Version 2.0

EDANA Dossier

Absorbent Hygiene Products (AHPs)

A compilation of AHPs key facts with a focus on the Analysis and Risk Assessment of CODEX ™ listed trace chemicals

01.04.2022

Foreword

Founded in 1971, EDANA is the leading global association and voice of the nonwovens and related industries with more than 300 member companies. EDANA represents suppliers and manufacturers of absorbent hygiene products (AHPs) covering a large market share of branded and private label products in Europe, Middle East and Africa. EDANA provides for its members a comprehensive range of services to enhance the industry's goals and performance. Through safe and open networking platforms, EDANA supports sustainability ambitions, responsible product stewardship, and address common technical, regulatory and market challenges.

The principle that products must be safe for consumers, employees, and the environment is paramount for the AHP industry whose products have a long history of safe use worldwide. It is essential to maintain high standards for product safety and quality and the EDANA member companies manufacturing AHPs have a longstanding commitment to the protection of human health.

To further strengthen the industry's safety efforts and enhance consumer confidence. EDANA and its members have embraced a new level of action and transparency on levels of trace substances with the voluntary Stewardship Program for AHP. The Stewardship Program allows companies to voluntarily go beyond current EU and national legislation and the participants are free to go beyond the established criteria of the Stewardship Program based on their specific quality assurance processes.

It is fundamental for EDANA to provide this information in a transparent manner for upcoming evidence-based discussions with respective stakeholders. The work underlines the responsibility of EDANA member companies manufacturing AHPs in placing safe products onto the market.

Pierre Wiertz, General Manager

This document in no way limits or replaces the responsibility of individual manufacturers of Absorbent Hygiene Products to place safe products on the market.

If you have any questions about the document, please contact info@edana.org

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Abbreviations

ADI	Acceptable Daily Intake
ADME	Absorption, Distribution, Metabolism and Elimination
AHP	Absorbent Hygiene Product
ALARP	As Low as Reasonably Possible
AMPA	Aminomethylphosphonic acid
ATSDR	Agency for Toxic Substances and Disease Registry
CAS	Chemical Abstracts Service
CDC	Centers for Disease Control and Prevention
CV	Coefficient of Variation
DNEL	Derived No-Effect Level
EBRA	Exposure-Based Risk Assessment
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemical Agency
ED	Endocrine Disruptor
EFSA	European Food Safety Agency
EPA	Environmental Protection Agency
EU	European Union
GLP	Good laboratory practices
GMP	Good manufacturing practices
HRV	Human Reference Value
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IFRA	International Fragrance Association
INCI	International Nomenclature Cosmetic Ingredients
IPCS	International Program on Chemical Safety
ISO	International Organization for Standardization
LOQ	Limit of Quantification
MADL	Maximum Allowable Dose Level
MOE	Margin of Exposure
MOS	Margin of Safety
NESIL	No Expected Sensitization Induction Level
NGO	Non-Governmental Organisation
NIAS	Non-intentionally added substances
NOAEL	No-observed-adverse-effect level
NOEL	No observable effect level
NSRL	No Significant Risk Level
NWSP	Nonwovens standard procedure
OECD	Organisation for Economic Co-operation and Development
OEHHA	California Environmental Protection Agency's Office of Environmental Health Hazard Assessment
PAH	Polycyclic aromatic hydrocarbons
PBPK	Physiologically Based Pharmacokinetic
PCB	Polychlorinated biphenyls
PDE	Permitted Daily Exposure
PoD	Point of departure
QMS	Quality Management System
RA	Risk Assessment
RAC	ECHA' Risk Assessment Committee
RfD	Reference dose

SAR	Structure-Activity Relationship
SAP	Superabsorbent polymers
SCCS	Scientific Committee on Consumer Safety
SCHER	Scientific Committee on Health and Environmental Risks
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SEAC	ECHA' Committee for Socio-economic Analysis
SRP	Scientific Review Panel
STS	Secondary top sheet
SP	Stewardship Program
SVHC	Substances of very high concern
TCCR	Transparency, clarity, consistency and reasonableness
TDI	Tolerable daily intake
TTC	Threshold of Toxicological Concern
UN	United Nations
VOC	Volatile organic compounds
WHO	World Health Organisation

Introduction

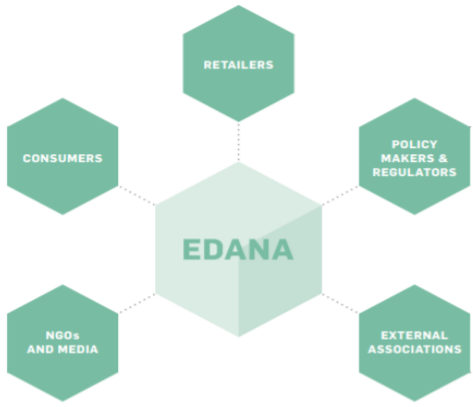
This dossier addresses various key aspects and facts around disposable absorbent hygiene products (AHPs) covering the product categories of baby diapers, adult incontinence products and feminine hygiene products. It reflects the current state of the art knowledge of EDANA member companies manufacturing AHPs and it aims at all those with an interest in the safe use of AHPs including e.g., consumer organisations, policy makers and regulators (see fig 1). It allocates important, fact-based information on these everyday consumer products in a transparent manner.

It is structured through various chapters ranging from general information on AHPs, their regulatory framework to the processes for selecting respective feedstock materials, the manufacturing processes etc. A major focus is on the safety evaluation of these products and the potential presence of trace substances in the finished product. On the analytical part the dossier provides information of the new analytical method developed by EDANA to determine trace chemicals in AHPs and which reflects consumer relevant aspects. The investigation of toxicological aspects in exposure-based risk assessments (EBRA) is essential to ensure the safe use of products for consumers.

The dossier outlines the details of the voluntary EDANA industry voluntary standard for AHPs in Europe, the EDANA Stewardship Program, which can be regarded as a further industry code of practice, and which has been endorsed by the vast majority of AHP manufacturers in Europe, in order to respond to consumer concerns on perceived safety issues and increase trust in AHPs.

The various chapters that compile facts relevant for the topic dealt with in this section can be read also as standalone information.

Figure 1: EDANA and its stakeholders



EDANA regards this dossier as an open platform for future cooperative science-based dialogues with authorities and any stakeholders interested in the topics covered by this report. Once new scientific insights become available, EDANA member companies are determined to engage with stakeholders in a transparent way to discuss these in order to further enhance consumer trust in the safety of these products.

1. General Information on AHPs

1.1. Market/Usage data

Millions of consumers worldwide rely on disposable Absorbent Hygiene Products (baby diapers, feminine hygiene products in particular napkins, panty liners and tampons and adult incontinence products) on a daily basis.

These everyday products have made a very important contribution to the quality of life and skin health for the user, parents and caregivers.

Nowadays baby diapers are highly absorbent products that are comfortable to wear due to the softness, lightness and 'breathability' of the materials used. They provide essential health and hygiene features of modern-day life and have become the product of choice for nearly all families across Europe, reducing the burden of domestic chores, freeing parents to spend more time on other activities.

Various feminine hygiene products are available, ranging from tampons to napkins and pantyliners. They facilitate the increasing independence of girls and women and their ability to be active at all times of the month, be it in the private environment or at school and work. Feminine hygiene products provide a means to manage menstrual flow and between cycle discharge for the entire reproductive stage of a woman's life.

Incontinence can dramatically change an individual's ability to participate in everyday life. Incontinence can cause isolation, result in depression and psychological problems, prohibit social activity and active participation in the workforce. Modern incontinence products for mobile people enable users to maintain a sense of dignity, to retain independence and to take part in social activities because hygiene and cleanliness can be maintained. For caregivers, taking care of bedridden people, effective adult incontinence products can be a great help as they save valuable care-taker' time in changing and disposing of products allowing more time for other important caring activities.

The benefits of AHPs are reflected by the usage numbers, as shown in table 1.

Table 1: overall numbers of units sold per AHP category in greater Europe (which includes Turkey and Russia) during 2020 (source EDANA/Euromonitor).

Baby diapers	33 billion
Feminine hygiene products	55 billion
Adult incontinence products	10,6 billion

Although the markets for baby diapers and feminine hygiene products appear to be saturated in some countries in Western Europe, there is further growth expected in countries in Eastern Europe and in the adult incontinence segment. The latter is directly related to demographic developments.

1.2. Legal framework of absorbent hygiene products

AHPs are subject to different legislations worldwide. For this dossier the focus is Europe. Products must comply with all relevant European and national legislations relating to chemicals and product safety.

Products like incontinence products are classified as medical devices and they must comply with the Regulation (EU) 2017/745 on medical devices. Medical devices manufacturers must undergo the legal procedure for CE marking. The CE marking applied to a medical device guarantees that the essential requirements are met and thus that the performance, safety and benefits of the medical device have been demonstrated for the intended use. Post-market surveillance by the Competent Authorities and a medical device surveillance and vigilance system by manufacturers guarantee that medical devices continue to be safe and perform as expected. Surveillance systems allow evaluation of consumer feedback and ensure actions are undertaken if the risk of continued use of the medical device outweighs the benefits.

Baby diapers and feminine hygiene products are considered commodities in Europe and are subject to the General Product Safety Directive (GPSD) 2001/95/EC. This Directive applies to all 'non-harmonised products' for which no specific EU harmonised legislation exists. According to the GPSD, a product is regarded as safe if it meets all statutory safety requirements under European or national law. The Directive provides a generic definition of a safe product, namely that products must be safe under normal or reasonably foreseeable conditions of use by consumers. Manufacturers selling AHPs must therefore guarantee that only safe products are placed on the market. Producers are expected to undertake a risk assessment of their products before they are placed on the market. This will form the basis of their conclusion that the product satisfies the general safety obligation and can be marketed. It also provides a reference for subsequent reassessment of further risk information and whether the product continues to satisfy the definition of "safe product".

Article 3 of GPSD describes how conformity is assessed with reference to national legislation, European standards and other reference material. Where suitable European standards do not exist the GPSD allows other elements to be taken into account in assessing the safety of a product: national standards, codes of good practice, etc. For the latter the EDANA Tampon Code of Practice and the EDANA Stewardship Program for AHPs are examples.

In addition to the present European legal framework, certain regulatory requirements relevant for AHPs do exist at national level and must be checked by the manufacturer for each product type.

AHPs manufacturers have the duty to inform consumers of any risks associated with the products they supply and to make sure that any product deemed unsafe present on the market can be traced so that it can be removed to avoid any risks to consumers. The procedure in Annex II of the Guideline for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors in Accordance with Article 5(3) of Directive 2001/95/EC assists

manufacturers to decide whether a specific hazardous situation caused by a product requires notification to the authorities. EU general risk assessment methodology implementing Article 20 of Regulation (EC) No 765/2008 assists Authorities in their market surveillance activities.

In case a dangerous product is identified, the Safety Gate[1] - the EU rapid alert system for dangerous non-food products - ensures that the relevant authorities are rapidly informed. As emergency measures and under certain conditions the Commission may adopt a formal decision requiring the Member States to ban the marketing of an unsafe product, to recall it from consumers or to withdraw it from the market.

Finished AHPs are considered to be articles under REACH Regulation (EC) No 1907/2006 and manufacturers are obliged to generate rigorous information about the potential presence of substances of very high concern (SVHC) in their products. When such substances are added to the Candidate List, manufacturers are required to:

- Notify[2] ECHA (the European Chemicals Agency) if the article contains such a substance:

a. in quantities totalling over 1 tonne per producer or importer per year of the substance, and

b. above a concentration of 0.1 % weight by weight. This threshold of 0.1% applies to any component of the article as produced or imported.

The notification must be submitted to ECHA no later than 6 months after the inclusion of the substance in the Candidate List (unless an exemption applies).

- Provide sufficient information to allow safe use of the article to their customers. Where a substance in the Candidate List is present in any component of an article in a concentration above 0.1% weight by weight, the company placing that article on the market must provide all customers receiving the article with sufficient information about the safe use of the article, including, as a minimum, any component where the substance is present and the name of the substance. This information is to be provided immediately, i.e., as soon as it is known that the substance is present in any component of the article above 0.1%. Upon request, the manufacturer must provide the same information to any consumer within 45 days of receipt of the request.

A number of substances are included in the Annex XVII of REACH Regulation (EC) No 1907/2006 meaning that their presence in consumer articles may be banned or restricted (in full or for specific uses) to a specified amount or a specified migration limit. Certain categories of articles might be exempted from the restriction. Examples for restrictions

[1] The Safety Gate system (formerly RAPEX) enables quick circulation of information about non-food dangerous products among the national authorities responsible for product safety in the Single Market countries.

[2] A separate notification is required under the EU Waste Framework Directive. EU suppliers of articles containing substances on the Candidate List in a concentration above 0.1% w/w when placing them on the EU market have to register the substance in the SCIP database, available to waste operators and consumers.

under Annex XVII are certain phthalates in plasticised materials in childcare articles[3] (entry 51) and polycyclic-aromatic hydrocarbons (PAH) in plastic components (entry 50). Similarly, entry 43 on azocolourants and azodyes covers among other consumer products "nappies and other sanitary items" and entry 20 on organostannic compounds covers childcare articles and female hygiene products for Dioctyltin (DOT).

1.3. Criteria for feedstock selection

Raw materials for the manufacture of AHPs are rigorously selected according to various criteria that include, behind technical, safety, quality, regulatory aspects also information on chemical substances, whether they are intentionally added or present as possible trace impurities. Long-lasting relationships with suppliers of feedstocks are common and the basis for a trustful partnership.

EDANA AHP members are using approved external suppliers with demonstrated capability to provide suitable feedstocks from both technical and Quality Management System point of view (see fig 10).

Figure10: raw material related processes, (source: EDANA member companies)

Control Point Area	Characteristic That is Assessed
Definition of Raw Materials and Suppliers	• Materials are assessed for safety and not incorporated into finished products unless the material meets all safety expectations • Materials are defined through Material Specifications • Materials are validated to achieve expected performance requirements • Suppliers Material Quality Management System expectations (initially and regularly maintained)
Receipt of Raw Material	• Material Certificate of Analysis (COA) – where defined through the specification • Periodic review of supplier capability for execution of test methods • Confirmation of Material Identity upon receipt
Storage and Handling of Raw Materials	• Housekeeping and packaging standards are in place to prevent inadvertent contamination of materials from environmental sources or other materials • Transportation and Facility standards are in place to ensure material suitability prior to, during, and after assembly into Finished Product.

EDANA member companies manufacturing AHPs implement their own, extensive product qualification and safety procedures throughout their supply chains which often go beyond existing legal requirements.

The information (in the form of questionnaires and possibly also declarations of conformity) that need to be provided by a feedstock supplier to an AHP manufacturer may vary. However, detailed information about every material and any subsequent changes is required to ensure they can be assessed for safety prior to use.

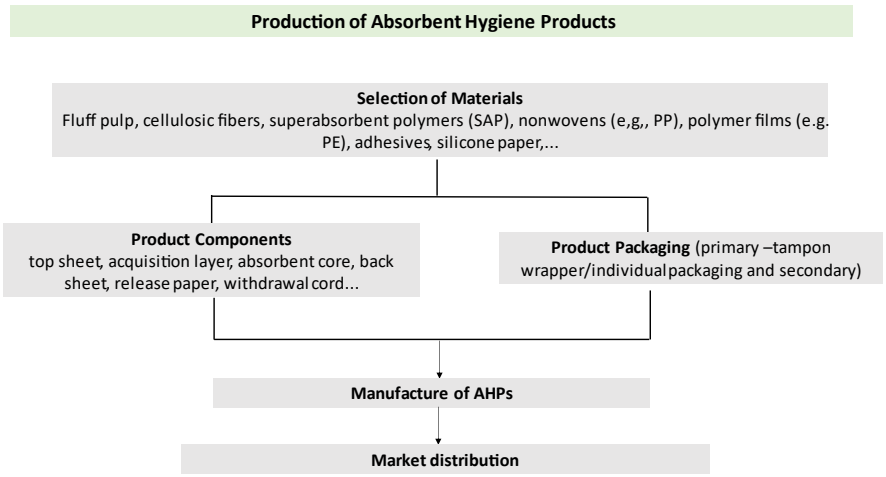
EDANA has developed a comprehensive supply chain guidance document outlining basic information about product safety and regulatory requirements for placing AHPs on the EU market [REF16]. It outlines basic technical, safety and regulatory information that is needed in the qualification process of a raw material to ensure the regulatory compliance of finished AHPs.

[3] A current definition of childcare articles as per entries 51 and 52 of Annex XVII to REACH Regulation (EC) No 1907/2006 includes any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. Single-use baby diapers can be considered as childcare articles regarding the above definition.

For packaging materials and in particular the primary packaging materials that are in direct contact with the product, similar qualification processes are applied.

1.4 Manufacture of AHPs

Figure 4 AHP production flow scheme



While absorbent hygiene products will be different with each brand and come in different shapes and sizes, the manufacturing steps are similar (see figure 4 and **Appendix B**). The production process of AHPs in principle is an assembly process where the different components are converted in to finished products and subsequently packed. This converting process is in most cases a fully automated, high-speed process that takes place in a dry environment meeting high hygienic standards. The full operation is based on good manufacturing practices (GMP). Speed in units per minute depends on the state of technology used in the time the manufacturing line was constructed and on the size of the individual products. The manufacturing equipment typically is capable of running at a certain linear speed (meters/minute). Modern baby diaper lines can produce over 1000 pieces a minute, smaller panty liner production can exceed a speed of 2000 units a minute.

Elevated temperatures (90-170 °C[4]) may occur but generally only in the area where hot-melt glue is used to bond components together. Temperature control mechanisms are established to prevent overheating as this can affect glue bond strength and manufacturing process and product reliability.

Strict quality control systems are in place to ensure the quality and hygiene requirements are met throughout the converting process: from incoming raw materials, via the converting process up to and including the finished product. Manufacturing process controls include visual (camera system based) controls and feedback loops that use online measurements to continuously keep the machine settings within the pre-defined limits. The products and manufacturing sites are regularly audited to ensure they consistently deliver the required product quality. Different tests are carried out on samples taken from

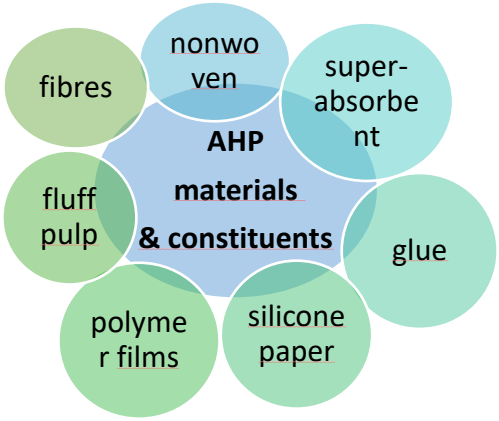
[4] surveys of EDANA manufacturers

the manufacturing process and on the final products to ensure that the products meet the high quality and safety standards imposed by the manufactures, prior to release to the market.

1.5 Composition of AHPs

Absorbent hygiene products are complex products made from a variety of constituents and materials that have individual production chains (figure 2).

Figure. 2: AHP composition details (source Outlook EDANA conference presentation 2019)



The product is made by assembling the various components that have different functions resulting in products with the desired properties. The product design is based on efficient absorption capacity of body fluids and the objective to keep wetness away from the skin. At the same time products should provide ease of use and comfort.

Over the roughly six decades AHP products have been commercially available on a larger scale, they have been constantly improved to address the needs of consumers. Most notable is that diapers have become much thinner (figure 3) and thus lighter but at the same time more absorbent due to the higher absorbing superabsorbent polymers (SAP).

Figure.3: thickness of diapers, (source EDANA member company)

AHPs that are worn externally (outside the body) like diapers, napkins, panty liners and incontinence products have a multilayer structure, i.e.:

- a fluid permeable surface layer (topsheet),
- an acquisition / distribution layer,
- an absorbent core,
- a fluid impermeable backsheet,

Additionally, there is adhesive to fix the product in the underwear or to ensure the integrity of the product, release paper that protects the adhesive layer on the back of the product prior to use and various elastics (e.g., to optimize fit).

Tampons usually consist of a surface material/cover, the absorbent core, a withdrawal string and some tampons come along with an applicator to help to insert the product.

Pigments and dyes may be used in small amounts for improved aesthetics and user friendliness, to indicate wetness status of a product or to print lot code numbers to facilitate consumer feedback on products they have purchased. Printed or coloured areas are usually sandwiched between the outer layer of the products.

Please refer to **appendices A** and B that reveal AHPs' composition and construction details.

AHPs might have a primary packaging (e.g., individual wrapper for pantyliners and napkins or the tampon wrapper) which is removed prior to product usage. A secondary packaging (either a pouch made of flexible packaging material or a carton) protects the products during the transportation pathways.

