± 1.5	5	6	7	4–5
Size 4 (10–17 kg)	150	4.4 ± 1.5	5	6	7	4
Size 5 (14–18 kg)	150	4.1 ± 1.5	5	6	6	3
Overall (all sizes)	650	4.7 ± 1.8	5	6	7	

Parents kept a diary of disposable diaper usage for the performance consumer testing on diapers of various sizes.

The frequency of diaper changes also varies depending on the country. In France, an average of 4.7 diapers are used per day (Dey *et al.*, 2016a*).

Table 21: Diaper frequency of use by country (Dey *et al.*, 2016a*)

Country	No. of participants	Diaper use per day				
		Mean	50th percentile	75th percentile	90th percentile	95th percentile
India [a]	285	0.3	0	0	1	2
China [a]	2267	1.5	1	2	4	4
Philippines [a]	461	2.3	2	3	4	5
Russia [a]	722	3.2	4	5	6	7
Saudi Arabia [a]	545	4	4	5	6	7
France [b]	587	4.7	5	6	7	7
Germany [b]	567	4.7	5	6	6	7
UK [b]	901	5	5	6	8	8
Japan [b]	326	5.5	5	7	8	10
US [b]	972	5.9	6	7	10	10

Parents recorded the average number of disposable diapers used each day.

[a] Interviewer administered, door-to-door.

[b] Self-administered by mail.

The following table summarises the data on the frequency of use of single-use diapers.

Table 22: Summary of the data on the frequency of use of single-use diapers

Reference	Frequency of use (number/day)	Comment
UK Environment Agency (2005b)	4.16 Average daytime frequency < 6 months: 6.98 6 - 12 months: 5.66 12 - 18 months: 5.75 18 - 24 months: 4.95 24 - 30 months: 4.85 30 - 36 months: 3.7 + one diaper/night	Average
Krause *et al.* (2006)* Rai *et al.* (2009)*	5 Size 1 (2-5 kg): 6 Size 2 (3-6 kg): 5-6 Size 3 (4-9 kg): 4-5 Size 4 (7-20 kg): 4 Size 5 (11-25 kg): 3	Average
France Nature Environnement (2011)	5	Average
Dey *et al.* (2016a)*	Mean: 4.7 Median: 5 P75: 6 P90 and P95 = 7	In France (n = 587) see Table 21
	4.7 ± 1.8 Size 2 (5-8 kg): 5.6 ± 2.1 Size 3 (7-13 kg): 4.7 ± 1.5 Size 4 (10-17 kg): 4.4 ± 1.5 Size 5 (14-18 kg): 4.1 ± 1.5	Average USA (collection of data on the frequency of use of size-2 to -5 diapers between 2010 and 2012)
De Vito and Schecter (2002)	0-6 months: 10 6-24 months: 6	Hypothesis
Ishii *et al.* (2015)	12	JHPIA, 2015

8.3.4.2.4 Transfer of chemicals from the material to the skin and reflux ratio

The skin transfer of a chemical expresses its ability to migrate to the skin from the various parts of a diaper.

Several industrial studies have estimated this parameter based on the location of the chemical in the parts of single-use diapers (Krause *et al.*, 2006*; Erasala *et al.,* 2007*; Rai *et al.*, 2009*; Kosemund *et al.*, 2009*; Dey *et al.*, 2016a*):

- Chemicals in direct contact with the skin (topsheet, lotion, leak guards, belt section) can be transferred to the skin directly or by solubilisation in sweat, urine, faeces or sebum. Only a fraction is transferred to the skin during use. According to Odio *et al.* (2000*), 7% is actually transferred to the skin. This figure was estimated based on the transfer of a tracer ingredient (stearyl alcohol) found in lotions in the topsheet whose objective is precisely to be transferred to the skin. This transfer factor for lotions was also used by default for most of the ingredients in the topsheet and elastics. It was deemed conservative by the authors since a lotion is intended to be transferred to the skin, unlike other ingredients;

- For substances in <u>indirect contact with the skin</u> (acquisition layer, SAP, core, nonwoven material surrounding it, glue), transfer can occur by extraction or solubilisation in body fluids followed by migration to the topsheet and release onto the skin under pressure (**reflux**). In the absence of data, the authors recommend a reflux value of 100%. The highest reflux value would be 0.223% after testing diapers that can be worn through the night with a high urine load. The authors selected the value of 0.25%, which they considered conservative (Rai *et al.*, 2009*). This value is recommended by EDANA (2005). A new method for calculating reflux has been developed to more realistically simulate the wearing of diapers: Prolonged Exposure Rewet Method in Diapers (PERMID). This method uses a gravimetric approach where collagen is used as a skin mimic. It takes into account the pressure a child may apply to a diaper, the urine load during diaper wear, the gap between urine voids, the exposed surface area, and diaper wear time (Dey *et al.*, 2016a*). This pressure was measured in 174 children between the ages of two weeks and 56 months, in four positions (sitting up straight, lying on the stomach, lying on the back, and falling on the buttocks). Thanks to this new method, an average reflux factor of 0.46% (0.32-0.66%) was adopted, considering 50% of the diaper surface area since in real conditions of use, only a small portion of a diaper is under pressure;

- The authors assumed skin contact to be negligible for the backsheet, printed surfaces, fastening system and ear tabs.

Table 23: Transfer from the material to the skin and reflux ratio

Reference		Comment
Krause *et al.* (2006)*	Direct contact of the material with the skin: 10-20% Indirect contact (reflux): 0.25-2.5% Negligible contact: 0%	-
Rai *et al.* (2009)*	Direct contact: 7% Indirect contact (reflux): 0.25%	Default factor
Dey *et al.* (2016a)*	Direct contact: - 4% after three hours of wear - 3% after six hours of wear - 4.3% after a night Indirect contact (reflux): 0.46%	PERMID method

8.3.4.2.5 Fraction absorbed by the skin or mucous membranes

Dermal absorption depends on the specific physico-chemical properties of the chemical, the maturity of the skin tissue and the exposure conditions (state of the skin, occlusive or semi-occlusive conditions).

Until a child is toilet trained, the diaper area is a warm, occlusive and moist environment with ideal kinetic conditions facilitating the percutaneous absorption of substances. Nonetheless, despite the potential risks associated with the occlusive nature of this environment, a significant decrease in the incidence and severity of diaper rash has been observed over the past few years and has been attributed to the quality of single-use diapers (AFSSAPS, 2010a). However, the wearing of diapers continues to cause skin diseases in the buttocks area that can affect dermal absorption. In that case, skin penetration can be increased. Stamatas *et al.* (2011*) compared skin barrier function in infants with dermatitis, considering areas of lesional skin, non-lesional skin and control skin (skin on the outer thigh). Barrier function was similar for the non-lesional and control skin (transepidermal water loss (TEWL)[20] 47 ± 29 g/m²/hr vs 48 ± 30 g/m²/hr). The lesional skin showed higher TEWL (104 ± 67 g/m²/hr) than the non-lesional skin and control skin, indicating that skin with erythema can be vulnerable due to loss of stratum corneum, resulting in increased TEWL (Stamatas *et al.,* 2011*). Skin conditions such as contact dermatitis and diaper rash can potentially increase the dermal penetration of substances depending on their physico-chemical characteristics and the degree of skin damage. For example, skin compromised by diaper rash or by mechanical or chemical damage has shown variable penetration properties, with slightly higher dermal penetration compared to normal skin (Gattu and Maibach, 2011 cited in Dey *et al.*, 2016a*). Conversely, other studies indicate that compromised skin does not necessarily result in increased dermal penetration (McCormack *et al.,* 1982 cited in Dey *et al.*, 2016a*; Dey *et al.*, 2015*).

At European level, the Scientific Committee on Consumer Safety (SCCS) recommends using a default absorption rate of 50%. However, the buttocks area has its own particular conditions: wearing of diapers, uncontrolled urination and defecation, and diseases that can damage the skin. Modern diaper technology has shown increasing compatibility with the skin, leading to a reduction in the frequency and severity of diaper dermatitis. That

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[20] Transepidermal water loss refers to a mixed phenomenon of passive diffusion and water vapour loss as a result of sweating. When the skin is damaged, transepidermal water loss is increased. On the other hand, it returns to normal baseline values when the skin barrier is restored. The value of transepidermal water loss measured with an evaporimeter is expressed as a mass of evaporated water per unit area of skin per unit of time (g/m²/hr).

said, diaper dermatitis cannot be completely avoided and may have an impact on the dermal absorption of substances. Thus, the potential impact of irritation on the dermal absorption of chemicals should be taken into account in the final quantitative risk assessments of products intended to be used on the buttocks (SCCS, 2016a).

It should be noted that for the assessment of cosmetics intended for children under three years of age, the ANSM recommends applying a worst-case scenario, i.e. 100% topical penetration, when calculating margins of safety for products likely to be applied to the buttocks (ANSM, 2010).

8.3.4.2.6 Body weight

Body weight depends on the age and sex of the individual and his/her physiological condition. During the diaper wearing period, the weight of a child varies. On average, it is 3.5 to 4 kg for a newborn, 10 kg for a one-year-old child, and 18 to 25 kg for a toddler (Rai *et al.,* 2009*).

Companies consider an average body weight of 8 kg (Rai *et al.,* 2009*; Dey *et al*., 2016a*; EDANA). As part of a worst-case scenario, they recommend using the smallest body weight for newborns (Rai *et al.,* 2009*).

Body-weight data from the 2013 BEBE-SFAE survey, on the eating habits and food consumption of children between the ages of zero and 36 months in metropolitan France, are also available. This study was conducted in the field by TNS-SOFRES for the French Association for Children's Food. Consumption data were collected from 1188 mothers of children between the ages of 15 days and 36 months, meant to be a representative sample of the French population[21]. Body weights were recorded by the interviewer in the children's homes using a bathroom scale or recent weighing data (Table 24).

Table 24: Reported French body weights (girls and boys) – zero to 36 months (SFAE, 2013)[22]

Age group (years)	Body weight (kg)						
	Min	Q.5	Q.25	Q.50	Q.75	Q.95	Max
0-1 year	2.6	4.1	5.6	7.5	8.8	10.3	11.5
1-2 years	8	9	10.0	11.1	12.0	13.3	16
2-3 years	9.88	11	12.0	13.2	15	17.0	20

The 2014-2015 French Individual and National Food Consumption Survey (INCA 3) documented this parameter (ANSES, 2017b). This was a study that first and foremost aimed to collect individual food consumption data for the population living in France, but the participants' anthropometric data were also recorded. All of the participants were weighed in their homes using electronic bathroom scales. Any participants who refused were invited to report their body weight. As part of the study, body-weight data were thus collected for 5842 individuals aged from zero to 79 years out of the 5855 surveyed, i.e. 3145 adults and 2697 children (Table 25).

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[21] Excluding highly vulnerable populations, based on the following criteria: the baby's age and sex, the mother's occupation, and the family's socio-professional category and region/metropolitan area
[22] The body-weight data presented in the table were obtained by processing the raw data from the SFAE study.

Table 25: Distribution of body weight (kg) according to sex and age for children aged zero to 17 years (n = 2697) (ANSES, 2017b)

	Boys (n=1406)					**Girls** (n=1291)					**Total** (n=2697)					**Test**
	Mean	**SD**	p5	Med.	p95	**Mean**	**SD**	p5	Med.	p95	**Mean**	**SD**	p5	Med.	p95	
0-11 months n=80	**6.6**	**2.2**	3.1	6.0	11.0	**6.5**	**1.7**	3.3	5.5	10.3	**6.6**	**1.9**	3.1	6.0	10.4	ns
1-3 years n=229	**13.0**	**1.5**	9.8	13.0	16.0	**12.7**	**1.8**	9.6	12.4	17.0	**12.9**	**1.7**	9.6	12.7	16.7	ns
4-6 years n=454	**18.9**	**3.6**	14.5	18.3	25.2	**19.3**	**4.1**	13.6	18.4	27.0	**19.1**	**3.9**	14.2	18.4	26.0	ns
7-10 years n=643	**29.5**	**7.6**	20.5	28.0	44.7	**29.0**	**7.6**	19.0	27.8	43.9	**29.3**	**7.6**	19.8	27.9	44.7	ns
11-14 years n=736	**46.9**	**13.4**	30.2	46.0	67.6	**45.8**	**12.1**	30.0	45.0	65.1	**46.4**	**12.8**	30.0	45.0	67.6	ns
15-17 years n=555	**66.1**	**17.3**	44.0	63.0	96.6	**57.3**	**12.5**	42.0	55.6	76.8	**61.8**	**15.9**	44.0	60.0	92.8	***
Test of differences by sex: ns (not significant), * (p.0.05), ** (p<0.01), *** (p<0.001)																
Source: INCA3 study (2014-2015), data processing by ANSES																

8.3.5 Risk characterisation

Risk characterisation enables the expected risk in a population to be quantified, taking into account exposure to the substance in question and its effects (toxicity). Risk characterisation is the final QHRA phase and consists in calculating the expected risk level for the chosen type of effect, based on the calculation of:
- a hazard quotient (HQ) for substances with a threshold effect,
- an Individual Excess Risk (IER) for substances with a no-threshold effect (carcinogenic effect).

8.3.5.1 For substances with a threshold effect

For substances with a threshold effect, the risk level is expressed by the HQ, which is the ratio between the daily exposure dose (DED) and the appropriate TRV. The numerical value of this ratio is used to determine whether or not the dose received exceeds the TRV.

$$HQ = DED/TRV$$

The result of the HQ calculation is interpreted as follows: an HQ greater than 1 means that the toxic effect may occur, without it being possible to predict its likelihood of occurrence in the exposed population, whereas an HQ less than 1 means that no toxic effect is theoretically expected in the exposed population.

8.3.5.2 For substances with a no-threshold effect

For substances with a no-threshold effect (mainly genotoxic carcinogens), an Individual Excess Risk (IER) is calculated. It corresponds to the probability of developing cancer as the result of lifetime exposure to the substance in question. The IER is determined using the following equation:

$$IER = ERU \times [(DED \times T) / Tm]$$

where: ERU: excess risk per unit
   T: duration of the exposure period in years, i.e. the duration of diaper wearing (three years)
   Tm: duration of lifetime exposure in years, conventionally set at 70 years.

Various excess risks can be calculated based on different exposure concentrations; depending on the case, there can be excess risks of 10^{-4} to 10^{-6} (for carcinogenic effects, this means one additional case of cancer in an exposed population of 10,000 to 1,000,000 individuals). **In this study, the acceptable risk was set at 10^{-6}, the most conservative value.**

8.3.5.3 In the absence of TRVs

For chemicals for which it was not possible to select a TRV, the adopted approach involved first choosing a reference margin of exposure (MOEref, without a unit). The MOEref represents a margin of minimal exposure in humans with respect to an experimentally obtained critical dose (e.g. NOAEL, LOAEL or BMD in animals). The MOEref was then compared to a margin of exposure (MOE) calculated as the ratio of the No Observed Adverse Effect Level in animals to the value of the daily exposure dose:

$$MOE = \text{Critical dose} / DED$$

When MOEref/MOE < 1, it is possible to rule out the potential occurrence of an adverse health effect by comparing a reference margin of exposure predictive of a lack of effect to a probability of occurrence for calculated margins of exposure.
The MOEref is the product of the uncertainty factors, i.e.

$$MOEref = UF_A \times UF_H \times UF_{L/B} \times UF_S \times UF_D$$

These uncertainty factors reflect uncertainty related to inter-species or inter-individual transposition or the transposition of one exposure situation to another. They also reflect the state of scientific knowledge at the time of the MOEref's establishment (ANSES, 2017a). The various uncertainty factors proposed in the literature are shown in Table 26.

Table 26: Uncertainty factors proposed in the literature (ANSES, 2017a)

Uncertainty factor (UF)	UF interpretation
UF_A	Inter-species variability (toxicokinetics/toxicodynamics)
UF_H	Intra-species variability (toxicokinetics/toxicodynamics)
$UF_{L/B}$	LOAEL to NOAEL/Use of a BMD
UF_S	Subchronic to chronic toxicity
UF_D	Data sufficiency (quality and quantity)
	Severity of the effect

It should be noted that the determination of a reference margin of exposure cannot replace the notion of risk acceptability, which is the responsibility of risk managers.

8.3.5.1 Specific case of PAHs

For PAHs, since all of the organisations (OEHHA and US EPA) proposed no-threshold carcinogenic TRVs for the reference compound, BaP, they recommend applying a specific factor to calculate carcinogenic risks in children (ADAF for the US EPA, ASF for OEHHA). This factor assumes the following <u>default</u> values by age group:
-    10 for children under two years of age,

-    3 for children between the ages of two and 15 years,

-    1 from the age of 16 years.

This factor does not apply when establishing the TRV but rather when calculating the risk. Thus, risk calculations were performed as follows, with the application of a factor of 10 from zero to two years of age and a factor of 3 from two to three years of age:

$$IER = ERU \times DED \times TEF \times [(10 \times 2 \text{ years}/70 \text{ years}] + (3 \times 1 \text{ year}/70 \text{ years})]$$

8.4   QHRA using the worst-case approach

This "worst-case" approach enables an initial simplified quantitative health risk assessment to be undertaken. Its usefulness is limited to demonstrating that health thresholds have not been exceeded for a substance. Nevertheless, if potential cases of the TRVs being exceeded are observed, it is necessary to conduct a more complex and refined assessment to obtain more realistic results.

8.4.1 Summary of the TRVs and critical doses considered with the worst-case approach

For each chemical, the chronic oral TRVs were identified (Annex 8). The following tables list the lowest chronic oral TRVs (threshold and no-threshold) for each of the substances considered. In the absence of chronic oral TRVs, the subchronic TRV was used for 1,3-dichlorobenzene. In the absence of TRVs for pentachloroaniline (a metabolite of quintozene), the TRV of the pentachloroaniline + quintozene mixture was used. Likewise, for AMPA (a metabolite of glyphosate), the TRV of the glyphosate + AMPA mixture was used.

Table 27: Summary of the threshold TRVs used to conduct the QHRA according to a worst-case scenario

Chemicals	Type of TRV	Organisation (year)	Value	Target organ/critical effect
VOCs				
Naphthalene	Chronic	US EPA (1998)	$2 \cdot 10^{-2}$ mg/kg/day	↓ average terminal body weight in males
Styrene	Chronic	Health Canada (1993) / RIVM (2001)	0.12 mg/kg/day	Developmental toxicity /↓ body weight
Toluene	Chronic	US EPA (2005)	0.08 mg/kg/day	Nephrotoxicity
1,4-dichlorobenzene	Chronic	ATSDR (2006)	0.07 mg/kg/day	Hepatotoxicity
1,3-dichlorobenzene	Subchronic	ATSDR (2006)	0.02 mg/kg/day	Endocrinology
Mixed xylenes	Chronic	WHO (2004)	0.0179 mg/kg/day	↓ body weight
Chlorobenzene	Chronic	US EPA (1989)	0.02 mg/kg/day	Hepatotoxicity
n-propylbenzene	Chronic - provisional	US EPA (2009)	0.1 mg/kg/day	Nephro- and hepatotoxicity of ethylbenzene
1,2,3-trichlorobenzene	Chronic	Health Canada (1992)	$1.5 \cdot 10^{-3}$ mg/kg/day	Nephrotoxicity Hepatotoxicity Effects on the thyroid
1,2,4-trichlorobenzene	Chronic	OEHHA (1999)	10^{-3} mg/kg/day	Endocrinology
1,3,5-trimethylbenzene	Chronic	US EPA (2016)	0.01 mg/kg/day	Neurotoxicity
Formaldehyde				
Formaldehyde	Chronic	WHO/IPCS (2005)	0.15 mg/kg/day	Stomach irritation and nephrotoxicity
Pesticides				
Hexachlorobenzene	Chronic	ATSDR (2015)	$7 \cdot 10^{-5}$ mg/kg/day	Hepatotoxicity
Quintozene	Chronic	US EPA (1987)	$3 \cdot 10^{-3}$ mg/kg/day	Liver tumours
Quintozene + pentachloroaniline	Chronic	EC (2000)	0.01 mg/kg/day	Not indicated
Glyphosate	Chronic	US EPA (1987)	0.1 mg/kg/day	Development / nephrotoxicity
Glyphosate + metabolites including AMPA	Chronic	JMPR (2016)	0-1 mg/kg	Carcinogenicity / salivary gland
Fragrances				
Benzyl derivatives including benzyl alcohol	Chronic	EFSA (2011)	≥ 5 mg/kg/day	No reprotoxic, teratogenic or carcinogenic effects
Coumarin	Chronic	EFSA (2008)	< 0.1 mg/kg	Hepatotoxicity
Limonene	Chronic	EFSA (2012)	0.1 mg/kg/day	Hepatotoxicity
Citral, geranyl acetate, citronellol, linalool and linalyl acetate	Chronic	JECFA (1998)	< 5 mg/kg/day	No effects
PCDD/Fs + DL-PCBs				
2,3,7,8-TCDD → Application of TEFs for dioxins, furans and DL-PCBs*	Chronic	US EPA (2012)	$7 \cdot 10^{-10}$ mg/kg/day	Reproductive and developmental toxicity
PAHs				
Benzo[a]pyrene Application of TEFs for PAHs	Chronic	US EPA (2017)	$3 \cdot 10^{-4}$ mg/kg/day	Developmental toxicity

Table 28: Summary of the no-threshold TRVs used to conduct the QHRA according to a worst-case scenario

Chemicals	Organisation (year)	Value	Target organ/critical effect
VOCs			
1,4-dichlorobenzene	OEHHA (2009)	0.042 $(mg/kg/day)^{-1}$	Liver tumours
1,2,4-trichlorobenzene	OEHHA (1999)	$3.6 \cdot 10^{-3}$ $(mg/kg/day)^{-1}$	Hepatocellular carcinomas
Pesticides			
Hexachlorobenzene	OEHHA (2011)	1.8 $(mg/kg/day)^{-1}$	Liver tumours
PAHs			
Benzo[a]pyrene → Application of TEFs for the different PAHs	OEHHA (2009)	12 $(mg/kg/day)^{-1}$	Gastrointestinal tumours

Regarding naphthalene, only one organisation proposed a no-threshold oral TRV (OEHHA, 2011). However, it was based on a study on exposure by inhalation highlighting nasal tumours in rats. **The CES did not accept the OEHHA ERU** since tumours observed by inhalation are local tumours.

No TRVs were identified for the following chemicals: p-isopropyltoluene, benzyl salicylate, butylphenyl methylpropional, hydroxyisohexyl 3-cyclohexene carboxaldehyde and alpha-isomethyl ionone. Critical doses were therefore investigated for use in the QHRA.

In 2016 and 2017 (draft), the SCCS assessed the safety of butylphenyl methylpropional in cosmetic products. The SCCS considered a NOAEL of **5 mg/kg bw/day** for the systemic effects and maternal toxicity observed due to chronic exposure in the following studies:
   - A repeated dose toxicity study in albino rats exposed for 90 days by gavage to 0, 2, 5, 25 and 50 mg/kg bw/day (Givaudan, 1990 cited in SCCS, 2016b and 2017). At 25 mg/kg bw/day, systemic effects (increases in liver weights (absolute and relative), a significant decrease in plasma cholinesterase activity and lower plasma cholesterol levels) were observed in both sexes;
   - A teratogenicity study in pregnant Wistar rats exposed by gavage from gestation days 6 to 20 to doses of 0, 5, 15 and 45 mg/kg bw/day (BASF SE, 2004 cited in SCCS, 2016b and 2017). From 15 mg/kg bw/day, significant decreases in body weight gain were observed, in addition to significant increases in alanine aminotransferase (ALT) levels, decreases in serum cholinesterase levels, increases in liver weights and decreases in average uterus weights.
Thus, the critical dose of 5 mg/kg bw/day had been deemed appropriate and was therefore used in their QHRA (SCCS, 2016b). In 2017, the SCCS reassessed butylphenyl methylpropional but did not undertake a health risk assessment due to potential genotoxic effects (SCCS, 2017). In 2012, butylphenyl methylpropional was listed as a contact allergen in humans with between 11 and 100 positive skin reactions reported (SCCS, 2012).

In 2011, the SCCS concluded that **hydroxyisohexyl 3-cyclohexene carboxaldehyde** was not to be used in consumer products in order to prevent cases of contact allergy and limit the consequences for individuals already sensitised. Changes in biochemical parameters (increases in ALT and alkaline phosphatase levels in females, increases in albumin and decreases in cholesterol and glucose levels in males) and effects on the liver (increases in absolute and relative liver weights and hepatocyte enlargement) were observed in rats (males and females) exposed to 150 mg/kg bw/day by gavage for 28 days. These changes could be considered as early indicators of liver impairment observed

at higher doses. Thus, the SCCS adopted a NOAEL of **15 mg/kg bw/day** (SCCS, 2011). In 2012, hydroxyisohexyl 3-cyclohexene carboxaldehyde was listed as a contact allergen in humans with more than 1000 positive skin reactions reported (SCCS, 2012).

In 2007, the Research Institute for Fragrance Materials (RIFM) assessed ionones used as fragrance ingredients. For **alpha-isomethyl ionone**, a systemic NOAEL of **50 mg/kg bw/day** for dermal exposure for 90 days in Sprague-Dawley rats and a NOAEL of 30 mg/kg bw/day for oral exposure can be used to conduct a QHRA on the use of ionones as fragrance ingredients (RIFM Expert Panel, 2007). In 2012, alpha-isomethyl ionone was listed as a contact allergen in humans with between 11 and 100 positive skin reactions reported (SCCS, 2012).

JECFA assessed a group of flavouring agents that consisted of hydroxy- and alkoxy-substituted benzyl derivatives comprising 46 substances including **benzyl salicylate**. Benzyl salicylate was assigned to structural class I (substances that have simple chemical structures and efficient modes of metabolism which suggest low toxicity by the oral route). The threshold of concern for structural class I is 1800 mg/person/day (WHO, 2002).
In 2012, benzyl salicylate was listed as a contact allergen in humans with between 11 and 100 positive skin reactions reported (SCCS, 2012). A proposal to classify benzyl salicylate as a skin sensitiser, category 1B (H317) according to the criteria of the CLP Regulation was submitted by Germany based on the positive results of a local lymph node assay (LLNA) in mice (ECHA, 2018a).
In addition, as part of the REACh Regulation, benzyl salicylate was to be assessed by Germany due to concerns about endocrine disrupting properties (BAUA, 2018). In 2010, as part of the US High Production Volume (HPV) programme, the US EPA undertook a screening-level hazard assessment for 10 benzyl derivatives classified into three sub-categories according to the chemical structure of the substituents and functional groups: benzaldehyde derivatives, benzyl and benzoate esters and 2-hydroxybenzoate esters. Benzyl salicylate belongs to the latter sub-group, along with methyl salicylate (CAS No. 119-36-8) and pentyl salicylate (CAS No. 2050-08-0). The pharmacokinetic data support the contention that the toxicity of derivatives in the same sub-group should be similar based on the formation of similar stable metabolites (i.e. benzoic acid derivatives corresponding to the category members). A review of the available data was undertaken for the three substances included in the sub-category of 2-hydroxybenzoate esters. Data were only available for methyl salicylate, for repeated dose toxicity and for reproductive and developmental toxicity. The lowest NOAEL identified by the US EPA (NOAEL = 50 mg/kg/day) was taken from a chronic study in rats and dogs (Webb and Hansen, 1963). These authors fed methyl salicylate to male and female Osborne-Mendel rats (50 animals/dose) at concentrations of 0%, 0.1%, 0.5%, 1.0% or 2.0% (0, 50, 250, 500 and 1000 mg/kg bw/day) for two years. At the highest dose, all the rats died by the 49th week. There was a significant decrease in body weight for both sexes at the two highest doses. An increase in cancellous bone in the metaphyses was observed at the two highest doses. Relative testis weight was significantly increased, as were relative heart and kidney weights in females receiving 500 mg/kg/day (not examined at 1000 mg/kg/day). Gross pituitary gland lesions were observed in 10 rats having received 250 mg/kg/day (four rats in the control group). The same authors administered methyl salicylate in capsule form to beagles (two/sex/dose) at doses of 0, 50, 150 or 350 mg/kg/day, six days a week for two years. At 150 and 350 mg/kg/day, the dogs showed a reduction in body weight and liver enlargement, seen under a microscope as enlarged hepatic cells. These two studies enabled a NOAEL of 50 mg/kg/day to be identified for methyl salicylate. Thus, a NOAEL of

50 mg/kg bw/day was adopted for benzyl salicylate, after read-across with methyl salicylate.

JECFA assessed a group of five aromatic hydrocarbons used as flavouring agents including **p-isopropyltoluene** (p-cymene). P-cymene was assigned to structural class I (substances that have simple chemical structures and efficient modes of metabolism which suggest low toxicity by the oral route). The threshold of concern for structural class I is 1800 mg/person/day. The use of p-cymene as a flavouring agent in food does not pose any risks (WHO, 2005).

A proposal for classification according to the CLP Regulation has been submitted for public consultation (ECHA, 2018b[23]).

No experimental studies were identified dealing with the short-term, subchronic or chronic effects of p-cymene via the oral route or its effects on development or reproduction (US EPA, 2011; EFSA, 2015). The data are limited to a single acute toxicity study in rats (Jenner *et al.*, 1964 cited in US EPA, 2005 and 2011). Thus, in 2011, the US EPA concluded that it was not possible to derive a subchronic or chronic oral TRV. However, as a terpene hydrocarbon, p-cymene is closely related in structure to another naturally occurring plant component, cumene or isopropylbenzene. Based on similarity in their physical properties, chemical reactivity and pharmacokinetic and metabolic data, p-cymene and cumene belong to the chemical category of aromatic monoterpene hydrocarbons (US EPA, 2005). Thus, data on cumene can be used to assess the risks associated with p-cymene, which was the approach used by EFSA in 2015. EFSA thus considered the dose of **154 mg/kg bw/day** as the NOAEL, applying an uncertainty factor of 100 to calculate the maximum safe intake for the target species and the maximum safe feed concentration (EFSA, 2015). Female rats were exposed to 0, 154, 462 or 769 mg/kg bw/day of cumene (in olive oil) by gavage, five days a week for six months. The only effect reported for the higher two doses was an increase in average kidney weight (not specified if absolute or relative weight), not accompanied by histopathological changes. This effect was described as "slight" at 462 mg/kg bw/day and as "moderate" at 769 mg/kg bw/day (Wolf *et al.*, 1956).

MOErefs have been proposed for chemicals for which a critical dose was selected, i.e. p-isopropyltoluene, butylphenyl methylpropional, hydroxyisohexyl 3-cyclohexene carboxaldehyde, alpha-isomethyl ionone and benzyl salicylate (Table 29). The uncertainty factors taken into account for the MOErefs have been applied by default, in the same way for all the chemicals:

- An inter-species uncertainty factor (UF_A) of 10 to take into account differences in toxicokinetics and toxicodynamics between animals and humans, in the event of a study undertaken in animals;
- An inter-individual uncertainty factor (UF_H) of 10 to take into account differences in toxicokinetics and toxicodynamics within the human species;
- Where applicable, an uncertainty factor (UF_L) of 3 related to the use of a LOAEL instead of a NOAEL;
- Where applicable, an uncertainty factor (UF_S) of 3 related to the use of a subchronic study.

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[23] Proposed classification: Flam. Liq. 3, H226, Acute Tox. 3, H331, Inhalation: ATE=3 mg/L (vapour), Asp. Tox. 1, H304, Aquatic Acute 1, H400, Aquatic Chronic 3, H412. Consultation from 21/05/2018 to 20/07/2018

Table 29: Reference margins of exposure (MOErefs)

	Critical dose	Uncertainty factor (UF)					MOEref
		UF_A	UF_H	$UF_{L/B}$	UF_S	UF_D	
Butylphenyl methylpropional	NOAEL = 5 mg/kg bw/day	10	10	1	1	1	100
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	NOAEL = 15 mg/kg bw/day	10	10	1	3 (key study for 28 days)	1	300
Alpha-isomethyl ionone	NOAEL = 50 mg/kg bw/day	10	10	1	1	1	100
Benzyl salicylate	NOAEL = 50 mg/kg/day	10	10	1	1	1	100
p-isopropyltoluene	NOAEL = 154 mg/kg/day	10	10	1	1	1	100

8.4.2 Summary of exposure parameters

Based on the available data described above (see §8.3.4.2), the CES used the following values for each exposure parameter to calculate the DED according to a "worst-case" scenario, corresponding to a newborn with a very low body weight who is changed very frequently, considering that all of the chemicals contained in the diaper or urine simulant are transferred from the diaper to the skin and then completely absorbed (Table 30).

Table 30: Summary of the exposure parameters selected for the worst-case approach

Parameter	Value	Reference
Concentration	For quantified chemicals: the highest concentration in each diaper For detected chemicals: LQ	SCL (2017, 2018) and INC (2017, 2018)
Weight of a diaper	24 g (size 1)	Krause *et al.* (2006)* Rai *et al.* (2009)*
Frequency of use	12/day (newborn in the first few weeks of life)	Ishii *et al.* (2015)
Transfer of the substance to the skin	100%	ANSM (2010)
Reflux ratio	100%	Default hypothesis
Dermal absorption	100%	Default hypothesis
Body weight	2.6 kg (lowest body weight for children aged zero to one year, survey)	SFAE (2013)

Regarding the transfer of the substance from the material to the skin and the reflux ratio, the CES selected the value of 100% to take into account uncertainties surrounding the determination of values for these parameters given the lack of available information.

Exposure was calculated assuming 100% mucocutaneous absorption as part of a "worst-case" scenario, to take into account uncertainties surrounding the determination of the value for this parameter in order to amplify the risk.

8.4.3 Calculation of the DED and risks for a worst-case approach

A daily exposure dose was calculated for each chemical detected or quantified in the tests undertaken by the INC and/or SCL. This DED was compared with the TRV or critical dose in order to estimate the risk (Table 32). The detailed results obtained with the various types of tests are given in Annex 10.

In addition, DEDs and risk calculations for each chemical detected or quantified in the tests undertaken by Group'Hygiène are described in Annex 11 (confidential).

Table 31: Interpretation of the risk calculation results

Threshold effects	HQ < 0.1	0.1 < HQ < 1	HQ > 1
	No toxic effects are expected in the exposed population.	It is necessary to ensure that there are no other concomitant sources of exposure, to not risk exceeding the TRV by combining intakes from all the sources of exposure to these substances.	The occurrence of a risk cannot be ruled out, although it is not possible to predict its likelihood of occurrence in the exposed population.
No-threshold effects	IER < 10^{-7}	10^{-7} < IER < 10^{-6}	IER > 10^{-6}
	The number of expected cancer cases is less than one out of 10 million exposed people.	The number of expected cancer cases is between one out of one million and one out of 10 million exposed people.	The number of expected cancer cases is greater than one out of one million exposed people.

Table 32: Summary of the QHRA results obtained with the various types of tests according to a worst-case approach

	Scenario 1					Scenario 2.1		Scenario 2.2	
	Solvent extraction					Urine simulant			
	Shredded whole diapers		Shredded diaper parts			Shredded whole diapers		Whole diapers	
	INC, 2017 and 2018; SCL, 2017		INC, 2017; SCL, 2017			SCL, 2017		SCL, 2018	
	HQ or MOEref/MOE	IER	Part	HQ	IER	HQ	IER	HQ	IER
PAHs									
Benzo[g,h,i]perylene			Elastic part	$1.85 \cdot 10^{-3}$	$2.18 \cdot 10^{-6}$			3.09	$3.65 \cdot 10^{-3}$
Benzo[b]fluoranthene				$1.85 \cdot 10^{-2}$	$1.93 \cdot 10^{-5}$			28.2	$3.33 \cdot 10^{-2}$
Benzo[a]anthracene				$1.85 \cdot 10^{-2}$	$1.93 \cdot 10^{-5}$				
Indeno[1,2,3-c,d]pyrene				0.22	$2.62 \cdot 10^{-4}$				
Cyclopenta[c,d]pyrene								23	$2.72 \cdot 10^{-2}$
Chrysene								1.84	$2.18 \cdot 10^{-3}$
5-methylchrysene								2.30	$2.72 \cdot 10^{-3}$
Benzo[k]fluoranthene								27.2	$3.22 \cdot 10^{-2}$
Benzo[j]fluoranthene								27.2	$3.22 \cdot 10^{-2}$
Benzo[e]pyrene								4.41	$5.22 \cdot 10^{-3}$
Benzo[a]pyrene								299	0.35
Dibenzo[a,h]anthracene								230	0.27
VOCs									
Naphthalene	0.4								
Styrene	$4.26 \cdot 10^{-2}$								
Toluene	$6.51 \cdot 10^{-2}$								
1,4-dichlorobenzene	$1.58 \cdot 10^{-3}$	0.2							
1,3-dichlorobenzene	$5.54 \cdot 10^{-3}$								
o-xylene + styrene	$4.33 \cdot 10^{-2}$								
m-xylene + p-xylene	$8.04 \cdot 10^{-2}$								
Chlorobenzene	$7.75 \cdot 10^{-2}$								
p-isopropyltoluene	$1.22 \cdot 10^{-3}$								
n-propylbenzene	$5.57 \cdot 10^{-2}$								
1,2,3-trichlorobenzene	18.5								
1,2,4-trichlorobenzene	76.8	$1.18 \cdot 10^{-5}$							
1,3,5-trimethylbenzene	1.33								

	Scenario 1					Scenario 2.1		Scenario 2.2	
	Solvent extraction					Urine simulant			
	Shredded whole diapers		Shredded diaper parts			Shredded whole diapers		Whole diapers	
	INC, 2017 and 2018; SCL, 2017		INC, 2017; SCL, 2017			SCL, 2017		SCL, 2018	
	HQ or MOEref/MOE	IER	Part	HQ	IER	HQ	IER	HQ	IER
Pesticides									
Hexachlorobenzene	3.16	$1.71 \cdot 10^{-5}$							
Quintozene	0.48								
Pentachloroaniline + quintozene	0.28								
Glyphosate	$2.55 \cdot 10^{-2}$								
AMPA + glyphosate	$7.31 \cdot 10^{-3}$								
Fragrances									
Benzyl alcohol	1.11								
Coumarin	55.4								
Limonene	55.4								
Linalool	1.11								
Benzyl salicylate	11.1								
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	111								
Butylphenyl methylpropional	111								
Alpha-isomethyl ionone	11.1								
Formaldehyde									
Formaldehyde	27.6							2.03	

	Scenario 1					Scenario 2.1		Scenario 2.2	
	Solvent extraction					Urine simulant			
	Shredded whole diapers		Shredded diaper parts			Shredded whole diapers		Whole diapers	
	INC, 2017 and 2018; SCL, 2017		INC, 2017; SCL, 2017			SCL, 2017		SCL, 2018	
	HQ	IER	Part	HQ	IER	HQ	IER	HQ	IER
Dioxins and furans									
1,2,3,6,7,8-HxCDD	2.09								
1,3,6,7,8-HxCDD								$8.7 \cdot 10^{-2}$	
1,2,3,4,6,7,8-HpCDD	1.63		Topsheet	$3.85 \cdot 10^{-2}$		3.83		$9.63 \cdot 10^{-2}$	
OCDD	0.10			$5.11 \cdot 10^{-3}$		0.15		$8.76 \cdot 10^{3}$	
2,3,7,8-TCDF						1.65		$5.8 \cdot 10^{-2}$	
2,3,4,7,8-PeCDF						12.4		0.73	
1,2,3,4,7,8-HxCDF						1.77		$6.96 \cdot 10^{-2}$	
1,2,3,6,7,8-HxCDF	0.7					0.87		0.13	
2,3,4,6,7,8-HxCDF	1.69		Backsheet	1.19		0.73		0.3	
1,2,3,4,7,8,9-HpCDF	0.42					0.21		$1.28 \cdot 10^{-2}$	
1,2,3,4,6,7,8-HpCDF	2.44	Carcinogen with a threshold	Other (excluding topsheet, backsheet and core)	$7.33 \cdot 10^{-2}$	Carcinogen with a threshold	2.58	Carcinogen with a threshold	0.16	Carcinogen with a threshold
OCDF	0.62			$2.95 \cdot 10^{-2}$		1		$6.52 \cdot 10^{-3}$	
			Backsheet	$5.04 \cdot 10^{-2}$					
			Topsheet	$6.67 \cdot 10^{-4}$					
Sum of the quantified dioxins and furans	6.30					14.6		1.4	
PCB-81	$8.40 \cdot 10^{-2}$							$1.05 \cdot 10^{-2}$	
PCB-126								9.39	
PCB-77	0.34					$5.94 \cdot 10^{-2}$		$1.63 \cdot 10^{-2}$	
PCB-123	$5.55 \cdot 10^{-2}$					$6.53 \cdot 10^{-3}$		$2.75 \cdot 10^{-3}$	
PCB-118	3.60					0.68		0.34	
PCB-114	0.15					$1.5 \cdot 10^{-2}$		$1.09 \cdot 10^{-2}$	
PCB-105	2.05					0.3		0.14	
PCB-167	0.18					$6.39 \cdot 10^{-2}$		$4.27 \cdot 10^{-2}$	
PCB-156	0.44					$9.33 \cdot 10^{-2}$		$8.54 \cdot 10^{-2}$	
PCB-157	0.13					$3.49 \cdot 10^{-2}$		$1.11 \cdot 10^{-2}$	
PCB-169								0.29	
PCB-189						$1.65 \cdot 10^{-2}$		$1.75 \cdot 10^{-2}$	
Sum of the quantified DL-PCBs	6.87					1.19		1.01	
Sum of dioxins + furans + DL-PCBs	9.40					14.7		1.03	

No cases of the health thresholds being exceeded were found using a worst-case scenario for the chemicals listed in the following table.

Table 33: Chemicals not posing a health risk with a worst-case scenario, according to the various types of tests

	Shredded materials		Whole diapers
	Whole diapers	**Diaper parts**	
Solvent extraction	HQ < 0.1		
	Styrene Toluene 1,4-dichlorobenzene 1,3-dichlorobenzene p-isopropyltoluene n-propylbenzene o-xylene + styrene m-xylene + p-xylene Chlorobenzene Glyphosate Glyphosate + AMPA PCB-81 PCB-123	Benzo[g,h,i]perylene Benzo[b]fluoranthene Benzo[a]anthracene OCDF 1,2,3,4,6,7,8-HpCDF 1,2,3,4,6,7,8-HpCDD OCDD	
Urine simulant	HQ < 0.1		HQ < 0.1
	PCB-77 PCB-123 PCB-114 PCB-167 PCB-156 PCB-157 PCB-189		1,3,6,7,8-HxCDD 1,2,3,4,6,7,8-HpCDD OCDD 2,3,7,8-TCDF 1,2,3,4,7,8-HxCDF 1,2,3,4,7,8,9-HpCDF OCDF PCB-81 PCB-77 PCB-123 PCB-114 PCB-157 PCB-189

Using the worst-case approach, several chemicals, listed in the following table, exceeded the health thresholds (HQ > 1 or ERU > 10^{-6}). A risk calculation was thus performed for these chemicals according to a refined scenario.

Table 34: Chemicals exceeding the health thresholds with a worst-case scenario, according to the various types of tests

	Shredded materials		Whole diapers
	Whole diapers	**Diaper parts**	
Solvent extraction	**HQ > 1**		
	1,2,3-trichlorobenzene 1,2,4-trichlorobenzene 1,3,5-trimethylbenzene Hexachlorobenzene 1,2,3,6,7,8-HxCDD 1,2,3,4,6,7,8-HpCDD 2,3,4,6,7,8-HxCDF 1,2,3,4,6,7,8-HpCDF PCB-118 PCB-105 Sum of the quantified dioxins and furans Sum of the quantified DL-PCBs Sum of the quantified dioxins, furans and DL-PCBs Benzyl alcohol Coumarin Limonene Linalool Benzyl salicylate Hydroxyisohexyl 3-cyclohexene carboxaldehyde Butylphenyl methylpropional Alpha-isomethyl ionone Formaldehyde	2,3,4,6,7,8-HxCDF	
	IER > 10^{-6}		
	Hexachlorobenzene 1,2,4-trichlorobenzene	Benzo[g,h,i]perylene Benzo[b]fluoranthene Benzo[a]anthracene Indeno[1,2,3-c,d]pyrene	
Urine simulant	**HQ > 1**		**HQ > 1**
	1,2,3,4,6,7,8-HpCDD 2,3,7,8-TCDF 2,3,4,7,8-PeCDF 1,2,3,4,7,8-HxCDF 1,2,3,4,6,7,8-HpCDF OCDF Sum of the quantified dioxins and furans Sum of the quantified DL-PCBs Sum of dioxins, furans and DL-PCBs		Cyclopenta[c,d]pyrene Chrysene 5-methylchrysene Benzo[b]fluoranthene Benzo[k]fluoranthene Benzo[j]fluoranthene Benzo[e]pyrene BaP Dibenzo[a,h]anthracene Benzo[g,h,i]perylene Formaldehyde Sum of the quantified dioxins + furans Sum of the quantified DL-PCBs Sum of dioxins, furans and DL-PCBs PCB-126
			IER > 10^{-6}
			Cyclopenta[c,d]pyrene Chrysene 5-methylchrysene Benzo[b]fluoranthene Benzo[k]fluoranthene Benzo[j]fluoranthene Benzo[e]pyrene Benzo[g,h,i]perylene Benzo[a]pyrene Dibenzo[a,h]anthracene

For the chemicals listed in the table below, the HQs are between 0.1 and 1, i.e. exposure is equivalent to 10% of the TRV and/or the ERU is around 10^{-7} (orange in Table 32: Summary of the QHRA results obtained with the various types of tests according to a worst-case approach). These thresholds make it necessary to ensure that there are no other concomitant sources of exposure, to avoid any risk of exceeding the TRV by combining intakes from all the sources of exposure to these chemicals (environment, food, consumer products, etc.).

Table 35: Chemicals with an HQ between 0.1 and 1 and an IER of around 10^{-7} with a worst-case scenario, according to the various types of tests

	Shredded materials		Whole diapers
	Whole diapers	**Diaper parts**	
Solvent extraction	**0.1 < HQ < 1**		
	Naphthalene Quintozene Quintozene + pentachloroaniline OCDD 1,2,3,6,7,8-HxCDF 1,2,3,4,7,8,9-HpCDF OCDF PCB-77 PCB-114 PCB-167 PCB-156 PCB-157	Indeno[1,2,3-c,d]pyrene	
	IER #10^{-7}		
	1,4-dichlorobenzene		
Urine simulant	**0.1 < HQ < 1**		**0.1 < HQ < 1**
	OCDD 1,2,3,6,7,8-HxCDF 2,3,4,6,7,8-HxCDF 1,2,3,4,7,8,9-HpCDF OCDF PCB-118 PCB-105		2,3,4,7,8-PeCDF 1,2,3,6,7,8-HxCDF 2,3,4,6,7,8-HxCDF 1,2,3,4,6,7,8-HpCDF PCB-118 PCB-105 PCB-167 PCB-156 PCB-169

8.5   QHRA using the refined approach

A risk calculation was undertaken using a refined scenario for chemicals found in **whole diapers, shredded whole diapers or shredded diaper parts, extracted using a solvent or urine simulant**, for which the health thresholds for threshold or no-threshold effects were found to be exceeded using the worst-case approach.

The CES reiterates that the DED that seemed the most realistic from these various analyses was that calculated from the extractions in whole diapers with a urine simulant (see §8.3.4.1).

8.5.1   Summary of the selected TRVs

The following tables list the chronic oral TRVs (threshold and no-threshold effects) selected after a critical analysis. These TRVs can be applied to children between the ages of zero and 36 months (Annex 12).

Table 36: Summary of the threshold TRVs and critical doses used to conduct the QHRA according to a refined scenario

Chemicals	Type of TRV	Organisation (year)	TRV or NOAEL	Target organ/critical effect
VOCs				
1,2,3-trichlorobenzene	Chronic	RIVM (2001)	$8 \cdot 10^{-3}$ mg/kg/day	significant ↑ in relative liver weights and mild to moderate histopathological changes in the liver, kidneys and thyroid
1,2,4-trichlorobenzene	Chronic	ATSDR (2014)	0.1 mg/kg/day	Hepatocellular hypertrophy in males
1,3,5-trimethylbenzene	Chronic	US EPA (2016)	0.01 mg/kg/day	Neurotoxicity
Pesticides				
Hexachlorobenzene	Chronic	ASTDR (2015)	$7 \cdot 10^{-5}$ mg/kg/day	Hepatotoxicity
Dioxins and furans + DL-PCBs				
2,3,7,8-TCDD → Application of TEFs for dioxins, furans and DL-PCBs	Chronic	US EPA (2012)	0.7 pg/kg/day	Reproductive and developmental toxicity
PAHs				
Benzo[a]pyrene → Application of TEFs for the different PAHs	Chronic	US EPA (2017)	$3 \cdot 10^{-4}$ mg/kg/day	Developmental toxicity
Formaldehyde				
Formaldehyde	Chronic	WHO-IPCS (2005)	0.15 mg/kg/day	Stomach irritation and nephrotoxicity
Fragrances				
Benzyl alcohol	Chronic	EFSA (2011)	≥ 5 mg/kg/day	No reprotoxic, teratogenic or carcinogenic effects
Coumarin	Chronic	EFSA (2008)	< 0.1 mg/kg	Hepatotoxicity
Limonene	Chronic	EFSA (2012)	0.1 mg/kg/day	Hepatotoxicity
Linalool	Chronic	JECFA (1998)	< 5 mg/kg/day	No effects
Butylphenyl methylpropional	Chronic	SCCS (2016)	NOAEL = 5 mg/kg/day	Systemic effects and maternal toxicity
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	Chronic	SCCS (2011)	NOAEL = 15 mg/kg/day	Hepatotoxicity
Alpha-isomethyl ionone	Chronic	Belsito *et al.* (2007)	NOAEL = 50 mg/kg/day	Systemic effects
Benzyl salicylate	Chronic	US EPA (2010)	NOAEL = 50 mg/kg/day	Hepatotoxicity (dogs) and bone effects (rats)

Table 37: Summary of the no-threshold TRVs used to conduct the QHRA according to a refined scenario

Chemicals	Organisation (year)	Value	Target organ/critical effect
1,2,4-trichlorobenzene	OEHHA (1999)	$3.6 \cdot 10^{-3}$ (mg/kg/day)$^{-1}$	Hepatocellular carcinomas
Pesticides			
Hexachlorobenzene	OEHHA (2011)	1.8 (mg/kg/day)$^{-1}$	Liver tumours
PAHs			
Benzo[a]pyrene → Application of TEFs for the different PAHs	US EPA (2017)	1 (mg/kg/day)$^{-1}$	Gastrointestinal tumours

8.5.2 Summary of exposure parameters

The population of interest was divided into six age groups in order to better take account of rapid developments in terms of weight and psychomotor development in children between the ages of zero and 36 months involving the use of different diaper sizes and a daily frequency of use adapted to each age group.

Based on the available data described above, the CES selected the following values for each exposure parameter to calculate the DED according to a "refined" scenario (Table 38):

- For the weight of a diaper, the CES considered the only available data set for the defined age groups (Krause *et al.,* 2006*; Rai *et al*., 2009*).
- Regarding the daily frequency of use, the CES used the data from a study undertaken in 2002-2003 in the United Kingdom in more than 2000 households with a child who was in diapers or had worn diapers in the recent past, due to the robustness of this study.
- The CES used the body weights from the SFAE survey (2013) conducted in a representative sample of the French population.
- Regarding the transfer of the substance from the material to the skin and the reflux ratio, the CES considered the only available data, which came from publications produced by companies.
- Lastly, even though the frequency of diaper dermatitis has decreased due to the use of diapers with increasing skin compatibility, diaper dermatitis cannot be completely avoided and may have an impact on the dermal absorption of chemicals. Thus, the CES assumed a mucocutaneous absorption rate of 100% to calculate exposure.

Table 38: Summary of the exposure parameters used with the refined approach

Parameter	Refined approach		
	Value		**Reference**
Concentration	For quantified chemicals: the highest concentration in each diaper For detected chemicals: LQ/2		SCL (2017 and 2018); INC (2017 and 2018)
Weight of a diaper by age group	0-6 months exclusive	24 g	Krause *et al.* (2006)* Rai *et al.* (2009)*
	6-12 months inclusive	33 g	
	13-18 months inclusive	33 g	
	19-24 months inclusive	40 g	
	25-30 months inclusive	40 g	
	31-36 months inclusive	45 g	
Daily frequency of use (average)	0-6 months exclusive	7.98	UK Environment Agency, 2005b (average daytime frequency + one diaper/night)
	6-12 months inclusive	6.66	
	13-18 months inclusive	6.75	
	19-24 months inclusive	5.95	
	25-30 months inclusive	5.85	
	31-36 months inclusive	4.7	
Transfer of the substance to the skin	7%		Odio *et al.* (2000)*
Reflux ratio (for tests by urine extraction from shredded diapers)	1.32%		Dey *et al.* (2016)*
Dermal absorption	100%		ANSM (2010)
Body weight	0-6 months exclusive	3.9 kg	SFAE (2013)
	6-12 months inclusive	7 kg	
	13-18 months inclusive	8.4 kg	
	19-24 months	9.2 kg	
	25-30 months inclusive	10 kg	
	31-36 months inclusive	11.4 kg	

8.5.3 Calculation of the DED and risks using a refined approach

A daily exposure dose (DED) was calculated for each chemical detected or quantified in the tests undertaken by the INC and/or SCL with shredded whole diapers or diaper parts using solvent extraction and with whole diapers or shredded whole diapers using extraction in a urine simulant (for which cases of the health thresholds being exceeded had been found using the worst-case approach). This DED was compared with the TRV or critical dose in order to estimate a health risk. The detailed results obtained with the various types of tests are given in Annex 13.

Table 39: Summary of the QHRA results obtained with the various types of tests according to a refined approach

Scenario		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	**Age group**	**Solvent extraction**					**Urine simulant**			
		Shredded whole diapers		**Shredded diaper parts**			**Shredded whole diapers**		**Whole diapers**	
		INC, 2017 and 2018; SCL, 2017		**INC, 2017; SCL, 2017**			**SCL, 2017**		**SCL, 2018**	
		HQ	**IER**	**Part**	**HQ**	**IER**	**HQ**	**IER**	**HQ**	**IER**
PAHs										
Benzo[g,h,i]perylene	0-6 months exclusive				$2.86 \cdot 10^{-7}$	$6.14 \cdot 10^{-12}$			0.68	$1.47 \cdot 10^{-5}$
	6-12 months inclusive				$1.83 \cdot 10^{-6}$	$7.85 \cdot 10^{-11}$			0.44	$1.87 \cdot 10^{-5}$
	13-18 months inclusive				$1.55 \cdot 10^{-6}$	$9.94 \cdot 10^{-11}$			0.4	$2.38 \cdot 10^{-5}$
	19-24 months inclusive				$1.51 \cdot 10^{-6}$	$1.29 \cdot 10^{-10}$			0.36	$3.09 \cdot 10^{-5}$
	25-30 months inclusive				$1.37 \cdot 10^{-6}$	$1.26 \cdot 10^{-10}$			0.33	$3.00 \cdot 10^{-5}$
	31-36 months inclusive				$1.08 \cdot 10^{-6}$	$6.63 \cdot 10^{-10}$			0.26	$2.55 \cdot 10^{-5}$
Benzo[b]fluoranthene	0-6 months exclusive				$2.86 \cdot 10^{-6}$	$6.14 \cdot 10^{-11}$			6.24	$1.34 \cdot 10^{-4}$
	6-12 months inclusive				$1.83 \cdot 10^{-5}$	$7.85 \cdot 10^{-10}$			3.99	$1.71 \cdot 10^{-4}$
	13-18 months inclusive				$1.55 \cdot 10^{-5}$	$9.94 \cdot 10^{-10}$			3.37	$2.17 \cdot 10^{-4}$
	19-24 months inclusive				$1.51 \cdot 10^{-5}$	$1.29 \cdot 10^{-9}$			3.29	$2.82 \cdot 10^{-4}$
	25-30 months inclusive				$1.37 \cdot 10^{-5}$	$1.26 \cdot 10^{-9}$			2.97	$2.74 \cdot 10^{-4}$
	31-36 months inclusive			Elastic part	$1.08 \cdot 10^{-5}$	$1.07 \cdot 10^{-9}$			2.36	$2.32 \cdot 10^{-4}$
Benzo[a]anthracene	0-6 months exclusive				$2.86 \cdot 10^{-5}$	$6.14 \cdot 10^{-11}$				
	6-12 months inclusive				$1.83 \cdot 10^{-4}$	$7.85 \cdot 10^{-10}$				
	13-18 months inclusive				$1.55 \cdot 10^{-4}$	$9.94 \cdot 10^{-10}$				
	19-24 months inclusive				$1.51 \cdot 10^{-4}$	$1.29 \cdot 10^{-9}$				
	25-30 months inclusive				$1.37 \cdot 10^{-4}$	$1.26 \cdot 10^{-9}$				
	31-36 months inclusive				$6.88 \cdot 10^{-5}$	$1.07 \cdot 10^{-9}$				
Indeno[1,2,3-c,d]pyrene	0-6 months exclusive				$4.40 \cdot 10^{-4}$	$1.47 \cdot 10^{-9}$				
	6-12 months inclusive				$3.71 \cdot 10^{-4}$	$1.88 \cdot 10^{-8}$				
	13-18 months inclusive				$3.62 \cdot 10^{-4}$	$2.39 \cdot 10^{-8}$				
	19-24 months inclusive				$3.28 \cdot 10^{-4}$	$3.10 \cdot 10^{-8}$				
	25-30 months inclusive				$2.60 \cdot 10^{-4}$	$3.02 \cdot 10^{-8}$				
	31-36 months inclusive				$6.88 \cdot 10^{-5}$	$2.56 \cdot 10^{-8}$				
Cyclopenta[c,d]pyrene	0-6 months exclusive								5.10	$1.09 \cdot 10^{-4}$
	6-12 months inclusive								3.26	$1.40 \cdot 10^{-4}$
	13-18 months inclusive								2.75	$1.77 \cdot 10^{-4}$
	19-24 months inclusive								2.69	$2.30 \cdot 10^{-4}$
	25-30 months inclusive								2.43	$2.24 \cdot 10^{-4}$
	31-36 months inclusive								1.93	$1.90 \cdot 10^{-4}$

Scenario		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	Age group	Solvent extraction					Urine simulant			
		Shredded whole diapers		Shredded diaper parts			Shredded whole diapers		Whole diapers	
		INC, 2017 and 2018; SCL, 2017		INC, 2017; SCL, 2017			SCL, 2017		SCL, 2018	
		HQ	IER	Part	HQ	IER	HQ	IER	HQ	IER
Chrysene	0-6 months exclusive								0.41	$8.75 \cdot 10^{-6}$
	6-12 months inclusive								0.26	$1.12 \cdot 10^{-5}$
	13-18 months inclusive								20.22	$1.42 \cdot 10^{-5}$
	19-24 months inclusive								0.22	$1.84 \cdot 10^{-5}$
	25-30 months inclusive								0.19	$1.79 \cdot 10^{-5}$
	31-36 months inclusive								0.15	$1.52 \cdot 10^{-5}$
5-methylchrysene	0-6 months exclusive								0.51	$1.09 \cdot 10^{-5}$
	6-12 months inclusive								0.33	$1.40 \cdot 10^{-5}$
	13-18 months inclusive								0.28	$1.77 \cdot 10^{-5}$
	19-24 months inclusive								0.27	$2.30 \cdot 10^{-5}$
	25-30 months inclusive								0.24	$2.24 \cdot 10^{-5}$
	31-36 months inclusive								0.19	$1.90 \cdot 10^{-5}$
Benzo[k]fluoranthene	0-6 months exclusive								6.03	$1.29 \cdot 10^{-4}$
	6-12 months inclusive								3.86	$1.65 \cdot 10^{-4}$
	13-18 months inclusive								3.26	$2.09 \cdot 10^{-4}$
	19-24 months inclusive								3.18	$2.72 \cdot 10^{-4}$
	25-30 months inclusive								2.87	$2.65 \cdot 10^{-4}$
	31-36 months inclusive								2.28	$2.25 \cdot 10^{-4}$
Benzo[j]fluoranthene	0-6 months exclusive								6.03	$1.29 \cdot 10^{-4}$
	6-12 months inclusive								3.86	$1.65 \cdot 10^{-4}$
	13-18 months inclusive								3.26	$2.09 \cdot 10^{-4}$
	19-24 months inclusive								3.18	$2.72 \cdot 10^{-4}$
	25-30 months inclusive								2.87	$2.65 \cdot 10^{-4}$
	31-36 months inclusive								2.28	$2.25 \cdot 10^{-4}$
Benzo[e]pyrene	0-6 months exclusive								0.98	$2.10 \cdot 10^{-5}$
	6-12 months inclusive								0.63	$2.68 \cdot 10^{-5}$
	13-18 months inclusive								0.53	$3.40 \cdot 10^{-5}$
	19-24 months inclusive								0.52	$4.42 \cdot 10^{-5}$
	25-30 months inclusive								0.47	$4.30 \cdot 10^{-5}$
	31-36 months inclusive								0.37	$3.64 \cdot 10^{-5}$

Scenario		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	Age group	Solvent extraction					Urine simulant			
		Shredded whole diapers		Shredded diaper parts			Shredded whole diapers		Whole diapers	
		INC, 2017 and 2018; SCL, 2017		INC, 2017; SCL, 2017			SCL, 2017		SCL, 2018	
		HQ	IER	Part	HQ	IER	HQ	IER	HQ	IER
Benzo[a]pyrene	0-6 months exclusive								66.3	$1.42\cdot10^{-3}$
	6-12 months inclusive								42.4	$1.82\cdot10^{-3}$
	13-18 months inclusive								35.8	$2.30\cdot10^{-3}$
	19-24 months inclusive								34.9	$2.99\cdot10^{-3}$
	25-30 months inclusive								31.6	$2.91\cdot10^{-3}$
	31-36 months inclusive								25.1	$2.47\cdot10^{-3}$
Dibenzo[a,h]anthracene	0-6 months exclusive								51	$1.09\cdot10^{-3}$
	6-12 months inclusive								32.6	$1.40\cdot10^{-3}$
	13-18 months inclusive								27.5	$1.77\cdot10^{-3}$
	19-24 months inclusive								26.9	$2.30\cdot10^{-3}$
	25-30 months inclusive								24.3	$2.24\cdot10^{-3}$
	31-36 months inclusive								19.3	$1.90\cdot10^{-3}$
VOCs										
1,2,3-trichlorobenzene	0-6 months exclusive	0.11								
	6-12 months inclusive	$6.87\cdot10^{-2}$								
	13-18 months inclusive	$5.80\cdot10^{-2}$								
	19-24 months inclusive	$5.66\cdot10^{-2}$								
	25-30 months inclusive	$5.12\cdot10^{-2}$								
	31-36 months inclusive	$4.06\cdot10^{-2}$								
1,2,4-trichlorobenzene	0-6 months exclusive	$2.38\cdot10^{-2}$	$6.13\cdot10^{-8}$							
	6-12 months inclusive	$1.52\cdot10^{-2}$	$7.83\cdot10^{-8}$							
	13-18 months inclusive	$1.29\cdot10^{-2}$	$9.92\cdot10^{-8}$							
	19-24 months inclusive	$1.25\cdot10^{-2}$	$1.29\cdot10^{-7}$							
	25-30 months inclusive	$1.14\cdot10^{-2}$	$1.46\cdot10^{-7}$							
	31-36 months inclusive	$9.00\cdot10^{-3}$	$1.39\cdot10^{-7}$							
1,3,5-trimethylbenzene	0-6 months exclusive	$4.13\cdot10^{-2}$								
	6-12 months inclusive	$2.64\cdot10^{-2}$								
	13-18 months inclusive	$2.23\cdot10^{-2}$								
	19-24 months inclusive	$2.17\cdot10^{-2}$								
	25-30 months inclusive	$1.97\cdot10^{-2}$								
	31-36 months inclusive	$1.56\cdot10^{-2}$								

Scenario		Scenario 1						Scenario 2.1		Scenario 2.2	
Chemicals	Age group	Solvent extraction						Urine simulant			
		Shredded whole diapers		Shredded diaper parts				Shredded whole diapers		Whole diapers	
		INC, 2017 and 2018; SCL, 2017		INC, 2017; SCL, 2017				SCL, 2017		SCL, 2018	
		HQ	IER	Part	HQ	IER		HQ	IER	HQ	IER
Fragrances											
Benzyl alcohol	0-6 months exclusive	$1.72 \cdot 10^{-2}$									
	6-12 months inclusive	$1.10 \cdot 10^{-2}$									
	13-18 months inclusive	$9.28 \cdot 10^{-3}$									
	19-24 months inclusive	$9.05 \cdot 10^{-3}$									
	25-30 months inclusive	$8.19 \cdot 10^{-3}$									
	31-36 months inclusive	$6.49 \cdot 10^{-3}$									
Coumarin	0-6 months exclusive	0.86									
	6-12 months inclusive	0.55									
	13-18 months inclusive	0.46									
	19-24 months inclusive	0.45									
	25-30 months inclusive	0.41									
	31-36 months inclusive	0.33									
Limonene	0-6 months exclusive	0.86									
	6-12 months inclusive	0.55									
	13-18 months inclusive	0.46									
	19-24 months inclusive	0.45									
	25-30 months inclusive	0.41									
	31-36 months inclusive	0.33									
Linalool	0-6 months exclusive	$1.72 \cdot 10^{-2}$									
	6-12 months inclusive	$1.1 \cdot 10^{-2}$									
	13-18 months inclusive	$9.28 \cdot 10^{-3}$									
	19-24 months inclusive	$9.05 \cdot 10^{-3}$									
	25-30 months inclusive	$8.19 \cdot 10^{-3}$									
	31-36 months inclusive	$6.49 \cdot 10^{-3}$									