1.6. Origin of possible chemical trace residues

Traces of substances (e.g., in the ppm/ppb range) that are not intentionally added to the product (NIAS) and have no function in the products might be possibly present in AHPs like in many other consumer products. They are often unavoidable and may have several different origins. For example, they may be anthropogenic pollutants originating from agriculture or forestry such as glyphosate or from different sources in our daily environment, like incineration/combustion from traffic, energy production or crematories, or naturally occurring disasters like forest fires and volcanoes. An example of the widespread occurrence of certain chemicals in the environment is the presence of dioxins [Dopico et al., 2015, REF2]. Trace substances can also originate from impurities in the production of raw materials e.g., catalysts used in feedstock production, trace levels of unreacted monomers, processing aids etc. Other traces might originate from materials made of resins (e.g., polypropylene, polyethylene), stability and performance subcomponent additives like spin finishes, etc. When producing AHPs, it cannot be excluded that trace chemicals might be present from constituents and materials in the finished product. However, due to the significantly low percentage of each feedstock subcomponent in the finished article the likelihood to be detected is little. In case trace chemicals are detected, a thorough safety evaluation (see chapter 3) will be always conducted to ensure that, even at very low levels, they do not affect the safety profile of the product. The category of possible trace substances can be subdivided into:

- Contaminants of a known origin by the industry and the related supply chain: AHP manufacturers and the entire supply chain make a strong effort to minimize these potential trace chemicals by using appropriate control measures and by improving processes where it deems necessary.
- Ubiquitous contaminants that are generally unavoidable: EDANA members manufacturing AHPs together with their supply chain undertakes efforts to work around these in order to avoid their potential presence in finished products as far as possible.
- Unknown contaminants that may be detected by the industry during analytical quality control measurements: The detection of unknown contaminants, however, is rare these days and in case it occurs, a root cause investigation is made.

EDANA AHP manufacturers have been investigating the potential presence of known trace chemicals for a long time, examples are monitoring dioxins/furans, organotins, phthalates. Since 2001, EDANA members have strictly adhered to self-imposed limits on the presence of organotins in AHPs, long before the enactment of the Commission decision of 28 May 2009 amending Council Directive 76/769/EEC as regarding restrictions on the marketing and use of organostannic compounds for the purpose of adapting its Annex I on technical progress, addressing concerns of users and the public. The Commission acknowledged the industry's position and even offered to issue a public statement clarifying that, indeed, there is no safety issue stemming from organotins in AHPs.

1.7. Post market surveillance related information

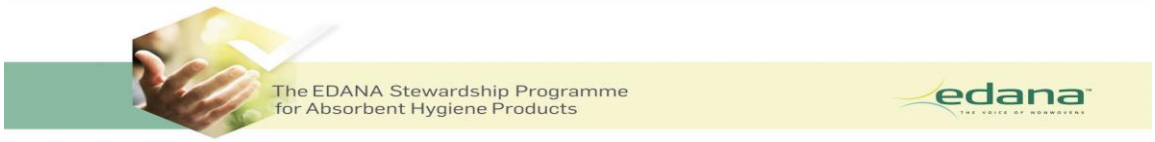
AHP products have a long history of safe usage over decades due to the fact that industry responsibly takes all necessary steps to ensure this.

Post-market surveillance data reveal a low incidence of reported health related complaints (Table 4). This low incidence can be attributed to the safety process which starts with high quality raw material choices and is supported by a rigorous toxicological safety assessment for all components. Clinical in-use studies and skin tests can complement this assessment. Analytical testing to identify possible impurities is performed to ensure they are below established guidance values. Furthermore, all of this is supported by a manufacturing process under high quality controls. Taking all this together it allows for manufacturers to put safe and high-quality products on the market. Based on the available data, to the best of EDANA members' knowledge the Safety Gate (previously RAPEX Rapid Alert System for Non-Food Products of the European Commission) has never recorded any case of a non-compliant AHP. Importantly, companies monitoring data for health-related adverse events/ in-market complaints shows that AHPs do not trigger any significant number of health complaints based on typical product use.

Table 4: Overview data collated by EDANA (based on the data provided by member companies)

Product type	Health-related events **per million** AHPs sold in Europe (2016-2020)
Baby diapers	0.40
Feminine hygiene products	0.46
Adult incontinence products	0.16

1.8 EDANA's Stewardship Program and the CODEX™



The voluntary EDANA Stewardship Program for AHPs [REF1] builds on the longstanding record of responsible safeguarding of these products. It provides increased transparency and enhanced reassurance for consumers regarding trace levels of impurities found in AHPs.

The Program addresses concerns regarding possible trace chemicals that may be found in AHPs when sensitive analytical methods are applied in specialized laboratories. Despite of the fact that those potential trace chemicals are well below existing regulatory limits and pose no risk to health, in 2018 the Stewardship Program was set up to further build consumer trust in the safe use of AHPs. EDANA members believe it is their responsibility to initiate harmonised consumer relevant testing methodologies to analyze possible trace levels of substances in AHPs.

The Stewardship Program has a foundation built from several elements. Its core part is the CODEX™ which is detailed further below. The two other pillars of the Program comprise the Charter, the formal signatory document to which adhering companies commit and the governance structure featuring a Steering Committee and a Scientific Review Panel. The program is open to any company manufacturing and/or placing absorbent hygiene products on the market, regardless of whether these companies are members of EDANA or not. More details about the Program can be found on the EDANA website (REF 1).

The CODEX ™ consists of several elements:

- A list of trace chemicals purposely chosen by EDANA
- Guidance values for each substance/substance class
- Standardized test methods to evaluate products for possible traces of substances

Exposure based risk assessment (EBRA) is the method of choice, as a scientifically sound approach using realistic exposure parameters.

Figure 5: Stewardship Program CODEX™ elements

Companies that subscribe to the EDANA Stewardship Program commit to not exceed guidance values of a defined list of substances identified in the CODEX™ in absorbent hygiene products that are tested using harmonised, consumer relevant test methods.

Complying with the CODEX ™ is the basis of the EDANA Stewardship Program, which is a further step of demonstrating that manufacturers increase the already high level of consumer protection by a proper management of possibly hazardous substances that might be present in AHPs.

- <u>List of chemicals</u>

The list of trace impurities covers chemical substances that are not intentionally used to manufacture AHPs, but that may be present in trace amounts.

Criteria for selection of the chemicals include:

- ubiquitous substances or substances that have a theoretical likelihood of occurrence in the supply chain,
- Substances that are subject to regulatory scrutiny, ongoing investigation by competent authorities or general consumer concern
- Substances which have a long history of being tracked within the EDANA membership.

All participants (members and non-members) remain totally free to go beyond that list and include other chemicals into their own analytical investigation programs and product safety verifications.

Chemicals or classes of chemicals involved in this industry effort include PAHs, dioxins & furans, dl-PCBs, phthalates, certain phenols and pesticides, organotins, metals and formaldehyde (see table 2).

Table 2: CODEX™ relevant chemicals and their respective guidance values

	Dioxins and Furans and Dioxin-like Polychlorinated Biphenyls			PAHs	Phenols	Phthalates	Pesticides	Organotins	Formalde-hyde	Metals
Dermal penetration *	60% to 10%					<1% to <0.01%		< 10 to 1%		
Trace chemicals	**Dibenzo-p-dioxins (PCDDs)**	**Dibenzofurans (PCDFs):**	**DL-PCBs:**							
	2,3,7,8-TCDD (CAS 1746-01-6)	2,3,7,8-TCDF (CAS 51207-31-9)	**Non-ortho PCBs:**	Benzo(a)anthracene (CAS 56-55-3)	Bisphenol A (CAS 80-05-7)	DINP (CAS 28553-12-0)	Glyphosate (CAS 1071-83-6)	Monobutyltin (CAS 78763-54-9)	Formaldehyde (CAS 50-00-0)	Antimony (CAS 7440-36-0)
	1,2,3,7,8-PeCDD (CAS 40321-76-4)	1,2,3,7,8-PeCDF (CAS 57117-41-6)	PCB 77 (CAS 32598-13-3)	Benzo(a)pyrene (CAS 50-32-8)	Nonylphenol-di-ethoxylate	DEHP (CAS 117-81-7)	AMPA (CAS 1066-51-9)	Dibutyltin (CAS 1002-53-5)		Cadmium (CAS 7440-43-9)
	1,2,3,4,7,8-HxCDD (CAS 39227-28-6)	2,3,4,7,8-PeCDF (CAS 57117-31-4)	PCB 81 (CAS 70362-50-4)	Benzo(e)pyrene (CAS 192-97-2)	Nonylphenol	DNOP (CAS 117-84-0)	Quintozene (CAS 82-68-8)	Triphenyltin (CAS 668-34-8)		Chromium (CAS 7440-47-3)
	1,2,3,6,7,8-HxCDD (CAS 57653-85-7)	1,2,3,4,7,8-HxCDF (CAS 70648-26-9)	PCB 126 (CAS 57465-28-8)	Chrysene (CAS 218-01-9)		DIDP (CAS 26761-40-0/ 68515-49-1)	Hexachlorobenzene (CAS 118-74-1)	Dioctyltin (CAS 15231-44-4)		Lead (CAS 7439-92-1)
	1,2,3,7,8,9-HxCDD (CAS 19408-74-3)	1,2,3,6,7,8-HxCDF (CAS 57117-44-9)	PCB 169 (CAS 32774-16-6)	Benzo(b)fluoranthene (CAS 205-99-2)		BBP (CAS 85-68-7)		Monooctyltin (CAS 15231-57-9)		Mercury (CAS 7439-97-6)
	1,2,3,4,6,7,8-HpCDD (CAS 35822-46-9)	1,2,3,7,8,9-HxCDF (CAS 72918-21-9)	**Mono-ortho PCBs:**	Benzo(k)fluoranthene (CAS 207-08-9)		DBP (CAS 84-74-2)		Tributyltin (CAS 688-73-3)		
	OCDD (CAS 3268-87-9)	2,3,4,6,7,8-HxCDF (CAS 60851-34-5)	PCB 105 (CAS 32598-14-4)	dibenzo(a,h)anthracene (CAS 53-70-3)		DiBP (CAS 84-69-5)				
		1,2,3,4,6,7,8-HpCDF (CAS 67562-39-4)	PCB 114 (CAS 74472-37-0)	Benzo[j]fluoranthene (CAS 205-82-3)		DIHP (CAS 71888-89-6)				
		1,2,3,4,7,8,9-HpCDF (CAS 55673-89-7)	PCB 118 (CAS 31508-00-6)	Benzo[g,h,i]perylene (CAS 191-24-2)		BMEP (CAS 117-82-8)				
		OCDF (CAS 39001-02-0)	PCB 123 (CAS 65510-44-3)	Indeno[1,2,3-cd]pyrene (CAS 193-39-5)		DPP/DIPP (CAS 605-50-5)				
			PCB 156 (CAS 38380-08-4)	Phenanthrene (CAS 85-01-8)		DnPP (CAS131-18-0)				
			PCB 157 (CAS 69782-90-7)	Pyrene (CAS 129-00-0)		DnHP (CAS 84-75-3)				
			PCB 167 (CAS 52663-72-6)	Anthracene (CAS 120-12-7)		DMP (CAS 131-11-3)				
			PCB 189 (CAS 39635-31-9)	Fluoranthene (CAS 206-44-0)		DHNUP (CAS 68515-42-4)				
				Naphthalene (CAS 91-20-3)		DCHP (CAS 84-61-7)				
						DHxP (CAS 68515-50-4)				
						DIHxP (CAS 71850-09-4)				
						DIOP (CAS 27554-26-3)				
						DPrP (CAS 131-16-8)				
						DNP (CAS 84-76-4)				
						1,2-benzenedicarboxylic acid, di-C6-10 alkyl esters (CAS 68515-51-5)				
						1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (CAS 68648-93-1)				
Guidance values**	2ng/kg sum TEQ of the detected congeners of PCDDs, PCDFs and DLPCBs			0,2 mg/kg each	0,001% (BPA) 10mg/kg (each Nonylphenol and Nonylphenol-di-ethoxylate)	0,01% each	0,5 mg/ kg each	2ppb (TBT) 10 ppb (other organotins-each)	16mg/kg	Sb: 30mg/kg ; Cd: 0,1mg/kg; Cr: 1mg/kg; Pb: 0,2mg/kg; Hg: 0.02 mg/kg
Analytical method	EDANA NWSP 360 parts 1-3									

Notes:

**the dermal penetration (based on dermal absorption estimates and toxicity classification) is in general and specific values would apply where data exists

*Regulatory references:

Dioxin,Furans and Dioxin-like Polychlorinated Biphenyls : Reference value adapted from Regulation EC 1259/2011 on contaminants in foodstuff (infant food) taking into account that the systemic exposure via skin uptake is likely 10 % of the oral exposure

PAHs: Recommendation BfR/German BauA AfPs

BPA: REACH restriction proposal on bisphenols

Nonylphenols: Oeko-Tex-Standard 100, annex 4

Phthalates: Oeko-Tex® Standard 100, annex 6

Pesticides, Formaldehyde, Metals : Oeko-Tex® Standard 100, annexes 4& 6

ver. 1.4 March 2023

In the EU, chemicals in the voluntary CODEX ™ list are subject to the classification, labelling and packaging of substances and mixtures implemented in the Regulation (EC) 1272/2008 (see more information in **Appendix C**).

Endocrine disruptors: If a substance has been identified as an endocrine disruptor, EDANA members' approach would be to avoid using it. In cases where such chemical may be present as unavoidable impurity at trace level, its inclusion into the CODEX ™ will be considered and the substance will be assessed based on the safety evaluation approach outlined in **Appendix D.**

The list of substances and their respective guidance values may evolve over time if new scientific data and insights are available or regulatory limits are updated. Volatile organic compounds (VOC) might be future candidates of the substance list provided suitable reference values and analytical methods are available. Certain fragrance raw materials that are subject to classification as potential allergens might be considered for future lists although manufacturers producing fragranced AHPs assure that their products comply with the International Fragrance Association (IFRA) standards for fragrances [REF8] "that are recognized by government authorities and trade bodies around the world".

- <u>Guidance values</u>

The guidance values for each listed substance or substance class in a product are the levels not to be exceeded by the signatories of the voluntary EDANA Stewardship Program. In the unlikely case that a guidance value is not met for a product, it is the responsibility of the manufacturer to evaluate this further and to take corrective measures with the supply chain involved, if necessary.

Guidance values defined are reflective of the current regulatory landscape including those of neighboring sectors (e.g., textile and toys), related existing standards or industry experience when using appropriate test methods.

The development of guidance values follows a tiered approach.

First step:

Do EU/ National regulatory limits exist in related sectors?

If yes, the established thresholds from the REACH legislation (e.g., SVHC limit of 0.1%) or those from neighboring regulatory legislation such as for textiles but possibly also food etc. are taken into consideration with the option to set stricter values based on available industry data/experience. If such regulatory limit does not exist as reference points,

Second step

Do substance limits exist in standards for related product areas, e.g., Oeko-Tex ® standard 100 [REF11] for class 1 (baby products), German BauA AfPS GS [REF12] for category 1, etc.?

If yes, these standard limits can be taken into consideration.

If neither EU regulations nor other standards are available as reference points,

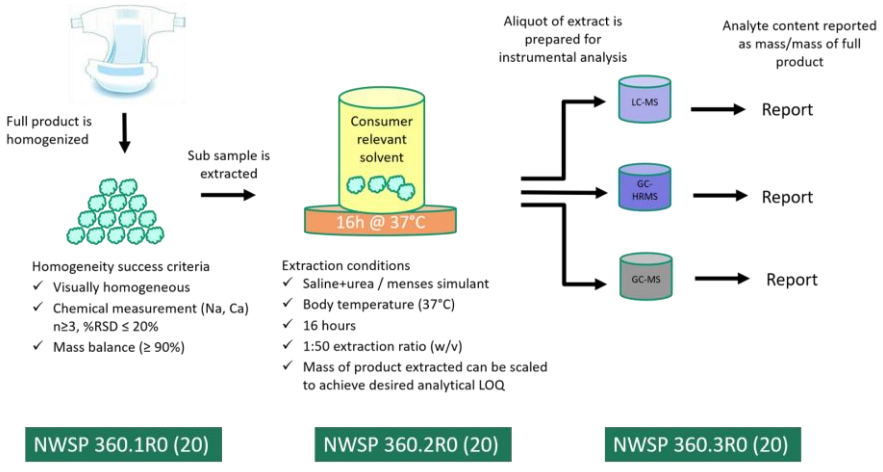
Third step Guidance value might be based on the Limit of Quantification from an applicable analytical method.

The requirement to perform the necessary assessment according to the General Product Safety Directive 2001/95/EC as described in section 2.1.2 is irrespective of the compliance with the CODEX™ guidance values.

- <u>Standardized test methods (see also chapter 2.2)</u>

An integral part of the CODEX ™ is the test method which has been developed by EDANA to check compliance with the guidance values laid down in the CODEX™. This development work was undertaken since there is a lack of a peer-reviewed, fully validated and harmonised, analytical methods to assess the classes of substances listed in the CODEX™ in a product user relevant way. Recently the Committee of Risk Assessment (RAC) and the Socio-Economic Analysis Committee of ECHA (SEAC) [REF13] acknowledged the lack of harmonised analytical methods. The use of an agreed and harmonised test method amongst all stakeholders is critical because the choice of the test method significantly affects the results, which is even more important when testing very low concentrations, close to the level of quantification, as is by default the case with trace chemicals. The EDANA method is the result of a development process aiming for an approach that is relatively easy to adopt (so that all players can use it), robust (repeatable and reproducible) and reflects consumer relevant aspects. A thorough exploration of options has led to a procedure that consists of three distinct parts: sample preparation, analyte extraction and analytical instrumental analysis (fig. 7).

Figure 7: EDANA CODEX™ Test Method Approach



AHP manufacturers are recommended to have their products tested against this newly developed method in any independent laboratory, working according to Good Laboratory Practice (GLP), who can demonstrate its ability to meet the described analytical requirements. The new method has been added to the existing catalogue of Nonwovens

Standard Procedures (NWSP) and is available from EDANA. For the analysis of feminine hygiene products, the biological fluid simulant is currently under development, the respective part of NWSP 360.2 is planned to be amended accordingly.

A detailed description how the analytic method was developed and what choices were made by EDANA is given in section 2 below.

2. Analytical investigations for the determination of possible trace chemicals in AHPs

2.1 Examples of analytical studies performed by Competent Authorities

Due to millionfold daily use of AHPs by consumers which is including the more vulnerable populations of babies and elderly people there has been an interest to investigate these products by regulatory agencies for the potential presence of trace chemicals since many years. This also to address the consumer concerns that are triggered by published reports and the media.

In 2009, the Danish Environmental Protection Agency (Danish EPA) conducted in 2009 [REF3] a survey and health assessment for the exposure to chemical substances in consumer products including baby diapers. A variety of substances were selected including dioxins/furans, certain phthalates, Bisphenol A etc. The analysis program consisted of three elements: 1. Screening analyses, 2. quantitative analyses and 3. migration analyses. All the products including diapers were extracted with dichloromethane and analyzed using GC/MS to determine the content of extractable organic substances.

In 2018 Kemi, the Swedish Chemicals Agency [REF4], undertook a survey of hazardous chemical substances in feminine hygiene products on the Swedish market performing quantitative and qualitative chemical analysis. A variety of chemicals was investigated including formaldehyde, dioxins & furans, polycyclic-aromatic hydrocarbons (PAHs), glyphosate etc. The analyses were performed by accredited laboratories. Analysis was done in two steps. First was a screening analysis done followed by a quantitative directed analysis of 62 selected substances (incl. formaldehyde, phthalate, D5 siloxane, abietic acid, organotin, etc.).

In 2018, the Belgian Federal Public Service of Health, Food Chain Safety and Environment [REF5] released a report presenting results of quantitative determinations of selected substances in baby diapers including PAHs, glyphosate, phthalates and dioxins using specific analytical techniques. Various organic solvents were used for the extraction of the products.

In 2018, the Swiss Federal Food Safety and Veterinary Office (FSVO) [REF6] carried out tests on single-use diapers available on the Swiss market screening the products among others for substances like dioxins and furans, PAHs, glyphosate and AMPA, phthalates etc. Already in 2016 feminine hygiene products were tested for the presence of dioxins & furans, PAHs, phthalates, formaldehyde etc.

In December 2020 the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) submitted a restriction proposal [REF7] under Annex XV to REACH including information about the analysis for the detection of hazardous substances in single use diapers. Chemicals in scope of the restriction proposal were dioxins & furans, dioxin-like PCBs, PCBs, formaldehyde and PAHs. ANSES outlined the use of various test scenarios ranging from solvent extraction of chemicals in aliquots of shredded whole diapers or diaper parts to what is called “migration” tests carried out with urine simulant

onto whole diapers and shredded whole diapers. Reference is made to the ANSES report of 2019 (REF7, page 15, footnote 2) in which the scenario where chemicals have been found using a migration test in a whole diaper by using urine simulant was considered as the most representative scenario of the reality of use.