Scenario		Scenario 1						Scenario 2.1		Scenario 2.2	
Chemicals	Age group	Solvent extraction						Urine simulant			
		Shredded whole diapers		Shredded diaper parts				Shredded whole diapers		Whole diapers	
		INC, 2017 and 2018; SCL, 2017		INC, 2017; SCL, 2017				SCL, 2017		SCL, 2018	
		MOEref/MOE	IER	Part	HQ	IER		HQ	IER	HQ	IER
Benzyl salicylate	0-6 months exclusive	0.17									
	6-12 months inclusive	0.11									
	13-18 months inclusive	$9.28 \cdot 10^{-2}$									
	19-24 months inclusive	$9.05 \cdot 10^{-2}$									
	25-30 months inclusive	$8.19 \cdot 10^{-2}$									
	31-36 months inclusive	$6.49 \cdot 10^{-3}$									
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	0-6 months exclusive	1.72									
	6-12 months inclusive	1.1									
	13-18 months inclusive	0.93									
	19-24 months inclusive	0.91									
	25-30 months inclusive	0.82									
	31-36 months inclusive	0.65									
Butylphenyl methylpropional	0-6 months exclusive	1.72									
	6-12 months inclusive	1.1									
	13-18 months inclusive	0.93									
	19-24 months inclusive	0.91									
	25-30 months inclusive	0.82									
	31-36 months inclusive	0.65									
Alpha-isomethyl ionone	0-6 months exclusive	0.17									
	6-12 months inclusive	0.11									
	13-18 months inclusive	$9.28 \cdot 10^{-2}$									
	19-24 months inclusive	$9.05 \cdot 10^{-2}$									
	25-30 months inclusive	$8.19 \cdot 10^{-2}$									
	31-36 months inclusive	$6.49 \cdot 10^{-2}$									
Pesticides											
Hexachlorobenzene	0-6 months exclusive	$9.82 \cdot 10^{-2}$	$8.84 \cdot 10^{-8}$								
	6-12 months inclusive	$6.28 \cdot 10^{-2}$	$1.13 \cdot 10^{-7}$								
	13-18 months inclusive	$5.30 \cdot 10^{-2}$	$1.43 \cdot 10^{-7}$								
	19-24 months inclusive	$5.17 \cdot 10^{-2}$	$1.86 \cdot 10^{-7}$								
	25-30 months inclusive	$4.68 \cdot 10^{-2}$	$2.11 \cdot 10^{-7}$								
	31-36 months inclusive	$3.71 \cdot 10^{-2}$	$2.00 \cdot 10^{-7}$								

Scenario		Scenario 1					Scenario 2.1		Scenario 2.2	
Chemicals	Age group	Solvent extraction					Urine simulant			
		Shredded whole diapers		Shredded diaper parts			Shredded whole diapers		Whole diapers	
		INC, 2017 and 2018; SCL, 2017		INC, 2017; SCL, 2017			SCL, 2017		SCL, 2018	
		HQ	IER	Part	HQ	IER	HQ	IER	HQ	IER
Formaldehyde										
Formaldehyde	0-6 months exclusive	$2.57 \cdot 10^{-2}$					Carcinogen with a threshold		0.9	
	6-12 months inclusive	$1.64 \cdot 10^{-2}$							0.58	
	13-18 months inclusive	$1.39 \cdot 10^{-2}$							0.49	
	19-24 months inclusive	$1.35 \cdot 10^{-2}$							0.47	
	25-30 months inclusive	$1.23 \cdot 10^{-2}$							0.43	
	31-36 months inclusive	$9.71 \cdot 10^{-3}$							0.34	

Scenario		Scenario 1			Scenario 2.1	Scenario 2.2
Chemicals	Age group	Solvent extraction			Urine simulant	
		Shredded whole diapers	Shredded diaper parts		Shredded whole diapers	Whole diapers
		INC, 2017 and 2018; SCL, 2017	INC, 2017; SCL, 2017		SCL, 2017	SCL, 2018
		HQ	Part	HQ	HQ	HQ
Dioxins, furans and DL-PCBs						
1,2,3,6,7,8-HxCDD	0-6 months exclusive	$6.48 \cdot 10^{-2}$				
	6-12 months inclusive	$4.14 \cdot 10^{-2}$				
	13-18 months inclusive	$3.50 \cdot 10^{-2}$				
	19-24 months inclusive	$3.41 \cdot 10^{-2}$				
	25-30 months inclusive	$3.09 \cdot 10^{-2}$				
	31-36 months inclusive	$2.45 \cdot 10^{-2}$				
1,2,3,4,6,7,8-HpCDD	0-6 months exclusive	$5.06 \cdot 10^{-2}$			$2.24 \cdot 10^{-3}$	
	6-12 months inclusive	$3.23 \cdot 10^{-2}$			$1.43 \cdot 10^{-3}$	
	13-18 months inclusive	$2.73 \cdot 10^{-2}$			$1.21 \cdot 10^{-3}$	
	19-24 months inclusive	$2.66 \cdot 10^{-2}$			$1.18 \cdot 10^{-3}$	
	25-30 months inclusive	$2.41 \cdot 10^{-2}$			$1.07 \cdot 10^{-3}$	
	31-36 months inclusive	$1.91 \cdot 10^{-2}$			$8.47 \cdot 10^{-4}$	
2,3,7,8-TCDF	0-6 months exclusive				$9.63 \cdot 10^{-4}$	
	6-12 months inclusive				$6.16 \cdot 10^{-4}$	
	13-18 months inclusive				$5.20 \cdot 10^{-4}$	
	19-24 months inclusive				$5.07 \cdot 10^{-4}$	
	25-30 months inclusive				$4.59 \cdot 10^{-4}$	
	31-36 months inclusive				$3.64 \cdot 10^{-4}$	
2,3,4,7,8-PeCDF	0-6 months exclusive				$7.25 \cdot 10^{-3}$	
	6-12 months inclusive				$4.64 \cdot 10^{-3}$	
	13-18 months inclusive				$3.92 \cdot 10^{-3}$	
	19-24 months inclusive				$3.82 \cdot 10^{-3}$	
	25-30 months inclusive				$3.46 \cdot 10^{-3}$	
	31-36 months inclusive				$2.74 \cdot 10^{-3}$	
1,2,3,4,7,8-HxCDF	0-6 months exclusive				$1.04 \cdot 10^{-3}$	
	6-12 months inclusive				$6.63 \cdot 10^{-4}$	
	13-18 months inclusive				$5.60 \cdot 10^{-4}$	
	19-24 months inclusive				$5.46 \cdot 10^{-4}$	
	25-30 months inclusive				$4.94 \cdot 10^{-4}$	
	31-36 months inclusive				$3.92 \cdot 10^{-4}$	

Scenario		Scenario 1			Scenario 2.1	Scenario 2.2
Chemicals	**Age group**	**Solvent extraction**			**Urine simulant**	
		Shredded whole diapers	**Shredded diaper parts**		**Shredded whole diapers**	**Whole diapers**
		INC, 2017 and 2018; SCL, 2017	**INC, 2017; SCL, 2017**		**SCL, 2017**	**SCL, 2018**
		HQ	**Part**	**HQ**	**HQ**	**HQ**
2,3,4,6,7,8-HxCDF	0-6 months exclusive	$5.25 \cdot 10^{-2}$	Backsheet	$3.69 \cdot 10^{-3}$		
	6-12 months inclusive	$3.36 \cdot 10^{-2}$		$2.36 \cdot 10^{-3}$		
	13-18 months inclusive	$2.84 \cdot 10^{-2}$		$1.99 \cdot 10^{-3}$		
	19-24 months inclusive	$2.77 \cdot 10^{-2}$		$1.94 \cdot 10^{-3}$		
	25-30 months inclusive	$2.50 \cdot 10^{-2}$		$1.76 \cdot 10^{-3}$		
	31-36 months inclusive	$1.99 \cdot 10^{-2}$		$1.39 \cdot 10^{-3}$		
1,2,3,4,6,7,8-HpCDF	0-6 months exclusive	$7.56 \cdot 10^{-2}$			$1.51 \cdot 10^{-3}$	
	6-12 months inclusive	$4.84 \cdot 10^{-2}$			$9.65 \cdot 10^{-4}$	
	13-18 months inclusive	$4.08 \cdot 10^{-2}$			$8.15 \cdot 10^{-4}$	
	19-24 months inclusive	$3.98 \cdot 10^{-2}$			$7.95 \cdot 10^{-4}$	
	25-30 months inclusive	$3.60 \cdot 10^{-2}$			$7.19 \cdot 10^{-4}$	
	31-36 months inclusive	$2.86 \cdot 10^{-2}$			$5.70 \cdot 10^{-4}$	
OCDF	0-6 months exclusive				$5.86 \cdot 10^{-4}$	
	6-12 months inclusive				$3.75 \cdot 10^{-4}$	
	13-18 months inclusive				$3.17 \cdot 10^{-4}$	
	19-24 months inclusive				$3.09 \cdot 10^{-4}$	
	25-30 months inclusive				$2.79 \cdot 10^{-4}$	
	31-36 months inclusive				$2.21 \cdot 10^{-4}$	
Sum of the quantified dioxins and furans	0-6 months exclusive	0.2			$8.52 \cdot 10^{-3}$	0.62
	6-12 months inclusive	0.13			$5.45 \cdot 10^{-3}$	0.4
	13-18 months inclusive	0.11			$4.60 \cdot 10^{-3}$	0.34
	19-24 months inclusive	0.1			$4.49 \cdot 10^{-3}$	0.33
	25-30 months inclusive	$9.31 \cdot 10^{-2}$			$4.06 \cdot 10^{-3}$	0.3
	31-36 months inclusive	$7.38 \cdot 10^{-2}$			$3.22 \cdot 10^{-3}$	0.23
PCB-126	0-6 months exclusive					4.16
	6-12 months inclusive					2.66
	13-18 months inclusive					2.25
	19-24 months inclusive					2.19
	25-30 months inclusive					1.98
	31-36 months inclusive					1.57

Scenario		Scenario 1			Scenario 2.1	Scenario 2.2
Chemicals	Age group	Solvent extraction			Urine simulant	
		Shredded whole diapers	Shredded diaper parts		Shredded whole diapers	Whole diapers
		INC, 2017 and 2018; SCL, 2017	INC, 2017; SCL, 2017		SCL, 2017	SCL, 2018
		HQ	Part	HQ	HQ	HQ
PCB-118	0-6 months exclusive	0.11				
	6-12 months inclusive	$7.15 \cdot 10^{-2}$				
	13-18 months inclusive	$6.04 \cdot 10^{-2}$				
	19-24 months inclusive	$5.89 \cdot 10^{-2}$				
	25-30 months inclusive	$5.33 \cdot 10^{-2}$				
	31-36 months inclusive	$4.22 \cdot 10^{-2}$				
PCB-105	0-6 months exclusive	$6.35 \cdot 10^{-2}$				
	6-12 months inclusive	$4.06 \cdot 10^{-2}$				
	13-18 months inclusive	$3.43 \cdot 10^{-2}$				
	19-24 months inclusive	$3.34 \cdot 10^{-2}$				
	25-30 months inclusive	$3.03 \cdot 10^{-2}$				
	31-36 months inclusive	$2.40 \cdot 10^{-2}$				
Sum of the quantified DL-PCBs	0-6 months exclusive	0.21			$6.99 \cdot 10^{-4}$	4.46
	6-12 months inclusive	0.14			$4.47 \cdot 10^{-4}$	2.85
	13-18 months inclusive	0.12			$3.78 \cdot 10^{-4}$	2.41
	19-24 months inclusive	0.11			$3.68 \cdot 10^{-4}$	2.35
	25-30 months inclusive	0.10			$3.33 \cdot 10^{-4}$	2.13
	31-36 months inclusive	$8.05 \cdot 10^{-2}$			$2.64 \cdot 10^{-4}$	1.69
Sum of dioxins + furans + DL-PCBs	0-6 months exclusive	0.29			$8.62 \cdot 10^{-3}$	4.58
	6-12 months inclusive	0.19			$5.51 \cdot 10^{-3}$	2.93
	13-18 months inclusive	0.16			$4.66 \cdot 10^{-3}$	2.48
	19-24 months inclusive	0.15			$4.54 \cdot 10^{-3}$	2.41
	25-30 months inclusive	0.14			$4.11 \cdot 10^{-3}$	2.18
	31-36 months inclusive	0.11			$3.26 \cdot 10^{-3}$	1.73

No cases of the health thresholds being exceeded were found using a refined scenario for the chemicals in the table below.

Table 40: Chemicals not posing a health risk with a refined scenario, according to the various types of tests

	Shredded diapers		Whole diapers
	Whole diapers	**Diaper parts**	
Solvent extraction	**HQ < 0.1**		
	1,2,4-trichlorobenzene 1,3,5-trimethylbenzene Hexachlorobenzene 1,2,3-trichlorobenzene (6-36 months) Benzyl alcohol Linalool Benzyl salicylate (13-36 months) Alpha-isomethyl ionone (13-36 months) 1,2,3,6,7,8-HxCDD 1,2,3,4,6,7,8-HpCDD 2,3,4,6,7,8-HxCDF 1,2,3,4,6,7,8-HpCDF Sum of dioxins and furans (25-36 months) PCB-118 (6-36 months) PCB-105 Sum of DL-PCBs (31-36 months) Formaldehyde	2,3,4,6,7,8-HxCDF Benzo[b]fluoranthene Benzo[a]anthracene Indeno[1,2,3-c,d]pyrene	
	$10^{-7} < IER < 10^{-6}$		
	Hexachlorobenzene (0-6 months) 1,2,4-trichlorobenzene (0-18 months)	Benzo[g,h,i]perylene Benzo[b]fluoranthene Benzo[a]anthracene Indeno[1,2,3-c,d]pyrene	
Urine simulant	**HQ < 0.1**		**HQ < 0.1**
	1,2,3,4,6,7,8-HpCDD 2,3,7,8-TCDF 2,3,4,7,8-PeCDF 1,2,3,4,7,8-HxCDF 1,2,3,4,6,7,8-HpCDF OCDF Sum of dioxins and furans Sum of DL-PCBs Sum of dioxins, furans and DL-PCBs		/

Using the refined approach, several chemicals, listed in the following table, exceeded the health thresholds (HQ > 1 or ERU > 10^{-6}).

Table 41: Chemicals exceeding the health thresholds with a refined scenario, according to the various types of tests

	Shredded materials		Whole diapers
	Whole diapers	**Diaper parts**	
Solvent extraction	**HQ > 1**		
	Hydroxyisohexyl 3-cyclohexene carboxaldehyde (0-12 months) BMHCA (0-12 months)	/	
	IER > 10^{-6}		
	/		
Urine simulant	**HQ > 1**		**HQ > 1**
	/		Benzo[b]fluoranthene Cyclopenta[c,d]pyrene Benzo[k]fluoranthene Benzo[j]fluoranthene Benzo[a]pyrene Dibenzo[a,h]anthracene PCB-126 Sum of DL-PCBs Sum of dioxins + furans + DL-PCBs
			IER > 10^{-6}
			Benzo[g,h,i]perylene Benzo[b]fluoranthene Cyclopenta[c,d]pyrene Chrysene 5-methylchrysene Benzo[k]fluoranthene Benzo[j]fluoranthene Benzo[e]pyrene Benzo[a]pyrene Dibenzo[a,h]anthracene

For the chemicals listed in the table below, the HQs are between 0.1 and 1, i.e. exposure is equivalent to 10% of the TRV and/or the ERU is around 10^{-7} (orange in the table). These thresholds make it necessary to ensure that there are no other concomitant sources of exposure, to avoid any risk of exceeding the TRV by combining intakes from all the sources of exposure to these chemicals (environment, food, consumer products, etc.).

Table 42: Chemicals with an HQ between 0.1 and 1 and an IER of around 10^{-7} with a refined scenario, according to the various types of tests

	Shredded materials		Whole diapers
	Whole diapers	**Diaper parts**	
Solvent extraction	0.1 < HQ < 1		
	1,2,3-trichlorobenzene (0-6 months) Coumarin Limonene Hydroxyisohexyl 3-cyclohexene carboxaldehyde (13-36 months) BMHCA (13-36 months) Alpha-isomethyl ionone (13-36 months) Benzyl salicylate (0-12 months) Sum of dioxins and furans (0-24 months) PCB-118 (0-6 months) Sum of DL-PCBs (0-30 months) Sum of dioxins + furans + DL-PCBs	/	
	IER #10^{-7}		
	1,2,4-trichlorobenzene (19-36 months) Hexachlorobenzene (6-36 months)	/	
Urine simulant	0.1 < HQ < 1		0.1 < HQ < 1
	/		Benzo[g,h,i]perylene Chrysene 5-methylchrysene Benzo[e]pyrene Formaldehyde Sum of dioxins and furans

8.6 Comparison with the concentrations found in feminine hygiene products and food

The concentrations of the quantified and/or detected chemicals extracted using solvents from shredded baby diapers were compared with those measured in food as part of the infant Total Diet Study (iTDS) (common foods[24]) (ANSES, 2016a).

The routes of exposure to these sources are very different, but comparing concentrations can enable contamination levels to be contrasted. For simplification purposes, the maximum concentration measured in diapers in the SCL (2017) or INC (2017 and 2018) studies was compared with the maximum concentration measured in the iTDS study.

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[24] Non-alcoholic beverages, dairy-based desserts, cream desserts and jellied milks, milk, vegetables (excluding potatoes), mixed dishes, fish, ultra-fresh dairy products, meat, poultry and game

Table 43: Comparison of chemical concentrations from the iTDS study and in shredded diapers

Chemicals	Diaper part	Max in diapers (mg/kg)	Max from the iTDS (mg/kg)	iTDS/diaper concentration ratio	Type of feminine hygiene product	Max in feminine hygiene products (mg/kg)	Feminine hygiene product/diaper concentration ratio
PAHs							
Benzo[g,h,i]perylene	Whole diaper	0.1*	$3.5 \cdot 10^{-5}$	$3.5 \cdot 10^{-4}$	Tampon	$5 \cdot 10^{-3}$	0.05
Benzo[b]fluoranthene		0.1*	$1.44 \cdot 10^{-4}$	$1.44 \cdot 10^{-3}$		$5 \cdot 10^{-3}$	0.05
Benzo[a]anthracene		0.1*	$8.4 \cdot 10^{-5}$	$8.4 \cdot 10^{-4}$		$5 \cdot 10^{-3}$	0.05
Indeno[1,2,3-c,d]pyrene	Plastic part	1.2	$2.3 \cdot 10^{-5}$	$1.91 \cdot 10^{-5}$		$5 \cdot 10^{-3}$	$4 \cdot 10^{-3}$
Fragrances							
Butylphenyl methylpropional	Whole diaper	50*	-	-	Panty liner	10	0.2
Dioxins and furans							
1,2,3,6,7,8-HxCDD	Whole diaper	$1.32 \cdot 10^{-7}$	$1.68 \cdot 10^{-5}$	127	Tampon	$29.7 \cdot 10^{-9}$	0.22
1,2,3,4,6,7,8-HpCDD	Whole diaper	$1.03 \cdot 10^{-6}$	$2.61 \cdot 10^{-5}$	25.33		$4.9 \cdot 10^{-7}$	3.58
	Topsheet	$6.09 \cdot 10^{-7}$		42.86			0.8
OCDD	Whole diaper	$2.15 \cdot 10^{-6}$	$3.33 \cdot 10^{-4}$	154.88		$3.9 \cdot 10^{-6}$	1.81
	Topsheet	$2.69 \cdot 10^{-6}$		123.79			1.45
1,2,3,6,7,8-HxCDF	Whole diaper	$4.42 \cdot 10^{-8}$	$3.05 \cdot 10^{-5}$	690.04	-	-	-
2,3,4,6,7,8-HxCDF	Whole diaper	$1.0721 0^{-7}$	$2.13 \cdot 10^{-5}$	199.06	-	-	-
	Backsheet	$5.01 \cdot 10^{-7}$		42.51	-	-	-
1,2,3,4,6,7,8-HpCDF	Whole diaper	$1.54 \cdot 10^{-6}$	$6.42 \cdot 10^{-5}$	41.68	Tampon	$7.7 \cdot 10^{-8}$	0.05
	Other parts	$1.93 \cdot 10^{-7}$		332.64			0.39
1,2,3,4,7,8,9-HpCDF	Whole diaper	$2.62 \cdot 10^{-7}$	$8.7 \cdot 10^{-6}$	33.2	-	-	-

Chemicals	Diaper part	Max in diapers (mg/kg)	Max from the iTDS (mg/kg)	iTDS/diaper concentration ratio	Type of feminine hygiene product	Max in feminine hygiene products (mg/kg)	Feminine hygiene product/diaper concentration ratio
OCDF	Whole diaper	$1.30 \cdot 10^{-5}$	$6.33 \cdot 10^{-5}$	4.87	Tampon	$24.8 \cdot 10^{-6}$	1.91
	Backsheet	$7.08 \cdot 10^{-6}$		8.94			3.50
	Topsheet	$3.51 \cdot 10^{-7}$		180.34			70.65
	Other parts	$2.59 \cdot 10^{-6}$		24.44			9.57
Pesticides							
Glyphosate	Whole diaper	0.023	0.003	0.13	Panty liner	$2.5 \cdot 10^{-2}$	1.09
AMPA		0.045	-	-		0.1	2.22
Hexachlorobenzene		0.002	-	-	Towel	$2 \cdot 10^{-3}$	1
Quintozene		0.013	-	-		$2.1 \cdot 10^{-2}$	7.33
Pentachloroaniline		0.012	-	-		$1.9 \cdot 10^{-2}$	1.58
DL-PCBs							
PCB-81	Whole diaper	$1.77 \cdot 10^{-6}$	$1.1 \cdot 10^{-11}$	$0.62 \cdot 10^{-5}$	-	-	-
PCB-77		$2.13 \cdot 10^{-5}$	$8.4 \cdot 10^{-11}$	$3.94 \cdot 10^{-6}$			
PCB-123		$1.17 \cdot 10^{-5}$	$1.7 \cdot 10^{-5}$	1.45			
PCB-118		$7.56 \cdot 10^{-4}$	$2.33 \cdot 10^{-6}$	$0.3 \cdot 10^{-2}$			
PCB-114		$3.17 \cdot 10^{-5}$	$1.6 \cdot 10^{-8}$	$0.5 \cdot 10^{-3}$			
PCB-105		$4.32 \cdot 10^{-4}$	$6.69 \cdot 10^{-7}$	$1.55 \cdot 10^{-3}$			
PCB-167		$3.88 \cdot 10^{-5}$	$1.78 \cdot 10^{-7}$	$0.46 \cdot 10^{-2}$			
PCB-156		$9.21 \cdot 10^{-5}$	$1.61 \cdot 10^{-4}$	1.75			
PCB-157		$2.80 \cdot 10^{-5}$	$8.3 \cdot 10^{-8}$	$2.96 \cdot 10^{-3}$			

*: detected chemicals

For the 8 identified chemicals, the maximum concentration levels in diapers for dioxins and furans were always lower than those found in food. Conversely, the maximum concentration levels in diapers for DL-PCBs and glyphosate were always higher than those found in food. Lastly, the concentrations of PAHs detected in shredded baby diapers were higher than those found in food.

Similarly, the concentrations of the chemicals found in baby diapers were compared with those found in feminine hygiene products, in particular sanitary towels and panty liners, due to their similar composition and the chemicals identified in these products (ANSES, 2018). The concentrations of the majority of the dioxins/furans found in shredded diapers were higher than those found in feminine hygiene products. The concentrations of pesticides were of the same order of magnitude in shredded baby diapers and in feminine hygiene products. Lastly, the concentrations of PAHs and fragrances detected in shredded baby diapers were higher than those found in feminine hygiene products.

These results reflect far higher contamination levels in diaper materials than in food, weakening the assumption of "environmental" contamination for diaper materials. It is therefore more likely that the observed PAH and PCB contamination levels were related to the diaper manufacturing processes themselves and not the contamination of the resource used to create the materials.

8.7   Analysis of uncertainties and discussion

In order to be able to judge the limitations of this risk assessment, it is worthwhile to analyse the sources of uncertainty and limitations associated with the approach that was followed. The QHRA of the chemicals contained in baby diapers was undertaken using the four-step approach advocated by the NRC in 1983 (NRC, 1983).

Uncertainty is inherent in every step of the risk assessment process: the identification and characterisation of hazards and dose-response relationships, the assessment of exposure and the characterisation of risks. The analysis reported here examined these different steps. It especially focused on the choices that could lead to uncertainty in the conclusions in terms of risks. The table below provides a structured list of the various sources of uncertainty identified, classified into various categories:
- Uncertainties related to the context and formulation of the question,
- Uncertainties related to the body of knowledge,
- Uncertainties related to the risk assessment methodology via the
  - identification of hazards,
  - TRVs,
  - estimation of exposure through the various parameters used,
  - characterisation of risks.

The impact of these uncertainties on the QHRA results was assessed (direction: underestimation, overestimation, not classifiable, not applicable; amplitude of the impact: low, high, nil or not classifiable) on the basis of expert judgement. For certain parameters, it was not possible to conclude as to how the uncertainty impacted the results.

The analysis of uncertainties revealed knowledge gaps that may require specific studies to limit overall uncertainty. However, the assumptions considered to conduct this QHRA have reasonably amplifying effects.

Table 44: Sources of uncertainty and impact on the results of the health risk assessment of the chemicals analysed in the tested diapers

Class	Sub-class	Source of uncertainty			Amplitude of the impact on the QHRA results (low, high, nil or not classifiable)	Direction (under/overestimation, variation, centred, not classifiable, not applicable)
		Subject	Choices made	Origin: available information explaining the choice		
Context	**Framing** What is induced by the context/scope	Media context	Objective scientific choices	Topic frequently covered by the media (newspapers, television, etc.) increasing the perception of risks	Nil	Not applicable
	Formulation of the question What falls within the scope of the expert appraisal	No identified uncertainties				
Body of knowledge	**State of knowledge** Absence, incompleteness, inadequacy, etc.	Chemicals assessed in the QHRA	Selection of the chemicals detected and quantified in the SCL and INC tests	Results of the measurements taken by the SCL and INC. Analysis of numerous chemicals	Low	Not classifiable
		Effect of the mixing of chemicals found in diapers	Dioxins/furans/DL-PCBs and PAHs	Assessment by class for dioxins/furans and PAHs with the use of toxicity equivalency factors	Not classifiable	Correct estimation
			Other chemicals	Numerous chemicals potentially having similar effects were found in diapers. Mixtures could not be assessed	Not classifiable	Not classifiable
		Other sources of exposure to chemicals via various media	Concentrations in food and feminine hygiene products	No real comparisons of chemical concentrations in other media except for food and feminine hygiene products. No aggregated risk calculation	High	Underestimation
	Data collection methods Representativeness, protocol, power,	Sampling of the tested diapers	INC: best-selling diapers in France	Possible to have results for diapers no longer	Low	Not classifiable

measurement method, etc.		SCL: same products as the INC + additional products	available on the market. Nonetheless good representativeness of the models available on the market at the time of testing		
	SCL and INC tests with shredded materials using solvent extraction and a urine simulant	Measurements taken with shredded whole diapers	Risk of overestimating (chemical found in a part that is not in contact with the skin) or underestimating (dilution of a chemical found only in one diaper part)	High	Over- or underestimation
		Diaper shredding method	Unknown method	High	Not classifiable
		Analytical method (solvent extraction)	Not representative of normal use but enabled a maximum number of chemicals to be identified and recovered in theory	High	Overestimation
		Analytical method (urine simulant)	Not representative of normal use (shredded material) but enabled the chemicals actually extracted by urine to be identified	High	Overestimation
		INC tests	No knowledge of the name of the laboratory that performed these tests or details pertaining to the methods used	High	Not classifiable
	SCL tests with whole diapers, extraction with a urine simulant	Analytical method (urine simulant)	Representative of normal use enabling the chemicals actually extracted by urine to be identified	High	Correct estimation
Available models Adequacy, validity, parameters, etc.	QHRA method	Use of the traditional approach	Use of the QHRA method traditionally	Not classifiable	Not classifiable

				used (NRC, 1983)		
Assessment method	**Selected data** Selection criteria, expert judgements, extrapolation, etc.	Toxicological assessment method		Toxicological methods used do not enable the actual impacts in humans to be calculated. Do not cover ED or sensitising effects	High	Not classifiable
		Hazard identification	Classifications Lack of toxicological profiles	Pragmatic decision on the part of the experts given the number of chemicals to be analysed (known chemicals)	Low	Not classifiable
		TRVs	Selection of the TRVs available in national and international databases	Worst-case approach: choice of the most disadvantageous TRV	High	Overestimation
				Refined scenario: expert judgement	Not classifiable	Not classifiable
				Application of a lifetime TRV to children between the ages of zero and three years	Not classifiable	Not classifiable
		Concentrations	Choice of the highest concentrations for the quantified chemicals	Worst-case and refined approaches	Low	Overestimation
			For detected chemicals: LQ using the worst-case approach and LQ/2 using the refined approach	Approach traditionally used in the area of the environment	Low	Over- or underestimation
		Diaper weights	Literature data	Data from the literature	Low +++	Correct estimation
		Frequency of use	Worst-case scenario: the most disadvantageous choice	Data from the literature	Low	Correct estimation
			Refined scenario: choices for the	Data from the literature	Low	Correct estimation

			various age groups			
		Worst-case scenario: 100%	Disadvantageous data	High	Overestimation
	Transfer of the substance from the material to the skin	Refined scenario: 7%	Industrial data for chemicals found in parts directly in contact with the skin whereas in the SCL and INC tests with shredded diapers, the locations of the chemicals are not known	High	Not classifiable
		Worst-case scenario: 100%	Disadvantageous data	High	Overestimation
	Reflux ratio	Refined scenario: 1.32%	Data from a publication financed by companies - choice of the most disadvantageous value	High	Correct estimation
	Mucocutaneous absorption	Worst-case and refined scenarios: 100%	Approach adopted by the SCCS and ANSM for products for the buttocks area due to the frequency of skin diseases in the diaper area in babies	Low for lipophilic chemicals High for hydrophilic chemicals	Overestimation
	Body weight	Worst-case scenario: disadvantageous choice	Disadvantageous choice corresponding to the body weight of an newborn. Recent French literature data	Low	Overestimation
		Refined scenario: body weights by age group	Recent French literature data: 5th percentile	Low	Not classifiable
Data integration methods In connection with the conceptual framework established in the planning stage: choice of parameters, extrapolation, number of simulations, etc.	Calculation of the risk indicator (HQ or ERU)	Traditional approach	Traditional approach if available TRV. Otherwise, margin-of-exposure approach	Not classifiable	Not classifiable

Reporting of results	**Interpretation of results**	No identified uncertainties
	Presentation of results (mode, selection)	No identified uncertainties
	Expression of results	No identified uncertainties

9 Conclusion and recommendations

ANSES received a formal request in April 2017 to assess the safety of baby diapers.

The CES reiterates that reusable diapers were not studied. Therefore, the experts cannot take a position as to the safety of these products or the impact of washing them.

As instructed in the formal request, the CES focused on the potential chemical risks induced by baby diapers by studying the composition of these products on the one hand and undertaking a quantitative health risk assessment on the other hand. To do so, it held a series of hearings with various professionals in the sector between April and May 2017.

Regarding the **composition of baby diapers**, the macromolecular materials can be broken down into two main categories:
- Products of natural origin, derived from wood cellulose, which all undergo chemical treatment (bleaching). The exact nature of these cellulose products, which influences their physicochemical properties, was not provided as part of this formal request.
- Synthetic products such as polyolefins (polyethylenes and polypropylenes) or polyacrylates for superabsorbent polymer (SAP or sodium polyacrylate). There are very different manufacturing processes that provide these polymers with specific properties, but these processes differ by the nature of the polymerisation initiators and/or catalysts, of which traces can be found in the finished material. SAP is contained in all single-use diapers.

It should be noted that the precise nature of the materials which single-use baby diapers are made of could not be determined through the hearings that were held. The same lack of information was noted for the description of processing aids such as glues, and for intentionally added substances (fragrances, inks, etc.).
Nonetheless, certain stages of the manufacturing processes appear to use silica, a percentage of which is in nanoparticle form. The CES reiterates that declaration in the national R-Nano registry is required for any substance with nanoparticle status, whether it is produced, imported or distributed in France, as is, contained in a mixture without being bound to it, or contained in a material intended to release it under normal conditions of use.

The INC and SCL conducted **composition tests with shredded whole single-use diapers and shredded diaper parts**, in order to screen for the presence of chemicals. Solvent extraction was used to extract as many chemicals as possible. The chemicals quantified and/or detected in single-use diapers sold in France, via the tests conducted by the INC and SCL in 2016 and 2017, were:
- in shredded **whole diapers**:
  - volatile organic compounds (naphthalene, styrene, toluene, 1,4-dichlorobenzene, 1,3-dichlorobenzene, p-isopropyltoluene, xylenes, chlorobenzene),

○ pesticides (hexachlorobenzene, quintozene and its metabolite pentachloroaniline, glyphosate and its metabolite AMPA),

○ dioxins, furans and DL-PCBs,

○ formaldehyde,

○ fragrances (benzyl alcohol, benzyl salicylate, coumarin, hydroxyisohexyl 3-cyclohexene carboxaldehyde, butylphenyl methylpropional, limonene, linalool, alpha-isomethyl ionone);

- in shredded **diaper parts**:

   ○ dioxins, furans (in the inner layer, outer layer and other parts except the core),

   ○ PAHs in the elastics (benzo[b]fluoranthene, benzo[a]anthracene, indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene).

The SCL also carried out **migration tests with whole diapers and shredded whole diapers for single use in a urine simulant**. Dioxins, furans and DL-PCBs, PAHs and formaldehyde were quantified or detected.

Regardless of the test, the detected and/or quantified chemicals were the same overall. However, due to the use of analytical methods of varying precision, for the same diaper product, the same chemical could be detected in one test and quantified or not detected in another.

It should be noted that the pesticides found in these products are currently prohibited in the EU (lindane and quintozene since 2000, hexachlorobenzene since 2004) with the exception of glyphosate which continues to be authorised in France and the EU.

According to the data from the literature and the information provided during the hearings, the chemicals detected or quantified in diapers by the SCL or INC are not intentionally added by the manufacturers, with the exception of fragrances. The majority of the chemicals detected or quantified in diapers can either be the result of raw-material contamination (e.g. pesticides) or be formed during manufacturing processes such as bleaching or bonding (e.g. DL-PCBs, furans and dioxins). Today, the cellulose used in these products is no longer bleached by elemental chlorine. However, processes using chlorinated agents such as chlorine dioxide, for example, are used and can be responsible for the formation of dioxins and furans. Regarding the presence of PAHs in single-use diapers, the experts do not rule out PAH formation during the manufacture of these diapers due to the use of high temperatures for certain manufacturing processes (Abdel-Shafy and Mansour, 2016).

Contaminants were found both in "eco-friendly" diaper products and in other diaper products.

Initially, a **quantitative health risk assessment** was undertaken for the chemicals detected or quantified in single-use baby diapers using a worst-case approach in order to rapidly eliminate substances posing no health risks. It was based on the various analyses undertaken by the SCL and INC:

- Solvent extractions in shredded whole diapers or diaper parts (SCL, 2017; INC, 2017 and 2018; Group'Hygiène, 2018[25]),
- Extractions with a urine simulant in shredded whole diapers (SCL, 2017),
- Extractions with various urine simulants in whole diapers (SCL, 2018; Group'Hygiène, 2018[26]).

The experts considered that of the various analyses listed above, the extractions with urine simulants in whole diapers conducted by the SCL in 2018 seemed the most realistic.

In a second phase, if potential cases of the health thresholds being exceeded were observed, a refined approach was implemented to conduct as realistic an assessment as possible.

Regarding the chemicals measured by solvent extraction in **shredded whole diapers**, a risk calculation was undertaken using a refined scenario for all fragrances, dioxins, furans and DL-PCBs and their sums, as well as for three VOCs[27] and hexachlorobenzene.

It showed cases in which the health threshold was exceeded for infants aged zero to 12 months inclusive, for two **fragrances (hydroxyisohexyl 3-cyclohexene carboxaldehyde and butylphenyl methylpropional)** detected in one of the diaper products out of the 19 analysed.

Regarding the chemicals quantified by solvent extraction in **certain diaper parts**[28], no cases of the health threshold being exceeded were found for PAHs or for 2,3,4,6,7,8-HxCDF, for children aged zero to 36 months.

Regarding dioxins, furans and DL-PCBs and their sums found by extraction with a **urine simulant in shredded whole diapers**, a risk calculation was undertaken according to a refined scenario. It did not show any cases of the health threshold being exceeded for children aged zero to 36 months.

Regarding the chemicals found by extraction with a urine simulant in **whole diapers**, a risk calculation was undertaken according to a refined scenario for 10 PAHs, formaldehyde, PCB-126, the sum of dioxins and furans, the sum of DL-PCBs and the sum of dioxins, furans and DL-PCBs[29]. It highlighted the following, for children aged zero to 36 months:

- **cases in which the risk indicator (no-threshold carcinogenic effects) was exceeded for the 10 PAHs (benzo[g,h,i]perylene, benzo[b]fluoranthene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene);**
- **cases in which the health threshold[30] (threshold effects) was exceeded for six PAHs (benzo[b]fluoranthene, cyclopenta[c,d]pyrene, benzo[k]fluoranthene,**

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[25] Confidential tests

[26] Confidential tests

[27] 1,2,3-trichlorobenzene; 1,2,4-trichlorobenzene; 1,3,5-trimethylbenzene

[28] Plastic parts and backsheet

[29] Classifications of these chemicals and sector-specific regulations are available in Annex 5.

[30] TRVs established based on developmental effects for PAHs and reprotoxic and developmental effects for dioxins, furans and DL-PCBs (Annex 1)

> **benzo[j]fluoranthene, benzo[a]pyrene, dibenzo[a,h]anthracene) and for PCB-126, the sum of DL-PCBs, and the sum of dioxins, furans and DL-PCBs.**

The above exposure calculations were limited to exposure related to baby diapers, excluding other possible exposure sources (environmental, dietary, consumer products). The possibility of cumulative exposure through various exposure routes leading to an increase in the estimated risks could not be ruled out, especially for substances found in baby diapers whose HQ was between 0.1 and 1 or whose IER was around 10^{-7} (orange cells), such as:

- dioxins,
- furans,
- DL-PCBs,
- PAHs (benzo[g,h,i]perylene, chrysene, 5-methylchrysene, benzo[e]pyrene),
- some VOCs (1,2,4-trichlorobenzene and 1,2,3-trichlorobenzene),
- hexachlorobenzene,
- fragrances (coumarin, limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, butylphenyl methylpropional, benzyl salicylate),
- formaldehyde.

Dioxins, furans, DL-PCBs and PAHs are ubiquitous substances that can be found, for example, in food and particularly in breast milk.

The risk calculations performed did not take endocrine-disrupting or skin-sensitising effects into account. However, a number of the substances are possible EDs[31] or are classified as known or suspected skin sensitisers[32]. These skin-sensitising effects were confirmed by data from the literature.

In conclusion, there are no epidemiological data demonstrating health effects related to the wearing of diapers. However, hazardous chemicals have been found in these diapers. Based on the results of the INC and SCL tests and the literature data, a quantitative health risk assessment was undertaken for single-use baby diapers according to realistic scenarios. **This QHRA showed cases of the health thresholds being exceeded for several substances. Therefore, to date and in the current state of knowledge, it is not possible to rule out a health risk associated with the wearing of single-use diapers.**

Recommendations
On the basis of the above conclusions, the CES is issuing the following recommendations:

Recommendations for the public authorities:

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[31] Naphthalene, styrene, toluene, 1,4- and 1,3-dichlorobenzene, m-xylene + p-xylene, hexachlorobenzene, quintozene, glyphosate, benzyl salicylate, butylphenyl methylpropional, PAHs, dioxins, furans and DL-PCBs (BKH, DHI, SIN List, TEDX List)

[32] BaP, formaldehyde, quintozene, linalool, limonene and hydroxyisohexyl 3-cyclohexene carboxaldehyde classified as skin sensitisers according to the CLP Regulation; 1,2,3-trichlorobenzene, butylphenyl methylpropional, alpha-isomethyl ionone, benzyl salicylate and coumarin self-classified under the REACh Regulation

-    Regarding the regulatory framework

The existing regulatory system governing the composition, use and manufacture of single-use diapers as defined in the General Product Safety Directive is insufficient, due to the presence of hazardous chemicals in these products. The CES recommends developing a more stringent regulatory framework to limit the presence of these substances. This regulatory framework could involve a restriction procedure for each type of product according to the REACh Regulation (Annex XVII). The chemicals quantified or detected in this expert appraisal could be used as a basis for a list of substances to be included in this regulatory measure.

-    Regarding the monitoring of hazardous chemicals in single-use diapers

The CES recommends pursuing measurement campaigns for all products on the market, according to the protocol used by the SCL in 2018 (extraction with a urine simulant from a whole single-use diaper), in order to ensure that the conclusions and recommendations of this opinion intended for manufacturers and companies marketing products are taken into account.

Recommendations for manufacturers and companies marketing products regarding the composition of single-use diapers and the chemical risks:
- Since the health thresholds were observed to be exceeded in this study, the CES recommends eliminating the use of all fragrances, especially those likely to have skin-sensitising effects.
- The CES recommends better controlling the origin of natural raw materials that can become contaminated even before manufacture (need to develop and enforce more stringent specifications, for example).
- The CES recommends improving diaper manufacturing processes in order to reduce as far as possible the presence of hazardous chemicals, such as dioxins, furans, DL-PCBs, formaldehyde and PAHs, in the materials used in single-use baby diapers. To limit chlorinated dioxins and furans, the bleaching phases for materials could be undertaken without any chlorinated agents (such as chlorine dioxide, sodium or calcium hypochlorite, etc.). Techniques are available to achieve this, such as the use of dioxygen and hydrogen peroxide.
- Pending changes to the regulations, the CES recommends setting a maximum concentration not to be exceeded for each chlorinated dioxin and furan and DL-PCB congener that would be of the same order of magnitude as the limit of quantification. Initially, the lowest LQ used in this expert appraisal (around 0.02 ng/kg) could be proposed. This value is not a health threshold.

Recommendations regarding the acquisition of knowledge:
In order to be capable of assessing the risks posed by hazardous substances intentionally added by manufacturers and those associated with contaminants found in these products, the CES recommends:
- conducting studies to obtain substantiated scientific information on the transfer of substances from the material to the skin/mucous membranes;
- developing TRVs for the mucocutaneous route, which currently does not have any;
- developing more realistic experimental protocols conducted with the urine of babies wearing single-use diapers.

Date of validation of the report by the Expert Committee: 15 November 2018

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Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

ANNEXES

Annex 1 : Request letter about feminime hygiene product safety

ANSES Reçu le

0 9 MAI 2016

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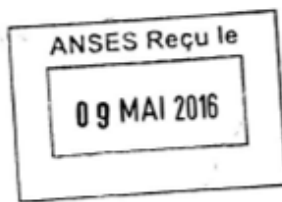
2016 -SA- 0 1 0 8

Paris, le

Ministère de l'économie, de l'industrie
et du numérique

Direction générale de la concurrence,
de la consommation et de la repression des fraudes

Ministère des affaires sociales et de la santé

Direction générale de la santé

Paris le   **2 9 AVR. 2016**

La Directrice générale de la concurrence, de la
consommation et de la répression des fraudes

Le Directeur général de la santé

à

Madame la Directrice générale suppléante de l'Agence
nationale de sécurité sanitaire de l'alimentation, de
l'environnement et du travail,
27-31 avenue du Général Leclerc
94701 Maisons-Alfort Cedex

Objet : Saisine relative à la sécurité des produits de protection intime

Nous avons l'honneur de vous faire parvenir une saisine relative à la sécurité et à la commercialisation
des produits de protection intime (tampons, serviettes hygiéniques, et protège-slips) en matière de risques
d'infection, d'allergie ou d'intolérance, et/ou liés à l'action chimique, par contact cutané ainsi que par
contact avec des muqueuses.

Cette problématique, qui fait l'objet de débats récents dans les médias, nous semble en effet mériter un
approfondissement en matière d'analyse des risques, compte tenu, d'une part, du nombre de substances
chimiques potentiellement utilisées dans la confection des produits de protection intime et, d'autre part,
du risque sanitaire potentiel lié à ces substances chimiques qui, pour la plupart d'entre elles, ne sont pas
réglementées par rapport à ce type d'usage.

L'expertise de l'ANSES est plus particulièrement souhaitée aux fins :
- A. d'étudier la composition-type des produits de protection intime (tampons, serviettes
  hygiéniques, et protège-slips.) ;
- B. d'identifier les substances chimiques préoccupantes, réglementées ou non, susceptibles d'être
  présentes dans ces produits d'hygiène, le cas échéant à l'état de trace ;
- C. de réaliser un état des lieux des connaissances sur les dangers présentés par ces substances en
  particulier par contact avec les muqueuses vaginales ;
- D. d'évaluer la pertinence de définir ou non des seuils pour la présence de ces substances dans les
  produits de protection intime (tampons, serviettes hygiéniques et protège-slips...) notamment
  au regard du temps et du mode d'exposition ;
- E. le cas échéant d'émettre des recommandations afin de favoriser un meilleur encadrement des
  modes de fabrication, de la composition et de l'information du consommateur notamment au
  niveau communautaire.

Vous trouverez ci-jointe une note précisant le contexte ainsi que les questions précises sur lesquelles nous sollicitons votre expertise.

Nous vous remercions de bien vouloir accuser réception de la présente demande en nous précisant le ou les comités d'experts spécialisés qui seront saisis du dossier.

La directrice générale de la DGCCRF

Nathalie HOMOBONO

Le directeur général de la santé

Benoit VALLET

Annex 2: Request letter about baby diaper safety

ANSES Reçu le

26 JAN. 2017

2017 -SA- 0 0 19

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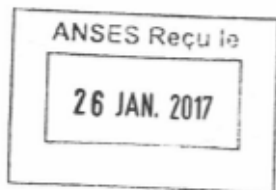
*La ministre de l'Environnement,
de l'Énergie et de la Mer
en charge des Relations
internationales sur le climat*

*La ministre des Affaires
Sociales et de la Santé*

*La Secrétaire d'État auprès du
Ministre de l'Économie, de
l'Industrie et du Numérique,
chargée du Commerce, de
l'Artisanat, de la Consommation
et de l'Économie sociale et
solidaire*

Paris, le 25 janvier 2017

Objet : Saisine relative à la sécurité des couches pour bébé

Monsieur le Directeur général,

Une étude récente s'appuyant sur des résultats d'analyse fait état de la présence de pesticides, dioxines, furanes, hydrocarbures aromatiques polycycliques (HAP) et composés organiques volatils à l'état de trace dans les couches pour bébés.

Les pouvoirs publics sont interpellés sur ce sujet, notamment sur le manque de données scientifiques et médicales sur l'évaluation des risques liés à ces substances potentiellement toxiques, notamment par voie cutanée au niveau du siège et des parties génitales chez le jeune enfant.

Cette problématique fait déjà l'objet d'une analyse bibliographique par vos services, pour identifier les substances chimiques préoccupantes susceptibles d'être retrouvées à l'état de trace, en accord avec le contrat d'expertise répondant à la saisine numéro 2016-SA-0108 relative à la sécurité des produits de protection intime.

Nous souhaiterions un approfondissement en matière d'analyse des risques chimiques liés au port des couches pour les bébés. Des données sur la présence et les quantités retrouvées de contaminants chimiques peuvent être recueillis auprès de la direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF), que ce soit les données de l'enquête de 60 millions de consommateurs ou des essais menés par le service des laboratoires commun de la DGCCRF.
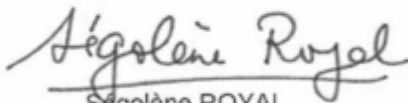
**Monsieur Robert GENET
Directeur général de l'ANSES
14 rue Pierre et Marie Curie
94701 MAISONS ALFORT CEDEX**

Hôtel de Roquelaure - 246, Boulevard Saint-Germain - 75007 Paris

L'expertise de l'ANSES est donc souhaitée pour faire suite à ces travaux. Nous vous demandons :

- de réaliser une analyse des risques liés à ces substances en particulier dans le cas d'une exposition par contact chez le jeune enfant (public sensible) ;

- d'évaluer la pertinence de définir ou non des seuils pour la présence de ces substances dans les couches notamment au regard du temps et du mode d'exposition ;

- le cas échéant, d'émettre des recommandations afin de favoriser un meilleur encadrement des modes de fabrication, de la composition et de l'information du consommateur notamment au niveau communautaire.

Nous vous remercions de bien vouloir accuser réception de la présente demande en me précisant le ou les comités d'experts spécialisés qui sont associés au traitement de la saisine. L'avis de l'agence est attendu pour la fin de l'année.

Ségolène ROYAL

Marisol TOURAINE

Martine PINVILLE

Annex 3: International consultation synthesis

Institute	Country	Realized or On-going studies	Existing National framework on feminine hygiene products (description, origin, impact on manufacturers)	Feminine Hygiene products composition	Assays (chemical or microbiology) ans associated risks	Relevance of a proposed threshold
Contact points Rapex (Rapide Alert System for dangerous non-food products)[33]	Greece	/	No specific regulation. Relevant regulation : 2001/95/CE Directive (General Safety products) + REACh regulation + 76/7768/EEC regulation (cosmetic products) + European directive : 93/42/EEC (medical devices) Same manufacturers in the EU (Procter & Gamble, SCA hygiene product) + greec manufacturer that exports in the EU (Mega disposables S.A.)	/	2012-2016 : Investigations following odor complaints（unpleasant odors, pimples, physical hazards, allergies, microbiological problems, possible risk of contamination by insects or rodents, etc.）	/
	Slovakia	/	/	/	/	Relevant to define restrictions (e.g threshold)
	Germany	BfR, 2011	No specific regulation Considered as articles intended to be in contact with the human body for a long time according to the German law on human and veterinary food (art. 2 paragraphe 6 n°6) Consumer products manufactured for not putting consumers at risk.	/	/	/

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[33] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

			No approval procedure → manufacturers responsible for the safety of their products and must ensure that all legal requirements are met. Specific German requirements for consumer products are defined in the German Ordinance on Consumer Goods(Bedarfsgegenständeverordnung) 2001/95/CE Directive (General safety products) transposed in the «Produktsicherheitsgesetz (ProdSG)» Chemicals legislation (in particular (CE) n°1907/2006 regulation) applies to consumer goods. Control of consumer products is the responsablity of the competent authorities of the federal states in Germany.			
BfR (Bundesintitut für Risikobewertung)	Germany	no	No specific regulation. Considered as articles intended to be in contact with the human body for a long time according to the German law on human and veterinary food (art. 2 paragraphe 6 n°6) BfR recomendations for feminine hygiene products assessment (BfR, 2011) → BfR recomendations usually followed by industry.	- cellulose and mechanical pulp for the cellulose fluff - polyacrylate as superabsorbant core - polyethylene and polypropylene as impermeable underwear protection film - polyethylene, polypropylene and conditionning agents for the non-woven	Products partly made of cotton → pesticides residues can potentially be present In 2015 and 2016, residual amounts of glyphosate have been measured in different products made of cotton including feminine hygiene products.→ BfR concluded that the amounts measured were too low to pose a health risk for consumers.	Recommendations to compile information on what substances could be present in these consumer products. Safety assessments of manufactures and the BfR recommendation could be a good starting point. (ex. : Woeller and Hochwalt, 2015)

				- covering - thermoplastic rubber, resins, waxes, oils for adhesive/holtmelt. - silicone paper - colourants, binders, perfume oils		
Danish EPA	Denmark	No	No specific regulation		Danish EPA, 2009	
KEMI (Kemikalieinspektionen)	Sweden	2012 : study on 11 diapers to look for organotin compounds (TBT, DBT and DOT) → no chemicals found	2001/95/CE Directive (General Safety products) REACh Regulation (annexe XVII) : Organotin restriction No specific recomendation from Kemi	EDANA's website	/	/
US FDA (Food and Drug Administration) – CDRH	USA	Baby diapers are not in the FDA field because they are not regulated.				

Annexe 4: Voluntary scheme criteria

EcoLabel

- The pulp used to manufacture fibres shall not be bleached with the use of chlorine gas.
- Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the cotton
- Plastic materials ans superabsorbent polymers
  o Contents of lead, cadmium, hexavalent chrome and related compounds shall be lower than 0,01 % (100 ppm) of the mass of each plastic material and synthetic polymer used in the product
  o Additives used in plastics in concentration above 0,10 % by weight shall not be classified with any of the listed hazard statements (CMR, Acute Tox 1 or 2, STOT cat 1,hazardous for the aquatic environment cat 1 and 2),
- Superabsorbent polymers :
  o Acrylamide shall not be intentionnaly added,
  o Superabsorbent polymers used in the product may contain a maximum of 1 000 ppm residual monomers that are classified with the H-statements reported in criterion 7 on excluded or limited substances or mixtures. For sodium polyacrilate these represent total of unreacted acrylic acid and cross linkers
  o Superabsorbent polymers used in the product may, as a maximum, contain 10 % (weight/weight) of water-soluble extracts and these shall comply with criterion 7 on excluded or limited substances or mixtures. For sodium polyacrilate these represent monomers and oligomers of acrylic acid with lower molecular weight than the superabsorbent polymer according to ISO 17190.
- Adhesive materials shall not contain colophany resins, DIBP, DINP, Formaldehyde. This requirement shall not apply if those substances are not intentionnaly added to the amterial or the final product and are present in the adhesive mateirals in concentrations below 100ppm

- The product and any homogeneous part of it shall not be dyed.(derogation shall apply to tampon strings, packaging material and tapes, titanium dioxide in polymers and viscose, materials not directly in contact with the skin may be dyed if the dye fulfils specifi functions)

- Fragrances :
  o Products marketed as designed and intended for children as well tampons and nursing pads shall be fragrance-free.
  o Any ingoing substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of IFRA
  o Any fragrance used shall also comply with Criterion 7 on excluded or limited substances or mixtures regardless of the concentration in the final product.
  o Fragrances and ingredients of the fragrance mixtures that are identified as established contact allergens of special concern by the Scientific Committee on Consumer Safety as well as the fragrances whose presence, in accordance with Annex III to Regulation (EC) No 1223/2009 is required to be

indicated in the list of ingredients shall not be used. Further the use of nitromusks and polycyclic musks is not allowed.

- o The use of fragrances shall be indicated on the product packaging. Further, fragrances and/or ingredients of the fragrance mixtures that are identified as established contact allergens in humans by the Scientific Committee on Consumerand are not restricted by Criterion 6.3 (c) and (d) shall additionally be named.

- Lotions
  - o Lotions shall not be used in feminine care pads, tampons and nursing pads. The use of lotions in other products shall be indicated on the packaging
  - o Any lotion used in products other that feminine care pads, tampons and nursing pads shall comply with criterion6.3 on fragrances and criterion 7 on excluded or limited substances and mixtures regardless or their concentration in the final product.
  - o Triclosan, parabens, formaldehyde, formaldehyde releasers shall bot be used.
- Neither D4 nor D5 shall be present in chemical products used in silicone treatmen of components. This requirement shall not apply where D4 and D5 are not intentionnaly added to the material or to the final product and where D4 and D5 are present in the silicone in concentration beloww 100 ppm.
- Nanosilver particles shall not be intentionnaly added to the product or to any homogeneous part or material of it.
- The EU Ecoloabel may not be awarded if the product or any article of it, or any homogeneous part of it contain substances or mixtures meeting the cirteria for classification with the hazard statements or risks phrases[34]

Nordic Swan

The criteria that diapers have to fulfill in order to get the Nordic Swan Ecolabel are :
- Description of the product and material composition,
- Chemicals products and their classification,
- Chemicals substances, CMR,
- Other excluded substances : Substances on the Candidate List, Organotin compounds, phthalates, APEO, Halogenated organic compounds, Flame retardants, PBT/VPvB, endocrine disruptors, preservatives that are bioaccumulative, antibacterial agents.
- Indicate if silicone treatment of the whole or part of the product is used
- Adhesives/binders used in the composition of the product and additional components are required ;
- Fragrance, scents, lotion, skin care and/or moisturing preparations must not be added,
- No odour control substances,
- No medicament and antibacterial agents can be added

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[34] H300, H301, H304, H310, H311, H330, H331, H340, H341, H350, H350i, H360F, H360D, H360FD, H360fD, H360Fd, H361f, H361d, H361fd, H362, H370, H371, H372, H373, H400, H410, H411, H412, H413, EUH059, EUH029, EUH031, EUH032, EUH070, H317 1A et 1B et H334

- Products must not be dyed (except for tampon strings). Material/component that are not directly in contact with the skin may, however, be dyed if the dye has a special function.
- Printing inks used in a product or the components of the ink must fulfill a Nordic Swan document.
- Recycled material is not allowed in sanitary product with the exception of recycled plastic,
- Requirements regarding cellulose based pulp/fluff/air-laid are needed.
- Cotton must not be bleached with the aid of chlorine gas. The cotton must be organically cultivated or cultivated in the transitionary phase to organic production.
- Chlorine gas must not be used to bleach cellulose pulp or cellulose fibre.
- Sanitary products, additional components and their packaging must not be halogen-based,
- According to the amount of polymer in the article, some chemicals must not be present.
- Polyurethane/Elastane require a closed process when using isocyanate in the production, organotin compounds shall not be used, PUR foam and thermoplastic PUR must fulfill EU ECOLABEL requirements,
- For superabsorbent polymers, acrylamide must not be used as a monomer, and SAP may as a maximum contain 10%w of water soluble extracts.
- Requirements are needed for non woven parts.
- Procedure requirements are needed.

Annexe 5: Detected, semi-quantified or quantified chemicals in tested baby by Danish EPA (Danish EPA, 2009)

○   **Table 45 : Detected, semi-quantified or quantified chemicals in tested baby by Danish EPA (2009)**

Baby diaper description	Information stated on the packaging or product	Filling material	Elastic rim	Strech closures	Volnner waist lining	Frontal print	All parts of the diaper (not in the filling material)
Diaper with strech closure. Print on the front side of diaper. Junio/5 11-25 kg	Latex free. Contains no lotion or fragrance -Contains: Cellulose, bleached without chlorine, polypropylene, polyethylene, polyurethane, synthetic rubber.		2,4-di-tert-butylphénol = 14 µg/g BHT = 100 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 480 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 180 µg/g Irgafos 168 oxydized = 200µg/g	2,4-di-tert-butylphénol = 19µg/g BHT = 29 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 1000 µg/g Irgafos 168 oxidized = 180 µg/g	BHT = 18 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 430 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 92 µg/g Irgafos 168 oxyized = 98 µg/g	BHT = 25 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 130 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 100 µg Irgafos 168 oxydized = 81µg/g	2.4-bis (1,1-dimethylethyl)-phenol BHT Tris(2,4-ditert-butylphenyl) phosphite Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
Trouser diaper, print on the front side of diaper. 13.20 kg	-Anti leak technology - All-round soft fit	Irganox 245 = 160 µg/g	2,4-di-tertbutylphenol = 14 µg/g BHT = 9 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 1200 µg/g Irgafos 168 oxydized = 180µg/g	No sterch closure	BHT = 7 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 890 µg/g Irgafos 168 oxydized = 61 µg/g	2,4-di-tert-butylphenol = 8 µg/g BHT = 7 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 960 µg/g Irgafos 168 oxydized = 160µg/g	2.4-bis (1,1-dimethylethyl)-phénol BHT Tris(2,4-ditert-butylphenyl) phosphite Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
Diaper with strech closure. Print on the front and back sides of the diapers. Junior 11-25 kg	- Non-stop fit - Stretch & Hold - Contains: Petrolatum, stearyl alcohol, paraffinum liquidum, aloe barbadensis extract.		2,4-di-tert-butylphenol = 8 µg/g BHT = 11 µg/g 1-Octadecanol = 4800µg/g Tris(2,4-ditert-butylphenyl) phosphite = 550 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 280 µg/g	Limonene = 42 µg/g 2,4-di-tert-butylphénol = 11 µg/g BHT = 9 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 300 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 500 µg/g	BHT = 8 µg/g Naugard Tris(2,4-ditert-butylphenyl) phosphite = 550 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 55 µg/g Irgafos 168 oxydé = 67 µg/g	2,4-di-tert-butylphenol = 8 µg/g BHT = 10 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 430 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 150 µg/g Irgafos 168 oxydized = 140µg/g	Limonene 2.4-bis (1,1-dimethylethyl)-phenol BHT 1-Octadecanol Tris(2,4-ditert-butylphenyl) phosphite Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)pro

Baby diaper description	Information stated on the packaging or product	Filling material	Elastic rim	Strech closures	Volnner waist lining	Frontal print	All parts of the diaper (not in the filling material)
			Irgafos 168 oxydized = 240 µg/g				pionate
Diaper with strech closure. Print on the front side of diaper. Junior 12-22. Kg	Fragrance and lotion free		2,4-di-tert-butylphenol = 7 µg/g BHT = 8 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 560 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 76 µg/g Irgafos 168 oxydized = 150µg/g	Limonène = 60 µg/g 2,4-di-tert-butylphenol = 10 µg/g BHT = 10 µg/g 13-Docosenamide = 82 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 210 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 480 µg/g Irgafos 168 oxydizedé = 89µg/g	Tris(2,4-ditert-butylphenyl) phosphite = 380 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 50 µg/g Irgafos 168 oxydized = 180 µg/g	Limonene = 41 µg/g Caprolactame = 610 µg/g 2,4-di-tert-butylphenol = 7 µg/g BHT = 6 µg/g Isobutyle palmitate = 210 µg/g sobutyle stearate = 560 µg/g Octadecyle oleat = 210 µg/g	Limonene Caprolactame 2.4-bis (1,1-diméthyléthyl)-phénol BHT Isobutyle palmitate isobutyle stearate Octadecyle oleate 13-Docosenamide Tris(2,4-ditert-butylphenyl) phosphite Irganox 1076 Formaldehyde
Diaper with strech closure. Print on the front side of diaper.	- 100% free of chlorine - Contains over 50% "renewable resources". - Compostable packaging. - Dermatologically and clinically tested - Breathable foil 100% biodegradable		Limonene = 140 µg/g Dilactide = 160 µg/g 2,4-di-tert-butylphénol = 6 µg/g BHT = 8 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 260 µg/g Phthalate containing a long a alkyl chain = 170 µg/g Irgafos 168 oxydized = 130µg/g	Limonene = 210 µg/g 2,4-di-tert-butylphénol = 25 µg/g BHT = 41 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 830 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 62 µg/g Irgafos 168 oxydized = 100µg/g	Limonene= 33 µg/g Dilactide = 220 µg/g BHT = 10 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 220 µg/g Phthalate containing a long alkyl chain = 100 µg/g Irgafos 168 oxydized = 41 µg/g	Limonène = 92 µg/g Caprolactame = 240 µg/g Palmitate d'isobutyle = 1200 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 390 µg/g	Limonene 3.6-Dimethyl-1.4-dioxan-2.5-dione Caprolactame 2.4-bis (1,1-diméthyléthyl)-phénol BHT Isobutyl stearate Tris(2,4-ditert-butylphenyl) phosphite Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate Phthalates containing a long alkyl chain Ester

Annex 6: Description of the Group'Hygiene's assays (CONFIDENTIAL)

Annex 7: Physical-chemical properties of relevant chemicals

Chemicals (CAS Number)	Chemical and physical properties								
	State	molar mass (g/mol)	Density	Vapour pressure (Pa)	Melting point (°C)	Boiling point (°C)	Water solubility (mg/L)	Log Kow	Koc (L/kg)
VOC									
Naphtalene (91-20-3)	Solid	128.19	1 .069	10 .5-11	78-80	218	30 .8-34 .4	3.30	3.35-3 .4
Styrene (100-42-5)	Liquid	104.15	0 .9	620	-30 .65	145 .3	300-320	2.95-3.2	352-912
Toluene (108-88-3)	Liquid	92.139	0.87	$30.889.10^3 - 41.3.10^3$	-95	110.6	573-587	2.73	-
1,4-dichlorobenzene (106-46-7)		147	1.25-1.46	133.32	53.09	174	68-70	3.44	450-600
1,3-dichlorobenzene (541-73-1)	Liquid	147-286 .6	1.069	10.5-11	-24.8	78-80.218	111	3.53	375.3
p-isopropyltoluene (99-87-6)	Liquid	134.22	0 .85	133.32	-68.9	177.1	23.4	4.1	-
o-xylene (95-47-6)	-	-	-	-	-	-	-	-	-
m-xylene + p-xylene (1330-20-7)	-	107.175		933.25	-	138.5	106	3.16	-
chlorobenzene (108-90-7)	Liquid	-	1.085-1 .11	$11.73 - 56.78.10^3$	-46.55	13-33	207-546	2.46 – 3.79	-
Pesticides									
Hexachlorobenzene (118-74-1)	Solid	264 .78	2.044	0.00145-0.0023	227-231	319-326	0.005-0.01	3.93-6.53	$4.9.10^{-6}$
Pentachloroaniline (527-20-8)	Solid	265.36	-	399.97	232-235	-	0.03	4.82-5.08	12386
Quintozene (82-68-8)	Solid	295 .34	1.7	-	227-231	319-326	0.4	4.46	-
Glyphosate (1071-83-6)	Solid	169.01-169.07	1.7-1.705	$1.31.10^{-5}$	189.5-230	-	10200-10500	-1 to -3.2	-
AMPA (1066-51-9)	Solid	111.04	-	-	300	-	50	-	-