The various reports show that substantially different analytical approaches are chosen which reflects the RAC/SEAC acknowledgement of a missing harmonised analytical method to investigate possible traces of chemicals in complex products like AHPs. The product investigations are performed on intact products, shredded products, parts of products or shredded parts of products and products after removing the superabsorbent material of the absorbent core. Various solvents are used ranging from polar (artificial urine) to nonpolar (organic solvents) ones. Frequently organic solvents are used for the extraction part in the above investigations. This route aims at determining the maximum release potential of trace substances possibly present in a product. However, it is far from a consumer relevant urine or other body fluid extraction that occurs in real life. The various studies showed the detection of a variety of substances in very low amounts based on the extraction method chosen. Most of these studies conclude that the presence of these very low amounts of substances, found under exaggerated, non-physiologically relevant conditions show a negligible health risk.

2.2. EDANA Method for Assessing Trace Chemicals in AHPs

Like the various stakeholders, EDANA also takes consumer concerns on trace chemicals very seriously. Building on the expertise of EDANA member companies, AHP manufacturers and experienced laboratories[5] [6], an alternative analytical approach based on homogeneously milled products and aqueous body fluid simulant has been chosen. Two independent laboratories (that are no members of EDANA) participated in the process.

Sound analytical methods are the basis for any analysis of trace substances possibly present in AHPs. Methods must be easy to handle, robust and applicable to a state-of-the-art laboratory that is working according to Good Laboratory Practice (GLP).

Solid analytical methods are also the prerequisite for performing toxicological assessments (see chapter 3).

EDANA set first analytical grounds many years ago (early 2000s) when the analysis of organotin compounds in AHPs became important to address public concerns about these substances.

In 2018 EDANA started a new initiative to assess the levels of trace chemicals potentially present in disposable absorbent hygiene products (baby diapers, adult incontinence products and feminine hygiene products). This work was done in the framework of completing the EDANA CODEX™. There were no standardized test methods (addressing elements of sample preparation, extraction, analytical instrumental analysis) available and optimized to be applicable across the entire scope of AHPs. Individual laboratories,

[5] https://www.galab.com/

[6] https://www.sgs.com/en/campaigns/sgs-consumer-goods-and-retail-services

in response to measurement requests from customers, typically have adapted methods originally developed for trace chemicals in environmental (e.g., soil and water) or medical (e.g., blood serum) samples to test for traces in AHP's. Even within what might be considered "harsh-organic extraction," there is no well-defined process (e.g., sample preparation possibly involving shredding/milling, solvent used etc.), leaving some questions as to the consistency or comparability of results. Moreover, harsh-organic extractions themselves are not intended toward true potential consumer exposure. Therefore, an important step toward greater consumer relevance in method design is to expose AHP articles to simulants representative of body fluids (e.g., urine, menses) that will contact the product during use.

A method mimicking the real usage situation of products involving the need for sampling fluid that resurfaces to the skin from the product (rewet fluid), that may contain trace chemicals, was discarded for the time being. Reasons were the very low amount of rewet fluid that could possibly be obtained for further analysis, need for specialized equipment, etc. Due to product construction, intended function and high-performance, the vast amount of e.g., urine and possible trace chemicals therein is locked in the core of the product. The liquid will stay in the product core, even under pressure from the bodyweight of the user. Only a very small fraction, the rewet fluid, can return to the surface of the product. This small amount of fluid handicaps the sensitivity of subsequent instrumental analysis. Furthermore, rewet experiments are tedious and generally require a high level of manipulation by hand and a dedicated, non-standard apparatus which makes these particular physiologically relevant methodologies difficult to deploy across analytical labs.

The development of the new EDANA method aims to balance needs of relevance, robustness and deployability. However, a mutual tension generally exists between these three goals and a favorable overall balance of them needs to be achieved. This versus any existing, established approaches. By optimizing a method for one or two goals, the other(s) are often suboptimal. For example, a harsh organic extraction of a sample is generally fairly robust and can be performed in some form broadly, but it departs markedly from what can be extracted from the AHP under normal use conditions. The challenge with creating a more consumer relevant method is that the level of consumer relevance is often in competition with its robustness and broad deployability for routine execution. A recent example of this is the method developed by French Authorities [REF14] that uses an intact, full product oversaturated with a complex urine simulant and resorts to squeezing at an unknown pressure in a screw press. The method requires large open vessels and intensive manual material handling and with this is associated both a heightened risk of false positive results and suboptimal deployability.

The method eventually developed by EDANA is based on extracting finely divided, homogenized material from milled AHPs with a single aqueous-based body fluid simulant (urine for baby diapers, adult incontinence and menses for feminine hygiene products). The concentration of any trace chemical present in the extract is then analyzed via one or more analytical instrumental analyses. The method has proven to be easy to handle across a range of competent laboratories, is robust (repeatable and reproducible), and reflects consumer relevant aspects:

Relevant. Products are tested under circumstances that reflect aspects of typical consumer usage.

Robust. The method delivers consistent results independent of the operator or the laboratory that is running the test. In effect, the method is repeatable and reproducible within a tolerable level of uncertainty.

Validated. The method delivers reliable results within the operating parameters of the method (considering variable environmental background levels).

Deployable. Any laboratory with state-of-the-art analytical equipment and well-trained staff can run the method in a transparent and accessible manner.

The new method with the NWSP number 360 "Determination of trace chemicals extracted from absorbent hygiene products (AHPs) using simulated urine/menses" is composed of 3 subparts, the sample preparation (NWSP 360.1.R0 (20), Part 1), the analyte extraction (NWSP 360.2.R0 (20), Part 2) and the chemical analysis (NWSP 360.3.R0 (20), Part 3).

The outlined information in the chapters 2.2.1 – 2.2.4 below is based on the White Paper[7] on the *EDANA Method for Assessing Trace Chemicals in AHPs* (Determination of Trace Chemicals extracted from Absorbent hygiene Products (AHPs using simulated urine/menses') prepared by EDANA's Analytical Task Force. In this White Paper further detailed information can be found.

2.2.1 Homogeneous AHP sample preparation via milling entire products

The exact procedure is detailed in NWSP 360.1.R0 (20), "Determination of trace chemicals extracted from absorbent hygiene products (AHPs) using simulated urine/menses Part 1: Milling of AHPs to produce a homogenized sample".

AHP articles are milled to create a finely divided (< 2mm), homogenized sample for subsequent extraction and analytical instrumental analysis. Milling is performed on dry (equilibrated to laboratory conditions) AHPs on a capable mill such as, for example, a Retsch SM300. AHP articles are milled whole such that surfaces and materials that touch the skin during use are not distinguished from surfaces that do not touch the skin. Similarly, surfaces and materials that may be wetted during use are not distinguished from surfaces that are unlikely to be wetted during use. The materials associated with AHPs that are not part of the actual wearing experience – such as wrappers, release films, and applicators – are removed prior to milling. Milling the whole product as such already leads to an even more conservative approach, as there are still materials contained that are in negligible skin contact (see chapter 3.2). While partial articles can be extracted in principle, it is not always obvious how to halve or quarter an article such that all constituent components are faithfully represented, a problem that is overcome by milling entire products. The method specifies a means through which sufficient sample homogeneity is affirmed via visual assessment and chemical elemental analysis of several specimens of milled sample material. Acceptable mass recovery is also affirmed.

[7] The White Paper on the EDANA Method For Assessing Trace Chemicals in AHPs is available upon request from EDANA, www.edana.org

Two success criteria must be met for milled AHP material to be sufficiently homogeneous for further use in the method. The first is a simple visual check – visual homogeneity is deemed sufficient if the milled sample is visibly homogeneous after shaking for at least one minute, see figures 8 and 9.

Figure 8: Diaper sample after mechanical milling and shaking

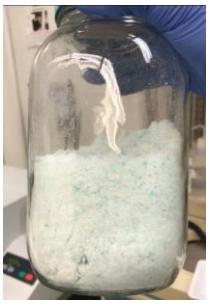


Figure 9: Homogenized feminine hygiene napkin (sample of 1g)

The second measure is a chemical homogeneity test based on elemental analysis. First, a marker element is identified based on AHP components that are most likely to segregate during milling. For example, if segregation of sodium polyacrylate superabsorbent polymer granules is a primary consideration, sodium is chosen as a marker element. Elemental analysis is then performed on three specimen portions taken from a single milled sample under evaluation. The sample is deemed to be sufficiently chemically homogenous if the coefficient of variation (CV) is less than 20% among these three samples. CVs of 20% to 30% are typical of instrumental trace chemical analyses, and therefore CVs of this same magnitude in sample composition do not significantly increase the CV of the overall method. Homogeneity results are specified to be reported as part of the method report output as is mass recovery. Mass recovery must be greater than 90% for the milling to be deemed successful.

2.2.2 Trace chemical extraction using aqueous biological fluid simulants

The exact procedure is detailed in NWSP 360.2.R0 (20), "Determination of trace chemicals extracted from absorbent hygiene products (AHPs) using simulated urine/menses Part 2: Extraction of trace chemicals from homogenized AHPs into a simulated urine/menses solution".

This part of the NWSP method covers the solid-liquid extraction step in which milled AHP material and body fluid simulant interact and trace chemicals potentially present in the AHP material can be extracted by the aqueous body fluid simulant.

A central aspect of the method is to expose AHP material to just a single, body fluid simulant. Careful consideration was made as to the composition of appropriate body fluid simulants for the investigation of baby diapers, adult incontinence, and feminine hygiene products. A urine simulant for the diaper and incontinence product extraction experiments had been identified during the developmental phase of the method resulting in what is called the "EDANA simulant" consisting of 0,9g/L sodium chloride and 9,3g/L urea. It captures both the dominant organic and dominant inorganic components typically present in urine. Studies are currently ongoing to identify the final composition of the menses body fluid simulant.

Parameters other than body fluid simulant composition that were considered were extraction time, extraction temperature, and ratio of simulant to mass of specimen of milled AHP sample being extracted. All of these is important to ensure that a sufficient quantity of free fluid remains. Experiments were designed and carried out on diaper samples with varying combinations of parameters using representative AHP material spiked with known amounts of representative trace chemicals. The results were analyzed to determine if a statistical basis was present to conclude that any extraction parameters were important drivers in the overall method results. Eventually the below experimental settings were chosen for baby diapers and incontinence products, relevant parameters for feminine hygiene products will be fixed once available.

Table 3: Final extraction parameters for baby diapers

Extraction Simulant	Extraction Temperature	Extraction Time	Sample/fluid ratio
EDANA simulant	37 °C (body temperature)	16 hours	1 g sample: 50 ml simulant

EDANA agrees that with the chosen aqueous body simulants potentially present trace substances that have a non-hydrophobic profile will predominantly be released into the aqueous fluids. This, however, mimics real life use where the product is exposed to such aqueous fluids. If the experiments were based on organic solvent extraction, the release potential of certain substances could possibly be higher, but exposure evaluations based on such results are clearly not relevant to normal use of the AHP. To investigate possibly present volatile trace substances a different experimental set-up must be chosen which was not yet part of the EDANA development work. Furthermore, the effect of skin lipids or skin creams on the transfer process of trace chemicals to the skin was not evaluated. Neither were products that contain cosmetic lotions investigated as their market share is very low compared to AHPs without such coatings. These addressed aspects can be subject of future investigations.

2.2.3 Chemical analysis of extracted trace chemicals

The exact procedure is detailed in NWSP 360.3.R0 (20), "Determination of trace chemicals extracted from absorbent hygiene products (AHPs) using simulated urine/menses Part 3: Analysis of trace chemicals in aqueous extracts (biological fluid simulants) of AHPs ".

NWSP 360.3 encompasses analytical instrumental analysis performed on filtered body fluid simulant extracts from method Part 2 to quantify any trace chemicals present. Typically, different instrumental techniques will be used for each trace chemical or class of related trace chemicals under study. In contrast to Parts 1 and 2, where specific conditions and parameter choices are specified in some detail, Part 3 allows for considerable latitude for laboratories to choose specific instrumental methods suitable for aqueous solutions and the trace chemicals under study.

This latitude reflects the following:

- Many contract laboratories have existing methods for investigating aqueous samples that can be adapted without undue effort to account for the composition of the consumer relevant body fluid simulant.
- Multiple instrumental methods may be suitable and validated for a particular trace chemical in an aqueous sample. Requiring conformance to a single instrumental method needlessly reduces the number of competent laboratories, and in doing so, reduces method deployability.
- Instrumental methods appropriate for, or most efficient for, a particular trace chemical may vary based on the target levels under study. This approach allows for instrumental methodologies to evolve – or to be modified to practically accommodate change in target levels without major method rework.

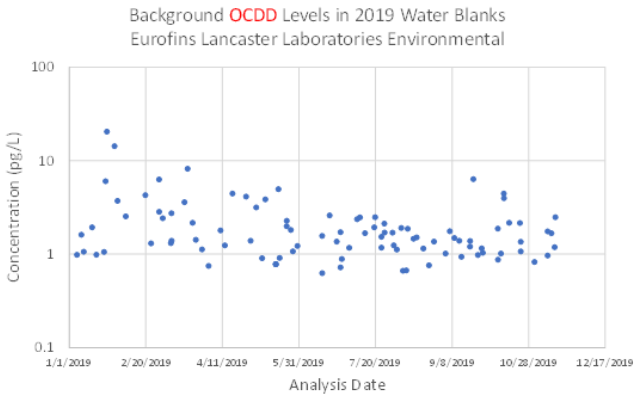
Common standard methods (ISO, EPA, etc.), broadly available for determining levels of trace chemicals in water samples and listed in an appendix of the part 3 method, may be applicable or may serve as starting points for laboratories to develop variations of instrumental analysis specifically suited for AHP matrices and the composition of the extraction solution.

A final reason that EDANA has chosen not to be prescriptive regarding the specifics of instrumental analysis is that trace instrumental analysis is difficult and tedious work. It is typical that laboratories specializing in this field implement specific and sometimes nonobvious measures to manage background levels of trace chemicals commonly found in the environment. It is beyond the scope of the EDANA method to attempt to anticipate and sufficiently specify all such particular measures that each lab may take. Instead, EDANA leaves these specific practices to the laboratories. Required instrumental method validation, demonstration of requisite LOQs, and mandatory blank sample performance serves to verify that laboratories have sufficient measures in place to ensure reliable instrumental results. A detailed reporting is mandatory. The target LOQs in the new NWSP method is the expected minimum amount of analyte that a laboratory must be capable of quantifying and was chosen to be no greater than 1/5 of the guidance value as specified in the EDANA CODEX™ (http://www.edana.org/www.EDANA.org)

Blank values determination

The sensitivity of trace chemicals analysis methods has developed over time and now allows the detection of very low amounts of analytes even to the levels that may mirror ubiquitous environmental background noise. This is important to keep in mind for analytical methods that could serve for any regulatory measures of chemicals under e.g., REACH Annex XVII or any other national regulations or standards. Many trace chemicals that are found at measurable levels in the environment and can be found at measurable levels in a laboratory setting, and false-positive detects can detract from overall method robustness. For example, background amounts of dioxins/furans can be detected in the ultrapure laboratory water of accredited laboratories, as illustrated by Graph 1 below:

Graph 1.: Background OCDD Levels in ultrapure laboratory water (source: Eurofins Lancaster Laboratories Environmental, 2019)



This underlines the need for a sound execution of blank runs to assure that detected substances present in the background are not attributed to the investigated product. EDANA has been explicit in its procedure about performing blank measurements. Blank samples are specified to be body fluid simulant portions that are carried through all steps of extraction and instrumental analysis but without specimen. Blank values must be reported if the blank value of a trace chemical is above the target LOQ of that trace chemical. Further, if a blank sample is measured to be greater than 1/3 of the target reference value under study for a particular trace chemical, analysis of that trace chemical is halted and not restarted until the source of the trace chemical in the blank sample has been proven to be remediated.

Final calculation:

Part 3 concludes with a calculation and reporting section. Masses and volumes captured throughout the overall sequence of NWSP 360 are brought together and used to produce a method output of mass of trace chemical per mass of AHP material, in units of mg/kg.

2.2.4 Affirmation of deployability and robustness

To evaluate a method's uncertainty, one typically sets up a ring test. For the EDANA method the task force that was assigned to develop the method has run a ring test with 4 independent laboratories. Although there are limitations, the conclusion from this ring test confirmed the robustness of the method. The limitations are that 4 labs represent the minimum number of participants in such a test to draw relevant conclusions. The reason for having only 4 participants is that the number of labs with the required capabilities is limited. Even amongst the 4 participants not all could test all analytes classes. However, EDANA has clear indications that the number of laboratories able to offer these tests will grow in the near future.

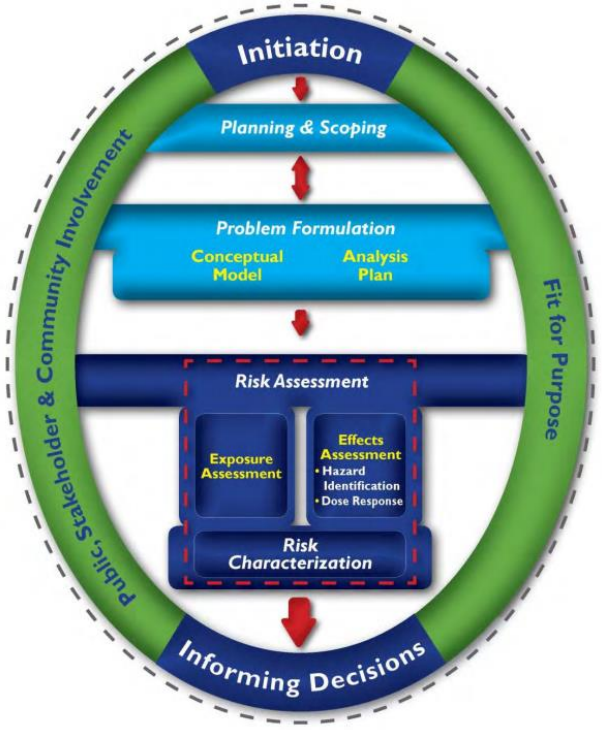
Concerning the results of the ring test, it was concluded that despite considerable differences in laboratory practices and/or instrumental approach indicated by the range of LOQs, the results for any particular analyte are highly consistent. There is no evidence of false positives, and there are no instances in which one lab quantified an analyte at a particular level and another lab, capable of measuring well below that same level, failed to detect the analyte. The largest observed difference in results between the laboratories is for Bisphenol A for which there is approximately a factor of four spread between the highest and lowest reported results. One explanation could be that BPA is unstable at 37°C (Vandenberg et al..2014, REF15]). Nonetheless, EDANA deems that these results on the whole demonstrate that the overall method is readily deployable and that it is sufficiently robust. It's important to realise that variation between test results increases considerably once the results get relatively close to the LOQ, variabilities of 50% are common.

3. Safety evaluation of AHPs

This chapter is aiming at outlining which principles industry is adhering to when it comes to safety evaluation of the here outlined products. The exposure-based risk assessment approach for this product category is being described in detail here, as well as how the correct risk values are being chosen. On top of this examples are given on how the margin of safety for certain trace chemicals is being calculated.

All absorbent hygiene products undergo a thorough safety assessment on top of what is required by the applicable regulatory framework (see chapter 1.2) before they are placed on the market. This is generally achieved through the human health risk assessment based on the outlined Framework by the US EPA (https://www.epa.gov/sites/default/files/2014-12/documents/hhra-framework-final-2014.pdf), which highlights the important roles of planning and scoping, as well as problem formulation, in designing a risk assessment that will serve a specific and documented purpose (Figure 11).

Figure 11: Framework for Human Health Risk Assessment



The key elements of the process for developing a risk assessment to inform decision making are as follows according to US EPA:

Planning and scoping: In this element, the process for conducting the risk assessment and its general scope are defined. This activity contributes to development of a sound risk assessment that serves its intended purpose. It also assists those interested in the risk assessment process in understanding the context of the risk assessment and the intended use of its results. A broad range of technical experts working as a team may be involved in this stage.

Problem formulation: This analytical consideration of the issue being assessed identifies the major factors to be considered in a specific assessment, thus informing the technical approach. An important outcome of problem formulation is a conceptual model that describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed lifestage(s), population(s), and endpoint(s) that will be addressed in the risk assessment. Based on the conceptual model, an analysis plan is developed, which describes the approach for conducting the risk assessment, including its design, methods and key inputs and intended outputs.

Risk Assessment:

Exposure and effects assessment: Exposure assessment, a core component of a risk assessment, will reflect the considerations identified in problem formulation. The parallel core component, effects assessment, includes hazard identification and dose-response assessment. Susceptible or more highly exposed populations may be identified in these assessments, when relevant information is available.