Chemicals (CAS Number)	Chemical and physical properties							
	State	Molar mass (g/mol)	Density	Vapour pressure (Pa)	Melting point	Boiling point (°C)	Water solubility (mg/L)	Log Kow/	Koc (L/kg)
PAH									
Benzo[g,h,i]perylene (191-24-2)	Solid	276.33	1.3-1.32	-	278.3	550	$2.6.10^{-4}$-3.10^{-4}	6.18-7.23	96000-2690000
Benzo[b]fluoranthene (205-99-2)	Solid	252.31	-	666.61	168.4	481	0.0015	5.78-6.6	-
Benzo[a]anthracene (56-55-3)	Solid	228.29	1.274	292	155-160	437.6	$9.4.10^{-3}$ – 0.01 et 25 °C	5.61-5.76	-
Indéno[1,2,3-c,d]pyrene (193-39-5)	Solid	176.33	-	$1.3.10^{-8}$	53.09	174	5.10^{-5} — $1.9.10^{-4}$ et 25°C	4.19-6.7	-
Fragrances									
Benzyl alcohol (100-51-6)	Liquid	108	1.02-1.06	7-63	-15.4	205.31	$4.29.10^{4}$	0.87-1.1	-
Benzyl salicylate (118-58-1)	Liquid	228.25	-	0.0004-0.01	-50	322	8.8-24.6	4-4.3	-
Coumarin (91-64-5)	Solid	146.14	0.935	0.088-0.131	33.4	290.74-301.71	1900	1.39	-
Hydroxyisohexyl 3-cyclohexene carboxaldéhyd (31606-04-4)	Liquid	210.31	-	< 0.001 mm Hg at 20 °C	-	318	184.6 at 25°C (calculated)	3.32(calculated)	-
BMHCA (80-54-6)	Liquid	204.3	0.94-0.96	0.25	279.5	279	0-33	4.2	-
Limonene (5989-27-5)	Liquid	136.23	0.844	190	-73.97 – 73.65	175.5 – 177.6	5.69 – 13.8	4.2 – 4.57	1120
Linalool (78-70-6)	Liquid	154.24	0.86	20-27	-74	196.3	854-1590	2.84-2.97	-
alpha-isomethyle ionone (1271-51-5)	-	206.33	-	-	-	-	-	4.84(calculated)	-
Dioxins and furans									
2,3,7,8 TCDD (1746-01-6)	Solid	321.96	1.8	133.32	305	446.5	2.10^{-5} – 2.10^{-4}	6.8-7.02	249100
1,2,3,7,8 PeCDD (40321-76-4)	-	356.4	12.3	666.61	240	-	$1.20.10^{-4}$ – $1.53.10^{-4}$	6.5-6.64	416100
1,2,3,4,7,8 HxCDD(39227-28-6)	-	390.84	13.49	$5.1.10^{-9}$ at25°C	273	-	$4.4.10^{-6}$	6.64-10.4	-
1,2,3,6,7,8 HxCDD (57653-85-7)	-	390.84	13.49	$4.8.10^{-9}$ at 25°C	285-286	-	$2.65.10^{-5}$	6.21-8.21	695200
1,2,3,7,8,9 HxCDD (19408-74-3)	-	390.87	-	133.32 at 25°C	243-244	478	$2.65.10^{-5}$	8.21	-
1,2,3,4,7,8-HpCDD (35822-46-9)	-	425.28	-	$9.33.10^{-8}$	264	507.2	$2.4.10^{-06}$- $1.9.10^{-3}$	7.52-11	-
OCDD (3268-87-9)	Solid	459.72	-	$1.066.10^{-10}$	300-330	485-510	$7.4.10^{-08}$ – 4.10^{-7}	8.2-13.37	-

Chemicals (CAS Number)	Chemical and physical properties								
	State	Molar mass (g/mol)	Density	Vapour pressure (Pa)	Melting point	Boiling point (°C)	Water solubility (mg/L)	Log Kow/	Koc (L/kg)
2,3,7,8 TCDF (51207-31-9)	Solid	305.96	-	0.001	227-228	-	$6.92.10^{-4}$	6.53	139500
1,2,3,7,8 PeCDF (57117-41-6)	Solid	340.37	-		206	-	$8.73.10^{-4}$	6.59-6.79	233000
2,3,4,7,8 PeCDF (57117-31-4)	-	340.40	-	$3.99.10^{-5}$	196-196.5	-	$2.35.10^{-4}$	6.92	233000
1,2,3,4,7,8 HxCDF (70648-26-9)	-	374.86	-		-	-	-	7.07	389300
1,2,3,6,7,8 HxCDF (57117-449)	-	374.86	-		-	-	-	7.02	389300
2,3,4,6,7,8 HxCDF (60851-34-5)	-	374.86	-		-	239.5	-	7.05	389300
1,2,3,7,8,9 HxCDF (72918-21-9)	-	374.86	-		-	-	-	6.99	389300
1,2,3,4,6,7,8 HpCDF (67562-39-4)	-	409.31	-	$2.66.10^{-6}$	-	-	$1.35.10^{-6}$	7.48-7.92	650300
1,2,3,4,7,8,9 HpCDF (55673-89-7)	-	409.31	-		-	-	-	7.45	650300
OCDF (39001-02-0)	-	443.75	-	$3.99.10^{-10}$	258	-	$1.16.10^{-6}$	-	-
DL-PCB									
PCB 81 (70362-50-4)	-	291.99	-	-	-	-	-	6.34	78100
PCB 77 (32598-13-3)	-	291.98	1.44	0.001	182-184	-	$5.69.10^{-4}$ -18.10^{-2}	6.63-6.72	-
PCB 123 (65510-44-3)	-	326.43	-	-	-	-	-	-	130500
PCB 118 (31508-00-6)	-	-	-	-	-	-	-	-	-
PCB 114 (74472-37-0)	-	326.43	-	-	98	-	0.016	6.98	130500
PCB 105 (32598-14-4)	-	326.43	1.52	0.00079	117	-	0.0034	6.79-6.88	-
PCB 126 (57465-28-8)	-	326.43	-	-	-	-	-	7.2	-
PCB 167 (52663-72-6)	-	380.86	-	$6.6.10^{-5}$	-	-	0.00223	7.5	209300
PCB 156 (38380-08-4)	-	291.98	1.59	0.0001	182-184	-	18.10^{-2} – $5.33.10^{-3}$	6.72-7.6	-
PCB 157 (69782-90-7)	-	380.88	-	-	-	-	-	-	213600
PCB 169 (32774-16-6)	-	360.86	-	-	-	-	$5.1.10^{-4}$	7.41-7.59	209300
PCB 189 (39635-31-9)	-	395.32	-	-	-	-	$7.53.10^{-4}$	8.27	349700

Annex 8: TRVs available in the literature

- **VOC TRVs**

Table 46 : oral chronic TRVs for VOC compounds

Chemicals (CAS number)	TRV	Organism	Year	Value	Targetted organ
Naphtalene (91-20-3)	Threshold	US EPA	1998	2.10^{-2} mg/kg/d	Decrease in average weight at the end of the study
		RIVM	2001	4.10^{-2} mg/kg/d	No construction details (value for aromatic hydrocarbons of 10-16 non-carcinogenic carbons)
		ATSDR	2005	No chronic MRL	
				Intermediate MRL : 0.6 mg/kg/d	Neurotoxicity
		Health Canada	2010	Choice of US EPA RfD	
	No-Threshold	OEHHA*	2011	0.12 (mg/kg/d)$^{-1}$	Adenomas basal epithelium and neuroblastomas of the olfactory nasal epithelium (route to route extrapolation)
Styrene (100-42-5)	Threshold	US EPA	1989	0.2 mg/kg/d	Haematotoxicityand hepatotoxicity
		ATSDR	2010	No chronic MRL (No long term study)	
		Health Canada	1993	0.12 mg/kg/d	Developmental toxicity
		RIVM	2001	0.12 mg/kg/d	Body weight loss
		OMS/FAO (JECFA)	1984	PMTDI 0.04 mg/kg/d	Provisional TRV
Toluene (108-88-3)	Threshold	US EPA	2005	0.08 mg/kg/d	Nephrotoxicity
		ATSDR	2017	No chronic due to lack of data	
				Intermediate MRL: 0.2 mg/kg/jd	Immunotoxicity
		Santé Canada	1992	1.25 mg/kg/d	Weight loss
		RIVM	2001	0.223 mg/kg/d	Increased liver and kidney weight
		OMS	1996	0.223 mg/kg/d	
1.4-dichlorobenzene (106-46-7)	Threshold	ATSDR	2006	0.07 mg/kg/d	Hepatotoxicity
		Health Canada	1992	0.11 mg/kg/d	Hepatotoxicity
		RIVM	2001	0.1 mg/kg/d	Various organs
		OMS	2004	0.107 mg/kg/d	Nephrotoxicity
		ECHA	2012	0.28 mg/kg/d	Hepatotoxicity
	No-Threshold	OEHHA	2009	$4.2.10^{-2}$ (mg/kg/ d)$^{-1}$	Hepatocellular carcinomas and adenomas

Chemicals (CAS Number)	TRV	Organism	Year	Value	
1,3-dichlorobenzene (541-73-1)	Threshold	ATSDR	2006	No chronic MRL due to lack of data	
				Intermediate MRL : 0.02 mg/kg/d	Endocrinology
p-isopropyltoluene (99-87-6)	Threshold and No-threshold	no TRV			
Xylene (mixture ; o-, m- et p-) (1330-20-7)	Threshold	US EPA	2003	0.2 mg/kg/d	Body weight loss and mortality increase
		ATSDR	2007	0.2 mg/kg/d	Neurotoxicity
		Health Canada	1991	1.5 mg/kg/d	Hepatotoxicity
		RIVM	2001	0.15 mg/kg/d	Nephrotoxicity
		OMS	2004	DJT : 0.0179 mg/kg	Body weight loss
Chlorobenzene (108-90-7)	Threshold	US EPA	1989	0.02 mg/kg/d	Hepatotoxicity
		ATSDR	1990	No chronic MRL	
				Intermediate MRL : 0.4 mg/kg/d	Hepatotoxicity
		Health Canada	1991	0.086 mg/kg/d	Nephrotoxicity, hematotoxicity, neurotoxicity
		RIVM	2001	0.02 mg/kg/ d	Hepatotoxicity
		OMS	1994	$DJT_{monochlorobenzène}$ = 85.7 µg/kg	Neoplastic nodules
n-propylbenzene (103-65-1)	Threshold	US EPA	2009	provisional RfD = 0.1 mg/kg/d	Hepato and nephrotoxicity of ethylbenzene
1,2,3 trichlorobenzene (CAS 97-61-6)	Threshold	RIVM	2001	8.10^{-3} mg/kg/d	Nephrotoxicity, hepatotoxicity and effect on thyroid
		OMS	1996	$7.7.10^{-3}$ mg/kg/d	
		Health Canada	1992	$1.5.10^{-3}$ mg/kg/d	
1,2,4 trichlorobenzene (120-82-1)	Threshold	RIVM	2001	8.10^{-3} mg/kg/d	Nephrotoxicity, hepatotoxicity and effect on thyroid
		Health Canada	1992	$1.6. 10^{-3}$ mg/kg/d	
		ATSDR	2014	0.1 mg/kg/d	Hepatotoxicity
		US EPA	1992	0.01 mg/kg/d	Endocrinology
		OEHHA	1999	10^{-3} mg/kg/d	Endocrinology
	No-Threshold	OEHHA	1999	$3.6.10^{-3}$ $(mg/kg/d)^{-1}$	Hepatocellular carcinoma
1,3,5 triméthylbenzene (108-67-8)	Threshold	US EPA	2016	0.01 mg/kg/d	Neurotoxicity

* Only one organism proposed a no-threshold TRV. However, this TRV is based on an inhalated route study that highlights nasal tumors in rats. The CES appraisal does not choose OEHHA ERU because the observed tumors by inhalation are local tumors.

- **pesticide TRVs**

Table 47 : Chronic oral TRVs for pesticides

Chemicals (CAS Number)	TRV	Organism	Year	Value	Targetted organ
Hexachlorobenzene	Threshold	US EPA	1988	8.10^{-4} mg/kg/d	Hepatotoxicity
		Health Canada	1992	500 ng/kg/d $= 5.10^{-4}$ mg/kg/d	
		OMS/IPCS	1997	0.17 µg/kg/d $= 1.7.10^{-4}$ mg/kg/d	
		RIVM	2001	5.10^{-4} mg/kg/d	
		ATSDR	2015	7.10^{-5} mg/kg/d	
	No-threshold	US EPA	1991	1.6 $(mg/kg/d)^{-1}$	Liver tumors
		Health Canada	1992	$DT_{0.05} = 0.06$ mg/kg/d $= 0.8$ $(mg/kg/d)^{-1}$	
		OMS-IPCS	1997	0.81 $(mg/kg\ bw/d)^{-1}$	
		OEHHA	2011	1.8 $(mg/kg/d)^{-1}$	
		RIVM	2001	$1.6.10^{-4}$ mg/kg/d for a 10^{-4} risk, meaning 0.625 $(mg/kg/d)^{-1}$	
Pentachloroaniline	Threshold	No TRV			
Quintozene	Threshold	US EPA	1987	3.10^{-3} mg/kg/d	Liver tumors
		JMPR	1995	0-0.01 mg/kg*	Endocrinology(thyroïd) Reprotoxicity
Quintozene + Pentachloroaniline	Threshold	European Commision	2000	10 µg/kg/d	Not indicated
Glyphosate	Threshold	US EPA	1987	0.1 mg/kg/d	Development toxicity / nephrotoxicity
		European Commision (Agritox)	2001	0.3 mg/kg/d	Digestive tract and urinary tract
		EFSA	2015	0.5 mg/kg/d	Development toxicity
Glyphosate + AMPA + N-acetyl-glyphosate + N-acetyl-AMPA N-acetyl-AMPA	Threshold	JMPR	2016	0-1 mg/kg	Salivary gland carcinogenicity

* quintozene with less than 0,1% of hexachlorobenzene

- **Formaldehyde TRV**

Tableau 48 : Chronic oral TRVs for formaldehyde

TRV	ORganism	Year	Value	Targetted organ/Criticla effect
Threshold	US EPA*	1990	0.2 mg/kg/d	Nephrotoxicity Gastrointestinal tract
	ATSDR	1999 and kept in 2010	0.2 mg/kg/d	Gastrointestinal tract
	Health Canada	2001	2.6 mg/L = 0.15 mg/kg/d	Gastrointestinal tract
	OMS/IPCS	2005	0.15 mg/kg/d	Stomach irritations and nephrotoxicity
No-threshold	OEHHA	2011	$2.1.10^{-2}$ $(mg/kg/d)^{-1}$ **	Nasal squamous cell carcinoma

* On-going re-assessment of the proposed RfD by US EPA-IRIS since 2014.

The oral route available data does not provide sufficient evidence of oral cancerogenic effects of formaldehyde (Anses, 2011).

- **PAH TRVs**

A TRV search was realized for the PAHs sum and BaP which is the reference compound. In fact, toxicity of few PAHs are really known. Some PAHs, especially the ones with a low molecular weight, induce non systemic non carcinogenic threshold effects (kidney, liver, heamatollogic essentially) for which TRVs have been set. Other PAHs, essentially the ones with high molecular weight, are carcinogenic and genotoxic.

The available TEF for tested PAHs in baby diapers are listed in table 17 using BaP as the reference compound.

Table 49 : Chronic oral TRVs for PAH and benzo[a]pyrene (BaP)

Chemicals (CAS Number)	TRV	Organism	Year	Value	Targetted organ
PAH Sum*	No-threshold	RIVM	1993	6.3 µg/kg/d for a risk of 10^{-4}, meaning 0.016 $(mg/kg/d)^{-1}$	Gastric tumors
Benzo[a]pyrene (50-32-8)	Threshold	US EPA	2017	3.10^{-4} mg/kg/d	Development toxicity
		OEHHA	2010	$1,7.10^{-3}$ mg/kg/d	Kidney toxicity
	No-threshold	RIVM	2001	5 $(µg/kg/d)^{-1}$ for a risk of 10^{-4}, meaning 0.02 $(mg/kg/d)^{-1}$	Multisites tumors
		OEHHA	2009	12 $(mg/kg/d)^{-1}$	Gastrointestinal tumors
		US EPA	2017	1 $(mg/kg/d)^{-1}$	Gastrointestinal tumors

* PAH Sum : acenaphtene, acenaphtylene, anthracene, benz[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[g,h,i]perylene, benzo[a]pyrene, chrysene, dibenz[a,h]anthracene, fluoranthene, fluorene, indéno[1,2,3-c,d]pyrene, naphtalene, phénanthrene, pyrene

- **Fragrance TRVs**

No available TRVs for: benzyl salicylate, hydroxyisohexyl 3-cyclohexene carboxaldehyde, butylphényl methylepropional and for l'alpha-isomethyle ionone. Available TRVs for other detected or quantified fragrances in baby diapers are listed below.

Table 50 : Available threshold TRVs for fragrances

Chemicals (CAS Number)	Benzyl alcohol (100-51-6)		Coumarin (91-64-5)		Limonene (5989-27-5)	Linalol (78-70-6)
Organism	OMS/FAO JECFA*	EFSA	BfR	EFSA	OMS/IPCS	OMS/FAO (JECFA)**
Year	1996 et 2001	2011	2006	2008	1998	1998
Value	0-5 mg/kg bw	ADI (groupe) ≤ 5 mg/kg/d	0.1 mg/kg	< 0.1 mg/kg	0.1 mg/kgd***	0-5 mg/kg bw
Targetted organ	No reprotoxic, teratogenic and carcinogenic effect	Value from JECFA	Hepatotoxicity		Hepatotoxicity	No effect

* Derived TRV for the whole derivated : benzyl (benzyl acetate, benzyl alcohol, benzaldehyde, benzoic acid, benzoate salts (calcium, potassium and sodium)
** TRV for : citral, geranyl acetate, citronellol, linalol and linalyl acetate
*** TRV evaluated by EFSA (2012) as protective taking into account liver effects like adaptative modifications.

- **Dioxin and furan TRVs (PCDD/F)**

  o **Table 51 : Chronic oral TRVs for dioxins and furans**

Chemicals	Organism	Year	Value	Targetted organ/ critical effect
Dioxins and DL compounds	OMS	2000	1 to 4 pg/kg/d	Reprotoxicity
Dioxins, furans and DL-PCB	SCF*	2001	14 pg/kg/week (2 pg/kg/d)	Reprotoxicity
	JECFA	2002	70 pg/kg bw/month 2.33 pg $_{TEQ}$/kg/d	Reprotoxicity
	EFSA	2012	SCF TRV	
PCDD/F	OEHHA	2011	$3.3.10^{-8}$ mg/kg/d = 33 pg/kg/d	Hepatotoxicity, reprotoxicite, ED, blood, respiratory, development effects,
	Health Canada	2010	$2,3.10^{-9}$ mg/kg/d = 2,3 pg/kg/d	
2,3,7,8 TCDD	Health Canada	1990	10 pg/kg/d	Reprotoxicity
	ATSDR	1998	1 pg/kg/d	Neurotoxicity
	OEHHA	2008	10 pg/kg/d	Hepatotoxicity
	Simon *et al.* reviewed by ITER	2009	1.10^{-7} mg/kg/d	Liver tumor
	RIVM	2009	2.10^{-9} mg $_{TEQ}$/kg/d	SCF et and JECFA TRV (provisional TRV)
	US EPA	2012	0.7 pg/kg/d	Reprotoxicity
2,3,4,7,8 PeCDF	ATSDR	1994	Intermediate MRL = 3.10^{-5} µg/kg/d	Hepatotoxicity
Furans	EFSA	2011	$BMD_{10}L_{ADJ}$: 0.96 mg/kg/d	Hepatocellular tumors

* Scientific Committee on Food

Two organims propose no-threshold TRVs for dioxins and furans (Table 55). However, JECFA considered in 2001, that dioxins, furans and DL-PCBs carcinogenic effects are not linked to mutagenic effect or to ADN liaisons and are observed for higher doses than for other toxic effects. So, JECFA concluded that a threshold exists for all the effects including the carcinogenic ones. Indeed, TCDD was not directly genotoxic and its carcinogenic activity is probably due to a long half-life (7.2 years), in particular in humans, causing an important activation of the Ah receptor (arylhydrocarbon receptor) (IARC, 2012).

So IARC concluded in a carcinogenic mechanism in humans mediated by a receptor. The main mechanism is the promotion of tumor development via the activation of cellular replication and the alteration of cellular senescence and apoptosis. IARC also considers a secondary mechanism related to the increase of oxidative stress resulting in DNA damage. In 2012, IARC also evaluated 1,3,4,7,8-PeCDF and PCB126 and also considered a receptor-mediated carcinogenesis mechanism based on carcinogenic effects observed in animals and extensive evidence identical activity with TCDD. IARC also concludes that the carcinogenic mechanism of TCDD is valid for all dioxins, furans and DL-PCBs.

On this basis, the CES expert appraisal considers dioxins and furans as threshold carcinogens.

Table 52: No threshold TRV for PCDD/F and DL-PCB

Chemicals (CAS Number)	US EPA	OEHHA
1,2,3,6,7,8 HxCDD (57653-85-7)	$6.2.10^3$ (mg/kg/d)$^{-1}$ LIver 1987	$1.3.10^4$ (mg/kg/d)$^{-1}$ Liver cancer 2011
1,2,3,7,8,9 HxCDD (19408-74-3)		$1,3.10^4$ (mg/kg/d)$^{-1}$ Liver cancer 2011
PCB	2 (mg/kg/d)$^{-1}$ Liver tumors 1996	2 (mg/kg/d)$^{-1}$ US EPA RfD, 1996

Annex 9: Available exposure equations in the literature

     o   **Table 53 : available exposures equations in published studies**

References	Equation	Parameters
De Vito and Schecter (2002)	$$DJE = \frac{Cd \times Md \times Nd \times Abs}{PC}$$ [worst case scenario]	Cd : Dioxin concentration in a diaper (TEQ pg/g) Md : Average weight of a diaper (kg) Nd : Number of diapers used per day Abs : skin absorbed fraction PC : Body weight (kg)
	$$DJE = \frac{\left(\frac{Cd \times Md}{Md \frac{Kp}{Ul}}\right) \times Nd \times Abs}{PC}$$ [only dioxins present in the urine are bioavailable and urine is in contact with the skin]	Cd : Dioxin concentration in a diaper (TEQ pg/g) Md : Average weight of a diaper (g) Nd : Number of diapers used per day Abs : skin absorbed fraction PC : Body weight (kg) Ul : Urinary load in a diaper (45 g/diaper) Kp : partition coefficient of TCDF paste-synthetic urine
Rai *et al.* (2009)*	(M x C x f x T) / S	M : Fragrance mass in a diaper (g/diaper) C : Fragrance concentration in a diaper (%) f : Frequency of use (Number of diapers used per day). T : Transfer of fluid to the skin from the internal parts of the TDCF paste-synthetic urine partition S : Exposed cutaneous surface (cm²) : 1186 cm² (smallest diaper)
Rai *et al.* (2009)* Dey *et al.* (2016a)*	(M x C x f x T x A) / BW	M : Raw material wieght in a diaper (g/diaper) C : Raw material concentration (ppm) f : Frequency of use (Number of diapers used per day). T : Transfer of the fluid to the skin from the inner parts of the layer A : Skin absorption BW : Body weight
Ishii *et al.* (2015)	(C x Md x Mig x Nd x Abs) / BW	C : Phthalate content in the topsheet (mg/g) Md : Topsheet weight (g) Mig : Eluted rate of phthalates into artifical sweat and artificial urine (%) Nd : Number of diapers used per day (/d) Abs : Transdermal absorption rate BW : Body weight of newborn
Krause *et al.* (2006)*	(Q x Ext x Tr x P x Freq)/BW	Q : Amount of substance in a product (mg) Ext : Soluble or extractable fraction Tr : transfer factor to the skin (%) P : Skin penetration factor Freq : Average frequency of use (number/day) PC : Baby Body weight

Annex 10: DED and risk calculation based on a worst case scenario

Table 54 : DED and risks calculation based on a worst case scenario for diapers shredded by solvent extraction (scenario 1)

Chemicals	Number of samples detected/quantified	Concentration (mg/kg)	DED (mg/kg/d)	TEF	DED Toxic equivalent (mg$_{TEQ}$/kg/d)	TRV (mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
VOC									
Naphtalene	Quantified in nine samples and detected in five samples	$7.00.10^{-2}$	$7.75.10^{-3}$			$2.00.10^{-2}$	0.4		
Styrene	Quantified in one refrence out of twelve	$4.61.10^{-2}$	$5.11.10^{-3}$			$1.20.10^{-1}$	4.2610^{-2}		
Toluene	Quantified in 15 references	$4.70.10^{-2}$	$5.21.10^{-3}$			$8.00.10^{-2}$	$6.51.10^{-2}$		
1.4-dichlorobenzene	Detected in one reference	10^{-3}	$1.11.10^{-4}$			$7.00.10^{-2}$	$1.58.10^{-3}$	$4.20.10^{-2}$	0.2
1.3-dichlorobenzène	Detected in one reference	10^{-3}	$1.11.10^{-4}$			$2.00.10^{-2}$	$5.54.10^{-3}$		
o-xylene + styrene	Quantified in eight samples and detected in two samples	$7.00.10^{-3}$	$7.75.10^{-4}$			$1.79.10^{-2}$	$4.33.10^{-2}$		
m-xylene + p-xylene	quantified in 10 samples and detected in four samples	$1.30.10^{-2}$	$1.44.10^{-3}$			$1.79.10^{-2}$	$8.04.10^{-2}$		
Chlorobenzene	Quantified in five samples and detected in eight samples	$1.40.10^{-2}$	$1.55.10^{-3}$			$2.00.10^{-2}$	$7.75.10^{-2}$		
n-propylbenzene	quantified in four samples out of 12	$5.03.10^{-2}$				**0.1**	$5.57.10^{-2}$		
1,2,3 trichlorobenzene	quantified in one sample out of 12	$2.5.10^{-1}$				$1.50.10^{-3}$	18.5		
1,2,4 trichlorobenzene	quantified in one sample out of 12	$6.93.10^{-1}$				$1.60.10^{-3}$	67.8		
1,3,5 triméthylbenzene	quantified in three samples out of 12	$1.20.10^{-1}$				10^{-2}	1.33		
Pesticides									
Hexachlorobenzene	Quantified in one sample	$2.00.10^{-3}$	$2.22.10^{-4}$			$7.00.10^{-5}$	3.16	1.80	$1.71.10^{-5}$
Quintozene	Quantified in three samples out of 12	$1.3.10^{-2}$	$1.44.10^{-3}$			$3.00.10^{-3}$	0.48		
Pentachloroaniline + quintozene	Quantified in three samples out of 12	$2.5.10^{-2}$	$2.77.10^{-3}$			10^{-2}	0.28		
Glyphosate	Quantified in one sample	$2.30.10^{-2}$	$2.55.10^{-3}$			0.1	$2.55.10^{-2}$		
AMPA + Glyphosate	Quantified in one sample	$6.60.10^{-2}$	$7.31.10^{-3}$			1	$7.31.10^{-3}$		
Dioxins and furans									
1,2,3,.6,7,8 HxCDD	Quantified in one sample	$1.32.10^{-7}$	$1.46.10^{-8}$	0.1	$1.46.10^{-9}$	2,3,7,8 TCDD : $7,00.10^{-10}$	2,09	Threshold carcinogen	
1,2,3,4,6,7,8 HpCDD	Quantified in 14sample	$1.03.10^{-6}$	$1.14.10^{-7}$	0.01	$1.14.10^{-9}$		1,63		
OCDD	Quantified in 17 sample	$2.15.10^{-6}$	$2.38.10^{-7}$	0.0003	$7.14.10^{-11}$		0.1		

1,2,3,6,7,8 HxCDF	Quantified in one sample	$4.42.10^{-8}$	$4.90.10^{-9}$	0.1	$4.90.10^{-10}$		0.7
2,3,4,6,7,8 HxCDF	Quantified in two samples	$1.07.10^{-7}$	$1.19.10^{-8}$	0.1	$1.19.10^{-9}$		1.69
1,2,3,4,6,7,8 HpCDF	Quantified in 14 samples	$1.54.10^{-6}$	$1.71.10^{-7}$	0.01	$1.71.10^{-9}$		2.44
1,2,3,4,7,8,9 HpCDF	Quantified in two samples	$2.62.10^{-7}$	$2.90.10^{-8}$	0.01	$2.90.10^{-10}$		0.42
OCDF	Quantified in six samples	$1.30.10^{-5}$	$1.44.10^{-6}$	0.0003	$4.33.10^{-10}$		0.62
Sum of dioxins and furans quantified (TEQ)	Quantified in 17 samples out of 19	$3.98.10^{-8}$			$4.41.10^{-9}$		6.30
Sum of DL-PCBs quantified (TEQ)	Quantified in 19 samples out of 19	$4.34.10^{-8}$			$4.81.10^{-9}$		6.87
Sum of dioxins, durans and DL-PCBs (TEQ)	Quantified in 19 samples out of 19	$5.94.10^{-8}$			$6.58.10^{-9}$		9.40
PCB 81	Quantified in six samples	$1.77.10^{-6}$	$1.96.10^{-7}$	0.0003	$5.88.10^{-11}$		$8.40.10^{-2}$
PCB 77	Quantified in 18 samples	$2.13.10^{-5}$	$2.36.10^{-6}$	0.0001	$2.36.10^{-10}$		0.34
PCB 123	Quantified in 19 samples	$1.17.10^{-5}$	$1.30.10^{-6}$	0.00003	$3.89.10^{-11}$		$5.55.10^{-2}$
PCB 118	Quantified in 19 samples	$7.59.10^{-4}$	$8.41.10^{-5}$	0.00003	$2.52.10^{-9}$		3.60
PCB 114	Quantified in 13 samples	$3.17.10^{-5}$	$3.51.10^{-6}$	0.00003	$1.05.10^{-10}$		0.15
PCB 105	Quantified in 19 samples	$4.31.10^{-4}$	$4.77.10^{-5}$	0.00003	$1.43.10^{-9}$		2.05
PCB 167	Quantified in seven samples	$3.88.10^{-5}$	$4.30.10^{-6}$	0.00003	$1.29.10^{-10}$		0.18
PCB 156	Quantified in 11 samples	$9.21.10^{-5}$	$1.02.10^{-5}$	0.00003	$3.06.10^{-10}$		0.44
PCB 157	Quantified in five samples	$2.80.10^{-5}$	$3.10.10^{-6}$	0.00003	$9.31.10^{-11}$		0.13
Fragrances							
Benzyl alcohol		50	5.54			5.54	1.11
Coumarine	Detected in one sample	50	5.54			0.1	55.4
Limonene		50	5.54			0.1	55.4
Linalol		50	5.54			5	1.11
Formaldehyde							
Formaldehyde	Quantified in 19 samples	37.4	4.14			0.15	27.6

○

Chemicals	Number of samples detected/quantified	Concentration (mg/kg)	DED (mg/kg/j)	Critical dose (mg/kg/j)	MOE	MOE ref	MOEref/MOE
VOC							
p-isopropyltoluene	Quantified in 14 samples and detected in 4 samples	$1.70.10^{-2}$	$1.88.10^{-3}$	**154**	$8.18.10^{4}$	100	$1.22.10^{-3}$
Fragrances							
Benzyl salicylate		50	5.54	50	65	100	1.54
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	Detected in one sample	50	5.54	15	2.71	300	111
butylphenyl méthylepropional		50	5.54	5.00	$9.03.10^{-1}$	100	111
alpha-isomethyle ionone		50	5.54	50	9.03	100	11.1

Table 55: DED and risks calculation based on a worst-case scenario for part of diapers shredded by solvent extraction (scenario 1)

Chemicals	Part of the diaper/ Number of samples detected/quantified	Concentration in the aprt of the diaper (mg/kg)	DED (mg/kg/d)	TEF	DED Toxic equivalent (mg$_{TEQ}$/kg/d)	TRV(mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
PAH									
Benzo[g,h,i]perylene	elastic part/detected in two samples	$1.00.10^{-01}$	$5.54.10^{-5}$	0.01	$5.54.10^{-7}$	BaP TRV $3.00.10^{-4}$	$1.85.10^{-03}$	BaP TRV : 12	$2.18.10^{-06}$
Benzo[b]fluoranthene	elastic part/detected in two samples	$1.00.10^{-01}$	$5.54.10^{-5}$	0.1	$5.54.10^{-6}$		$1.85.10^{-02}$		$2.18.10^{-05}$
Benzo[a]anthracene	elastic part/detected in one sample	$1.00.10^{-01}$	$5.54.10^{-5}$	0.1	$5.54.10^{-6}$		$1.85.10^{-02}$		$2.18.10^{-05}$
Indéno[1,2,3-c,d]pyrene	elastic part/quantified in one sample	1.20	$6.65.10^{-4}$	0.1	$6.65.10^{-5}$		0.22		$2.62.10^{-04}$
Dioxins/furans									
OCDF	Topsheet/ quantified in one sample	$7.08.10^{-6}$	$1.18.10^{-7}$	0.0003	$3.53.10^{-11}$	TRV of 2,3,7,8 TCDD : $7.00.10^{-10}$	$5.04.10^{-02}$	Threshold carcinogen	
	Aquisition layer/ quantified in one sample	$3.51.10^{-7}$	$1.56.10^{-9}$	0.0003	$4.67.10^{-13}$		$6.67.10^{-04}$		
	Other parts (except core and topsheet) / quantified in one sample	$2.59.10^{-6}$	$6.89.10^{-8}$	0.0003	$2.07.10^{-11}$		$2.95.10^{-02}$		
1,2,3,4,6,7,8 HpCDF	Other parts (except core and topsheet) / quantified in one sample	$1.93.10^{-7}$	$5.13.10^{-9}$	0.01	$5.13.10^{-11}$		$7.33.10^{-02}$		
1,2,3,4,6,7,8-HpCDD	Acquisition layer/ quantified in one sample	$6.09.10^{-7}$	$2.70.10^{-9}$	0.01	$2.70.10^{-11}$		$3.85.10^{-02}$		
OCDD	Acquisition layer / quantified in one sample	$2.69.10^{-6}$	$1.19.10^{-8}$	0.0003	$3.58.10^{-12}$		$5.11.10^{-03}$		
2,3,4,6,7,8 HxCDF	Topsheet/ quantified in one sample	$5.01.10^{-7}$	$8.32.10^{-9}$	0.1	$8.32.10^{-10}$		1.19		

Table 56 : DED and risks calculation based on a worst case scenario for diapers shredded by urine (1st 2017 SCLstudy) (scenario 2.1)

Chemicals	Number of samples detected or quantified (out of the 19 tested)	Concentration (mg/kg)	DED (mg/kg/j)	TEF	DED toxic equivalent (mg$_{TEQ}$/kg/d)	TRV (mg/kg/d)	HD	ERU (mg/kg/d)$^{-1}$	IER
					Dioxins and furans				
Sum of dioxins and furans quantified (TEQ)	Quantified in 19 diapers	$9.20.10^{-8}$			$1.02.10^{-8}$		14.6		
Sum of DL-PCBs quantified (TEQ)	Quantified in 19 diapers	$7.55.10^{-9}$			$8.36.10^{-10}$		1.19		
1,2,3,4,6,7,8 HpCDD	Quantified in 15 diaper	$2.42.10^{-6}$	$2.68.10^{-7}$	0.01	$2.68.10^{-9}$		3.83		
OCDD	Quantified in 16 diapers	$3.22.10^{-6}$	$3.57.10^{-7}$	0 .0003	$1.07.10^{-10}$		0.15		
2,3,7,8 TCDF	Quantified in one diaper	$1.04.10^{-7}$	$1.15.10^{-8}$	0.1	$1.15.10^{-9}$		1.65		
2,3,4,7,8 PeCDF	Quantified in one diaper	$2.61.10^{-7}$	$2.89.10^{-8}$	0.3	$8.67.10^{-9}$		12.4		
1,2,3,4,7,8 HxCDF	Quantified in two diapers	$1.12.10^{-7}$	$1.24.10^{-8}$	0.1	$1.24.10^{-9}$		1.77		
1,2,3,6,7,8 HxCDF	Quantified in one diaper	$5.49.10^{-8}$	$6.08.10^{-9}$	0.1	$6.08.10^{-10}$		0.87		
2,3,4,6,7,8 HxCDF	Quantified in one diaper	$4.64.10^{-8}$	$5.14.10^{-9}$	0.1	$5.14.10^{-10}$	TRV of 2,3,7,8 TCDD : 7.10^{-10}	0.73		Threshold carcinogen
1,2,3,4,6,7,8 HpCDF	Quantified in 16 diapers	$1.63.10^{-6}$	$1.81.10^{-7}$	0.01	$1.81.10^{-9}$		2.58		
1,2,3,4,7,8,9 HpCDF	Quantified in one diaper	$1.30.10^{-7}$	$1.44.10^{-8}$	0.01	$1.44.10^{-10}$		0.21		
OCDF	Quantified in 14 diapers	$2.10.10^{-5}$	$2.34.10^{-6}$	0.0003	$7.01.10^{-10}$		1		
PCB 77	Quantified in 10 diapers	$3.76.10^{-6}$	$4.16.10^{-7}$	0.0001	$4.16.10^{-11}$		$5.94.10^{-2}$		
PCB 123	Quantified in 12 diapers	$1.38.10^{-6}$	$1.52.10^{-7}$	0.00003	$4.57.10^{-12}$		$6.53.10^{-3}$		
PCB 118	quantified in 19 diapers	$1.43.10^{-4}$	$1.58.10^{-5}$	0.00003	$4.75.10^{-10}$		0.68		
PCB 114	Quantified in 7 diapers	$3.12.10^{-6}$	$3.5.10^{-7}$	0.00003	$1.05.10^{-11}$		$1.5.10^{-2}$		
PCB 105	quantified in 19 diapers	$5.41.10^{-5}$	7.10^{-6}	0.00003	2.10^{-10}		0.3		
PCB 167	Quantified in 6 diapers	$1.35.10^{-5}$	$1.49.10^{-6}$	0.00003	$4.47.10^{-11}$		$6.39.10^{-2}$		
PCB 156	Quantified in 11 diapers	$1.96.10^{-5}$	$2.18.10^{-6}$	0.00003	$6.53.10^{-11}$		$9.33.10^{-2}$		
PCB 157	Quantified in 5 diapers	$7.35.10^{-6}$	$8.14.10^{-7}$	0.00003	$2.44.10^{-11}$		$3.49.10^{-2}$		
PCB 189	Quantified in 3 diapers	$3.48.10^{-6}$	$3.86.10^{-7}$	0.00003	$1.16.10^{-11}$		$1.65.10^{-2}$		
Sum of dioxins + furans + DL-PCBs (TEQ)	Quantified in 19 diapers	$9.31.10^{-8}$			$1.03.10^{-8}$		14.7		

Table 57 : DED and risks calculation based on a worst case scenario for diapers by urine simulant (2nd SLC study) (scenario 2.2)

Chemicals	Number of samples detected or quantified (out of the 19 tested)	Concentration (mg/kg)	DED (mg/kg/j)	TEF	DED toxic equivalent (mg$_{TEQ}$/kg/d)	TRV (mg/kg/d)	HD	ERU (mg/kg/d)$^{-1}$	IER
Dioxins and furans									
Sum of dioxins and furans quantified (TEQ)	Quantified in 19 diapers	$8.84.10^{-9}$			$9.79.10^{-10}$		1,40		
Sum of DL PCB quantified (TEQ)	Quantified in 19 diapers	$6.36.10^{-8}$			$7.05.10^{-0}$		10,1		
1,3,6,7,8, Hx CDD	Quantified in 3 diapers	$5.50.10^{-9}$	$6.09.10^{-10}$	0.1	$6.09.10^{-11}$		$8,70.10^{-2}$		
1,2,3,4,6,7,8 HpCDD	Quantified in 19 diapers	$6.09.10^{-8}$	$6.74.10^{-9}$	0.01	$6.74.10^{-11}$		$9,63.10^{-2}$		
OCDD	Quantified in 18 diapers	$1.84.10^{-7}$	$2.04.10^{-8}$	0.0003	$6.13.10^{-12}$		$8,76.1^{0-3}$		
2,3,7,8 TCDF	Quantified in one diaper	$3.67.10^{-9}$	$4.06.10^{-10}$	0.1	$4.06.10^{-11}$		$5,80.10^{-2}$		
2,3,4,7,8 PeCDF	Quantified in six diapers	$1.54.10^{-8}$	$1.71.10^{-9}$	0.3	$5.12.10^{-10}$		0,731		
1,2,3,4,7,8 HxCDF	Quantified in one diaper	$4.40.10^{-9}$	$4.87.10^{-10}$	0.1	$4.87.10^{-11}$		$6,96.10^{-2}$		
1,2,3,6,7,8 HxCDF	Quantified in five diapers	$8.43.10^{-9}$	$9.34.10^{-10}$	0.1	$9.34.10^{-11}$		0,13		
2,3,4,6,7,8 HxCDF	Quantified in 10 diapers	$1.87.10^{-8}$	$2.07.10^{-9}$	0.1	$2.07.10^{-10}$		0,3		
1,2,3,4,6,7,8 HpCDF	Quantified in 16 diapers	$1.02.10^{-7}$	$1.13.10^{-8}$	0.01	$1.13.10^{-10}$		0,16		
1,2,3,4,7,8,9 HpCDF	Quantified in two diapers	$8.07.10^{-9}$	$8.94.10^{-10}$	0.01	$8.94.10^{-12}$		$1,28.10^{-2}$		
OCDF	Quantified in 18 diapers	$1.37.10^{-7}$	$1.52.10^{-0}$	0.0003	$4.56.10^{-12}$		$6,52.10^{-3}$		
PCB 81	Quantified in two diapers	$2.22.10^{-7}$	$2.46.10^{-8}$	0.0003	$7.37.10^{-12}$	TCDD TRV : $7.,10^{-10}$	$1,05.10^{-2}$		
PCB 126	Quantified in 3 diapers	$5.93.10^{-7}$	$6.57.10^{-8}$	0.1	$6.57.10^{-09}$		9,39		
PCB 77	Quantified in 10 diapers	$1.03.10^{-6}$	$1.14.10^{-7}$	0.0001	$1.14.10^{-11}$		$1,63.10^{-2}$		
PCB 123	Quantified in 12 diapers	$5.79.10^{-7}$	$6.42.10^{-8}$	0.0003	$1.93.10^{-12}$		$2,75.10^{-3}$		Threshold carcinogen
PCB 118	Quantified in 19 diapers	$7.22.10^{-5}$	$7.99.10^{-6}$	0.0003	$2.40.10^{-10}$		0,34		
PCB 114	Quantified in seven diapers	$2.29.10^{-6}$	$2.54.10^{-7}$	0.0003	$7.62.10^{-12}$		$1,09.10^{-2}$		
PCB 105	Quantified in 19 diapers	$2.93.10^{-5}$	$3.25.10^{-6}$	0.0003	$9.74.10^{-11}$		0,14		
PCB 167	Quantified in six diapers	$8.99.10^{-6}$	$9.96.10^{-7}$	0.0003	$2.99.10^{-11}$		$4,27.10^{-2}$		
PCB 156	Quantified in 11 diapers	$1.80.10^{-5}$	$1.99.10^{-6}$	0.0003	$5.98.10^{-11}$		$8,54.10^{-2}$		
PCB 157	Quantified in five diapers	$2.34.10^{-6}$	$2.59.10^{-7}$	0.0003	$7.78.10^{-12}$		$1,11.10^{-2}$		
PCB 169	Quantified in one diaper	$6.01.10^{-8}$	$6.66.10^{-9}$	0.03	$2.00.10^{-10}$		0,29		
PCB 189	Quantified in 3 diapers	$3.70.10^{-6}$	$4.09.10^{-7}$	0.0003	$1.23.10^{-11}$		$1,75.10^{-0}$		
Sum of dioxins + furans + DL-PCBs (TEQ)	Quantified in 19 diapers	$6.53.10^{-8}$			$7.24.10^{-9}$		10,3		

Chemicals	Number of samples detected or quantified (out of the 19 tested)	Concentration (mg/kg)	DED (mg/kg/j)	TEF	DED toxic equivalent (mg_{TEQ}/kg/d)	TRV (mg/kg/d)	HD	ERU (mg/kg/d)$^{-1}$	IER
Formaldehyde									
Formaldehyde	Quantified in 13 diapers	2.75	0.305				2.03	Threshold carcinogen	
PAH									
Cyclopenta[c,d]pyrene	Detected in one diaper	$6.2.10^{-1}$	$6.90.10^{-2}$	0.1	$6.90.10^{-3}$		23		$2.72E^{-2}$
Chrysene	Detected in one diaper	$4.99.10^{-1}$	$5.52.10^{-2}$	0.01	$5.52.10^{-4}$		1.84		$2.18E^{-3}$
5-méthylchrysene	Detected in one diaper	$6.23.10^{-1}$	$6.90.10^{-2}$	0.01	$6.90.10^{-4}$		2.30		$2.72E^{-3}$
Benzo[b]fluoranthene	Detected in five diapers	$7.62.10^{-1}$	$8.45.10^{-2}$	0.1	$8.45.10^{-3}$		28.2		$3.33E^{-2}$
Benzo[k]fluoranthene	Detected in one diaper	0.737	$8.16.10^{-2}$	0.1	$8.16.10^{-3}$	BaP TRV = 0,0003	27.2	12	$3.22E^{-2}$
Benzo[j]fluoranthene	Detected in one diaper	0.737	$8.16.10^{-2}$	0.1	$8.16.10^{-3}$		27.2		$3.22E^{-2}$
Benzo[e]pyrene	Detected in nine diapers	1.195	$1.32.10^{-1}$	0.01	$1.32.10^{-3}$		4.41		$5.22E^{-3}$
Benzo[a]pyrene	Detected in four diapers	0.81	$8.98.10^{-2}$	1	$8.98.10^{-2}$		299		0.354
Dibenzo[a,h]anthracene	Detected in one diaper	0.623	$6.90.10^{-2}$	1	$1.88.10^{-1}$		230		0.272
Benzo[g,h,i]perylene	Detected in five diapers	0.836	$9.26.10^{-2}$	0.01	$2.53.10^{-3}$		3.09		$3.65E^{-3}$

Annex 11: DED and risk calculation based on the results of Group'Hygien assays (2017) – CONFIDENTIAL

Annex 12: QRA result synthesis according to a worst-case scenario for various assays– CONFIDENTIAL

Annex 13: Detailed analysis of the TRVs for the refined approach and applicability to children

a. Hexachlorobenzene

Five organisations propose chronic oral TRVs for hexachlorobenzene: the US EPA (1988), Health Canada (1992), WHO-IPCS (1997), RIVM (2001) and ATSDR (2015).

The following TRVs were not used for the reasons given:
- Establishment of the TRV lacking in detail for RIVM,
- Addition of an uncertainty factor of 10 to take carcinogenicity into account for Health Canada,
- Addition of an uncertainty factor of 3 to take the severity of the effect into account for WHO-IPCS. WHO-IPCS justifies this choice, affirming that HCB causes multiple non-neoplastic effects in several species and a number of effects are observed (no NOAEL) at doses very close to the NOEL considered as the critical dose.

The key study chosen by the US EPA and ATSDR was that undertaken with two generations by Arnold *et al.* (1985). Sprague-Dawley rats of both sexes were fed diets containing doses of 0 – 0.32 – 1.6 – 8.0 – 40 ppm of hexachlorobenzene for up to 130 weeks. Hepatic effects were observed in the F1 rats. This study was interpreted differently by the two organisations. The US EPA considered a LOAEL of 8 ppm even though hepatic effects had been observed at lower doses in male F1 rats (significant increases ($p < 0.05$) in the incidence of periportal glycogen depletion at 1.6 ppm, peribiliary lymphocytosis at 0.32, 1.6 and 40 ppm, and peribiliary fibrosis at 0.32 and 40 ppm). According to the US EPA, these effects were not considered as hexachlorobenzene-induced adverse effects because they were observed in a large number of F1 control males as well.

Conversely, ATSDR used the lowest tested dose as the LOAEL, considering the statistically significant increases in the incidence of peribiliary lymphocytosis and fibrosis in the male F1 rats at doses of 0.32 ppm or higher. These effects were considered by ATSDR to represent a "minimal effect". Indeed, they involved spontaneous lesions in ageing rats and occurred in approximately 30% of the controls in this study. Increases in the incidence of peribiliary fibrosis (statistically significant in the 0.32 and 40 ppm groups) were observed in all the treated groups, with no dose-response relationship. As for peribiliary lymphocytosis, its incidence increased in all the treated groups (statistically significant in the 0.32, 1.6 and 40 ppm groups) with a statistically significant trend. Incidences of these lesions in the control and treated females were similar to those in the control males, suggesting that the incidence levels in the control males were not unusually low. ATSDR concluded that these findings suggested that hexachlorobenzene produced a "minimal" hepatic effect in male rats at the lowest doses administered by increasing the incidence of age-related hepatic lesions.

The CES adopted ATSDR's TRV since it was a recent TRV whose establishment was well argued.

The available human data suggest that infants and young children are at increased risk from exposure to hexachlorobenzene compared to adults (Cripps *et al.*, 1984; Gocmen *et al.*, 1989; Peters *et al.*, 1982, 1987 cited in ATSDR, 2015). Studies were conducted in Turkey for 25 to 30 years in a population orally exposed to very high levels of hexachlorobenzene added as a fungicide to wheat seedlings. They reported 95% mortality in the exposed infants (under two years of age) associated with dermal lesions. Children (between the ages of six and 15 years) exhibited health effects (including 10% mortality and dermal lesions) more frequently than adults (Cripps *et al.*, 1984; Gocmen *et al.*, 1989; Peters *et al.*, 1982, 1987 cited in ATSDR, 2015). Other studies focusing on children's health found suggestive evidence of neurological and immunological effects, but did not assess exposure (Belles-Isles *et al.,* 2000; Darvill *et al.*, 2000; Dewailly *et al.*, 2000; Hosie *et al.*, 2000; Sala *et al.*, 1999 cited in ATSDR, 2015). Although immunological effects had been seen in humans exposed as adults (Richter *et al.*, 1994; Queiroz *et al.*, 1997, 1998a and b cited in ATSDR, 2015), neurological effects had not, suggesting that children may be more susceptible than adults to the neurotoxicity of hexachlorobenzene.

These studies were taken into account by ATSDR in its establishment of the TRV in 2015. **Thus, the selected TRV is considered applicable to children between the ages of zero and three years.**

Five organisations have proposed no-threshold TRVs: the US EPA (1992), Health Canada (1992), WHO-IPCS (1997), RIVM (2001) and OEHHA (2011). These TRVs were based on liver tumours. Only OEHHA considered, in addition to liver tumours, adrenal pheochromocytoma in rats.

The CES adopted OEHHA's ERU since it was established in a transparent manner, on the basis of several studies describing liver tumours in several species.

Table 58 : Chronic oral threshold chronic TRV for hexachlorobenzene

Type of TRV	threshold TRV				
Organism	ATSDR	RIVM	OMS-IPCS	Health Canada	US EPA
year	2015	1991 taken over in 2001	1997	1992	1988
TRV name	MRL chronic	DJA	TDI	DJA	RfD
TRV value	7.10^{-5} mg/kg/d	5.10^{-4} mg/kg/d	$1.7.10^{-4}$ mg/kg/d	5.10^{-5} ng/kg/d	8.10^{-4} mg/kg/d
critical effect	Hepatotoxicity (lymphocytosis and peribiliary fibrosis in F1 ♂)	Hepatotoxicity(ultrastructural modifications of the liver)	Hepatotoxicity*	Hepatotoxicity*	Hepatotoxicity (basophilic centrilobular hepatic basophilic chromogenesis in F1)
Species	Sprague Dawley rats	Rats	1. Pigs 2. and 3. Rats	1. Pigs and 3. Rats	Sprague Dawley rats
Exposure time	F0 : 90 days before mating to 21 days after birth (=weaning) ; F1 : from weaning to 130 weeks	3, 6 or12 months	1. 90 days 2. F0 : 90 days before mating to 21 days after birth(=weaning) ; F1 : to weaning to 130 weeks 3-12 months	1. 90 days 2. F0 : 90 days before mating to 21 days after birth (=weaning) ; F1 : to weaning to 130 weeks 3. 3, 6 or 12 months	F0 : 90 days before mating to 21 days after birth (=weaning) ; F1 : to weaning
Exposure route	Oral (diet)	Oral (diet)	Oral (diet)	Oral (diet)	Oral (diet)
Critical dose	LOAEL = 0.022 mg/kg/d = 0,32 ppm	NOAEL = 0/05 mg/kg pc/d	NOEL = 0.05 mg/kg pc/d	NOEL = 0.05 mg/kg pc/d	NOAEL = 0.08 mg/kg/d = 1,6 ppm LOAEL = 0.29 mg/kg/d = 8 ppm
Adjustement	/	/	/	/	/
UF	300 UF_A = 10, UF_H = 10, UF_L = 3	100	300 UF_A = 10, UF_H = 10, $UF_{effect\ severity}$ = 3	1000 UF_A = 10, UF_H = 10, UF ~~carcinogenic proof~~ = 10	100 UF_A = 10, UF_H = 10
Key study	Arnold *et al.* (1985)	Mollenhauer *et al.* (1975, 1976)	1. Den Tonkelaar *et al.* (1978) 2. Arnold *et al.* (1985) 3. Mollenhauer *et al.* (1975, 1976)	1. Den Tonkelaar *et al.* (1978) 2. Arnold *et al.* (1985) 3. Mollenhauer *et al.* (1975, 1976)	Arnold *et al.* (1985)

* Mollenhauer *et al.* (1975, 1976) : ultra-structural changes in the liver (SER proliferation, changes in mitochondria, ↑ number of storage vesicles) in rats exposed chronically; Arnold *et al.* (1985) : ↑ organ weight (heart, brain and livre) in F0 males, histological changes related to liver compounds in both sexes of F1 rats exposed chronically, Den Tonkelaar *et al.* (1978) : ↑ urinary coproporphyrin activity and liver microsomal enzymes in pigs exposed subchronically

Tableau 59 : No threshold TRV for hexachlorobenzene

Type of TRV	no threshold TRV				
Organism	OEHHA	RIVM	OMS-IPCS	Health Canada	US EPA
year	2011	2001	1997	1992	1991
TRV name	Slope factor	TDI	TD_5*	$DT_{0,05}$	ERU
TRV value	1.8 $(mg/kg/d)^{-1}$	$1.6.10^{-4}$ mg/kg/d for a risk of10^{-4}, meaning 0,625 $(mg/kg/d)^{-1}$	0,81 mg/kg pc/d	0,06 mg/kg/d meaning 0,8 $(mg/kg/d)^{-1}$	1,6 $(mg/kg/d)^{-1}$
critical effect	Liver tumors (hepatomas in hamsters and rats, hepatocellular carcinomas in female rats) and adrenal pheochromocytomas in rats	Liver tumors (hepatocellular carcinonas, neoplastic hepatic nodules)	Neoplastic hepatic nodules in females	Liver tumors hépatiques (neoplastic hepatic nodules in females)	Liver tumors (hepatocellular carcinomas)
Species	1. Syrian golden hamsters 2. et 3. Sprague Dawley rats	Rats	Rats	Sprague Dawley rats	Sprague Dawley rats
Exposure time	1. entire lifetime 2. 2 years 3. F0 : 90 daysbefore mating to 21 days after birth (=weaning) ; F1 : from weaning to 130 weeks	1. 2 years 2. F0 : 90 daysbefore mating to 21 days after birth (=weaning) ; F1 : from weaning to 130 weeks	2 generations. Exposure up to30 weeks post utero	F0 : daysbefore mating to 21 days after birth (=weaning) ; F1 : from weaning to 130 weeks	2 years
Exposure route	Oral (diet)				
Critical dose	LMS modeling Allometric adjustement $(weight_{Human}/weight_{animal})^{1/3}$	1. NOAEL = 5 mg/kg pc/d 2. LOAEL = 0,08 mg/kg pc/d; NOAEL = 0,016 mg/kg pc/d	TD_5 = 0,81 mg/kg pc/d (multi-stage model)	multi-stage model	LOAEL = 75 ppm Allmoetric adustement : $LOAEL_{HED}$ = 0.73 mg/kg/d Linearized multi-stage model
Adjustement	1. et 2. Slope factor = 1.7 $(mg/kg/d)^{-1}$ 3. Slope factor = 1.8 $(mg/kg/d)^{-1}$	Extrapolation linéaire à l'origine	/		
UF			5000 (mode of'action insufficiently known)		
Key study	1. Cabral *et al.* (1977) 2. Lambrecht *et al.* (1983a, b, Ertürk *et al.* (1986) 3. Arnold *et al.* (1985)	1. Ertürk *et al.*, (1986) 2. Arnold *et al.* (1985) et Arnold et Krewski (1988)	Crump & Howe, 1982	Arnold *et al.* (1985)	Ertürk *et al.* (1986)

* dose associated with an exces of 5% tumor incidence

a. Dioxins, furans and DL-PCBs

Several organisations propose no-threshold TRVs for dioxins and furans. However, in 2001, JECFA considered that carcinogenicity due to dioxins, furans and DL-PCBs was not related to mutagenicity or DNA binding, and it occurred at higher doses than other toxic effects. Thus, JECFA concluded that there was a threshold for all effects, including carcinogenic effects.

Indeed, TCDD is not directly genotoxic and its carcinogenic activity is likely to be due to a relatively long half-life (7.2 years), especially in humans, resulting in sustained activation of the aryl hydrocarbon (Ah) receptor (IARC, 2012). Thus, IARC concluded there was evidence of a receptor-mediated mechanism for carcinogenesis in humans. The primary mechanism is the promotion of tumour development through the activation of cellular replication and the alteration of cellular senescence and apoptosis. IARC also considered a secondary mechanism related to increases in oxidative stress causing DNA damage. In 2012, IARC also assessed 1,3,4,7,8-PeCDF and PCB-126 and also considered a receptor-mediated mechanism of action for carcinogenesis on the basis of carcinogenic effects observed in animals and extensive evidence showing activity identical to TCDD. IARC also concluded that the mechanism of carcinogenicity for TCDD was valid for all dioxins, furans and DL-PCBs.

On this basis, the CES considered dioxins and furans as carcinogens with a threshold. Therefore, only chronic threshold TRVs were identified.

Ten organisations and one publication propose chronic threshold TRVs for dioxins and dioxin-like (DL) compounds, for dioxins, furans and DL-PCBs, or only for the leader for this class, 2,3,7,8-TCDD. All of the TRVs, except that of the US EPA, were based on animal studies. According to ANSES's method of establishing TRVs (ANSES, 2017a), epidemiological data should be favoured over animal data. **The CES adopted the US EPA's TRV since it was recent, described clearly and transparently, and established based on epidemiological studies.**

The US EPA's TRV covers long-term effects on spermatogenesis linked to exposure from childhood and neonatal disruptions in thyroid function related to maternal exposure (ANSES, 2016a). **This TRV is considered applicable to children between the ages of zero and three years.**

Table 60: Chronic oral threshold chronic TRV for dioxins, furans and DL-PCBs

Type of TRV	Health Canada	ATSDR	OMS	SCF		JECFA		OEHHA	Simon et al., reviewed byITER	RIVM	EFSA	US EPA	
Organism	1990	1998	2000	2001		2002		2008	2009	2009	2012	2012	
year	TCDD	TCDD	Dioxins and DL compounds	Dioxins, furans and DL-PCBs				TCDD	TCDD	TCDD	Dioxins, furans and DL-PCBs	TCDD	
TRV name	ADI	MRL	TDI	DHT		DMTP		REL	TRV	provisionnal TRV	SCF TRV	RfC	
TRV value	10 pg/kg/d	1 pg/kg/d	1 to 4 pg/kg/d	14 pg/kg/ week (2 pg/kg/d)		70 pg/kg/months 2,33 pg TEQ/kg/d		10 pg/kg/d	10^{-7} mg/kg/d	2.10^{-9} mg TEQ/kg/d		0.7 pg/kg/d	
critical effect	Reproduction (fertility, litter size, fetal resorption, organs function)	Altered social behaviour in young	Rats, in the offsprings : ↓ sperm count, immunosuppression, ↑ genital malformations. monkeys: endométriosis or neurobiologic effects (learning of the object) in the offspring	Reprotoxicity (↓ anogenital distance in males pups)	Reprotoxicity (↓ sperm production and altered sexual behaviour in males pups)	Effects on the male reproductive system		↑ plasma levels of alkaline phosphatase, γGT and ALAT, histopathological changes in the liver	Hepatocellular aAdenomas and cholangiocarcinomas	SCF TRV and JECFA TRV		↓ concentration and sperm mobility in human	↑ TSH in newborns exposed *in utero*
Species	SD Rats	Rhesus monkeys	Rats and monkeys	Holzman rats	Wistar rats	Wistar rats	Holtzman rats	SD Rats	Females SD rats			Human	
Exposure time	3 geeérations	During mating, gestation and lactation	*In utero* Perinatal or 4 years	Single exposure at GD15	Before and during mating, gestation and lactation	Before and during mating, gestation and lactation	Single xposure at GD15	Chronic(2 years)				Chronic (Seveso industrial accident)	
Exposure route	Oral	Oral	Oral	Oral (gavage)	SC	SC	Oral	Oral	Oral(gavage)			Oral	

Critical dose	NOAEL = 1 ng/kg/d	LOAEL = 2.10^{-4} µg/kg pc/d	LOAEL = 28–73 ng/kg pc/d	NOAEL = 25 ng/kg NOAEL (equilibrium body burden in mothers at GD16) = 20 ng/kg	LOAEL = 12.5 ng/kg LOAEL (equilibrium body burden in mothers at GD15) = 40 ng/kg	LOEL = 25 ng/kg pc/d	NOEL = 13 ng/kg pc/d	NOAEL = 1 ng/kg pc/d LOAEL = 10 ng/kg pc/d	PBPK modeling to express the dose in average hepatic concentration over the entire lifetime (LALC) BMD_{01} = $2,.1.10^{-3}$ mg/kg LALC			LOAEL = 68 ppt (maternal serum TCDD concentration adjusted on lipids)	LOAEL = 235 ppt (maternal serum TCDD concentration adjusted on lipids during during)
Adjustement	Not specified	No adjustement	Allometric adjustement $LOAEL_{HED}$ = 14-37 pg/kg pc/d	Allometric adjustement $NOAEL_{HED}$ = 10 pg/kg /d	Allometric adjustement $LOAEL_{HED}$ = 20 pg/kg/d	Allometric adjustement $LOEL_{HED}$ = 630 pg/kg pc/d	Allometric adjustement $NOEL_{HED}$ = 330 pg/kg pc/d	No adjustement	Allometric adjustement $BMD_{01\ HED}$ = $1,3.10^{-6}$ mg/kg/d			$LOAEL_{ADJ}$ (PBPK) = 0,02 ng/kg pc/j	
UF	**100** UF_A = 1 UF_H = 10 UF_D = 10	**100** UF_A = 3 UF_H = 10 UF_H = 3	**10**	**3,2** UF_A = 1 UF_{H-TK} = 3,2 UF_{H-TD} = 1	9,**6** UF_A = 1 UF_{H-TK} = 3,2 UF_{H-TD} = 1 UF_L = 3	**9,6** UF_H = 3,2 UH_L = 3	**3,2** UF_H = 3,2	**100** UF_A = 10 UF_H = 10	**100** UF_{A-TD} = 0,1 UF_H = 10			**30** UF_H = 3 UF_L = 10	
Key study	Murray *et al.* (1979)	Schantz *et al.* (1992)	Leeuwen *et al.* (2000)	Ohsako *et al.* (2001)	Faqi *et al.* (1998)	Faqi *et al.* (1998)	Ohsako *et al.* (2001)	Kociba *et al.* (1978)	NTP (2006)			Mocarelli *et al.* (2008)	Baccarelli *et al.* (2008)

a. PAHs

Only the toxicity of a limited number of PAHs is currently known. Some PAHs, primarily those with a low molecular weight, induce systemic non-carcinogenic threshold effects (mainly kidney, liver and blood disorders) for which TRVs have been established. Other PAHs, in particular those with a high molecular weight, appear to be carcinogenic and genotoxic. Benzo[a]pyrene (BaP) was considered as a marker of PAH exposure and effects (WHO-IPCS, 1998[35]).

Two organisations propose chronic threshold TRVs for BaP: the US EPA (2017) and OEHHA (2010).

Tableau 61 : Chronic oral threshold chronic TRV for benzo[a]pyrene

Organism	US EPA	OEHHA
year	2017	2010
TRV name	RfD	Value in drinking water
TRV value	3.10^{-4} mg/kg/d	$1{,}7.10^{-3}$ mg/kg/d
critical effect	Developmental toxicity (neurobehavior changes)	Tubular kidney toxicity
Species	Sprague-Dawley rats	F344 rats
Exposure time	PND5-11	90 days
Exposure route	Oral (gavage)	Oral (diet)
Critical dose	BMD = 0.21 mg/kg/d $BMDL_{1sd}$ = 0.092 mg/kg/d	LOAEL = 5 mg/kg/d
Adjustement	Allometric adjustement $BMDL_{1sd\ AJD\ HED}$ = 0.092 mg/kg/d	/
UF	300 UF_A = 10 UF_H = 10 UF_D = 3	3000 UF_A = 10 UF_H = 10 UF_L x UF_S = 30
Key study	Chen *et al.* (2012)	Knuckles *et al.* (2001)

The US EPA selected three types of effects observed in orally exposed animals to represent the critical effect: developmental toxicity (neurobehavioural changes and cardiovascular effects in rats and mice), reprotoxicity (decreased sperm counts, ovary weight and follicle numbers) and immunotoxicity (decreased immunoglobin and B-cell numbers and thymus weight in adult animals). In humans, although BaP exposure occurs in conjunction with other PAHs, some studies have reported developmental, neurobehavioural, reproductive and immune effects that were generally similar to those observed in animals. The US EPA derived candidate RfDs for each of these effects.