One of the key components in risk assessment is understanding the potential exposure the consumer will have to AHP components and product constituents during use; consumer exposure is dictated by the product construction and its use. NGOs and the general population often fail to understand that the mere presence of a chemical does not necessarily constitute a risk. Safety should always be evaluated by also taking exposure into account in an exposure-based risk assessment (EBRA).

Risk characterization: This step of the risk assessment, in which the exposure and effects assessments are integrated, provides risk managers with risk estimates and a useful, synthesized set of conclusions about the risk. It is intended to adhere to four principles: transparency, clarity, consistency and reasonableness (TCCR).

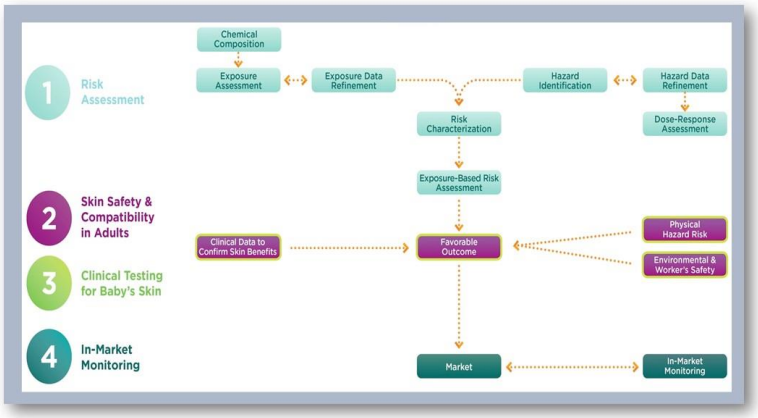
Informing decisions: The goal of the risk assessment team is to provide a comprehensive assessment for a range of possible risk management options. The description of the decision should clarify how the risk assessment and other factors informed the decision.

3.1 Exposure and effects assessment

Intentionally added ingredients, which are used to construct the AHPs, are well characterized from a safety perspective, while unintentionally added trace chemicals (see chapter 1.4) often require additional consideration in terms of product safety for consumers. The following chapters will outline how both intentionally and unintentionally added substances are evaluated for their safety.

Quantitative methods of risk assessment have been established by a number of international/regulatory agencies [REF17]. These methods are used to support human safety from a variety of exposures ranging from contaminants in the air and drinking water, to pesticides and other contaminants in food. EDANA industry members apply these same conservative, health-protective methods to assure the safety of AHP's (Figure 12).

Figure 12: Safety assessment process (source: EDANA members companies)



During an initial assessment, conservative default assumptions are commonly used. The conclusion of an initial risk characterization may be that there are sufficient data to support the chemical (even using conservative, default assumptions) or that additional data are needed to refine the assessment. Otherwise, the use of the constituent at the intended level cannot be supported and recommendation to either decrease the level of the chemical under evaluation or to reformulate with a different material is warranted. If it is necessary to obtain additional data, the risk characterization step is repeated once those data become available. The entire risk assessment process is repeated until sufficient data exist or until it is determined that the chemical under evaluation cannot be supported.

Initially the complete chemical composition of each product component proposed for use in an AHP is obtained. Details may include constituent information from primary and downstream suppliers and may also include information on known or expected contaminants of these product components. Data are entered into a comprehensive, proprietary database for access by project toxicologists. When the chemical composition of the product components is known, an in-depth safety evaluation is completed.

For AHP's, the careful choice of materials and their single components is a pre-requisite for safe AHP's. AHPs are mainly made of polymeric materials that have a well-known safety profile with a long history of use. These materials are of limited toxicological concern as their large molecular weight precludes any significant bioavailability. The safety of these polymers depends on the toxicological profile of individual residual monomers or other low molecular weight ingredients. Therefore, the safety assessment focuses on the low level non-polymeric substances such as monomers, solvents, and additives used in polymerization reactions or syntheses and on aesthetic ingredients such as colorants or scents. Further, known "non intentionally added chemicals (NIAS)" that might enter via environment or other contaminations are potentially assessed.

The major toxicological endpoints to consider relevant in the AHP context include but are not limited to systemic toxicity (acute, subchronic, or chronic toxicity, reproductive and developmental toxicity, genetic toxicology, carcinogenicity) and local effects (skin irritation, allergic contact dermatitis). The safety data evaluated during the hazard

identification phase can come from a variety of sources. For animal toxicity, studies that are existing within the published scientific literature historically have been the primary and most reliable source of hazard data. However, nowadays, other sources such as in vitro and in-silico models, probabilistic pharmacokinetics as well as epidemiology studies are adding valuable additional information about the potential hazard of a material. Today, alternative tools such as Structure-Activity Relationship (SAR), Threshold of Toxicological Concern (TTC), and Physiologically Based Pharmacokinetic (PBPK) modelling enable a mechanism to fill toxicity data gaps and/or refine assumptions used throughout the risk assessment process. All available hazard data are reviewed, and the most relevant critical effect is determined; hazard data also provides critical contextual information specific to mode of action, species differences in response, and characteristics of the dose-response relationship.

Exposure based risk assessment (EBRA)

Estimating exposure is the process of identifying the dose of a compound and/or mixture to a population. It includes the routes, magnitude, duration, and frequency of exposure. Exposure can be assessed by direct measurement or estimated with an exposure model as described in chapter 3.3. AHP exposure assessment starts with conservative default assumptions that are commonly used as a starting point for risk assessment (1st Tier, (Meek et al., 2011, REF18).

The assessment then may be refined as needed by replacing these conservative default assumptions with data that are specific to the product and product use that is under evaluation (Tier 2). Generally, external exposure is calculated by multiplying the concentration/fraction of a substance in a source with the amount of the source that is applied on, or reaches, a specified site. To save time and resources, a tiered approach is normally followed that first investigates exposure based on generic exposure scenarios with conservative point values as model parameters (screening level).

Where necessary, these conservative exposure estimates are refined in a higher tier by using probabilistic approaches or other means of refinement (see also below tiered assessment).

Tiered assessment

The approach to the exposure-based risk assessment is tiered and iterative.

- Tier 1: applies conservative defaults (e.g., 100% dermal or mucosal membrane penetration, direct skin contact with a given chemical constituent etc.), to derive a worst-case estimate of exposure.
- Tier 2: applies additional refinements such as chemical and product specific information (e.g., construction or use characteristics). The outcome of Tier 2 may warrant additional refinements and assessments (dermal absorption data for example).

Further tiers might be possible.

Dose Response

Dose-response evaluations characterize the relationship between a dose of a chemical and the incidence or severity of an adverse health effect in the exposed population. In the dose response assessment phase of risk assessment, an understanding of the potency, the magnitude of the effect and the shape of the dose response curve with respect to the associated adverse effect is assessed. This dose-effect relationship is used to establish the basis for predicting effects at various levels of exposure. The dose-response assessment, is an iterative process and the first-tier assessment generally utilizes conservative (health-protective) default assumptions, recognizing that these can be refined with data as appropriate.

Select relevant human reference values

One component of the toxicological Tier 1 assessment is the limit at which daily and lifelong exposure can occur without adverse health effects. This limit is defined in several different variants e.g., TDI, RfD, DNEL, etc. The limits are specific for the exposure route i.e., oral, inhalation and dermal etc. Exposure resulting from using an AHP will occur via dermal exposure route and limits that are specific for dermal exposure route should be used for EBRA. Unfortunately, such limits are not always available for many of the trace chemicals. In these cases, a limit that is specific for oral exposure route can be considered thus resulting in most cases in an even more conservative risk value. If no data exist for the chemical, alternative methodologies such as SAR and TTC can be considered.

Risk Characterization

Risk characterization is the final step in risk assessment, integrating exposure assessment, hazard identification and dose-response assessment, into advice suitable for use in decision-making or risk management. There are two terms commonly used in risk characterization: Margin-of-Exposure (MOE) and Margin-of-Safety (MOS).

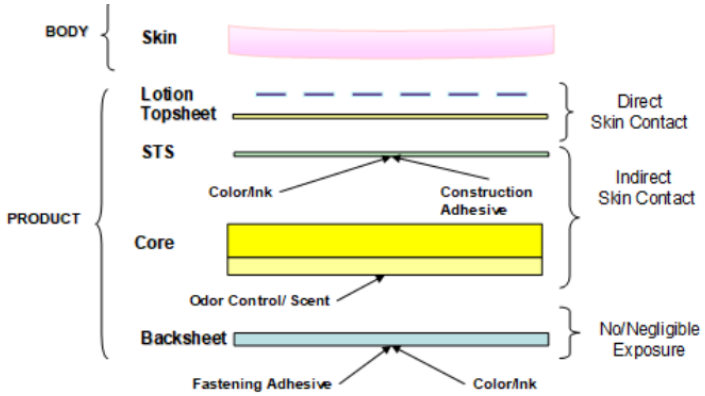
Margin-of-Exposure (MOE): A MOE is a comparison of the estimated human exposure to an experimental or extrapolated dose such as a No Observed Adverse Effect Level (NOAEL). It does not take into account any areas of data extrapolation or uncertainty.

Margin-of-Safety (MOS): A MOS is a comparison of the estimated human exposure to a risk value for which the risk of causing adverse effects is considered to be minimal such as a RfD (reference dose), an ADI (acceptable daily intake) or other risk value that has already incorporated areas of data extrapolation and uncertainty. A margin of safety value greater than 1 is typically judged by risk assessors and regulatory bodies to be unlikely to cause harm and provides an assurance of human safety.

3.2 Product components and body contact

The various categories of AHP components with regard to their skin contact potential (figure 13 and 14) are explained using the example of a single-use baby diaper. In Appendix A the product components and their functions are listed with further detailed information. The principle of differentiation between materials in direct, indirect and negligible body contact is applicable for the other AHP categories, too.

Fig 13: Illustration of typical layered product construct[8] in proximity to skin (source: EDANA member company)

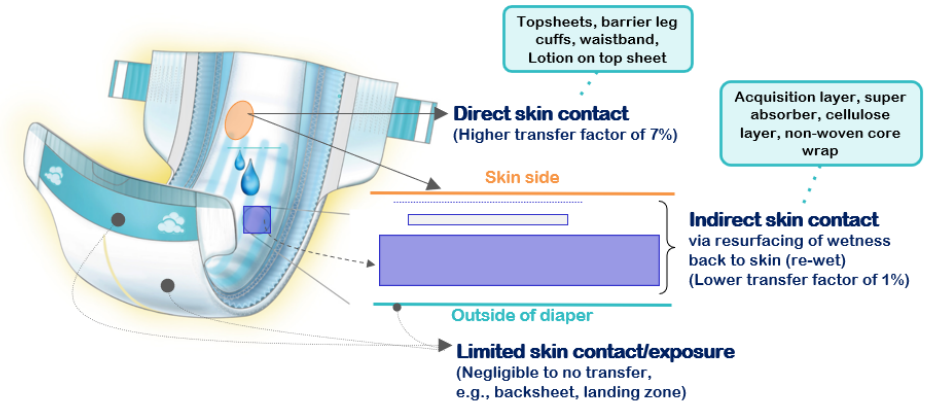


Materials with Direct Skin Contact

The topsheet consists of a soft nonwoven synthetic sheet, composed of e.g., polypropylene/polyethylene, either alone or as a blend and is in direct contact with the skin. The main function of this layer is to transfer urine and other liquids quickly to the absorbent layers beneath. The topsheet may be coated with a lotion to protect the skin from over-hydration and irritation. Diaper topsheet-lotion transfer to skin has been studied and can be used as a model for direct transfer to skin (Dey et al, REF19). From the topsheet, 3.0-4.3% of the starting amount of lotion was transferred to the skin. As a result, for constituents contained within a direct skin contact product component, a transfer factor of 7% is used to conservatively calculate the level of constituent in contact with the skin for diapers. Similarly, for feminine hygiene products studies using a lotion ingredient tracer showed a higher amount (i.e., <20% [Woeller et al. 2015, REF20]) of the lotion was transferred from the topsheet to the skin. According to the industry data a typical transfer factor is 10%. As a result, for constituents contained within a direct skin contact product component, a transfer factor of 10% is used to conservatively calculate the level of constituent in contact with the skin. In the case of tampons, exposure assessments assume that all components are in direct contact with the skin and that transfer and rewet is 100%, unless analytical data are available to suggest otherwise.

[8] The figure is showing the principles of typical body contact components of an AHP. The components may vary among product types.

Figure 14: Visualization of direct and indirect skin contact components, example baby diaper, (source: EDANA member company)



Additional elements of the diaper with direct skin contact include features primarily designed to ensure the diaper fits well and prevents leakage such as **stretchy side panels/backears, barrier leg cuffs and waistband.** However, most of these components stay dry during product usage or are only temporarily wetted (just prior to diaper change) during use.

Materials with Indirect Skin Contact

This category includes product components beneath the topsheet that are not directly in contact with the skin (figure 14). The diaper product components in this category are the **acquisition/distribution layer and absorbent core**.

The acquisition/distribution layer is usually composed of a modified cellulose patch and a polyester-based layer sandwiched between the topsheet and the core. Its main function is to facilitate the movement of liquid away from the baby and to distribute it more evenly across the entire diaper core for efficient and maximal absorbency.

The absorbent core is the innermost layer of the diaper. It typically consists of a blend of polyacrylate granules with fluff cellulose pulp (bleached by an elemental chlorine-free process) and encapsulated by either a cellulose or polypropylene nonwoven layer. The cellulose portion of the core has the function to quickly absorb and transfer urine to the polyacrylate superabsorber. The superabsorber is able to absorb urine and to lock it within its polymeric structure to keep it away from baby's skin, even under pressure as when a baby sits on a full diaper.

Potential trace chemicals found in these product components typically require a carrier or vehicle, such as urine, for transport to the diaper surface where they are available for potential direct skin exposure. This resurfacing of liquid phenomenon is known as rewet. The rewet value as described here is a simple gravimetric calculation of how much liquid resurfaces, combined with an assumption that constituents migrate back with the liquid. This can be refined by analytical measurements of those constituents. Rewet values have been estimated or calculated using benchtop analytical methods; data are dependent on

the test system, diaper design, amount of fluid added and diaper change frequency Urine resurfacing back to the topsheet under pressure was estimated at a range of 0.32-0.66% averaging 0.46% (Dey et al., REF19). The analytical laboratory SGS conducted further rewet testing using an even more consumer relevant wetted zone model (i.e., 75% of the core length). Their calculated rewet level for 100% of the core length gives a rewet value at 0.95%, clearly approaching the rewet value of the Dey et al. study (https://www.sgs.com/en/white-paper-library/convergence-of-rewet-data-in-nowadays-baby-diapers)

As a result, for ingredients contained within an indirect skin contact product component, a rewet factor of 1% is used to conservatively calculate the level of a constituent which might come in contact with the skin.

For feminine hygiene products the potential trace chemicals found in these product components also require a carrier or vehicle, such as menstrual fluid, for transport to the product surface where they are available for potential direct skin exposure. Rewet values have been estimated or calculated using benchtop analytical methods to be up to 5%[Woeller and Hochwalt 2015, REF20] depending on the test system, product design, amount of fluid added and product frequency. In the case of tampons, there is no differentiation between rewet and transfer.

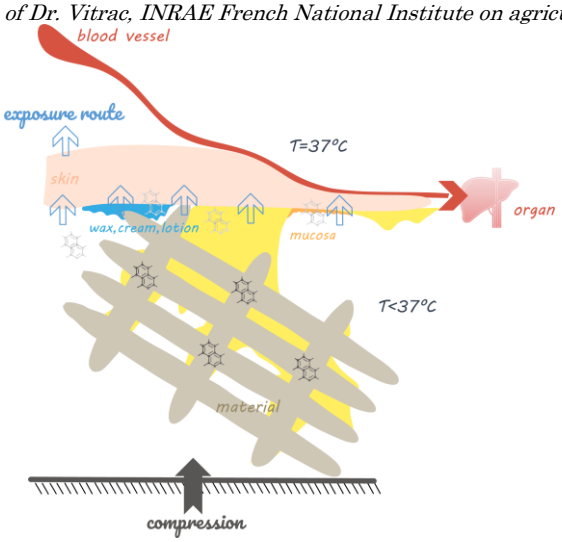
Materials with Negligible Skin Contact

This category includes the product components which have no or only transient contact with the baby's skin. The diaper components within this category are the **backsheet and the fastening system.** The backsheet is the water-resistant outer layer of the diaper, typically made of a polyethylene film laminated with a soft-textured, cloth-like polypropylene. Its function is to prevent liquid from leaking out of the diaper into the outer clothing. The fastening system helps to ensure a good fit. Historical experience, comparison with previous product component composition, product integrity standards, and analytical leachability evaluation can be used to support the assumption for no or negligible skin exposure to these raw material ingredients. A similar back-sheet is also applicable for feminine care napkins and pantyliners.

3.3 Dermal absorption

Dermal absorption is a dynamic process. It is heavily influenced by structural and physical-chemical characteristics of the chemical of interest, barrier properties of the skin, the vehicle solvent and the exposure scenario in which the chemical comes into contact with the skin surface and underlying layers. When using available dermal absorption data in toxicological risk assessment, it is critically important to evaluate the experimental conditions in which the measurements were obtained before the estimated absorption value can be used in the safety assessment. Data evaluation is needed to prevent unsafe or overly conservative outcomes from being considered for a given exposure scenario. Several guideline documents exist describing the experimental data generation and interpretation of in vivo and in vitro dermal absorption studies [Berry et al. 1993, REF28, Swanson et al. REF29, OECD Test Guideline 2004, REF30, SCCS Notes of guidance 2018, REF31, ECETOC Technical report 119, REF32, EFSA Journal 2017, REF33]. Figure 15 shows routes and factors that hypothetically may contribute to skin and/or systemic exposure for the user of the absorbent hygiene product.

Figure 15. Schematic description of the five hypothetical exposure pathways to chemicals originating from AHP: via direct contact, air, cream/wax/lotion/talc, urine, mucous. (source: courtesy of Dr. Vitrac, INRAE French National Institute on agriculture, food an environment)



Substances present in materials in direct skin (pink)/mucosa (orange) contact and on the product surface or which can migrate out of the materials can be directly transferred to the skin/mucosa of the user. When product materials contain lotions/creams (blue) or when the skin of the user is covered with lotions/creams the direct transfer from the material to the skin may be augmented (fig.15).

Substances which are present in materials that are exposed to biological liquids (yellow) may leach out of the product into the liquid. While the majority of the biological fluid will be absorbed by the product a fraction of these may migrate from the product to the skin. Depending on the type of substance, another fraction would be absorbed through the skin resulting in systemic exposure.

Several published in vitro and in vivo datasets for PAHs, dioxins, PCBs and formaldehyde provide evidence that dermal absorption is <100% and the relative absorption can vary considerably between studies that were performed under different experimental conditions.

Although the assumption of 100% dermal absorption can be used as a 'worst-case' estimate of dermal absorption, this carries the risk of overestimating exposure. The protective barrier properties of the skin, primarily the stratum corneum layer, and information from experimental datasets show that the dermal absorption of chemicals in scope is less than 100% [Hoang, 1992; Hewitt et al. 2020, REF23]. The recent notes of guidance from SCCS also recommends use of maximum default 50% dermal absorption for cosmetics, the products where the vehicles are more conducive for skin penetration as compared to AHPs (SCCS Notes of Guidance version 11, 2021, REF24). Hence for AHPs use of 50-100% dermal absorption is an excessively conservative consideration.

Even with diaper rash, absorption will rarely be 100%. Frequency, severity and extent of diaper ("seat") dermatitis [Felter et al. 2017, REF25], modelling of hydration during diaper rash [Saadatmand et al. 2017, REF26], and in vitro determination of the impact of skin compromise on dermal penetration [Dey et al. 2015, REF27] indicate that dermal penetration will not be at or near 100% for substances that are poorly absorbed through

healthy skin. In addition, compromised skin (as in the case with diaper rash) could potentially increase dermal penetration, however, babies do not have rash continuously for 3 years nor across the entire diaper area. An infant experiences diaper rash 20% of the time (approx. 6 days/month). When rash is present it is primarily mild in nature (60% assumed to be mild and ~40% assumed to be moderate to severe) and doesn't occur over the entire diapered area but only affects approximately 25% of the total surface area of the diapered skin. An in vitro skin penetration model [Saadatmand et al. 2017, REF26] for compromised skin estimated penetration of polyethylene glycol [^{14}C]-PEG-7 phosphate[4] is low (<5%), showing that even in severely damaged skin the absorption is not 100%, but rather is only 4-6x times higher as compared to mature/intact skin. Taken together, these observations indicate that the common perception that infant skin – particularly diapered skin – is highly permeable to chemicals appears to be a large exaggeration. While highly compromised skin will result in greater absorption of chemicals, the degree of increase for poorly penetrating chemicals remains low, near negligible (Hoang, 1992; Hewitt et al. 2020, REF23).