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[35] WHO-IPCS. (1998). Polycyclic aromatic hydrocarbons. Environmental Health Criteria; 202. Geneva.

Table 62 : candidates RfD proposed by US EPA (2017)

Endpoint and reference	POD$_{HED}$ (mg/kg-d)	POD type	UF$_L$	UF$_S$	UF$_A$	UF$_H$	UF$_D$	Composite UF	Candidate value (mg/kg-d)
Developmental									
Neurobehavioral changes in rats Chen et al. (2012)	0.092	BMDL$_{1SD}$	1	1	10	10	3	300	3×10^{-4}
Cardiovascular effects in rats Jules et al. (2012)	0.15	LOAEL	10	1	3	10	3	1,000	2×10^{-4}
Reproductive									
Decreased ovary weight in rats Xu et al. (2010)	0.37	BMDL$_{1SD}$	1	10	3	10	3	1,000	4×10^{-4}
Decreased ovarian follicles in rats Xu et al. (2010)	0.38	BMDL$_{10RD}$	1	10	3	10	3	1,000	4×10^{-4}
Decreased intratesticular testosterone in rats Zheng et al. (2010)	0.24	NOAEL	1	10	3	10	3	1,000	2×10^{-4}
Decreased sperm count and motility in mice Mohamed et al. (2010)	0.15	LOAEL	10	10	3	10	3	10,000	Not calculated due to UF >3,000[a]
Cervical epithelial hyperplasia in mice Gao et al. (2011)	0.06	BMDL$_{10}$	1	10	3	10	3	1,000	6×10^{-5}
Immunological									
Decreased thymus weight in rats Kroese et al. (2001)	1.9	BMDL$_{1SD}$	1	10	3	10	3	1,000	2×10^{-3}
Decreased serum IgM in rats De Jong et al. (1999)	1.7	NOAEL	1	10	3	10	3	1,000	2×10^{-3}
Decreased serum IgA in rats De Jong et al. (1999)	5.2	NOAEL	1	10	3	10	3	1,000	5×10^{-3}
Decreased number of B cells in rats De Jong et al. (1999)	5.2	NOAEL	1	10	3	10	3	1,000	5×10^{-3}

[a]As recommended in EPA's *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002), the derivation of a reference value that involves application of the full 10-fold UF in four or more areas of extrapolation should be avoided.

It then selected an RfD for each type of effect. These RfDs can be useful for cumulative risk assessments that consider the combined effect of multiple substances acting at the same site.

For underlined developmental effects, the US EPA did not use the lowest candidate RfD, based on cardiovascular malformations, since only one *in vivo* study in rodents had reported such effects. The US EPA selected the RfD based on neurobehavioural effects in rats (Chen *et al.*, 2012) since several *in vivo* studies in rats and mice had shown behavioural effects, a low uncertainty factor was applied, and it was based on several neurobehavioural parameters.

For underlined reproductive effects, the following candidate RfDs were not selected since:
- Only one study reported cervical effects as opposed to other reproductive effects that were confirmed by multiple studies.
- The uncertainty factor used to derive the candidate RfD based on decreased sperm counts and motility was too high (Mohamed *et al.*, 2010).
- The study used to derive the candidate RfD based on decreases in testosterone (Zheng *et al.*, 2010) did not observe a dose-response relationship.

Thus, the US EPA selected the candidate RfD established based on the study by Xu *et al.* (2010) reporting decreases in ovary weight and in the number of primordial follicles. Ovarian effects were supported by an extensive database of animal and human studies.

Regarding <u>immunotoxic effects</u>, the US EPA selected the candidate RfDs based on decreased thymus weight (Kroese *et al.*, 2001) and serum IgM levels in rats (De Jong *et al.,* 1999) since their values were comparable to the other candidate RfDs and provided the most sensitive point of departure.

Table 63 : RfD for developmetal effects, reprotoxocity and immunotoxicity

Effect	Basis	RfD (mg/kg-d)	Confidence
Developmental	Neurobehavioral changes Gavage neurodevelopmental study in rats (postnatal days [PNDs] 5–11) <u>Chen et al. (2012)</u>	3×10^{-4}	Medium
Reproductive	Decreased ovarian follicles and ovary weight Gavage subchronic (60 d) reproductive toxicity study in rats <u>Xu et al. (2010)</u>	4×10^{-4}	Medium
Immunological	Decreased thymus weight and serum IgM Gavage subchronic (35 d) study in rats <u>De Jong et al. (1999)</u> and <u>Kroese et al. (2001)</u>	2×10^{-3}	Low
Overall RfD	**Developmental toxicity (including developmental neurotoxicity)**	3×10^{-4}	**Medium**

In the end, the US EPA selected the lowest RfD with the highest confidence level, i.e. the RfD based on developmental effects and more specifically neurobehavioural changes persisting into adulthood observed in the study by Chen *et al.* (2012). Altered responses in three behavioural tests (Morris water maze, elevated plus maze, and open field tests) showed behavioural changes, which were selected to represent the critical effect due to the observation of a dose-response relationship and the consistency of the responses. Indeed, each response was altered in two separate cohorts of rats, including in juveniles and adults. Similar changes in these behavioural tests were observed across several studies.

In the study by Chen *et al.* (2012), rats were exposed at the start of the postnatal period (PNDs 5-11) corresponding to the period of brain development in rats. In humans, this period would correspond to brain development occurring in the third trimester of pregnancy. The mode of action for BaP-induced developmental neurotoxicity is not fully understood, and thus the exact window of susceptibility or the duration of exposure necessary to trigger adverse effects in humans cannot be determined with the data currently available.

BaP has other effects (toxic hepatic, renal, cardiovascular and nervous system effects in adult animals) but these were not selected by the US EPA since they had less robust evidence of hazard from the available subchronic and chronic studies. OEHHA selected renal toxicity as the critical effect since it was the effect occurring at the lowest dose in a subchronic study. However, few subchronic or chronic studies on renal effects are available. Confidence in the only subchronic study observing an increase in kidney lesions (only one sex) (Knuckles *et al.*, 2001) was decreased by incomplete reporting of the methods and results. Thus, the US EPA considered it was not possible to draw any conclusions as to renal toxicity.

The CES adopted the US EPA's TRV (2017). Although the selected key study was a study undertaken with an exposure period of a few days, the observed effect persisted into adulthood. In addition, this TRV protects against other effects (reprotoxicity, immunotoxicity) observed in subchronic and chronic studies. This TRV is considered applicable to children between the ages of zero and three years.

Three organisations have proposed no-threshold TRVs: RIVM (2001), OEHHA (1993 revised in 2009 and 2010) and the US EPA (2017). RIVM proposed a virtually safe dose (VSD) of 5 ng $_{TEQ}$/kg bw/day for a risk of 10^{-6} established based on tumour development in several organs (the liver and forestomach in particular) observed during a study undertaken in rats exposed to BaP by gavage for two years.

OEHHA proposed two excess risk per unit values: one in 1993 revised in 2009 and one in 2010 as part of a report on BaP in drinking water. In the latter, OEHHA considered the key study, selected in 1993 (Neal and Rigdon, 1967), to be of poor quality (combined groups of males and females were employed, the number of animals in each group was variable, BaP administration began at different ages, and treatment occurred for different time intervals). A more recent study, by Culp *et al.* (1998), was selected as the key study by OEHAA and the US EPA. OEHHA applied a traditional establishment method based on a study whereas the US EPA established several candidate TRVs:

Tableau 64 : no threshold TRVproposed by US EPA

Tumor	Species/ sex	Selected model	BMR	BMD (mg/kg-d)	POD = BMDL (mg/kg-d)	Slope factor[a] (mg/kg-d)$^{-1}$	
Forestomach, oral cavity: squamous cell tumors Kroese et al. (2001)	Male Wistar rats	Multistage Weibull	10%	0.453	0.281	0.36	
Hepatocellular adenomas or carcinomas Kroese et al. (2001)	Male Wistar rats	Multistage Weibull	10%	0.651	0.449	0.22	
Jejunum/duodenum adenocarcinomas Kroese et al. (2001)	Male Wistar rats	Multistage Weibull	10%	3.03	2.38	0.042	
Kidney: urothelial carcinomas Kroese et al. (2001)	Male Wistar rats	Multistage Weibull	10%	4.65	2.50	0.040	0.5[b]

Tumor	Species/ sex	Selected model	BMR	BMD (mg/kg-d)	POD = BMDL (mg/kg-d)	Slope factor[a] (mg/kg-d)⁻¹	
Skin, mammary: Basal cell tumors Squamous cell tumors Kroese et al. (2001)	Male Wistar rats	Multistage Weibull	10%	2.86 2.64	2.35 1.77	0.043 0.056	
Forestomach, oral cavity: squamous cell tumors Kroese et al. (2001)	Female Wistar rats	Multistage Weibull	10%	0.539	0.328	0.3	0.31[b]
Hepatocellular adenomas or carcinomas Kroese et al. (2001)	Female Wistar rats	Multistage Weibull	10%	0.575	0.507	0.2	
Jejunum/duodenum adenocarcinomas Kroese et al. (2001)	Female Wistar rats	Multistage Weibull	10%	3.43	1.95	0.05	
Forestomach, esophagus, tongue, larynx (alimentary tract): squamous cell tumors Beland and Culp (1998)	Female B6C3F₁ mice	Multistage Weibull	10%	0.127	0.071	1.4	1.4

[a]Human equivalent slope factor = $0.1/BMDL_{10HED}$; see Appendix E of the Supplemental Information for details of modeling results.
[b]Slope factor characterizing the risk of incurring at least one of the tumor types listed.

The CES adopted the US EPA's TRV since it was established in accordance with high quality standards and took into account a set of consistent studies. This TRV is considered applicable to children between the ages of zero and three years.

Tableau 65 : No threshold TRV for BaP

Organism	RIVM	OEHHA		US EPA
year	2001	1993 taken over in 2009	2010	2017
TRV name	VSD (virtually safe dose)	Oral slope factor	Oral slope factor	Oral slope factor
TRV value	5 $(ng/kg/d)^{-1}$ for a risk of 10^{-6}, meaning 0,2 $(mg/kg/d)^{-1}$	12 $(mg/kg/d)^{-1}$	2,9 $(mg/kg/d)^{-1}$	1 $(mg/kg/d)^{-1}$
critical effect	Multi-site tumors (mainly liver adn pre-stomach)	Gastrointestinal tumors (papillomas and squamous cell carcinomas)	Gastrointestinal tumors (pre-stomach, tongue, œsophagus)	Gastrointestinal tumors (pre-stomach, œsophagus, tongue and larynx)
Species	Wistar rats	CFW mouse	B6C3F1 mouse	
Exposure time	2 years, 5 d/week	110 days	2 years	
Exposure route	Oral (gavage)	Oral (diet)	Oral (diet)	
Critical dose	LOAEL = 10 mg/kg pc/d	Linear extrapolation at the origin	$BMD_{10}L_{95}$= 0,059 mg/kg/d q1* = 1,7 $(mg/kg/d)^{-1}$ ASAF** : q1* x 1,7 = 2,9 $(mg/kg/d)^{-1}$	Temporal and allometric adjustement then BMD calculation $BMD_{10\ HED}$ = 0,127 $BMDL_{10\ HED}$ = 0,071 mg/kg/d Linear extrapolation at the origine (multi stage model) + ADAF*** : 0,002 mg/kg/d
Adjustement				
UF	Calculation of VSD for each tumors (liver, pre-stomach, benign and malignant tumors or only malignant tuors and all combined tumors) = 5-19 ng/kg pc/d			
Key study	Kroese *et al.* (2001) supportée par Culp *et al.* (1998)	Neal et Rigdon, 1967	Culp *et al.* (1998)	Culp *et al.* (1998)

* HAP sum: acenaphtene, acenaphtylene, anthracene, benz[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[g,h,i]perylene, benzo[a]pyrene, chrysene, dibenz[a,h]anthracene, fluoranthene, fluorene, indeno[1,2,3-c,d]pyrene, naphthalene, phenanthrene, pyrene
***ADAF : Age-Dependent Adjustment Factors, ** ASF : Age Sensitivity Factor

a. Formaldehyde

Four organisations propose chronic threshold TRVs based on the same critical effect, the same key study and the same uncertainty factors: the US EPA (1990), Health Canada (2001), WHO/IPCS (2005) and ATSDR (2010).
In the study by Til *et al*., rats were exposed to formaldehyde for two years via drinking water. The males were exposed to 0, 1.2, 15 or 82 mg/kg/day and the females to 0, 1.8, 21 or 109 mg/kg/day. At 82 mg/kg/day for the males, histological changes in the forestomach (hyperplasia, hyperkeratosis, ulceration, chronic gastritis) and renal necrosis were observed. The NOAEL was therefore identified at 15 mg/kg/day. A factor of 10 for inter-species variability and a factor of 10 for interindividual variability were applied.

The four available TRVs are equivalent. The CES adopted WHO-IPCS's TRV since it was the most disadvantageous (not rounded).
The selected TRV is applicable to children between the ages of zero and three years. Indeed, studies during gestation were taken into account by WHO/IPCS in 2005 for the establishment of the TRV (Saillenfait *et al*., 1989; Martin, 1990 cited in WHO/IPCS, 2005).

Table 66: Chronic oral-route threshold TRVs for formaldehyde

Organism	Threshold			
	US EPA*	ATSDR	OMS/IPCS	Health Canada
year	1990	2010	2005	2001
TRV name	RfD	MRL	DJT	CT
TRV value	0.2 mg/kg/d	0.2 mg/kg/d	0.15 mg/kg/d	.,6 mg/L**
critical effect	Histological changes of the pre-stomach, hyperkeratosis		Stomach irritations and nephrotoxicity	No histopathological changes in the gastrointestinal tract
Species	Rats			
Exposure time	2 years			
Exposure route	Oral (drinking wtaer)			
Critical dose	NOAEL = 15 mg/kg/d LOAEL = 82 mg/kg/d			NOAEL = 260 mg/L = 0.15 mg/kg/d
Adjustement	/			
UF	100 UF$_A$ = 10, UF$_H$ = 10			
Key study	Til *et al.* (1989)			

* the RfD proposed by US EPA-IRIS has been under review since 2014.

** the value was not expressed in mg/kg/day since the authors considered that the observed effects are related to the concentration of formaldehyde consumed via drinking water and not to a cumulative effect (INERIS, 2005).

b. Fragrances

- **Limonene**

WHO/IPCS's TRV is considered applicable to children between the ages of zero and three years. Indeed, reprotoxicity studies were taken into account in the establishment of the TRV. There are no data showing that limonene is teratogenic or embryotoxic in the absence of maternal toxicity (WHO/IPCS, 1998).

- **Benzyl alcohol**

WHO/FAO's TRV is considered applicable to children between the ages of zero and three years. Indeed, reprotoxicity and teratogenicity studies for benzyl acetate, benzyl alcohol, benzaldehyde and sodium benzoate were taken into account in the establishment of the TRV (WHO/IPCS, 1998).

- **Linalool**

The toxicological profile produced by JECFA does not describe any studies on reprotoxicity or development. By default, **WHO/FAO's TRV is considered applicable to children between the ages of zero and three years.**

- **Coumarin**

The toxicological profile produced by EFSA does not describe any studies on reprotoxicity or development. By default, **EFSA's TRV is considered applicable to children between the ages of zero and three years.**

c. Trimethylbenzene

1,3,5-trimethylbenzene and 1,2,4-trimethylbenzene elicit effects on pregnant animals and developing foetuses, but at exposure levels greater than those that cause effects on the nervous system (critical effect selected by the US EPA). **Thus, the US EPA's TRV (2016) is considered applicable to children between the ages of zero and three years.**

d. Trichlorobenzene (TCB) isomers

Two organisations propose chronic threshold TRVs for all of the trichlorobenzene isomers based on the same critical effect and the same key study: the WHO (1996) and RIVM (2001).

In the study by Côté *et al*., SD rats were exposed by gavage to the three TCB isomers (1,2,3-; 1,2,4-; and 1,2,5-TCB) for 13 weeks. The rats were exposed to 0, 1, 10, 100 or 1000 mg/kg diluted in corn oil corresponding to 0, 0.07-0.08, 0.78-0.81, 7.6-7.8 and 78-82 mg/kg/day for the males and 0, 0.1-0.13, 1.3-1.5, 12-17 and 101-146 mg/kg/day for the females. The authors highlighted a statistically significant decrease in weight gain for the males at 10 and 1000 mg/kg of 1,2,3-TCB and nephrosis for a male exposed to 1000 mg/kg of 1,2,4-TCB. At the highest dose, a significant increase in the ratio of liver weight to body weight was observed for the three isomers. Mild to moderate histopathological changes in the liver (increase in cytoplasmic volume and anisokaryosis of hepatocytes, fatty infiltration), kidneys (moderate changes in the tubules) and thyroid (reduction in follicular size, increased epithelial height and reduced colloid density) were reported but were only statistically significant for the males at the highest dose. The authors considered NOAELs of 7.7 mg/kg/day for 1,2,3-TCB, 7.8 mg/kg/day for 1,2,4-TCB and 7.6 mg/kg/day for 1,2,5-TCB. An uncertainty factor of 1000 was applied to the NOAELs: 10 for inter-species variability, 10 for inter-individual variability and an additional factor of 10 that was different for the WHO (use of a subchronic study) and RIVM (lack of chronic data).

In 1992, Health Canada also used this study by Côté *et al.* (1988) to propose TRVs for 1,2,3-TCB and 1,2,4-TCB by using NOAELs specific to each isomer and applying an uncertainty factor of 5000: 10 for inter-species variability, 10 for inter-individual variability and 5 for the lack of data on carcinogenicity.

Four organisations have proposed chronic threshold TRVs for 1,2,4-TCB: Health Canada (1992, described above), the US EPA (1992), OEHHA (1999 – proposal of guideline values in drinking water) and ATSDR (2014). The US EPA and OEHHA based their reference values on a NOAEL of 14.8 mg/kg/day taken from a two-generation reprotoxicity study by Robinson *et al.* (1981). Two generations of rats were exposed to 0, 25, 100 or 400 ppm of 1,2,4-TCB in water for 95 days. At 400 ppm, a significant increase in adrenal weights was observed in both sexes (11% in males, 13% in females). A NOAEL of 14.8 mg/kg/day was identified in this study based on a dose rate calculation performed by the authors. Robinson *et al.* (1981) undertook an acute toxicity study in order to explore the adrenal enlargement related to TCB observed in the two-generation study. Female rats received 0, 250 or 500 mg/kg of 1,2,4-TCB by i.p. injection at the age of 22, 23 or 24 days. At 500 mg/kg, the 25-day-old rats had higher adrenal weights than the controls. To more specifically characterise the changes noted by Robinson *et al.* (1981), the US EPA (1997) conducted a study and found that increases in adrenal weights related to TCB were associated with histopathological lesions (vacuolisation of the *zona fasciculata* in the cortex).

The US EPA applied an uncertainty factor of 1000 (10 for inter-species variability, 10 for inter-individual variability and 10 for the lack of chronic data), whereas OEHHA applied a UF of 10,000 (10 for inter-species variability, 10 for inter-individual variability, 10 for the duration of the study and 10 for uncertainty about the occurrence of potential severe effects (carcinogenicity)).

ATSDR also recently proposed a TRV based on the carcinogenicity study of Robinson *et al.* (1994). Fisher-344 rats (50/sex/group) were fed a diet containing 0, 100, 350 or 1200 ppm of 1,2,4-TCB for 104 weeks, corresponding to 0, 5.6, 19.4 or 66.5 mg/kg/day for males and 0, 6.9, 23.5 or 81.4 mg/kg/day for females. At 66.5 mg/kg/day, a significant decrease in survival rates was observed in the males. In terms of haematology findings, only significant decreases in basophils at week 52 and monocytes at week 105 were observed for the males at the highest dose; they were considered as minor by the authors. Necropsy at termination showed an increased incidence of liver and kidney abnormalities in the males at the two highest doses and a slight increase in the incidence of uterine masses in the females. An increase in absolute and relative liver weights was observed in both the males and females receiving the highest doses, as well as a decrease in absolute and relative testes weights in the males at 5.6 and 19.4 mg/kg/day. Treatment-related histological alterations were restricted to the liver for both sexes and to the kidneys for males (hepatocellular hypertrophy, focal cystic degeneration, diffuse fatty change, transitional renal cell hyperplasia and increased severity of chronic nephropathy). Since there was evidence from the 14-week study (CMA, 1989) suggesting that the renal lesions in male rats could represent a male-specific response not relevant for TRV derivation and that the renal cell hyperplasia reported in the 104-week study was a typical response seen in male rat nephropathy, renal cell hyperplasia was not considered as a potential point of departure for TRV derivation. Thus, hepatic effects were selected as the critical effect. A BMDL was modelled using a BMR of 10% (due to a lack of data enabling a lower BMR to be considered). An uncertainty factor of 100 was applied in order to take inter- and intra-species variability into account.

The study by Côté *et al.* (1988) showed that the three isomers had very similar levels of toxicity, primarily in the liver. The NOAELs derived from the studies selected by the various organisations (Côté *et al.,* 1988; Robinson *et al*., 1981; Moore *et al*., 1994) were consistent. The main differences between the TRVs were related to the choice of uncertainty factors.

The CES adopted the following:
-   **ATSDR's chronic TRV (2014) for 1,2,4-trichlorobenzene, since it was based on a chronic study (104 weeks) enabling uncertainty to be reduced with more precise data processing (BMD) and therefore a lower uncertainty factor compared to the other available TRVs,**
-   **RIVM's TRV (2001) for 1,2,3-trichlorobenzene, based on the subchronic study by Côté *et al.* (1988).**

No studies were identified describing the health effects of TCB exposure on children or comparing health effects in young and adult animals to determine potential age-related differences in susceptibility. Furthermore, developmental toxicity studies in animals do not suggest that TCBs are embryotoxic or teratogenic or that they alter the development of young animals (ATSDR, 2014). Thus, **the selected TRV is considered applicable to children between the ages of zero and three years.**

Only one organisation has proposed a no-threshold TRV based on carcinogenesis in B6C3F1 mice. Fifty mice/sex/group were fed 0, 150, 700 or 3200 mg/kg/day for 104 weeks. Survival was considerably reduced in the animals exposed to high doses compared to the controls: at the highest dose, only 5/50 males and 0/50 females survived to termination, compared with 74% to 90% survival in all the other groups. The increase in mortality for the animals exposed to the highest doses began at approximately week 65-70 and progressed rapidly for the remainder of the study.

Most of the deaths in the mice exposed to high doses were caused by hepatocellular neoplasms, primarily carcinomas. These were found in all of the males and 92% of the females at the highest dose and around 55% of the males and females exposed to 700 mg/kg/day. The tumours were mainly large and often multiple, frequently with pulmonary metastases. The incidence of hepatocellular adenomas also increased (except in the males exposed to high doses, in which it was noted that they were likely overwhelmed by the extent of carcinoma development). Cases of combined adenomas and carcinomas were not observed. In addition to hepatic neoplastic lesions, 1,2,4-trichlorobenzene resulted in an increase in the number of hepatocytes in many males exposed to 700 or 3200 mg/kg/day, including in animals with and without concurrent hepatic neoplasia. Other hepatic alterations (focal necrosis, portal inflammation and fibrosis, regenerative changes) were also attributed to TCB exposure but were considered as secondary or influenced by the high degree of hepatic neoplasia observed in the animals. Average liver weights in the terminal phase were significantly higher for the males in all the groups, and for the females at 150 and 700 mg/kg/day (at 3200 mg/kg/day, all the females died prior to termination).

The histological examination also revealed degenerative changes in the adrenal glands, bilateral testicular degeneration and empty and contracted seminal vesicles. However, the groups exposed to 150 and 700 mg/kg/day had not undergone a complete

histopathological examination at the time when the report was written. As a result, it was not clear whether these effects were directly caused by TCB exposure or were secondary to a prolonged disease, as observed in the animals exposed to high doses.

A similar oral carcinogenicity study was undertaken in F344 rats (50/sex/group) and submitted to the US EPA with the results of the study in mice (US EPA, 1994b). In this study, 1,2,4-TCB was not found to be carcinogenic in rats of both sexes.

According to OEHHA, there seemed to be evidence of a strong carcinogenic effect in male and female B6C3F1 mice: almost all of the mice (50/50 males and 46/50 females) exposed to the highest dose developed hepatocellular carcinomas. The effect seemed to be related to treatment (US EPA, 1993a and b).

The CES adopted OEHHA's ERU since TCBs clearly appeared as being mutagenic substances *in vivo* and since the carcinogenesis study in mice showed a significant increase in the incidence of hepatocellular carcinomas with a clear dose-response effect.

Table 67: Chronic TRV for isomers of trichlorobenzene

Chemicals	TCB total	All TCB isomers	1,2,3 TCB	1,2,4 TCB				No threshold
				Threshold				No threshold
Organism	OMS	RIVM	Health Canada	Health Canada	US EPA	OEHHA	ATSDR	OEHHA
year	1996	2001	1992	1992	1992	1999	2014	1999
TRV name	TDI	TDI	DJT	DJT	RfD	REL	MRL	Oral slope factor
TRV value	$7.7.10^{-3}$ mg/kg/d	8.10^{-3} mg/kg/d	$1.5.10^{-3}$ mg/kg/d	$1.6.10^{-3}$ mg/kg/d	0.01 mg/kg/d	0.001 mg/kg/d	0.1 mg/kg/d	$3.6.10^{-3}$ $(mg/kg/d)^{-1}$
critical effect	↑ significant relative liver weightand mild to moderate histopathological changes in liver, kidneys and thyroid				↑ adrenal weight Vacualization of the fasciculated area in the cortex	↑ adrenal weight	Hepatocelluli hypertrophy in males	Hepatocellular carcinomas
Species	Spraque Dawley rats				Rats		Fishers rats	B6C3F1 mouse
Exposure time	13 weeks				2 generations – 95 days		104 weeks	104 weeks
Exposure route	Oral (gavage)				Oral (drinking water)		Oral (diet)	
Critical dose	NOAEL = 7.8 ; 7.7 et 7.6 mg/kg/d for 1,2,4- ; 1,2,3- and 1,3,5-TCB*		NOAEL = 7.7 mg/kg/d	NOAEL = 7.8 mg/kg/d	NOAEL = 14.8 mg/kg/d (♀) LOAEL = 53.6 mg/kg/d (♀)		$BMDL_{10}$ = 13.33 mg/kg/d	LED_{10} → LMS model → cancer slope factor (CSF) = $5,4.10^{-4}$ $(mg/kg/d)^{-1}$ Allomtric
Adjustement	/	/	/	/	/		/	
UF	1 000 UF_A = 10 UF_H = 10 UF_S = 10	1 000 UF_A = 10 UF_H = 10 UF_D = 10	5 000 UF_A = 10 UF_H = 10 UF_s = 10 UF_D = 5		1 000 UF_A = 10 UF_H = 10 UF_D = 10	10 000 UF_A = 10 UF_H = 10 UF_S = 10 UF_D = 10	100 UF_A = 10 UF_H = 10	

					adjustement CSF $_{Human}$ = $3,6.10^{-3}$ $(mg/kg/d)^{-1}$
Key study	Côté *et al.* (1988)			Robinson *et al.* (1981)	Moore *et al.* (1994)	US EPA (1993a et b)

* NOAEL consistent with the NOAEL of 6 mg/kg/d from the carcinogenicity study by Moore *et al.* (1994).

LED_{10} = lower limit of the confidence interval of the associated with ans 10% increase in tumor development

Annex 14: DED and risks calculations according to a refined scenario

Table 68 : DED and risks calculations according to a refined scenario for shredded diapers by solvent extraction (scenario 1)

Chemicals	Ages	Concentration (mg/kg)	DED (mg/kg/d)	FET	DEDtoxic equivalent (mg_{TEQ}/kg/d)	TRV (mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
Pesticides									
Hexachlorobenzene	0-6 months exclusive	0.002	$6.88.10^{-6}$			7.10^{-5}	$9.82.10^{-2}$	1.8	$8.84.10^{-8}$
	6-12 months inclusive		$4.4.10^{-6}$				$6.28.10^{-2}$		$1.13.10^{-7}$
	13-18 months inclusive		$3.71.10^{-6}$				$5.30.10^{-2}$		$1.43.10^{-7}$
	19-24 months inclusive		$3.62.10^{-6}$				$5.17.10^{-2}$		$1.86.10^{-7}$
	25-30 months inclusive		$3.28.10^{-6}$				$4.68.10^{-2}$		$2.11.10^{-7}$
	31-36 months inclusive		$2.60.10^{-6}$				$3.71.10^{-2}$		$2.00.10^{-7}$
VOCs									
1,2,3-trichlorobenzene	0-6 months exclusive	0.25	$8.59.10^{-4}$			8.10^{-3}	0.11		
	6-12 months inclusive		$5.49.10^{-4}$				$6.87.10^{-2}$		
	13-18 months inclusive		$4.64.10^{-4}$				$5.80.10^{-2}$		
	19-24 months inclusive		$4.53.10^{-4}$				$5.66.10^{-2}$		
	25-30 months inclusive		$4.10.10^{-4}$				$5.12.10^{-2}$		
	31-36 months inclusive		$3.25.10^{-4}$				$4.06.10^{-2}$		
1,2,4 trichlorobenzene	0-6 months exclusive	**0.693**	$2.38.10^{-3}$			**0.1**	$2.38.10^{-2}$	$3.6.10^{-3}$	$6.13.10^{-8}$
	6-12 months inclusive		$1.52.10^{-3}$				$1.52.10^{-2}$		$7.83.10^{-8}$
	13-18 months inclusive		$1.29.10^{-3}$				$1.29.10^{-2}$		$9.92.10^{-8}$
	19-24 months inclusive		$1.25.10^{-3}$				$1.25.10^{-2}$		$1.29.10^{-7}$
	25-30 months inclusive		$1.14.10^{-3}$				$1.14.10^{-2}$		$1.46.10^{-7}$
	31-36 months inclusive		$9.00.10^{-4}$				$9.00.10^{-3}$		$1.39.10^{-7}$
1,3,5 trimethylbenzene	0-6 months exclusive	**0.12**	$4.13.10^{-4}$			**0.01**	$4.13.10^{-2}$		
	6-12 months inclusive		$2.64.10^{-4}$				$2.64.10^{-2}$		
	13-18 months inclusive		$2.23.10^{-4}$				$2.23.10^{-2}$		
	19-24 months inclusive		$2.17.10^{-4}$				$2.17.10^{-2}$		
	25-30 months inclusive		$1.97.10^{-4}$				$1.97.10^{-2}$		
	31-36 months inclusive		$1.56.10^{-4}$				$1.56.10^{-2}$		

Chemicals	Ages	Concentration (mg/kg)	DED (mg/kg/d)	FET	DED toxic equivalent (mg$_{TEQ}$/kg/d)	TRV (mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
Formaldehyde									
Formaldehyde	0-6 months exclusive	37.4	0.13			0.15	$2.57.10^{-2}$		
	6-12 months inclusive		$8.22.10^{-2}$				$1.64.10^{-2}$		
	13-18 months inclusive		$6.94.10^{-2}$				$1.39.10^{-2}$		
	19-24 months inclusive		$6.77.10^{-2}$				$1.35.10^{-2}$		
	25-30 months inclusive		$6.13.10^{-2}$				$1.23.10^{-2}$		
	31-36 months inclusive		$4.86.10^{-2}$				$9.71.10^{-3}$		
Fragrances									
Benzyl alcool	0-6 months exclusive	25*	$8.59.10^{-2}$			5	$1.72.10^{-2}$		
	6-12 months inclusive		$5.49.10^{-2}$				$1.10.10^{-2}$		
	13-18 months inclusive		$4.64.10^{-2}$				$9.28.10^{-3}$		
	19-24 months inclusive		$4.53.10^{-2}$				$9.05.10^{-3}$		
	25-30 months inclusive		$4.10.10^{-2}$				$8.19.10^{-3}$		
	31-36 months inclusive		$3.25.10^{-2}$				$6.49.10^{-3}$		
Coumarine	0-6 months exclusive	25*	$8.59.10^{-2}$			0.1	0.86		
	6-12 months inclusive		$5.49.10^{-2}$				0.55		
	13-18 months inclusive		$4.64.10^{-2}$				0.46		
	19-24 months inclusive		$4.53.10^{-2}$				0.45		
	25-30 months inclusive		$4.10.10^{-2}$				0.41		
	31-36 months inclusive		$3.25.10^{-2}$				0.33		
Limonène	0-6 months exclusive	25*	$3.25.10^{-2}$			0.1	0.86		
	6-12 months inclusive		$3.25.10^{-2}$				0.55		
	13-18 months inclusive		$3.25.10^{-2}$				0.46		
	19-24 months inclusive		$3.25.10^{-2}$				0.45		
	25-30 months inclusive		$3.25.10^{-2}$				0.41		
	31-36 months inclusive		$3.25.10^{-2}$				0.33		
Linalol	0-6 months exclusive	25*	$8.59.10^{-2}$			5	$1.72.10^{-2}$		
	6-12 months inclusive		$5.49.10^{-2}$				$1.10.10^{-2}$		
	13-18 months inclusive		$4.64.10^{-2}$				$9.28.10^{-3}$		
	19-24 months inclusive		$4.53.10^{-2}$				$9.05.10^{-3}$		
	25-30 months inclusive		$4.10.10^{-2}$				$8.19.10^{-3}$		
	31-36 months inclusive		$3.25.10^{-2}$				$6.49.10^{-3}$		

Chemicals	Ages	Concentration (mg/kg)	DED (mg/kg/d)	TEF	DED toxic equivalent (mg_{TEQ}/kg/d)	TRV (mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
Dioxins and furans									
1,2,3,6,7,8 HxCDD	0-6 months exclusive	1.32.10^{-7}	4.54.10^{-10}	0.1	4.54.10^{-11}	2,3,7,8 TCDD TRV : 7.10^{-10}	6.48.10^{-2}	**Threshold carcinogen**	
	6-12 months inclusive		2.90.10^{-10}		2.90.10^{-11}		4.14.10^{-2}		
	13-18 months inclusive		2.45.10^{-10}		2.45.10^{-11}		3.50.10^{-2}		
	19-24 months inclusive		2.39.10^{-10}		2.39.10^{-11}		3.41.10^{-2}		
	25-30 months inclusive		2.16.10^{-10}		2.16.10^{-11}		3.09.10^{-2}		
	31-36 months inclusive		1.71.10^{-10}		1.71.10^{-11}		2.45.10^{-2}		
1,2,3,4,6,7,8 HpCDD	0-6 months exclusive	1.03.10^{-6}	3.54.10^{-9}	0.01	3.54.10^{-11}		5.06.10^{-2}		
	6-12 months inclusive		2.26.10^{-9}		2.26.10^{-11}		3.23.10^{-2}		
	13-18 months inclusive		1.91.10^{-9}		1.91.10^{-11}		2.73.10^{-2}		
	19-24 months inclusive		1.87.10^{-9}		1.87.10^{-11}		2.66.10^{-2}		
	25-30 months inclusive		1.69.10^{-9}		1.69.10^{-11}		2.41.10^{-2}		
	31-36 months inclusive		1.34.10^{-9}		1.34.10^{-11}		1.91.10^{-2}		
2,3,4,6,7,8 HxCDF	0-6 mois exclusive	1.07.10^{-7}	3.68.10^{-10}	0.1	3.68.10^{-11}		5.25.10^{-2}		
	0-6 months exclusive		2.35.10^{-10}		2.35.10^{-11}		3.36.10^{-2}		
	6-12 months inclusive		1.99.10^{-10}		1.99.10^{-11}		2.84.10^{-2}		
	13-18 months inclusive		1.94.10^{-10}		1.94.10^{-11}		2.77.10^{-2}		
	19-24 months inclusive		1.75.10^{-10}		1.75.10^{-11}		2.50.10^{-2}		
	25-30 months inclusive		1.39.10^{-10}		1.39.10^{-11}		1.99.10^{-2}		
1,2,3,4,6,7,8 HpCDF	0-6 months exclusive	1.54.10^{-6}	5.29.10^{-09}	0.01	5.29.10^{-11}		7.56.10^{-2}		
	6-12 months inclusive		3.38.10^{-09}		3.38.10^{-11}		4.84.10^{-2}		
	13-18 months inclusive		2.86.10^{-09}		2.86.10^{-11}		4.08.10^{-2}		
	19-24 months inclusive		2.79.10^{-09}		2.79.10^{-11}		3.98.10^{-2}		
	25-30 months inclusive		2.52.10^{-09}		2.52.10^{-11}		3.60.10^{-2}		
	31-36 months inclusive		2.00.10^{-09}		2.00.10^{-11}		2.86.10^{-2}		
Somme Dioxines + furanes + PCB-DL (TEQ)	0-6 months exclusive	5.94.10^{-8}			2.04.10^{-10}		0.29		
	6-12 months inclusive				1.31.10^{-10}		0.19		
	13-18 months inclusive				1.10.10^{-10}		0.16		
	19-24 months inclusive				1.08.10^{-10}		0.15		
	25-30 months inclusive				9.73.10^{-11}		0.14		
	31-36 months inclusive				7.71.10^{-11}		0.11		

Chemicals	Ages	Concentration (mg/kg)	DED (mg/kg/d)	TEF	DED toxic equivalent (mg$_{TEQ}$/kg/d)	TRV (mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
Sum of dioxins and furans (TEQ)	0-6 months exclusive	3.98.10^{-08}			1.37.10^{-11}		0.2		
	6-12 months inclusive				8.75.10^{-11}		0.13		
	13-18 months inclusive				7.39.10^{-11}		0.11		
	19-24 months inclusive				7.21.10^{-11}		0.10		
	25-30 months inclusive				6.52.10^{-11}		9.31.10^{-2}		
	31-36 months inclusive				5.17.10^{-11}		7.38.10^{-2}		
Sum of DL PCB (TEQ)	0-6 months exclusive	4.34.10^{-8}			1.49.10^{-10}		0.21		
	6-12 months inclusive				9.54.10^{-11}		0.14		
	13-18 months inclusive				8.06.10^{-11}		0.12		
	19-24 months inclusive				7.86.10^{-11}		0.11		
	25-30 months inclusive				7.11.10^{-11}		0.10		
	31-36 months inclusive				5.64.10^{-11}	2,3,7,8 TCDD TRV : 7.10^{-10}	8.05.10^{-2}		
PCB 118	0-6 months exclusive	7.59.10^{-4}	2.61.10^{-6}	0.00003	7.83.10^{-11}		0.11		
	6-12 months inclusive		1.67.10^{-6}		5.00.10^{-11}		7.15.10^{-2}		
	13-18 months inclusive		1.41.10^{-6}		4.23.10^{-11}		6.04.10^{-2}		
	19-24 months inclusive		1.37.10^{-6}		4.12.10^{-11}		5.89.10^{-2}		
	25-30 months inclusive		1.24.10^{-6}		3.73.10^{-11}		5.33.10^{-2}		
	31-36 months inclusive		9.86.10^{-7}		2.96.10^{-11}		4.22.10^{-2}		
PCB 105	0-6 months exclusive	4.31.10^{-4}	1.48.10^{-6}	0.00003	4.44.10^{-11}		6.35.10^{-2}		
	6-12 months inclusive		9.47.10^{-7}		2.84.10^{-11}		4.06.10^{-2}		
	13-18 months inclusive		8.00.10^{-7}		2.40.10^{-11}		3.43.10^{-2}		
	19-24 months inclusive		7.80.10^{-7}		2.34.10^{-11}		3.34.10^{-2}		
	25-30 months inclusive		7.06.10^{-7}		2.12.10^{-11}		3.03.10^{-2}		
	31-36 months inclusive		5.60.10^{-7}		1.68.10^{-11}		2.40.10^{-2}		

Chemicals	Ages	Concentration (mg/kg)	DED (mg/kg/d)	Critical dose (mg/kg/d)	MOE	MOE ref	MOEref/MOE
Fragrances							
Benzyl salicylate	0-6 months exclusive	25*	$8.59.10^{-2}$	50	4190	100	0.17
	6-12 months inclusive		$5.49.10^{-2}$		6550		0.11
	13-18 months inclusive		$4.64.10^{-2}$		7760		$9.28.10^{-2}$
	19-24 months inclusive		$4.53.10^{-2}$		7950		$9.05.10^{-2}$
	25-30 months inclusive		$4.10.10^{-2}$		8790		$8.19.10^{-2}$
	31-36 months inclusive		$3.25.10^{-2}$		11100		$6.49.10^{-3}$
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	0-6 months exclusive	25*	$8.59.10^{-2}$	15	175	300	1.72
	6-12 months inclusive		$5.49.10^{-2}$		273		1.10
	13-18 months inclusive		$4.64.10^{-2}$		323		0.93
	19-24 months inclusive		$4.53.10^{-2}$		331		0.90
	25-30 months inclusive		$4.10.10^{-2}$		366		0.82
	31-36 months inclusive		$3.25.10^{-2}$		462		0.65
Butylphenyl methylepropional	0-6 months exclusive	25*	$8.59.10^{-2}$	5	58.2	100	1.72
	6-12 months inclusive		$5.49.10^{-2}$		91		1.10
	13-18 months inclusive		$4.64.10^{-2}$		108		0.93
	19-24 months inclusive		$4.53.10^{-2}$		110		0.91
	25-30 months inclusive		$4.10.10^{-2}$		122		0.82
	31-36 months inclusive		$3.25.10^{-2}$		154		0.65
alpha-isomethyle ionone	0-6 months exclusive	25*	$8.59.10^{-2}$	5	582	100	0.17
	6-12 months inclusive		$5.49.10^{-2}$		910		0.11
	13-18 months inclusive		$4.64.10^{-2}$		1080		$9.28.10^{-2}$
	19-24 months inclusive		$4.53.10^{-2}$		1100		$9.05.10^{-2}$
	25-30 months inclusive		$4.10.10^{-2}$		1540		$8.19.10^{-2}$
	31-36 months inclusive		$3.25.10^{-2}$		1960		$6.49.10^{-2}$

* : detected chemical

Table 69 : DED and risks calculations according to a refined scenario for shredded diapers parts by solvent extraction (scenario 1)

Chemicals	Ages	concentration in the diaper part (mg/kg)	DED(mg/kg/d)	TEF	DED toxic equivalent (mgTEQ/kg/d)	TRV(mg/kg/d)	HS	ERU (mg/kg/d)$^{-1}$	IER
PAH									
Benzo[g,h,i] perylene	0-6 months exclusive	5.00.10^{-2}*	8.59.10^{-9}	0.01	8.59.10^{-11}	BaP TRV 3. .10^{-4}	2.86.10^{-7}	BaP TRV : 1.0	6,14.10^{-12}
	6-12 months inclusive		5.49.10^{-8}		5.49.10^{-10}		1.83.10^{-6}		7,85.10^{-11}
	13-18 months inclusive		4.64.10^{-8}		4.64.10^{-10}		1.55.10^{-6}		9,94.10^{-11}
	19-24 months inclusive		4.53.10^{-8}		4.53.10^{-10}		1.51.10^{-6}		1,29.10^{-10}
	25-30 months inclusive		4.10.10^{-8}		4.10.10^{-10}		1.37.10^{-6}		1,26.10^{-10}
	31-36 months inclusive		3.25.10^{-8}		3.25.10^{-10}		1.08.10^{-6}		6,63.10^{-10}
Benzo[b] fluoranthene	0-6 months exclusive	5.00.10^{-2}*	8.59.10^{-9}	0.1	8.59.10^{-10}		2.86.10^{-6}		6,14.10^{-11}
	6-12 months inclusive		5.49.10^{-8}		5.49.10^{-9}		1.83.10^{-5}		7,85.10^{-10}
	13-18 months inclusive		4.64.10^{-8}		4.64.10^{-9}		1.55.10^{-5}		9,94.10^{-10}
	19-24 months inclusive		4.53.10^{-8}		4.53.10^{-9}		1.51.10^{-5}		1,29.10^{-9}
	25-30 months inclusive		4.10.10^{-8}		4.10.10^{-9}		1.37.10^{-5}		1,26.10^{-9}
	31-36 months inclusive		3.25.10^{-8}		3.25.10^{-9}		1.08.10^{-5}		1,07.10^{-9}
Benzo[a] anthracene	0-6 months exclusive	5.00.10^{-2}*	8.59.10^{-9}	0.1	8.59.10^{-10}		2.86.10^{-5}		6,14.10^{-11}
	6-12 months inclusive		5.49.10^{-8}		5.49.10^{-9}		1.83.10^{-4}		7,85.10^{10}
	13-18 months inclusive		4.64.10^{-8}		4.64.10^{-9}		1.55.10^{-4}		9,94.10^{-10}
	19-24 months inclusive		4.53.10^{-8}		4.53.10^{-9}		1.51.10^{-4}		1,29.10^{-9}
	25-30 months inclusive		4.10.10^{-8}		4.10.10^{-9}		1.37.10^{-4}		1,26.10^{-9}
	31-36 months inclusive		3.25.10^{-8}		3.25.10^{-9}		1.08.10^{-4}		1,07.10^{-9}
Indeno[1,2,3-c,d]pyrene	0-6 months exclusive	1.2	2.06.10^{-7}	0.1	2.06.10^{-8}		6.88.10^{-5}		1,47.10^{-9}
	6-12 months inclusive		1.32.10^{-6}		1.32.10^{-7}		4.40.10^{-4}		1,88.10^{8}
	13-18 months inclusive		1.11.10^{-6}		1.11.10^{-7}		3.71.10^{-4}		2,39.10^{-8}
	19-24 months inclusive		1.09.10^{-6}		1.09.10^{-7}		3.62.10^{-4}		3,10.10^{-8}
	25-30 months inclusive		9.83.10^{-7}		9.83.10^{-8}		3.28.10^{-4}		3,02.10^{-8}
	31-36 months inclusive		7.79.10^{-7}		7.79.10^{-8}		2.60.10^{-4}		2,56.10^{-8}
Dioxins/Furans									
2,3,4,6,7,8 HxCDF	0-6 months exclusive	5.01.10^{-7}	2,58.10^{-11}	0,1	2,58.10^{-12}	2,3,7,8 TCDD TRV : 7.10^{-10}	3.69.10^{-3}	Threshold carcinogen	
	6-12 months inclusive		1,65.10^{-11}		1,65.10^{-12}		2,36.10^{-3}		
	13-18 months inclusive		1,39.10^{-11}		1,39.10^{-12}		1,99.10^{-3}		
	19-24 months inclusive		1,36.10^{-11}		1,36.10^{-12}		1,94.10^{-3}		
	25-30 months inclusive		1,23.10^{-11}		1,23.10^{-12}		1,76.10^{-3}		
	31-36 months inclusive		9,76.10^{-12}		9,76.10^{-13}		1,39.10^{-3}		

Table 70 : DED and risks calculation according to a refined scenario for shredded diapers by urine simulant extraction (1st SCL sutdy in 2017) (scenario 2.1)

Chemicals	Ages	Concentration (mg/kg)	DED (mg/kg/d)	TEF	DED toxic equivalent (mgTEQ/kg/d)	TRV (mg/kg/d)	HQ
Dioxins and furans							
Sum of dioxins and furans – SCL	0-6 months exclusive	$9.2.10^{-8}$			$5.96.10^{-12}$	2.3.7.8 TCDD TRV : 7.10^{-10}	$8.52.10^{-3}$
	6-12 months inclusive				$3.81.10^{-12}$		$5.45.10^{-3}$
	13-18 months inclusive				$3.22.10^{-12}$		$4.60.10^{-3}$
	19-24 months inclusive				$3.14.10^{-12}$		$4.49.10^{-3}$
	25-30 months inclusive				$2.84.10^{-12}$		$4.06.10^{-3}$
	31-36 months inclusive				$2.25.10^{-12}$		$3.22.10^{-3}$
Sum of DL- PCBs	0-6 months exclusive	$7.55.10^{-9}$			$4.89.10^{-13}$		$6.99.10^{-4}$
	6-12 months inclusive				$3.13.10^{-13}$		$4.47.10^{-4}$
	13-18 months inclusive				$2.64.10^{-13}$		$3.78.10^{-4}$
	19-24 months inclusive				$2.58.10^{-13}$		$3.68.10^{-4}$
	25-30 months inclusive				$2.33.10^{-13}$		$3.33.10^{-4}$
	31-36 months inclusive				$1.85.10^{-13}$		$2.64.10^{-4}$
1,2,3,4,6,7,8 HpCDD	0-6 months exclusive	$2.42.10^{-6}$	$1.57.10^{-10}$	0.01	$1.57.10^{-12}$		$2.24.10^{-3}$
	6-12 months inclusive		$1.00.10^{-10}$		$1.00.10^{-12}$		$1.43.10^{-3}$
	13-18 months inclusive		$8.47.10^{-11}$		$8.47.10^{-13}$		$1.21.10^{-3}$
	19-24 months inclusive		$8.26.10^{-11}$		$8.26.10^{-13}$		$1.18.10^{-3}$
	25-30 months inclusive		$7.47.10^{-11}$		$7.47.10^{-13}$		$1.07.10^{-3}$
	31-36 months inclusive		$5.93.10^{-11}$		$5.93.10^{13}$		$8.47.10^{-4}$
2,3,7,8 TCDF	0-6 months exclusive	$1.04.10^{-7}$	$6.74.10^{-12}$	0.1	$6.74.10^{-13}$		$9.63.10^{-4}$
	6-12 months inclusive		$4.31.10^{-12}$		$4.31.10^{-13}$		$6.16.10^{-4}$
	13-18 months inclusive		$3.64.10^{-12}$		$3.64.10^{-13}$		$5.20.10^{-4}$
	19-24 months inclusive		$3.55.10^{-12}$		$3.55.10^{-13}$		$5.07.10^{-4}$
	25-30 months inclusive		$3.21.10^{-12}$		$3.21.10^{-13}$		$4.59.10^{-4}$
	31-36 months inclusive		$2.55.10^{-12}$		$2.55.10^{-13}$		$3.64.10^{-4}$

Chemicals	Ages	Concentration (mg/kg)	DED (mg/kg/d)	TEF	DED toxic equivalent (mgTEQ/kg/d)	TRV (mg/kg/d)	HQ
2,3,4,7,8 PeCDF	0-6 months exclusive	2.61.10⁻⁷	$1.69.10^{-11}$	0.3	$5.08.10^{-12}$		$7.25.10^{-3}$
	6-12 months inclusive		$1.08.10^{-11}$		$3.25.10^{-12}$		$4.64.10^{-3}$
	13-18 months inclusive		$9.14.10^{-12}$		$2.74.10^{-12}$		$3.92.10^{-3}$
	19-24 months inclusive		$8.91.10^{-12}$		$2.67.10^{-12}$		$3.82.10^{-3}$
	25-30 months inclusive		$8.06.10^{-12}$		$2.42.10^{-12}$		$3.46.10^{-3}$
	31-36 months inclusive		$6.39.10^{-12}$		$1.92.10^{-12}$		$2.74.10^{-3}$
1,2,3,4,7,8 HxCDF	0-6 months exclusive	1.12.10⁻⁷	$7.26.10^{-12}$	0.1	$7.26.10^{-13}$		$1.04.10^{-3}$
	6-12 months inclusive		$4.64.10^{-12}$		$4.64.10^{-13}$		$6.63.10^{-4}$
	13-18 months inclusive		$3.92.10^{-12}$		$3.92.10^{-13}$		$5.60.10^{-4}$
	19-24 months inclusive		$3.82.10^{-12}$		$3.82.10^{-13}$		$5.46.10^{-4}$
	25-30 months inclusive		$3.46.10^{-12}$		$3.46.10^{-13}$		$4.94.10^{-4}$
	31-36 months inclusive		$2.74.10^{-12}$		$2.74.10^{-13}$		$3.92.10^{-4}$
1,2,3,4,6,7,8 HpCDF	0-6 months exclusive	1.63.10⁻⁶	$1.06.10^{-10}$	0.01	$1.06.10^{-12}$	2.3.7.8 TCDD TRV : 7.10^{-10}	$1.51.10^{-3}$
	6-12 months inclusive		$6.76.10^{-11}$		$6.76.10^{-13}$		$9.65.10^{-4}$
	13-18 months inclusive		$5.71.10^{-11}$		$5.71.10^{-13}$		$8.15.10^{-4}$
	19-24 months inclusive		$5.57.10^{-11}$		$5.57.10^{-13}$		$7.95.10^{-4}$
	25-30 months inclusive		$5.03.10^{-11}$		$5.03.10^{-13}$		$7.19.10^{-4}$
	31-36 months inclusive		$3.99.10^{-11}$		$3.99.10^{-13}$		$5.70.10^{-4}$
OCDF	0-6 months exclusive	2.11.10⁻⁰⁵	$1.37.10^{-9}$	0.0003	$4.10.10^{-13}$		$5.86.10^{-4}$
	6-12 months inclusive		$8.74.10^{-10}$		$2.62.10^{-13}$		$3.75.10^{-4}$
	13-18 months inclusive		$7.39.10^{-10}$		$2.22.10^{-13}$		$3.17.10^{-4}$
	19-24 months inclusive		$7.21.10^{-10}$		$2.16.10^{-13}$		$3.09.10^{-4}$
	25-30 months inclusive		$6.52.10^{-10}$		$1.96.10^{-13}$		$2.79.10^{-4}$
	31-36 months inclusive		$5.17.10^{-10}$		$1.55.10^{-13}$		$2.21.10^{-4}$
Sum fo dioxins+ furans + DL-PCBs	0-6 months exclusive	9.31.10⁻⁸			$6.03.10^{-12}$		$8.62.10^{-3}$
	6-12 months inclusive				$3.86.10^{-12}$		$5.51.10^{-3}$
	13-18 months inclusive				$3.26.10^{-12}$		$4.66.10^{-3}$
	19-24 months inclusive				$3.18.10^{-12}$		$4.54.10^{-3}$
	25-30 months inclusive				$2.88.10^{-12}$		$4.11.10^{-3}$
	31-36 months inclusive				$2.28.10^{-12}$		$3.26.10^{-3}$

Table 71 : DED and risks calculations according to a refined scenario for diapers in a urine simulant (2nd SCL study in 2018) (scenario 2.2)

Chemicals	Ages	concentration in the diaper part (mg/kg)	DED (mg/kg/d)	TEF	DED toxic equivalent (mgTEQ/kg/d)	TRV (mg/kg/d)	HQ	ERU (mg/kg/d)^-1	IER
Dioxins and furans									
Sum of dioxins and furans (TEQ)	0-6 months exclusive	8.84.10^-9			4.34.10^-10		0.62		
	6-12 months inclusive				2.77.10^-10		0.4		
	13-18 months inclusive				2.34.10^-10		0.34		
	19-24 months inclusive				2.29.10^-10		0.33		
	25-30 months inclusive				2.07.10^-10		0.3		
	31-36 months inclusive				1.64.10^-10		0.23		
Sum of DL-PCBs (TEQ)	0-6 months exclusive	6.36.10^-8			3.12.10^-9		4.46		
	6-12 months inclusive				2.00.10^-9		2.85		
	13-18 months inclusive				1.69.10^-9		2.41		
	19-24 months inclusive				1.65.10^-9		2.35		
	25-30 months inclusive				1.49.10^-9		2.13		
	31-36 months inclusive				1.18.10^-9		1.69		
PCB 126	0-6 months exclusive	5.93.10^-7	2.91.10^-8	0.1	2.91.10^-9	7.10^-10	4.16		
	6-12 months inclusive		1.86.10^-8		1.86.10^-9		2.66		
	13-18 months inclusive		1.57.10^-8		1.57.10^-9		2.25		
	19-24 months inclusive		1.53.10^-8		1.53.10^-9		2.19		
	25-30 months inclusive		1.39.10^-8		1.39.10^-9		1.98		
	31-36 months inclusive		1.10.10^-8		1.10.10^-9		1.57		
Sum of dioxins + furans+ DL-PCBs (TEQ)	0-6 months exclusive	6.53.10^-8			3.21.10^-9		4.58		
	6-12 months inclusive				2.05.10^-9		2.93		
	13-18 months inclusive				1.73.10^-9		2.48		
	19-24 months inclusive				1.69.10^-9		2.41		
	25-30 months inclusive				1.53.10^-9		2.18		
	31-36 months inclusive				1.21.10^-9		1.73		

Chemicals	Ages	concentration in the diaper part (mg/kg)	DED (mg/kg/d)	TEF	DED toxic equivalent (mgTEQ/kg/d)	TRV (mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
Formaldehyde									
Formaldehyde	0-6 months exclusive	2.75	0.135			0.15	0.9		
	6-12 months inclusive		$8.63.10^{-2}$				0.58		
	13-18 months inclusive		$7.29.10^{-2}$				0.49		
	19-24 months inclusive		$7.11.10^{-2}$				0.47		
	25-30 months inclusive		$6.44.10^{-2}$				0.43		
	31-36 months inclusive		$5.10.10^{-2}$				0.34		
PAH									
Cyclopenta [c,d]pyrene	0-6 months exclusive	0.311*	$1.53.10^{-2}$	0.1	$1.53.10^{-3}$	$3.00.10^{-4}$	5.51	1	$1.09.10^{-4}$
	6-12 months inclusive		$9.79.10^{-3}$		$9.79.10^{-4}$		3.26		$1.40.10^{-4}$
	13-18 months inclusive		$8.26.10^{-3}$		$8.26.10^{-4}$		2.75		$1.77.10^{-4}$
	19-24 months inclusive		$8.06.10^{-3}$		$8.06.10^{-4}$		2.69		$2.30.10^{-4}$
	25-30 months inclusive		$7.29.10^{-3}$		$7.29.10^{-4}$		2.43		$2.24.10^{-4}$
	31-36 months inclusive		$5.78.10^{-3}$		$5.78.10^{-4}$		1.93		$1.90.10^{-4}$
chrysene	0-6 months exclusive	0.249*	$1.22.10^{-2}$	0.01	$1.22.10^{-4}$	$3.00.10^{-4}$	0.41	1	$8.75.10^{-6}$
	6-12 months inclusive		$7.83.10^{-3}$		$7.83.10^{-5}$		0.26		$1.12.10^{-5}$
	13-18 months inclusive		$6.61.10^{-3}$		$6.61.10^{-5}$		0.22		$1.42.10^{-5}$
	19-24 months inclusive		$6.45.10^{-3}$		$6.45.10^{-5}$		0.22		$1.84.10^{-5}$
	25-30 months inclusive		$5.83.10^{-3}$		$5.83.10^{-5}$		0.19		$1.79.10^{-5}$
	31-36 months inclusive		$4.63.10^{-3}$		$4.63.10^{-5}$		0.15		$1.52.10^{-5}$
5-methylchrysene	0-6 months exclusive	0.311*	$1.53.10^{-2}$	0.01	$1.53.10^{-4}$		0.51	1	$1.09.10^{-5}$
	6-12 months inclusive		$9.79.10^{-3}$		$9.79.10^{-5}$		0.33		$1.40.10^{-5}$
	13-18 months inclusive		$8.26.10^{-3}$		$8.26.10^{-5}$		0.28		$1.77.10^{-5}$
	19-24 months inclusive		$8.06.10^{-3}$		$8.06.10^{-5}$		0.27		$2.30.10^{-5}$
	25-30 months inclusive		$7.29.10^{-3}$		$7.29.10^{-5}$		0.24		$2.24.10^{-5}$
	31-36 months inclusive		$5.78.10^{-3}$		$5.78.10^{-5}$		0.19		$1.90.10^{-5}$

Chemicals	Ages	concentration in the diaper part (mg/kg)	DED (mg/kg/d)	TEF	DED toxic equivalent (mgTEQ/kg/d)	TRV (mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
Benzo[b]fluoranthene	0-6 months exclusive	0.381*	$1.87.10^{-2}$	0.1	$1.87.10^{-3}$		6.24	1	$1.34.10^{-4}$
	6-12 months inclusive		$1.20.10^{-2}$		$1.20.10^{-3}$		3.99		$1.71.10^{-4}$
	13-18 months inclusive		$1.01.10^{-2}$		$1.01.10^{-3}$		3.37		$2.17.10^{-4}$
	19-24 months inclusive		$9.86.10^{-3}$		$9.86.10^{-4}$		3.29		$2.82.10^{-4}$
	25-30 months inclusive		$8.92.10^{-3}$		$8.92.10^{-4}$		2.97		$2.74.10^{-4}$
	31-36 months inclusive		$7.07.10^{-3}$		$7.07.10^{-4}$		2.36		$2.32.10^{-4}$
Benzo[k]fluoranthene	0-6 months exclusive	0.369*	$1.81.10^{-2}$	0.1	$1.81.10^{-3}$		6.03	1	$1.29.10^{-4}$
	6-12 months inclusive		$1.16.10^{-2}$		$1.16.10^{-3}$		3.86		$1.65.10^{-4}$
	13-18 months inclusive		$9.77.10^{-3}$		$9.77.10^{-4}$		3.26		$2.09.10^{-4}$
	19-24 months inclusive		$9.53.10^{-3}$		$9.53.10^{-4}$	$3.00.10^{-4}$	3.18		$2.72.10^{-4}$
	25-30 months inclusive		$8.62.10^{-3}$		$8.62.10^{-4}$		2.87		$2.65.10^{-4}$
	31-36 months inclusive		$6.84.10^{-3}$		$6.84.10^{-4}$		2.28		$2.25.10^{-4}$
benzo[j]fluoranthene	0-6 months exclusive	0.369*	$1.81.10^{-2}$	0.1	$1.81.10^{-3}$		6.03	1	$1.29.10^{-4}$
	6-12 months inclusive		$1.16.10^{-2}$		$1.16.10^{-3}$		3.86		$1.65.10^{-4}$
	13-18 months inclusive		$9.77.10^{-3}$		$9.77.10^{-4}$		3.26		$2.09.10^{-4}$
	19-24 months inclusive		$9.53.10^{-3}$		$9.53.10^{-4}$		3.18		$2.72.10^{-4}$
	25-30 months inclusive		$8.62.10^{-3}$		$8.62.10^{-4}$		2.87		$2.65.10^{-4}$
	31-36 months inclusive		$6.84.10^{-3}$		$6.84.10^{-4}$		2.28		$2.25.10^{-4}$
benzo[e]pyrene	0-6 months exclusive	0.598*	$2.94.10^{-2}$	0.01	$2.94.10^{-4}$		0.98	1	$2.10.10^{-5}$
	6-12 months inclusive		$1.88.10^{-2}$		$1.88.10^{-4}$		0.63		$2.68.10^{-5}$
	13-18 months inclusive		$1.58.10^{-2}$		$1.58.10^{-4}$		0.53		$3.40.10^{-5}$
	19-24 months inclusive		$1.55.10^{-2}$		$1.55.10^{-4}$		0.52		$4.42.10^{-5}$
	25-30 months inclusive		$1.40.10^{-2}$		$1.40.10^{-4}$		0.47		$4.30.10^{-5}$
	31-36 months inclusive		$1.11.10^{-2}$		$1.11.10^{-4}$		0.37		$3.64.10^{-5}$

Chemicals	Ages	concentration in the diaper part (mg/kg)	DED(mg/kg/d)	TEF	DED toxic equivalent (mgTEQ/kg/d)	TRV(mg/kg/d)	HQ	ERU (mg/kg/d)$^{-1}$	IER
Benzo[a]pyrene	0-6 months exclusive	0.405*	$1.99.10^{-2}$	1	$1.99.10^{-2}$	$3.00.10^{-4}$	66.3	1	$1.42.10^{-3}$
	6-12 months inclusive		$1.27.10^{-2}$		$1.27.10^{-2}$		42.4		$1.82.10^{-3}$
	13-18 months inclusive		$1.07.10^{-2}$		$1.07.10^{-2}$		35.8		$2.30.10^{-3}$
	19-24 months inclusive		$1.05.10^{-2}$		$1.05.10^{-2}$		34.9		$2.99.10^{-3}$
	25-30 months inclusive		$9.48.10^{-3}$		$9.48.10^{-3}$		21.6		$2.91.10^{-3}$
	31-36 months inclusive		$7.52.10^{-3}$		$7.52.10^{-3}$		25.1		$2.47.10^{-3}$
dibenzo[a,h] anthracene	0-6 months exclusive	0.311*	$1.53.10^{-2}$	1	$1.53.10^{-2}$		51	1	$1.09.10^{-3}$
	6-12 months inclusive		$9.79.10^{-3}$		$9.79.10^{-3}$		32.6		$1.40.10^{-3}$
	13-18 months inclusive		$8.26.10^{-3}$		$8.26.10^{-3}$		27.5		$1.77.10^{-3}$
	19-24 months inclusive		$8.06.10^{-3}$		$8.06.10^{-3}$		26.9		$2.30.10^{-3}$
	25-30 months inclusive		$7.29.10^{-3}$		$7.29.10^{-3}$		24.3		$2.24.10^{-3}$
	31-36 months inclusive		$5.78.10^{-3}$		$5.78.10^{-3}$		19.3		$1.90.10^{-3}$
benzo(ghi)perylene	0-6 months exclusive	0.418*	$2.05.10^{-2}$	0.01	$2.05.10^{-4}$		0.68	1	$1.47.10^{-5}$
	6-12 months inclusive		$1.31.10^{-2}$		$1.31.10^{-4}$		0.48		$1.87.10^{-5}$
	13-18 months inclusive		$1.11.10^{-2}$		$1.11.10^{-4}$		0.37		$2.38.10^{-5}$
	19-24 months inclusive		$1.08.10^{-2}$		$1.08.10^{-4}$		0.36		$3.09.10^{-5}$
	25-30 months inclusive		$9.78.10^{-3}$		$9.78.10^{-5}$		0.33		$3.00.10^{-5}$
	31-36 months inclusive		$7.76.10^{-3}$		$7.76.10^{-5}$		0.26		$2.55.10^{-5}$

* : detected chemical

Notes

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