The data in the table 5 below demonstrates that many factors influence the potential of substances to permeate the skin and the investigation results show that:

- The chemicals listed do not penetrate the skin 100%
- Dermal penetration through the skin is chemical specific and influenced by physico-chemical properties (e.g., molecular weight, lipophilicity, size, vapor pressure, etc.)
- Experimental conditions (dose, vehicle, duration, model, etc.) vary between studies influencing dermal absorption.
- Species differences in dermal absorption under similar conditions

Table 5: Example of publications in support of the above

Chemical		**Publication**	**Study Type**	**Species**	**Vehicle**	**Total absorbed (% applied dose)**
	TCDD					
		Roy et al 2008 [REF34]	In vivo	Rat	Neat Soil	33.3-77.6 16.3
			In vitro	Rat	Neat Soil	1.7-76 1.0-7.7
			In Vitro	Human	Neat Soil	0.27-1.1 2.4
		Banks and Birnbaum 1991[REF35]	In vivo	Rat	Acetone	19-41

		Weber 1991[REF36]	In vitro	Human	Mineral Oil Acetone	8-10 29-84
		Brewster 1989[REF37]	In vivo	Rat	Acetone	17-40
	PCB					
		Wester 1993 [REF38]	In vivo	Rhesus Monkey	Soil Mineral Oil Trichlorobenzene Acetone	13.8-14.1 20.4-20.8 14.6-18 21.4
			In vitro	Human	Soil Mineral Oil Water	1.6-2.6 6.7-10.1 44.4-46.4
	B(a)P					
		Wester 1990[REF39]	In vivo	Rhesus Monkey	Acetone Soil	51 13.2
			In vitro	Human	Acetone Soil	23.7 1.4
		Bartsch 2016[REF40]	Ex vivo	Human	None- direct contact with skin	20% with 10% systemically available
		Moody 2007[REF41]	In vitro	Human	Soil Acetone	14.8-15.8 50-56
		Payan 2009[REF42]	In vivo	Rats	Ethanol	52.7
	Formaldehyde					
		SCCS 2014[REF43]	In vivo (Bartnik 1985) In vivo (Jeffcoat 1983)	Rat Rat Guinea pig Monkey	Cream Aqueous solution (not well defined)	3.4-9.2 38.4-45 40.3-48.7 10 (all include skin fraction)

A relevant and appropriate study design for establishing dermal exposure from e.g., using diapers would utilize a urine-like vehicle, a dose that reflects the concentration of a

chemical that may migrate out of a diaper and an application frequency and duration of exposure that mimic real life. Since a study like this does not exist, to EDANA's knowledge, it is reasonable to assume a default dermal absorption of 50% when data on specific components is not available as suggested by SCCS 11th Notes of guidance [REF24]. Additional variables impacting the final absorption include but are not limited to: dose applied, duration of exposure, degree of occlusion. Same lack of specific study designs applies for the other AHP categories.

3.4 Specific Exposure Based Risk Assessment Parameters (EBRA) for AHPs

CODEX™ guidance values are reflective of the current regulatory landscape (see chapter 1.7) and are based on Good Stewardship principles and current analytical capabilities.

The Codex ™ guidance values are connected to the respective EDANA analytical methods of the SP program and the CODEX™ limits are in line with the CODEX™ substances that can be measured in an AHP based on the CODEX™ analytical method. Test results based on the Codex ™ analytical method represent the amount of chemical that is extractable from the product under the experimental conditions. Extractables, based on the Codex ™ analytical method are not directly comparable to migratable limits that are derived from scientific exposure limits. Detection indicates the mere presence of certain trace chemicals in a complex product matrix like baby diapers or sanitary napkins and is only indicative of a hazard, but not indicative of safety or risk of using these products. Exceeding CODEX™ limits does not necessarily mean the products are unsafe.

Exposure based risk assessment is therefore needed to assess whether the detected concentration of a chemical substance carries any risk from consumer safety perspective. Test results obtained following the CODEX™ analytical method can be used together with specific exposure parameters and state-of-the-science risk values to determine the margin of safety.

To have exposure to a trace chemical from an AHP, the trace chemical needs to reach the skin. Materials in direct contact with the skin, can transfer constituents to the skin and do not necessarily require solubilization in body fluids. Indirect skin contact materials require solubilization via urine or other body fluids. The liquid that resurfaces to the skin (rewet) could contain possible trace chemicals. Different transfer (for direct skin contact materials) and rewet factors (including all materials) are applied to estimate the consumer exposure. Default factors for these parameters may be utilized initially and refined appropriately as needed. As the EDANA analytical method is using all materials when milling and doesn't differentiate between direct and indirect skin contact materials, the rewet factor can only be applied here.

The parameters for exposure assessment represented below can be used as defaults and can be considered as conservative. Where product and trace chemical specific data is available this should take precedence.

Transfer factors for direct skin contact may vary from 7% in the case of diapers (Dey et al, REF19) to below 20% in the case of feminine hygiene products (Woeller and Hochwald. 2015, REF20).

Baby diapers

Exposure Parameter	Value	Rationale
Amount of trace chemical detected (using e.g., CODEX™ analytical methods)	Weight of substance/ weight of product, (% or ppm). If ppm/10000, to convert to %	Per analytical report
Mass of product	Grams	Weight of the product tested
Frequency of use	X diapers/ day	(e.g., Dey et al, 2016, REF19)
Rewet factor*	1%	Dey et al, 2016, REF19 ; SGS rewet testing
Transfer factor for direct skin contact	7%	Dey et al, 2016, REF19
Dermal absorption	100% unless specific dermal penetration data or other relevant information is available	Very conservative assumption in view of possible diaper rash that may influence the absorption.
Body weight	Kg	(e.g., mean body weight with age, Dey et al, 2016, REF19)

Notes:

** A rewet factor accounts for the fluid returning from the absorbent layers to the surface of an AHP under pressure. It can be used to calculate how much of extracted trace chemicals will migrate to the skin. This to address the fact that the CODEX™ test method measures trace chemicals that can be extracted from a milled product using a large volume of biological fluid simulant.*
The rewet factor should not be confused with the transfer factor. The transfer factor defines, based on experimental data, how much of chemicals will migrate from materials in direct skin contact.

Applicable equation:

Estimated daily consumer exposure = Trace element detected x Mass of product x Frequency of use/day x Rewet factor (or Transfer factor* for direct skin contact) x dermal absorption/ Body weight

** This is not applicable if evaluating data from a milled product*

Feminine hygiene products

Exposure Parameter	***Value***		***Rationale***
	Pads (Napkins)	***Liners***	
Amount of trace chemical detected (using e.g., CODEX™ analytical methods).	*Weight of substance/ weight of product, (% or ppm). If ppm/10000, to convert to %*		*Per analytical report*
Mass of product	*Grams*	*Grams*	Weight of the product tested

Frequency of use	*X pads/ day**	*X liners/ day*	*(e.g., Jihyun Bae 1, Hoonjeong Kwon and Jooyoun Kim. 2018 [REF21]*
*Rewet factor***	*<5%*	*<5%*	*(e.g., Woeller and Hochwalt. 2015 [REF20]*
Transfer factor for direct skin contact	*10%*	*10%*	*Woeller and Hochwalt. 2015 [REF20]*
Dermal absorption	*Default 50% unless* specific dermal penetration data or other relevant information is available		*According to SCCS [REF24] n the absence of experimentally determined dermal absorption. This conservative value may also be used in cases where only inadequate dermal absorption data are available.*
Body weight	*50kg*	*50kg*	*CDC tables, teenagers included*

Notes:

**For pads, duration correction is used as part of EBRA considering their use only for specific number of days in a year so that exposure represents a fraction of a year.*

Average Number of pads /menstruation day = number of pads used per day x 7 (number of days /month) x12 (number of months) /365

*** A rewet factor accounts for the fluid returning from the absorbent layers to the surface of an AHP under pressure. It can be used to calculate how much of extracted trace chemicals will migrate to the skin. This to address the fact that the CODEX™ test method measures trace chemicals that can be extracted from a milled product using a large volume of biological fluid simulant.*

The rewet factor should not be confused with the transfer factor. The transfer factor defines, based on experimental data, how much of chemicals will migrate from materials in direct skin contact.

Applicable equation:

Estimated daily consumer exposure = Trace element detected x Mass of product x Frequency of use/day x Rewet factor (or Transfer factor* for direct skin contact) x dermal absorption/ Body weight

** This is not applicable if evaluating data from a milled product*

Exposure Parameter	***Value***	***Rationale***
	Tampons	
Amount of Trace chemical detected (using e.g., CODEX™ analytical methods)	*Weight of substance/ weight of product, (% or ppm). If ppm/10000, to convert to %*	*Per analytical report*
Mass of product	*Grams*	Weight of the product tested
Frequency of use	*X tampons/ day**	*(e.g., Michael J DeVito and Arnold Schecter. 2002, REF22)*
Rewet factor/ Transfer factor**	*100%*	*In the case of tampons, exposure assessments assume that all components are in direct skin contact*

		and the assumption is 100%, until further data can be established to claim otherwise.
Mucosal absorption	*Default 100% unless specific mucosal absorption values are available*	*Very conservative assumption given the lack of scientific data, the nature of the product and the area of exposure*
Body weight	*50 kg*	*CDC tables, teenagers included*

Notes:

**For tampons, duration correction is used as part of EBRA considering their use only for specific number of days in a year,* so *that exposure represents a fraction of a year*

Average Number of tampons/menstruation day = number of tampons used per day x 7 (number of days /month) x12 (number of months) /365

***In the case of tampons, there is no differentiation between rewet and transfer.*
If there is internal data available on rewet/ transfer, it can be used instead.

Applicable equation:

Estimated daily consumer exposure = Trace element detected x Mass of product x Frequency of use/day x Rewet factor x mucosal absorption/ Body weight

Incontinence products

Exposure Parameter	***Value***	***Rationale***
Amount of trace chemical detected (using e.g., CODEX™ analytical methods)	*Weight of substance/ weight of product, (% or ppm). If ppm/10000, to convert to %*	*Per analytical report*
Mass of product	*Grams*	*Weight of the product tested*
Frequency of use	*X product/ day*	*e.g. (https://eprints.soton.ac.uk/189241/1/Absorbent_products_for_urinaryfaecal_incontinence.pdf*
Rewet factor*	*1%*	*Given the similarity to baby diapers, the same rewet factor can be assumed, unless other data is available on incontinence products specifically*
Transfer factor for direct skin contact	*e.g., 7% due to similarity to baby diapers*	Dey et al, 2016, REF19
Dermal absorption	*50% unless specific dermal penetration data or other relevant information is available*	*According to SCCS [REF24] n the absence of experimentally determined dermal absorption. This conservative value may also be used in cases where only inadequate dermal absorption data are available.*

Body weight	*Kg*	*CDC data applicable to the respective age group*

Notes:

***** A rewet factor accounts for the fluid returning from the absorbent layers to the surface of an AHP under pressure. It can be used to calculate how much of extracted trace chemicals will migrate to the skin. This to address the fact that the CODEX™ test method measures trace chemicals that can be extracted from a milled product using a large volume of biological fluid simulant.*
The rewet factor should not be confused with the transfer factor. The transfer factor defines, based on experimental data, how much of chemicals will migrate from materials in direct skin contact.

Applicable equation:

Estimated daily consumer exposure = amount of trace element detected x Mass of product x Frequency of use/day x Rewet factor (or Transfer factor* for direct skin contact) x dermal absorption/ Body weight

** This is not applicable if evaluating data from a milled product*

General remark applicable to all product categories:

In addition to the CODEX™ guidance values which define the extractable limits, it is also possible to back calculate the allowable migratable trace chemical mass using a specific risk value for the trace chemical (based on the appropriate scientific toxicological threshold) and the calculation is:

Maximum allowable migratable trace chemical amount in the product = Body Weight x Risk Value / Mass of product x Frequency of use/ day x Rewet x Dermal (mucosal) Absorption

As mentioned above the CODEX™ test method may not be a full account of migration of chemicals from the AHP to the skin of the user. The analyzed product is milled to create a finely divided, homogenized sample and ALL components of the product, will be exposed to the body simulant extraction liquid. This includes materials (e.g., backsheet plastic film and fastening system) that normally are not expected to be exposed to urine and are not in touch with the skin. This may lead to an overestimation of chemicals found in the extraction liquid.

The extraction procedure requires pre-defined amount of artificial urine to be able to recover any liquid from the milled product. This is not representative of urine volume under normal consumer usage, is greater than the mass/volume ratio recommended by ISO standards[9] and is expected to potentially lead to overestimation of lipophilic chemicals, where the solubility is limited in artificial urine.

Direct skin transfer of lipophilic chemicals from parts of the product that are in direct skin contact may not be represented well by the artificial urine extraction method. This

[9] Sources to be verified

may potentially lead to underestimation of some chemicals. This issue can be addressed by extracting materials in direct skin contact separately using organic solvents and a respective transfer to skin factor should be used. This transfer factor is used routinely for risk assessment of direct skin contact materials as described earlier.

3.5 Selection of Risk Values

Dose response models are used throughout toxicology to estimate risk to human health. These models describe the relationship between the amount of a chemical at a specific target within the body and the magnitude of the effect that chemical has on the body. Two of the simplest models that are used by regulators and still offer tremendous insight into the risk presented by different substances are the threshold model and the linear, non-threshold model. The point of departure (POD) is defined as the point on a toxicological dose-response curve established from experimental data or observational data generally corresponding to an estimated lowest observed (adverse) effect level [LO(A)EL] or no observed (adverse) effect level [NOAEL]. There are ways to derive PODs for threshold related toxicities and non-threshold related toxicities. For chemicals where toxicity is threshold based, usually NOAEL, LOAEL or statistical benchmark dose (BMD) are used as POD.

The threshold/non-threshold mechanisms of toxicity and severity of the adverse health effects are chemical and endpoint specific and demonstrate a dose-dependent relationship. The review of the mechanism of toxicity is a key consideration of the hazard identification and characterization steps of the risk assessment process following a thorough evaluation of the entirety of the relevant toxicological and clinical scientific data as described in the details in multiple guidance documents developed by authoritative international agencies.

The majority of chemicals are non-genotoxic and non-carcinogenic and have threshold-based mechanisms. Heavy metals (cadmium, chromium, lead) and organotin compounds (dibutyltin, tributyltin etc) are a few examples which are threshold based.

Chemicals that do not have an identifiable threshold of toxicity are called non-threshold chemicals. Most commonly chemicals with a non-threshold mechanism of action are mutagenic carcinogens. Such chemicals are typically trace substances and environmental contaminants and are being avoided in the manufacturing processes of AHPs where possible. A few examples for PODs based non-threshold mechanisms include highly potent genotoxic compounds like nitrosamines, aflatoxins, azo compounds. Trace chemicals in the CODEX™ list which are based on non-threshold mechanisms are PAHs (benzo(a)anthracene, benzo(b)fluoranthene etc), some phthalates (DEHP, DINP, etc), certain organochlorine pesticides like hexachlorobenzene etc. Their risk assessment is performed often utilising Point of Departure (POD) values that take the chemical-specific cancer potencies into account and employ a concept of an “acceptable risk”. The risk management of non-threshold chemicals follows the “As Low as Reasonable Possible” (ALARP) principle. Typically, the non-threshold chemicals are present in AHPs as technically unavoidable trace contaminants. The exposure-based risk assessment of every CODEX™ substance depends on well accepted point of departures, based on critical

toxicity endpoints reported in preclinical studies or epidemiological data from studied population(s).

Different human reference values are often derived by different agencies/regulatory bodies for a particular chemical. For example, there are several chemicals where OEHHA has established NSRL or MADL values which define the threshold exposure for Proposition 65 compliance. Compliance to Proposition 65 safety and labeling requirements are mandatory in certain geographies. Other safety reference values derived by other agencies, e.g., EPA, EFSA, ICH, ATSDR etc. might be available. The most appropriate reference value needs to be determined by the safety assessor taking latest scientific data into account, most appropriate study design (quality of study, relevant exposure route for example.), as well as local regulations. This would lead to selection of a reference value which is appropriate rather than inclining towards the most conservative approach by default.

The selected risk values derived from respective PODs for the substances in scope are identified in **Appendix E.**

3.6 Risk characterization for selected chemicals

To complete risk assessments for CODEX™ substances, an EBRA needs to be conducted. To outline the safety of these chemicals, one chemical from each chemical class in the CODEX™ list is selected for assessment (Table 6).

Table 6: Selected chemicals for assessment

Group	Selected chemical	Codex™ limit	CodexTM limit expressed as (mg/kg diaper)	HRV (mg/kg bw/day)
Dioxins/Furans /DL PCB	2,3,7,8-TCDD*	2 ng/kg TEQ	0,000002*	3,00E-10
PAH	Benzo(a)pyrene	0,2 mg/kg	0,2	4,00E-09
Formaldehyde	Formaldehyde	16 mg/kg	16	0,075
Phthalates	DEHP	0,01%	100	0,0044
Pesticides	HCB	0,5 mg/kg	0,5	0,0008
Pesticides	Glyphosate	0,5 mg/kg	0,5	0,1
Phenols	Bisphenol A	0,02%	200	0,05
Organotins	Tributyltin	2 ppb	0,002	3,00E-04
Metals	Antimony	30 mg/kg	30	6,00E-03
*TEF for TCDD=1				

The assessment in this case is performed on a baby diaper as most conservative category. The aim of this calculation is to illustrate what the MoS (see chapter 3.1) is, if a product is tested and found to contain substances just under the CODEX™ limit. A tiered approach is taken as described in chapter 3.1, with Tier 1 using conservative default parameters and Tier 2 with refined parameters (here, known dermal absorption is used).

Exposure calculations:

Estimated daily consumer exposure = Trace element detected x Mass of product x Frequency of use/day x Rewet factor x dermal absorption/ Body weight

Diaper use characteristics were derived from Dey et al, 2016, [REF19] and industry experience and they are considered to represent a realistic conservative approach (Table 7). Dermal absorption of 100 % is assumed (see chapter 3.3), for tier 1 and according to table 8 for tier 2 assessment. Rewet was set to 1% according to Dey et al, 2016 [REF19] and with respect to the analytical method where extraction is based on the whole diaper.

Table 7: Values of exposure parameters

Parameter	**Value**	**Reference**
Mass of product = weight of diaper (kg_{diaper})	0,025kg	Based on industry data
Trace element (mg/kg diaper) = tested concentration	CODEX™ limit	EDANA CODEX™
Frequency of use (diapers used/ day)	6	Dey et al, 2016, [REF19]
Rewet factor	1% of total volume	Dey et al, 2016 [REF19]
Dermal absorption	100% or other relevant for Tier 2	Very conservative assumption in view of possible diaper rash that may influence the absorption.
Body weight of user	8 kg	Dey et al, 2016, [REF19]

Risk characterization is performed as described above (see chapter 3.1).

A MoS characterization requires estimated human exposure and a HRV (Human Reference Value) under which the risk of causing adverse effects after daily exposure is considered to be minimal. Please refer to **Appendix E** for the full list of risk values. Since normal use of absorbent hygiene products result in primarily dermal exposure, relevant dermal HRV should be used in the risk characterization. In cases when dermal HRV is not available an oral HRV can be used as a conservative approximation. For tier 1 assessment oral HRV are used without change. Tier 2 assessments here are based on systemic exposure and consequently the HRV should also be adapted to reflect systemic exposure. This is achieved by taking the accurate oral absorption into account. For Tier 2 it is also acceptable to reflect on dermal absorption if robust data is available.

Table 8: Margin of safety for a baby diaper compliant to CODEX™ limits

CODEX™ chemical	CODEX™ limit/Test result (mg/kg diaper)	Exposure at CODEX™ limit (mg/kg bw/day)	Dermal absorption (%)	HRV type	HRV (mg/kg bw/day)	Oral absorption (%/100)	Margin of Safety	Tier
Formaldehyde	16	3,00E-03	100%	Oral	7,50E-02	100%	2,50E+01	1
DEHP	100	1,88E-02	1%[a]	Dermal	7,20E-01	37,5%[d]	3,84E+01	1
Glyphosate	0,5	9,38E-05	100%	Oral	1,00E-01	100%	1,07E+03	1
BPA	200	1,13E-02	30%[b]	Oral	5,00E-02	90%[e]	4,00E+00	2
HCB	0,5	9,38E-05	100%	Oral	8,00E-04	100%	8,53E+00	1
Tributyltin	0,002	3,75E-07	100%	Oral	3,00E-04	100%	8,00E+02	1
Antimony	30	1,46E-05	0,26%[c]	Oral	6,00E-03	1%[f]	4,10E+00	2

a: https://www.atsdr.cdc.gov/toxprofiles/tp9-c3.pdf
b: https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_240.pdf
c: https://www.epa.gov/sites/default/files/2015-09/documents/ato_ra_8-28-14_final.pdf
d: ECB (European Chemicals Bureau). 2008. European Union risk assessment report; CAS No: 117-81-7; EINECS No: 204-211-0; bis(2-ethylhexyl)phthalate (DEHP). Institute for Health and Consumer Protection. European Commission. 80: 588pp.
e: Pharmacokinetics of Bisphenol A in Humans Following a Single Oral Administration (nih.gov)
f: https://www.who.int/water_sanitation_health/dwq/chemicals/antimony.pdf

Following EBRA (Table 8), a MoS>1 was concluded for Formaldehyde, DEHP, Glyphosate, BPA, Tributyltin, HCB, and Antimony. Therefore, this approach confirms that for these selected chemicals compliance to the CODEX™ guidance values also means that potential risks are adequately managed.

If a test method does not exist for demonstrating MoS>1 for a substance, then the best option to control the presence of this substance is to make sure the substance is kept under the testing limit of the most sensitive relevant test method available (see Table 9).

Table 9: Comparison of test LOQ's

Substance	CODEX™ limit/Test result (mg/kg diaper)	HRV mg/kg bw(day	Maximum allowed concentration (mg/kg)	LOQ required to show MoS>1 (mg/kg)	LOQ achievable in CODEX™ (mg/kg)	Ratio existing/ required LOQ
TCDD	2,00E-06	3,00E-10	1,60E-06	3,20E-07	4,00E-07	1,25E+00
BaP	0,2	4E-09	2,13E-05	4,27E-06	4,00E-02	9,38E+03

MoS assessments was not performed for TCDD and BaP. The reason is that the CODEX™ test method is not sensitive enough for a meaningful MoS calculation. This postulation is based on the following reasoning:

(1) MoS=HRV/Exposure.

(2) For MoS to be >1, HRV must be >Exposure.

(3) Exposure= [Cdiaper(mg/kg) * W[1](kg/diaper) * Ndiaper(/day) *RW)] / BW(kg)

(4) Combine 2 and 3. HRV>[Cdiaper(mg/kg) * W(kg/diaper) * Ndiaper(/day) *RW)] / BW(kg)[1]

(5) Rearrange 4. Cdiaper(mg/kg) <HRV*BW/(W*N*RW)

(6) Cdiaper[1](mg/kg) in formula 5 describes the Maximum concentration that is allowed before the migration from the tested diaper exceed the HRV.

An analytical LOQ required to robustly demonstrate presence of a chemical around a limit value is widely accepted to be 1/5 of the limit value. This is required in the CODEX™ analytical method.

To robustly demonstrate presence around the Maximum allowed concentration, the LOQ must be Maximum allowed concentration*1/5.

Comparing the CODEX™ LOQ and the LOQ required to demonstrate that MoS>1 shows CODEX™ LOQ is higher. I.e., it will be impossible to use the CODEX™ method to demonstrate MoS>1. Only MoS<1 can be demonstrated. See table 9 for calculations made.

To the best of our knowledge the most relevant, sensitive and available test method for analysis of TCDD and BaP in AHP is the EDANA Stewardship Program CODEX™ method. The CODEX™ limits for TCDD and BaP in AHPs are the most sensitive enforceable limits available. This reasoning is also suggested by the ECHA Enforcement Forum during the Opinion development for the proposed restriction on Substances in single-use baby diapers.

Additional considerations:

Whereas current analytical methods can't provide an actual concentration of certain chemicals, epidemiological studies provide further inside into consumer risk. In the case of Dioxins/Furans/DL-PCB, an adequate MoS is demonstrated by considering the intake of these chemicals via breast feeding. As shown in recent publication (A. Bernard, 2021. REF44), following aspects should be considered: the daily intake from breast milk is, compared to the potential intake from diaper use, 266-336-fold higher than the exposure from using diapers. There is no evidence that at the current exposure levels in the European Union, dioxins and DL-PCBs in breast milk reduce the future fertility of breastfed boys. On the contrary, in a study conducted among adolescents, breastfeeding was associated in a dose dependent manner with an increase in serum inhibin B, a marker of fertility at adult age. For PAHs epidemiological, or case report studies provide no indication of adverse effects of diapers at all despite decades of use by almost all children in wealthy countries. If diapers were to pose cancer risks as high as 10−3 as suggested by the ANSES report, it is hard to believe that such risks could have passed undetected after such a long and widespread use as the large-scale use of disposable diapers started in the USA in 1961. In the anogenital region, the highly permeable scrotum has long been known to be particularly sensitive to the carcinogenic effects of PAHs. Squamous cell carcinoma

(SCC) is the type of scrotal malignancy caused by occupational exposure specifically to PAHs. With preventive measures implemented at workplace, SCC has become a very rare cancer with a steady incidence rate through the 20th century. The main non-occupational risk factors of SCC are sun exposure, human papilloma virus and several types of treatment for skin diseases. As the median range at diagnosis is 52–57 years, it appears unlikely that SCC could be initiated during infancy, even if the median SCC latency is close to 30 years. The considerations on PAH by Prof Bernard's publications [REF44, REF 45] are also applicable to BaP.

4. Discussions and Conclusions

4.1. CODEX™ related considerations

With regard to the CODEX™ listed chemicals, the related analytical method and the substance guidance values various considerations/scenarios appear:

Scenario 1: No codex substance is detected based on the EDANA developed CODEX™ analytical method

With such an analytical test result the requirements of the Stewardship Program are fulfilled which is also the case if a substance is detected but quantified below the given CODEX™ guidance value. However, this does not mean that the substance is not present in a product. By applying organic solvent treatments of AHPs a substance might be detectable using ultrasensitive analyses. However, such an approach aims at a maximum release potential, which is far away from considerations to simulate the real wearing situation in vivo. By using the EDANA test method the manufacturer has a solid basis to evaluate a product towards SP compliance. The need for thorough safety assessments of products remains valid regardless of the analytical results.

Scenario 2: The CODEX™ limit is exceeded after analysis with the EDANA CODEX™ method

Companies signing the charter of the EDANA SP commit that the CODEX™ guidance values for possibly present trace substances are not exceeded in their products. Should an investigation using the CODEX™ agreed analytical test method reveal test results above the guidance values, it is the responsibility of the manufacturer to further investigate this result. This can involve repetition of the measurements to check the previous test result. If the test results are confirmed to be too high, the manufacturer needs to investigate the case by exploring the reasons for the possible presence of this trace substance. This should be done in close cooperation with the feedstock supply chain and may require further detailed analysis of feedstock components, possibly including the involvement of pre-suppliers, investigations at the manufacturing site for contaminations due to the machinery equipment etc. The goal is to identify corrective measures that lead to acceptable analytical results. Nevertheless, exceeding CODEX™ guidance values does not necessarily mean the products are unsafe. Exposure based risk assessment (EBRA) is needed to assess whether the detected concentration of a chemical substance is of any toxicological concern.

Scenario 3: A new analytical approach to investigate AHPs for certain trace substances is available

EDANA will follow the developments of new analytical approaches with great interest. In the case that a new analytical method for detection of trace substances in AHPs is generated, EDANA will carefully evaluate these. New method development can be due to the engagement of analytical laboratories that are either private enterprises or laboratories run by regulatory bodies, e.g., the EU Joint Research Center. Any new method will be evaluated as to whether it offers advantages over the EDANA test design,

e.g. due to improvements in mimicking the in vivo wearing situation, the release of potential trace substances in a body fluid simulant or the practical execution as well as the robustness of the method. Also test methods following a different pathway by focussing on direct contact routes without fluid mediation, fat mediated transfers, in particular addressing volatile substances etc. will be monitored. After investigating a new method via consultation of the EDANA Scientific Review Panel, the EDANA Analytical Task Force and the Stewardship Program Steering Committee, an update of the EDANA approach as part of the EDANA CODEX™ is done where deemed necessary.

Scenario 4: A new chemical is identified for monitoring in AHPs

Should a regulatory body or the manufacturers themselves identify a new trace chemical (e.g., when new technologies are implemented) with the potential to be possibly present in AHPs and which is of importance from a toxicological perspective, the SRP will form an opinion and notify the respective EDANA SP bodies. A decision will be taken to include the respective substance or substance class into the CODEX™ substance list together with a guidance limit taken from any regulation (e.g., Annex XVII of REACH) or a standard for a related product category (e.g., toys, textiles). A non-inclusion of a substance in question has to be scientifically substantiated.

Scenario 5: A new regulatory or standard limit is published

Should a regulatory body define a new restriction limit of a substance or a substance class in AHPs or in products of related categories, this new limit will be revised right away by EDANA. It is the duty for manufacturers to meet new regulatory limits for substances or a substance class that are set for absorbent hygiene products based on the regulatory frame conditions. Quite often though, the analytical procedure for quantifying a substance is not defined when a restriction limit is set, or it is based on harsh extraction methods using organic solvent extraction. New regulatory or standards limits will be evaluated by the EDANA SRP in view of the CODEX™ and a decision will be taken whether the new regulatory limit requires an update of the CODEX™ with its related analytical method.

4.2. Risk mitigation aspects

Compliance with all relevant regulations on EU and/or national level is the overriding principle of any product development and commercialization.

An element that helps suppliers and manufacturers to mitigate risks already in the developmental phase of products and to support product stewardship in general is the EDANA supply chain information on the minimum safety and regulatory requirements to place AHPs on the EU market. In addition to the information needed to ensure the regulatory compliance of AHPs and their raw materials, this guidance contains information on best practices, industry programmes, national guidelines etc.

With the EDANA Stewardship Program, a voluntary industry standard has been established that allows member companies to go beyond existing legislation in order to give consumers full confidence in the safe use of AHPs. It is a further quality step in the manufacturing process. The SP program which is open for participation by non-EDANA

members is a vital program involving ad hoc and periodic reviews of the CODEX™ with its elements.

The duty of any AHP manufacturer to put only safe products on the market is irrespective of the compliance with the CODEX™. Manufacturers undertake every effort to ensure the safety of their products, which involves rigorous safety evaluations including product and/or raw material analysis. Compiling and keeping an internal technical dossier with all relevant technical and safety information about a product is common practice among manufacturers. It allows a fact-based exchange of information with regulatory bodies should this become necessary.

An important aspect for risk mitigation concerns product traceability and product identification systems. Manufacturers ensure that the products have a batch or serial number or another element which allows the identification of the product and that is easily visible and legible for consumers. Also, an on-pack contact information point or another communication channel such as a telephone number or a dedicated section on a website is provided for consumers in case of information requests or for submitting complaints. If necessary, manufacturers ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers. An example is the information provided for menstrual tampons.

Market surveillance is a further important tool that is well-established and cultivated in companies as it provides direct feedback from consumers. It has a long history in the AHP manufacturing companies. Consumer complaints that may include also possible health related complaints are collected and investigated in order to provide respective feedback to the complainant and to take any corrective measures should they be necessary to bring the product into conformity with the safety obligation of the EU General Product Safety Regulation. This may even include product withdrawal or recall. In the unlikely case of an occurrence of a serious product safety issue the manufacturer has processes in place to immediately alert consumers of the risk to their health and inform and cooperate with the respective regulatory bodies e.g., the national market surveillance authorities in order to prevent and minimize any risk for the consumer.

4.3. Conclusions

EDANA has always taken the view that products being placed on the market are safe, because industry responsibly takes all necessary steps to ensure this.

The dossier describes the elements of a new conservative and voluntary standard to respond to consumer demand, the Stewardship Program for AHPs. Companies that subscribe to this Program ensure that potentially present trace chemicals in AHP products, which might be perceived as a safety concern by consumers, are not exceeding certain limits. For this, a profound suitable analytical method has been developed EDANA and this is to be applied. EDANA member companies producing AHPs are committed to stay engaged to constantly evaluate the set AHP CODEX™ with regards to evolving regulations, new toxicological data, and new analytical methods. This evaluation might require adaptation of the guidance values should new data become available.

With regard to toxicological assessment of AHPs, EBRA is the method of choice, provided the correct exposure parameters are selected.

EDANA believes that the implementation of this voluntary industry standard represents a helpful addition to current regulatory initiatives in setting guidance values for certain trace substances in absorbent hygiene products to further enhance consumer protection and well-being. The advantage of a voluntary industry standard lies in the fact that it can be adopted and implemented far quicker than legislation where implementation often takes many years. Furthermore, it is a considerably more flexible process, that can evolve and adapt to new science at any time.

In this first edition of this dossier the current knowledge of the EDANA member companies manufacturing absorbent hygiene products is reflected. Once new scientific or company specific manufacturing knowledge becomes available EDANA is open to revise this report. Also, periodic updates may be considered.

EDANA members realize that there might be different scientific viewpoints on the need for regulatory measures and the methodologies that are applied and described in this dossier, whether in terms of analytical approach or the exposure-based risk assessment principle.

Future science-based stakeholder dialogues to discuss different viewpoints can be based on the contents of this dossier including the various aspects of the new voluntary EDANA industry standard and the elements and methodologies that industry applies.

In its role as a dialogue partner for any AHP stakeholder EDANA demonstrates with this dossier its continuous and transparent commitment to seriously address any safety concerns for AHPs and to reassure consumers and other stakeholders that AHPs are safe. EDANA member companies want to assure that consumer concerns and product safety have been and continue to be taken very seriously.

5. References

[1] https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products

[2] M.Dopico, A Gómez, Journal of the Air & Waste Management Association, 2015, Vol.65 (9), 1033-1049

[3] Survey and Health Assessment of the exposure of 2-year-olds to chemical substances in Consumer Products. Survey of Chemical Substances in Consumer Products, No. 102 2009. https://www2.mst.dk/udgiv/publications/2009/978-87-92548-81-8/pdf/978-87-92548-82-5.pdf Microsoft Word - Titelside.doc (mst.dk)

[4] https://www.kemi.se/en/publications/reports/2018/report-8-18-survey-of-hazardous-chemical-substances-in-feminine-hygiene-products

[5] https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/report_quantitative_analysis_baby_diapers_0.pdf

[6] https://www.blv.admin.ch/blv/de/home/gebrauchsgegenstaende/kinderartikel.html#accordion1557998867026

[7] https://echa.europa.eu/documents/10162/99f020fd-e8ae-1b66-4fe6-0ec40789db8a

[8] https://ifrafragrance.org/safe-use/introduction

[9] International Programme on Chemical Safety. (2002). Global assessment on the state of the science of endocrine disruptors. World Health Organization. https://apps.who.int/iris/handle/10665/67357

[10] https://www.efsa.europa.eu/en/efsajournal/pub/5311

[111] https://www.oeko-tex.com/en/our-standards/standard-100-by-oeko-tex

[12] https://www.baua.de/DE/Aufgaben/Geschaeftsfuehrung-von-Ausschuessen/AfPS/pdf/AfPS-GS-2019-01-PAK.pdf?__blob=publicationFile&v=5

[13]https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1840698d5

[14] Stratégie d'investigation du Service Commun des Laboratoires (SCL) sur la sécurité des couches pour bébé

[15] Laura N Vandenberg, Roy R Gerona, Kurunthachalam Kannan, Julia A Taylor, Richard B van Breemen, Carrie A Dickenson, Chunyang Liao, Yang Yuan, Retha R Newbold, Vasantha Padmanabhan, Frederick S Vom Saal, Tracey J Woodruff. A round robin approach to the analysis of bisphenol A (BPA) in human blood samples. Affiliations expand PMID: 24690217, PMCID: PMC4066311, DOI: 10.1186/1476-069X-13-25

[16] EDANA Supply Chain Information for AHPs, https://www.edana.org/docs/default-source/product-stewardship/edana-safety-and-regulatory-supply-chain-info-(2022).pdf?sfvrsn=ccc83bef_2

[17] National Academy of Science. 1983. Risk assessment in the federal government. National Research Council. Washington, DC: National Academy Press.

U.S. EPA. Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F, 2011.

World Health Organization., 2008. Harmonization Project Document No. 6. Available at: http://www.inchem.org/documents/harmproj/harmproj/harmproj6.pdf

US EPA., 1992. Guidelines for Exposure Assessment. U.S. Environmental Protection Agency, National Center for Environmental Assessment, Available at: http://www.epa.gov/raf/publications/pdfs/GUIDELINES_EXPOSURE_ASSESSMENT.PDF

[18] Meek ME, Boobis AR, Crofton KM, Heinemeyer G, Raaij MV, Vickers C, Risk assessment of combined exposure to multiple chemicals. A WHO/IPCS framework. Regul Toxicol Pharmacol 60:S1-S14 (2011). doi: 10.1016/j.yrtph.2011.03.010

[19] Swatee Dey, Mike Purdon, Taryn Kirsch, Hans Martin Helbich, Kenny Kerr, Lijuan Li, Shaoying Zhou. Exposure Factor considerations for safety evaluation of modern disposable diaper. Regulatory Toxicology and Pharmacology 81 (2016) 183e193

[20] K.E. Woeller and A.E.Hochwalt, Safety assessment of sanitary pads with a polymeric foam absorbent core. Regulatory Toxicology and Pharmacology 73 (2015) 419-424).

[21] Jihyun Bae 1, Hoonjeong Kwon and Jooyoun Kim, Safety Evaluation of Absorbent Hygiene Pads: A Review on Assessment Framework and Test Methods, Sustainability 10-4146 (2018) 3-17) https://www.mdpi.com/2071-1050/10/11/4146

[22] Michael J DeVito and Arnold Schecter, Exposure assessment to dioxins from the use of tampons and diapers (2002) Environ Health Perspect. 110(1): 23–28).

[23] Hoang, K.T., 1992. Dermal Exposure Assessment: Principles and Applications. U.S. Environmental Protection Agency, Office of Health and Environmental Assessment, EPA/600/8-91/011B, Washington, DC. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12188.
Hewitt et al. Measurement of the penetration of 56 cosmetic relevant chemicals into and through human skin using a standardized protocol. Journal of Applied Toxicology (2020); 40: 403-415.

[24] SCCS 1628/21 (2011) Notes of guidance for the testing of cosmetic products and their safety evaluation

[25] Felter, SP et al. Safety evaluation for ingredients used in baby care products: Consideration of diaper rash. (2017). Regulatory Toxicology and Pharmacology, Volume 90, Pages 214-221, ISSN 0273- 300

[26] Saadatmand M et al. Skin hydration analysis by experiment and computer simulations and its implications for diapered skin. Skin Res Technol (2017). 23:500-513

[27] Dey S, Rothe H, Page L, O'Connor R, Farahmand S, Toner F, Marsh R, Wehmeyer K, Zhou S. An in vitro Skin Penetration Model for Compromised Skin: Estimating Penetration of Polyethylene Glycol 14C-PEG-7 Phosphate. Skin Pharmacol Physiol (2015) 28:12-21 DOI: 10.1159/000362284.

[28] Berry, R. M., Luthe, C. E., & Voss, R. H. (1993). Ubiquitous nature of dioxins: a comparison of the dioxins content of common everyday materials with that of pulps and papers. Environmental science & technology, 27(6), 1164-1168.

[29] Swanson, S. E., Rappe, C., Malmström, J., & Kringstad, K. P., Emissions of PCDDs and PCDFs from the pulp industry. Chemosphere, 17(4), 681-691, (198).

[30] OECD Test Guideline 428 Test Guideline 428: Skin Absorption: In Vitro Method. OECD, Paris, 2004.

[31] SCCS (Scientific Committee on Consumer Safety), Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10th revision, 24-25 October 2018, SCCS/1602/18

[32] ECETOC Technical Report 119: Evaluation of Systemic Health Effects Following Dermal Exposure to Chemicals.

[33] EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017 ;15(6):4873, 60 pp. https://doi.org/10.2903/j.efsa. 2017.4873

[34] Roy et al., Percutaneous absorption of TCDD from soil (J Toxicol and Environ Health Part A (2008) 71: 1509-1515.

[35] Banks and Birnbaum. Absorption of TCDD after low dose dermal exposure (1991) 107; 302-310.

[36] Weber et al., Penetration, distribution and kinetics of 2,3,7,8-tetrachlorodibenzo-p-dioxin in human skin in vitro. Arch Toxicol (1991) 65: 421-428.

[37] Brewster et al., Comparative dermal absorption of 2,3,7,8-tetrachlorodibenzo-p-dioxin and three polychlorinated dibenzofurans. Toxicol. Appl. Pharmacol (1989) 97: 156-166.

[38] Wester et al., Percutaneous absorption of PCBs from soil: In vivo rhesus monkey, in vitro human skin, and binding to powdered human stratum corneum, Journal of Toxicology and Environmental Health, Part A Current Issues, (1993) 39:3, 375-382.

[39] Wester et al., Percutaneous Absorption of [14C] DDT and [14C] Benzo[a]pyrene from Soil. Fundamentals and Applied Toxicology (1990) 15:510-516.

[40] Bartsch et al: Skin permeation of polycyclic aromatic hydrocarbons: A solvent-based in vitro approach to assess dermal exposures against benzo[a]pyrene and dibenzopyrenes, Journal of Occupational and Environmental Hygiene (2016) 13:12, 969-979

[41] Moody et al., Contaminated soils (1): In vitro dermal absorption of BaP in Human skin. J Toxicol and Environ Health Part A (2007) 70: 1858-1865.

[42] Jean-Paul Payan et al: 3-Hydroxybenzo(a)pyrene as a biomarker of dermal exposure to benzo(a)pyrene. Arch Toxicol. (2009) 83: 873-883 DOI 10.1007/s00204-009-0440-0.

[43] SCCS/1538/14 (2014). The Safety of the Use of Formaldehyde in Nail Hardeners

[44] Bernard, A. Dermal Exposure to Hazardous Chemicals in Baby Diapers: A Critical Review of the Quantitative Health Risk Assessment ConDucted by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES). Int. J. Environ. Res. Public Health 2022, 19(7), 4159; https://doi.org/10.3390/ijerph19074159

[45] Bernard A, Dudler V. Health Risk Assessment of Dermal Exposure to Polycyclic Aromatic Hydrocarbons from the Use of Infant Diapers. Int. J. Environ. Res. Public Health 2022, 19(22), 14760; https://doi.org/10.3390/ijerph192214760

6. Appendices

Appendix A Absorbent Hygiene Products components

BABY DIAPERS (taped diapers & pants)			
Component *	Function	Material	Example of potential material components
Top Sheet (skin contact)	Brings comfort and keeps the skin dry/clean/comfortable by transferring the liquid to the acquisition distribution layer (ADL)	Ultra-thin cover made of cellulosic fibres, synthetic fibres or film of synthetic polymers	Polyester Polyethylene Polypropylene Mixture of Polyethylene/Polypropylene Viscose/rayon Cotton
Acquisition distribution layer	Transports liquid from the surface to the core of the product, where the liquid is locked in	Porous material consisting of cellulosic or synthetic fibres or nonwovens made of synthetic polymers	Polyester Polyethylene Polypropylene Viscose /rayon Cotton
Core wrap	Material that encircles absorbent core for core integrity and to contain the super absorbent polymer (SAP) or a mix of SAP and cellulosic fibres	Synthetic fibres or nonwovens made of synthetic polymers or cellulosic fibres	Polyester Polyethylene Polypropylene Viscose/rayon
Absorbent Core	Absorbs and locks in the liquids	Cellulosic or/and synthetic fibres with or without a super absorbent polymer (SAP) or SAP without fibres	Cellulose/Pulp fibre Cotton Superabsorbent polymer Polyester Polyethylene Polypropylene
Containment flap with elastic	Prevent leakage out of the diaper and to optimise fit	Nonwovens made of synthetic polymers	Polyethylene Polypropylene Polyurethane Synthetic elastic
Waistband	Provides/improves fit around the waist	Nonwovens made of synthetic polymers	Polyethylene Polypropylene Polyurethane Synthetic elastic

Backsheet	Waterproof layer to prevent leakage	Film/nonwoven made of synthetic polymers or cellulosic fibres	Polyethylene Polypropylene Cotton Calcium carbonate
Leg cuff with elastic	Prevent leakage (liquid feces) out of the diaper and to optimise fit	Nonwovens made of synthetic polymers	Polyethylene Polypropylene Polyurethane Synthetic elastic
Fastening system composed of: - Fasteners - Elastic ears (in case of self-gripping system) - A landing zone	Consists of a repositioning strip located on the front of the layer and fasteners attached to each rear side of the layer. Adhesive and self-gripping systems are the two repositioning existing systems that allows a better fit to baby	Synthetic polymers Adhesive	Polyethylene Polypropylene Polyurethane Synthetic elastic Thermoplastic polymers
Elastics	To maintain the diaper on baby	Elastic thread	Elastane
Adhesive	To ensure the integrity of the product	Adhesive	Synthetic resin Thermoplastic polymers

** Some of these components may not always be present in the final products*

a. Some layers may be colored by inks, pigments and dyes used in small amounts to assist in the identification of components for ease of use and to make the products more appealing to use.

b. Lotion may be added to protect the skin from overhydration and help reduce irritation. The added lotion is regulated under the EU Cosmetics Regulation (EC) N° 1223/2009. If so, the ingredients of the lotion should be indicated on the packaging (INCI names).

c. Some products are fragranced and if so, it is indicated on the pack.

TAMPONS			
Component *	**Function**	**Example of Material type**	**Example of material components**
Surface material/cover	Facilitates insertion/removal of the tampon, keeps the tampon fibres intact and aids the absorption of fluid	Ultra-thin cover made of cellulosic fibres, synthetic fibres or film of synthetic polymers	Polyester Polyethylene Polypropylene Mixture of Polypropylene/Polyester/ Polyethylene Viscose/rayon Cotton
Absorbent Core	Absorbs fluids	Cellulosic fibres	Viscose/rayon Cotton
Tampon withdrawal string	Allows removal of the tampon	Cellulosic or synthetic fibres or a blend of both	Polyester Viscose/rayon Cotton Any mixture of the above
Applicator	Helps to insert the tampon.	Cardboard or plastic	Cardboard Polyethylene Polypropylene Polylactic acid
Wrapper	Keep the tampon clean Used to dispose the tampon	Film or nonwoven made of synthetic polymers	Polyethylene Polypropylene Cellophane

* Some of these components may not always be present in the final products

PAD/LINER			
Component *	**Function**	**Material**	**Example of material components**
Surface material/cover (Body Side Liner)	Brings comfort and keeps the skin dry/clean/comfortable by transferring the liquid to the acquisition distribution layer (ADL)	Ultra-thin cover made of cellulosic fibres, synthetic fibres or film of synthetic polymers	Polyester Polyethylene Polypropylene Mixture of Polyethylene/Polypropylene Viscose/rayon Cotton
Acquisition distribution layer	Transports liquid from the surface to the core of the product, where the liquid is locked in	Porous material consisting of cellulosic or synthetic fibres or nonwovens made of synthetic polymers	Polyester Polyethylene Polypropylene Viscose /rayon Cotton Cellulose/Pulp fibre
Absorbent Core	Absorbs and locks in the liquids	Cellulosic or/and synthetic fibres with or without a super absorbent polymer (SAP)	Cellulose/Pulp fibre Cotton Superabsorbent polymer Polyester Polyethylene Polypropylene
Backsheet	Layer to prevent leakage and protect underwear	Typically, nonwoven or waterproof film	Polyethylene Polypropylene Polylactic acid
Adhesive	Attaches the product to the underwear For construction, adhesives may be used	Adhesive	Synthetic resin Thermoplastic polymers
Release paper/ Peel Strip	A paper that protects the glue on the back of the products	Paper with silicone coating	Paper Silicone coating
Wrapping or Pouch Wrapper	Used to dispose the product Keep the pad/liner clean	Film or nonwoven made of synthetic polymer that may be silicone coated film	Polyethylene Polypropylene Polylactic acid

	Can also replace the release paper Paper strip		with/without silicone coating

** Some of these components may not always be present in the final products*

Some layers may be colored by inks, pigments and dyes used in small amounts to assist in the identification of components for ease of use and to make the products more appealing to use

Some pads/lines are fragranced and if so, it is indicated on the pack

Some pads/liners may contain some odor-absorbing ingredients

BABY DIAPERS AND NAPPIES

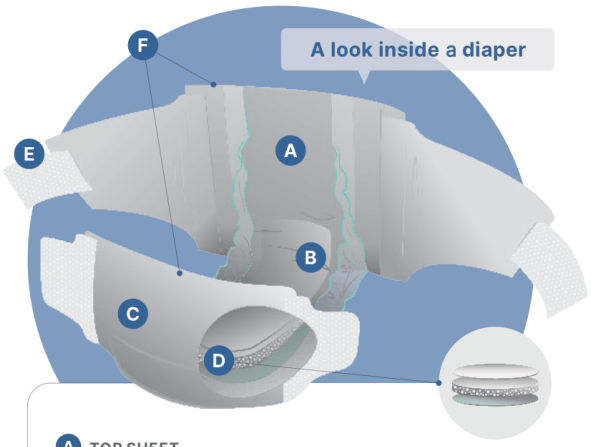
from raw materials to your supermarket shelf

A brief history of the baby diaper

Since their invention in the 1930s, single-use diapers have continuously improved, becoming lighter, more compact, more absorbent and easier to use with more than 95% of all parents and carers (in many countries) using them.
Since 1987, baby diapers have become 50% lighter, thanks to the use of fewer raw materials. As today's diapers are also thinner, transportation to your local store or supermarket is achieved with much lower energy use as well.
Modern diapers are recognised by doctors as being safe for infant skin, by keeping babies' skin dry, and have helped make diaper dermatitis (or nappy rash) not only less common, but also much less severe.
Around 33 billion nappies and diapers are sold across Europe every year.

How are they made?

While each brand or type of baby diaper (also called a 'nappy' in some countries) will be a little different, they are generally manufactured by the steps below. The steps illustrate a traditional diaper with fastening systems, whereas types like pant diapers only use elastics.



A TOP SHEET
A soft nonwoven sheet to ensure a comfortable feel against the skin

B ACQUISITION LAYER
An open structure nonwoven or cellulose layer to quickly transport fluids away from the skin

C BACKSHEET
A waterproof film-based layer to ensure there is no leakage out of the product. Some diapers include a breathable film for increased skin comfort. Additionally, some products come with printed design and graphics

D CORE
Absorbing materials (mostly superabsorbent materials and cellulosic fibres) to absorb fluids

E FASTENERS
Strips to secure the diaper around the baby and give a comfortable fit. The strips can stretch and easily be opened and possibly refastened

F ELASTICS
Elastic material is placed around the waist and legs to ensure a better fit, protection against leakage and comfort for the baby

1 RAW MATERIALS
Diapers are made from soft nonwoven materials, elastic materials, polyethylene film, superabsorbent polymers and cellulose (fluff pulp).

2 HANDLING OF RAW MATERIALS
After opening the packaging, and during manufacturing, the raw materials are stored in a safe environment where temperature and humidity is controlled.

3 DIFFERENT MATERIALS FOR EACH PART OF THE DIAPER
The materials for each part of the diaper are selected according to the type of the diaper, and to deliver benefits like elasticity, softness and absorption.

4 MAKING THE DIAPER
The various parts of a diaper, such as the core, the fastening system and elastics, are put together. Some diapers may be fragranced, others may contain odour absorbing ingredients. And some may contain a skin protection balm to protect the baby's bottom.

5 TESTING
Different tests are carried out on samples during the manufacturing process, and on the final diaper to ensure the products meet high quality and safety standards.

6 PACKAGING
Diapers are wrapped into a consumer pack, and put in protective packaging during the transport to your local supermarket or store.

www.edana.org

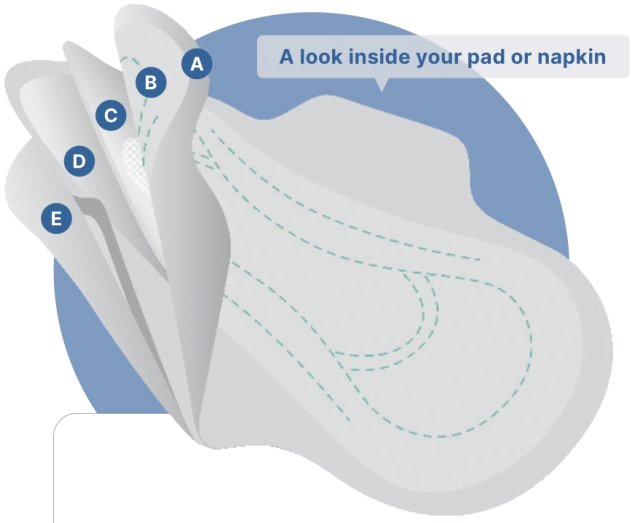
PADS & NAPKINS
from raw materials to your supermarket shelf

How are they made?

While each brand of sanitary pads and napkins will be different, they are generally manufactured by the steps below.

A brief history of the pad or napkin

Today pads and napkins are thinner, lighter and more effective than ever. It's amazing to think that this product goes back to the 10th century. Early versions of the modern single-use pads were introduced in the 1920s, with adhesive strips first placed on their back in the 1980s, later followed by wings and other improvements. Today pads and napkins come in different shapes and sizes to suit the needs of all women. A woman typically uses between 10-20 pads per menstrual cycle.



A TOP SHEET
A soft and liquid permeable sheet which is comfortable against the skin

B ACQUISITION LAYER & CHANNELS
Draws and directs fluids into the inner core

C INNER CORE
Absorb moisture or fluid (superabsorbent beads may also be integrated)

D BACKSHEET
A liquid proof layer to ensure there is no leakage

E ADHESIVE & RELEASE LAYER
Glue that sticks the pad to clothing, and a non-stick or wrap.

1 RAW MATERIALS
The absorbent core in pads are made from cellulosic fibres and other absorbent materials. The materials are rigorously selected and subject to strict quality control and hygiene requirements.

2 MAKING THE PAD
Multiple layers are used to make a pad,depending on their design or final use. Different materials, each with a specific role are layered together. Some pads may be fragranced, or may contain odour-absorbing ingredients.

3 ADHESIVE AND RELEASE
Once the pad is made, adhesive is added to the back of the product, so that it stays in place during use. As a final step, non-stick paper or wrap is then put on top of the adhesive.

4 TESTING
Different tests are carried out on samples during the manufacturing process, and on the final pads to ensure the products meet high quality and safety standards.

5 PACKAGING
Pads are either individually folded and wrapped or flat and unwrapped and then placed in a secondary box.

www.edana.org

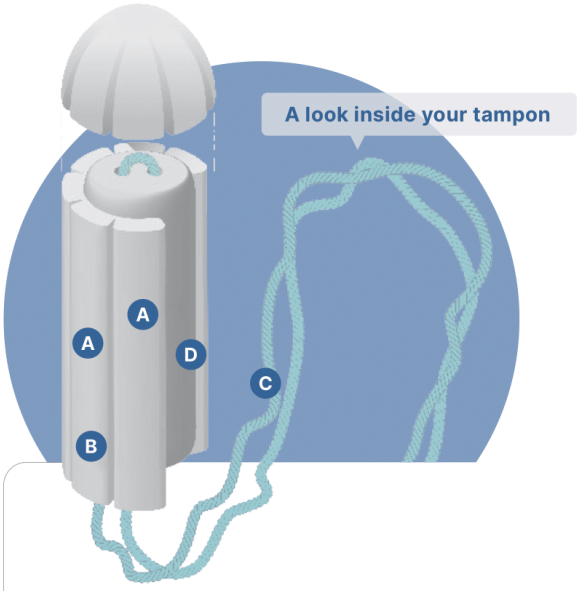
TAMPONS
from raw materials to your supermarket shelf

How are they made?

While each brand of tampon will have small differences, tampons are generally manufactured by the steps below.

A brief history of the tampon

Modern tampons have been safely used as a convenient aid by women across the globe since the patenting in the 1930s, but their early forms were used by women as far back as ancient Egypt.
On average, a woman might use up to 8,000 tampons during the years where she is menstruating.



A GROOVES
Can help the absorbency during use and an even distribution of fluid

B OUTER LAYER
Nonwoven (or perforated film) to facilitate insertion and removal of the tampon, keep the tampon fibres intact, and aid the absorption of fluid

C STRING
Polyester or cotton (or a mix of these with or without viscose) to help to remove the tampon after use

D CORE FIBRES
Viscose, cotton (or a mixture of the two) to absorb menstrual blood

1 RAW MATERIALS
Tampons are made from natural or regenerated fibres made from natural cellulose, such as viscose (sometimes called rayon) or cotton, or a blend of these two fibres. Raw materials are tested for skin sensitisation and irritation.

2 WEB FORMATION
The fibres are mixed and blended and formed into a web. Its thickness, weight, and width can vary depending on the size and type of tampon made.

3 FORMATION OF THE TAMPON
A cover made of nonwovens or a perforated film may be added to the web, which is then rolled, or folded. Before or after this step, a string will be added, knotted and secured to the inner part of the tampon, which is then compressed into shape.

4 APPLICATOR
Tampons can be contained in an applicator which is usually made of plastic or coated cardboard.

5 TESTING
Different tests are carried out on samples taken during the manufacturing process, and on the final tampons to ensure the products comply with high quality and safety standards.

6 PACKAGING
Each tampon is immediately wrapped in a thin plastic film to protect it, and is then transferred to a secondary box, bag or tin before being sent to your local supermarket or store for purchase.

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Appendix C: Harmonised and self-classification of formaldehyde, PAHs, dioxanes, PCDDs, furans, PCBs, phenols, heavy metals, organotins, phthalates and pesticides in the scope of EDANA CODEX™ and this document

Risks to human health and the environment posed by chemicals are classified and communicated globally as part of the chemical hazard communications system developed by the United Nations (UN) called Globally Harmonised System of Classification and Labelling of Chemicals, commonly known as GHS. To ensure a high level of protection of human health and the environment, manufacturers and distributors of chemicals in the EU self-classify and label chemicals. The classification and communication for hazards of the higher concern is harmonised throughout the EU. Legally binding harmonised classification is shown where available; self-classification was shown where harmonised classification does not exist. Regulatory classification was gathered from the ECHA Classification and Inventory database (accessed Oct 2021 Substance Information - ECHA (europa.eu)).

Formaldehyde has a harmonised classification for carcinogenicity, mutagenicity and skin sensitization according to Reg. (EC) 1272/2008 (CLP) Regulation.

PAHs addressed in this document have a harmonised or a self-classification for carcinogenicity, mutagenicity and environmental toxicity under the CLP regulation.

Dioxins, furans, DL-PCBs have a self-classification for target organ and environmental toxicity under the CLP regulation.

Phenols have a harmonised or a self-classification for toxicity to reproductive system, target organ and environmental toxicity under the CLP regulation.

Phthalates have a harmonised classification for toxicity to reproductive system and environmental toxicity under the CLP regulation.

Pesticides have either various' harmonised or substance specific self-classification for eye damage, sensitization and environmental toxicity under the CLP regulation.

Heavy metals and organotins have either various harmonised or self-classifications under the CLP regulations.

Group of substances	Substance name	CAS Number	Harmonised Hazard Classification	Hazard Self-classification
Formaldehyde	Formaldehyde	50-00-0	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* Skin Corr. 1B Skin Sens. 1 Muta. 2 Carc. 1B	-
Dioxanes and Dixane-like Polychlorinated	2,3,7,8-tetrachlorodibenzo[b,e][1,4] dioxin; 2,3,7,8-TCDD	1746-01-6	-	Acute Tox. 1 Acute Tox. 1

Bisphenyls (PCDDs):	1,2,3,7,8-pentachlorodibenzo-p-dioxin; 1,2,3,7,8-PeCDD	40321-76-4	-	Acute Tox. 1 Aquatic Chronic 4
	1,2,3,4,7,8-hexachlorodibenzo-p-dioxin; 1,2,3,4,7,8-HxCDD	39227-28-6	-	Acute Tox. 3 Eye Irrit. 2 STOT SE. 3 Muta. 2
	1,2,3,6,7,8-hexachlorodibenzo-p-dioxin; 1,2,3,6,7,8-HxCDD	57653-85-7	-	Acute Tox. 3 Eye Irrit. 2
	1,2,3,7,8,9-hexachlorodibenzo-p-dioxin; 1,2,3,7,8,9-HxCDD	19408-74-3	-	Acute Tox 4
	1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin; 1,2,3,4,6,7,8-HpCDD	35822-46-9	-	Eye Irrit. 2 STOT SE 3 Muta. 2
	octachlorodibenzo-p-dioxin; OCDD	3268-87-9	-	Acute Tox. 1 Aquatic Acute 1 Aquatic Chronic 1
Polychlorinated Dibenzofurans (PCDFs):	2,3,7,8-tetrachlorodibenzofuran; 2,3,7,8-TCDF	51207-31-9	-	Acute Tox. 1 Aquatic Acute 1 Aquatic Chronic 1
	1,2,3,7,8-pentachlorodibenzofuran; 1,2,3,7,8-PeCDF	57117-41-6	-	Acute Tox. 3 Eye Irrit. 2 STOT SE 3 Muta. 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3,4,7,8-pentachlorodibenzofuran; 2,3,4,7,8-PeCDF	57117-31-4	-	Acute Tox. 1 Eye Irrit. 2 STOT SE 3 Carc. 1 ASTOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	1,2,3,4,7,8-hexachlorodibenzofuran; 1,2,3,4,7,8-HxCDF	70648-26-9	-	Acute Tox. 3 Eye Irrit. 2 Aquatic Chronic 1
	1,2,3,6,7,8-hexachlorodibenzofuran; 1,2,3,6,7,8-HxCDF	57117-44-9	-	Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 Aquatic Acute 1 Aquatic Chronic 1
	2,3,4,6,7,8-hexachlorodibenzofuran; 2,3,4,6,7,8-HxCDF	60851-34-5	-	Acute Tox. 3 Eye Irrit. 2 Aquatic Chronic 4
	1,2,3,7,8,9-hexachlorodibenzofuran; 1,2,3,7,8,9-HxCDF	72918-21-9	-	Acute Tox. 3 Eye Irrit. 2 STOT SE 3 Muta. 2 Aquatic Acute 1 Aquatic Chronic 1

	1,2,3,4,6,7,8-heptachlorodibenzofuran; 1,2,3,4,6,7,8-HpCDF	67562-39-4	-	Acute Tox. 3 Eye Irrit. 2 Aquatic Chronic 1
	1,2,3,4,7,8,9-heptachlorodibenzofuran; 1,2,3,4,7,8,9-HpCDF	55673-89-7	-	Acute Tox. 1 Aquatic Acute 1 Aquatic Chronic 1
	octachlorodibenzofuran; OCDF	39001-02-0	-	Acute Tox. 1 Aquatic Acute 1 Aquatic Chronic 1
Dioxin-like Polychlorobiphenyls (DL-PCBs):	3,4,4′,5-tetrachloro-1,1′-biphenyl; PCB 81	70362-50-4	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	3,3′,4,4′-tetrachloro-1,1′-biphenyl; PCB 77	32598-13-3	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3′,4,4′,5′-pentachloro-1,1′-biphenyl; PCB 123	65510-44-3	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3′,4,4′,5-pentachloro-1,1′-biphenyl; PCB 118	31508-00-6	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3,4,4′,5-pentachloro-1,1′-biphenyl; PCB 114	74472-37-0	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3,3′,4,4′-pentachloro-1,1′-biphenyl; PCB 105	32598-14-4	-	Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	3,3′,4,4′,5-pentachloro-1,1′-biphenyl; PCB 126	57465-28-8	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3′,4,4′,5,5′-hexachloro-1,1′-biphenyl; PCB 167	52663-72-6	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3,3′,4,4′,5-hexachloro-1,1′-biphenyl; PCB 156	38380-08-4	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3,3′,4,4′,5′-hexachloro-1,1′-biphenyl; PCB 157	69782-90-7	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	3,3′,4,4′,5,5′-hexachloro-1,1′-biphenyl; PCB 169	32774-16-6	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3,3′,4,4′,5,5′-heptachloro-1,1′-biphenyl; PCB 189	39635-31-9	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
Total Polychlorobiphenyls (PCBs) including NDL-PCBs (non-	2,2′,3,5′-Tetrachloro-1,1′-biphenyl; PCB 44	41464-39-5	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,4,5′-Tetrachloro-1,1′-biphenyl; PCB 49	41464-40-8	-	Not Classified

exhaustive list- examples of NDL-PCB included)	2,2′,5,5′-Tetrachloro-1,1′-biphenyl; PCB 52	35693-99-3	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3′,4,4′-Tetrachloro-1,1′-biphenyl; PCB 66	32598-10-0	-	Not Classified
	2,4,4′,5-Tetrachloro-1,1′-biphenyl; PCB 74	32690-93-0	-	Not Classified
	2,2′,3,4,5′-Pentachloro-1,1′-biphenyl; PCB 87	38380-02-8	-	Not Classified
	2,2′,4,4′,5-Pentachloro-1,1′-biphenyl; PCB 99	38380-01-7	-	Not Classified
	2,2′,4,5,5′-Pentachloro-1,1′-biphenyl; PCB 101	37680-73-2	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3,3′,4′,6-Pentachloro-1,1′-biphenyl; PCB 110	38380-03-9	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,3,3′,4,4′-Hexachloro-1,1′-biphenyl; PCB 128	38380-07-3	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,3,4,4′,5′-Hexachloro-1,1′-biphenyl; PCB 138	35065-28-2	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,3,3′,4,4′,6-Hexachloro-1,1′-biphenyl; PCB 158	74472-42-7	-	Not Classified
	2,2′,3,4′,5,5′-Hexachloro-1,1′-biphenyl; PCB 146	51908-16-8	-	Not Classified
	2,2′,3,4′,5′,6-Hexachloro-1,1′-biphenyl; PCB 149	38380-04-0	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,3,5,5′,6-Hexachloro-1,1′-biphenyl; PCB 151	52663-63-5	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,4,4′,5,5′-Hexachloro-1,1′-biphenyl; PCB 153	35065-27-1	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,3,3′,4,4′,5-Heptachloro-1,1′-biphenyl; PCB 170	35065-30-6	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,3,3′,4,5,5′-Heptachloro-1,1′-biphenyl; PCB 172	52663-74-8	-	Not Classified
	2,2′,3,3′,4,5′,6′-Heptachloro-1,1′-biphenyl; PCB 177	52663-70-4	-	Not Classified
	2,2′,3,3′,5,5′,6-Heptachloro-1,1′-biphenyl; PCB 178	52663-67-9	-	Not Classified
	2,2′,3,4,4′,5,5′-Heptachloro-1,1′-biphenyl; PCB 180	35065-29-3	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,3,4,4′,5′,6-Heptachlorobiphenyl (PCB 183)	52663-69-1	-	Not Classified
	2,2′,3,4′,5,5′,6-Heptachloro-1,1′-biphenyl; PCB 187	52663-68-0	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1

	2,2′,3,3′,4,4′,5,5′-Octachloro-1,1′-biphenyl; PCB 194	35694-08-7	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	2,2′,3,3′,4,4′,5,6-Octachloro-1,1′-biphenyl; PCB 195	52663-78-2	-	Not Classified
	2,2′,3,3′,4,4′,5,6′-Octachloro-1,1′-biphenyl; PCB 196	42740-50-1	-	Not Classified
	2,2′,3,3′,4,5,5′,6′-Octachloro-1,1′-biphenyl; PCB 199	52663-75-9	-	Not Classified
	2,2′,3,4,4′,5,5′,6-Octachloro-1,1′-biphenyl; PCB 203	52663-76-0	-	Not Classified
	2,2′,3,3′,4,4′,5,5′,6-Nonachloro-1,1′-biphenyl; PCB 206	40186-72-9	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
	decachloro-1,1'-biphenyl; PCB 209	2051-24-3	-	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
Organotins	Tributyltin (TBT)	688-73-3	-	Acute Tox. 3 Skin Irrit. 2 Eye Irrit. 2 Repr. 1B STOT RE 1 Aquatic Acute 1
	Monobutyltin (MBT)	78763-54-9	-	-
	Dibutyltin (DBT)	1002-53-5	-	Acute Tox. 4
	Triphenyltin (TPT)	668-34-8	-	Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1
	Dioctyltin (DOT)	15231-44-4	-	-
	Monooctyl tin (MOT)	15231-57-9	-	-
Heavy Metals	Antimony	-	-	-
	Cadmium and its compounds	-	-	-
	Chromium VI and its compounds	-	-	-
	Lead and its compounds	-	-	-
	Mercury	7439-97-6	Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1 Repr. 1B	-
Phenols	Bisphenol A	80-05-7	Eye Dam. 1 Skin Sens. 1 STOT SE 3 Repr. 1B	-
	Nonylphenol	25154-52-3 (EC No: 246-672-0)	Acute Tox. 4 Skin Corr. 1B Aquatic Acute 1 Aquatic Chronic 1 Repr. 2	-

	Nonylphenol, ethoxylated	9016-45-9 (EC No: 500-024-6)	-	Acute Tox. 4 Eye Dam. 1 Skin Irrit. 2 Aquatic Chronic 2
	4-Nonylphenol, ethoxylated	26027-38-3 (EC No: 500-045-0)	-	Acute Tox. 4 Eye Irrit. 2 Skin Irrit. 2 Aquatic Chronic 2
	Nonylphenol, branched, ethoxylated, phosphated	68412-53-3 (EC No: 614-460-0)	-	Met. Corr. 1 Skin Irrit. 2 Eye Dam. 1
	4-Nonylphenol, branched, ethoxylated	127087-87-0 (EC No: 500-315-8)	-	Acute Tox. 4 Eye Dam. 1 Skin Irrit. 2 Aquatic Chronic 2
	Isononylphenol, ethoxylated	37205-87-1 (EC No:609-346-2)	-	Acute Tox. 4 Eye Dam. 1 Aquatic Chronic 2
	Nonylphenol, branched, ethoxylated	68412-54-4 (EC No: 500-209-1)	-	Aquatic Acute 1 Aquatic Chronic 1
Pesticides	Glyphoshate	1071-83-6	Eye Dam. 1 Aquatic Chronic 2	-
	Aminomethylphosphonic acid (AMPA)	1066-51-9	-	Skin Corr. 1A Acute Tox. 4
	Quintozene	82-68-8	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	-
Phthalates	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP) 7	1888-89-6	Repr. 1B	-
	Bis-(2-methoxyethyl) phthalate (BMEP)	117-82-8	Repr. 1B	-
	Diisopentylphthalate (DIPP)	605-50-5	Aquatic Acute 1 Repr. 1B	-
	Di-n-pentylphthalate (DnPP)	131-18-0	Aquatic Acute 1 Repr. 1B	-
	Di-n-hexylphthalate (DnHP)	84-75-3	Repr. 1B	-
	Diethyl phthalate (DEP)	84-66-2	-	Not Classified
	Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	Repr. 1B	-
	Dibutyl phthalate (DBP)	84-74-2	Aquatic Acute 1 Repr. 1B	-
	Benzyl butyl phthalate (BBP)	85-68-7	Aquatic Acute 1 Aquatic	-

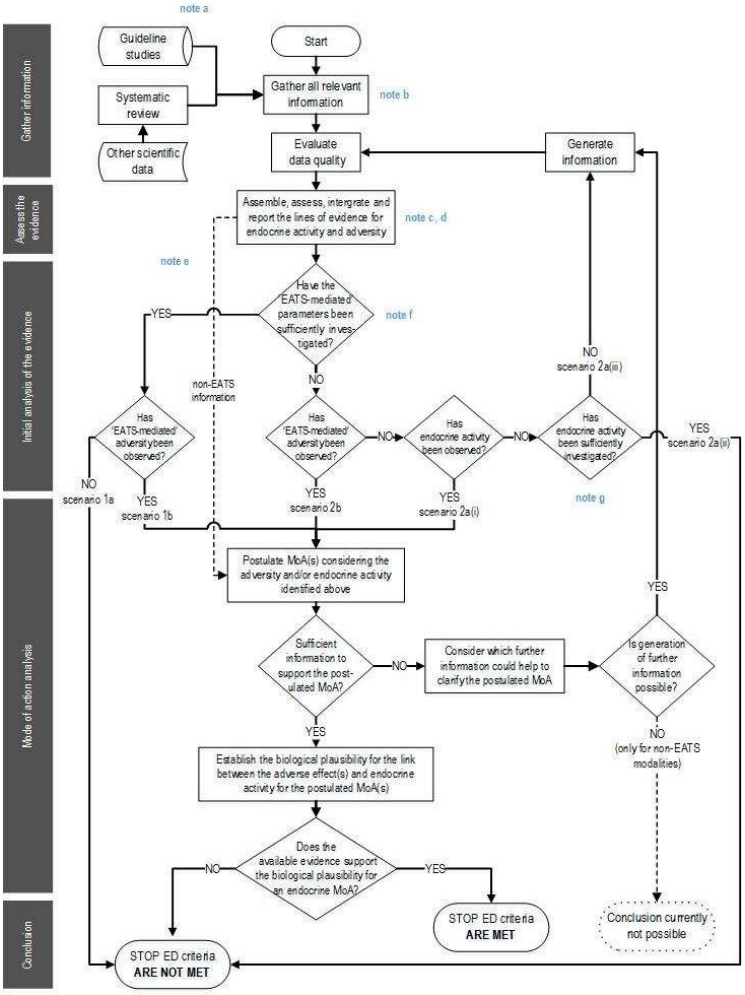
			Chronic 1 Repr. 1B	
	Diisobutyl phthalate (DIBP)	84-69-5	Repr. 1B	-
	Di-iso-decyl phthalate (DIDP)	26761-40-0	-	Not Classified
	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DiDP)	68515-49-1	-	Not Classified
	Di-isononyl phthalate (DINP)	28553-12-0	-	Not Classified
	Di-n-octyl phthalate (DNOP)	117-84-0	-	Not Classified

Appendix D: Endocrine Disruptors

As described in the "Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009" (ECHA and EFSA, 2018) an endocrine disruptor (ED) is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations (WHO/IPCS, 2002). The criteria for defining ED's are legally defined in Commission Delegated Regulation (EU) No 2017/2100 and Commission Regulation (EU) No 2018/605 for biocidal products and plant protection products, respectively. These are based on the 2002 WHO/IPCS [REF9] definition of an endocrine disruptor. The WHO/IPCS criteria ask for consideration, in a weight of evidence approach, of all relevant scientific information including human and/or animal evidence, therefore allowing for the identification of both known and presumed endocrine disrupting substances. To determine whether a substance causes adverse effect(s) that can be plausibly linked to endocrine activity, all ED relevant information and supporting toxicity information on the substance needs to be collected and assessed in accordance with the above-mentioned guidance from ECHA and EFSA as well as WHO/IPCS.

The assessment strategy is based on the three conditions stipulated in the ED criteria (adversity, endocrine activity, and a biologically plausible link between the two) and on the grouping of the parameters as described in the guidance. Below is a decision tree copied from the ECHA/EFSA 2018 Guidance document [REF10] that industry members follow to identify ED's. The EDs are actively monitored at the European Commission level. Any substances with confirmed ED classification are not intentionally used and any substance with suspected potential ED activity are evaluated in line with the here described methodology.

Figure 6: Decision tree for ED assessment (source: Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009)



Appendix E: Table of Risk Values

(Selection of most conservative threshold references, alternative values can be used as appropriate)

Substances	CAS #	Safety threshold/ Reference dose value (RfD)	Literature Reference
PAHs overall: DMEL of 0.004 based on dermal studies in mice (Schmähl et al., 1977; Fhl, 1997) assessed by BAuA (2010), in which BaP was applied as a component of PAHs mixture (most conservative DMEL of the range).			
Benzo[a]pyrene	50-32-8	0,006 ng/kg bw/day for BaP (dermal route)	derived from Knafla et al. (2006), in which only BaP was dermally applied to mice.
Benz[a]anthracene	56-55-3	NSRL - Oral: 0.033 µg/day or 4.71 E-7 mg/kg/day	https://oehha.ca.gov/chemicals/benzaanthracene
Dibenz[a,h]anthracene	53-70-3	NSRL: 0.2 µg/day or 2.86 E-6 mg/kg/day	https://oehha.ca.gov/proposition-65/chemicals/dibenzahanthracene
Benzo[e]pyrene	192-97-2	TTC: level is 0.15 µg/day or 2.5E-06 mg/kg/day	SCCS, SCHER, SCENIHR, Joint Opinion on the Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products, 8 June 2012
Benzo[b]fluoranthene	205-99-2	NSRL - Oral: 0.096 µg/day or 1.37 E-6 mg/kg/day	https://oehha.ca.gov/chemicals/benzobfluoranthene
Benzo[j]fluoranthane	205-82-3	NSRL - Oral: 0.11 µg/day or 1.57 E-6 mg/kg/day	https://oehha.ca.gov/chemicals/benzojfluoranthene
Benzo[k]fluoranthene	207-08-9	US EPA RFD (0.0003 mg/kg/day)	https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=452
Chrysene	218-01-9	NSRL - Oral: 0.35 µg/day or 5 E-6 mg/kg/day	https://oehha.ca.gov/chemicals/chrysene
Anthracene	120-12-7	US EPA RFD (0.3 mg/kg/day)	https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0434_summary.pdf
Benzo[ghi]perylene	191-24-2	US EPA RFD (0.0003 mg/kg/day)	https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0136_summary.pdf#nameddest=rfd

Fluoranthene	206-44-0	US EPA RFD 4E-2 mg/kg/day)	https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=444
Indeno[1,2,3-cd] pyrene	193-39-5	US EPA RFD (0.0003 mg/kg/day)	https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=457
Phenanthrene	85-01-8	TTC level is 0.15 µg/day or 2.5E-06 mg/kg/day	SCCS, SCHER, SCENIHR, Joint Opinion on the Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products, 8 June 2012
Naphthalene	91-20-3	No Significant Risk Level (NSRL): 5.8 µg/day or 8.3E-05 mg/kg/day	https://oehha.ca.gov/proposition-65/proposition-65-list
Organochlorine Pesticides and Pyrethroids			
Hexachlorobenzene (HCB)	118-74-1	NSRL: 0.4 µg/day or 5.7E-06 mg/kg/day, EPA RfD – 0,0008 mg/kg/day Can be used since HCB is non-genotoxic	https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-056502_11-Jul-06.pdf Hexachlorobenzene CASRN 118-74-1 | IRIS | US EPA, ORD
Quintozene (Pentachloronitro-benzene or PCNB)	82-68-8	EPA: RfD of 3E-3 for PCNB	https://cfpub.epa.gov/ncea/iris/search/index.cfm?keyword=82-68-8
		EPA also cites a RfD of 1E-3 mg/kg/day	https://ofmpub.epa.gov/apex/pesticides/f?p=109:5:::NO:RP:P5_HHBP_ID:2771
Glyphosate and AMPA			
Glyphosate	1071-83-6	Oral RfD: 1E-1mg/kg/day	https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0057_summary.pdf
Acid aminomethylphosphoniqµe (AMPA, metabolite of Glyphosate)	1066-51-9	Group ADI AMPA: 3E-1 mg/kg/day	WHO/SDE/WSH/03.04/97 (updated June 2005 to include additional sentence in section 3.2 and new reference (Kjaer et al., 2004)

Dioxins and Furans, PCDDs/Fs/DL-PCBs: DNEL (0.3 pg/kg bw/day) based on decreased semen parameters observed in Russian Children's Study and Total PCBs: DNEL (20 ng/kg bw/day) based on immunotoxicity and neurobehavioral changes in monkeys exposed to Aroclor 1254 (value used is based on TCDD and aligned to TEF value)			
1,2,3,4,6,7,8,9-Octachlorodibenzo-p-dioxin (OCDD)	3268-87-9	RfD of 7E-10 mg/kg/day*	U.S. Environmental Protection Agency. National Center for Environmental Assessment. Integrated Risk Information System (IRIS) Chemical Assessment Summary for 2,3,7,8-Tetrachlorodibenzo-p-dioxin; CASRN 1746-01-6. 2012 https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1024
1,2,3,4,6,7,8,9-Octachlorodibenzo fμran (OCDF)	39001-02-0	RfD of 7E-10 mg/kg/day*	U.S. Environmental Protection Agency. National Center for Environmental Assessment. Integrated Risk Information System (IRIS) Chemical Assessment Summary for 2,3,7,8-Tetrachlorodibenzo-p-dioxin; CASRN 1746-01-6. 2012
D/F/DL-PCB		0,25 pg/kg/bw/day (oral route)	EFSA (2019)
Organostannic			
Tributyltin	688-73-3	Tributyltin oxide (TBTO): EPA IRIS: RfD - 0.0003 mg/kg/d	https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0349_summary.pdf
		EU Risk assessment (see RPA page 105): 'group' TDI of 0.1 μg Sn/kg	Risk assessment studies on targeted consumer applications of certain organotin compounds, Final Report prepared for the European Commission, RPA September 2005
Dibutyltin	1002-53-5	ATSDR derived an intermediate-duration oral MRL of 0.005 mg/kg/day	https://www.atsdr.cdc.gov/toxprofiles/tp2.pdf
		EU Risk assessment (see RPA page 105): 'group' TDI of 0.1 μg Sn/kg	Risk assessment studies on targeted consumer applications of certain organotin compounds, Final Report prepared for the European Commission, RPA September 2005
Monobutyltin	78763-54-9	EU Risk assessment (see RPA page 105): 'group' TDI of 0.1 μg Sn/kg.	

		Risk assessment studies on targeted consumer applications of certain organotin compounds, Final Report prepared for the European Commission, RPA September 2005	
Triphenyltin	892-20-6		No risk value assigned yet
Dioctyltin	15231-44-4	ECHA DNEL: 0.02 mg/kg/d	ECHA DNEL
Monoctyltin	15231-57-9		No risk value assigned yet
Formaldehyde			
Formaldehyde	50-00-0	NSRL: 40 µg/day or 5.7E-4 mg/kg/day	https://oehha.ca.gov/proposition-65/chemicals/formaldehyde-gas
		0,075 mg/kg/d internal systemic (based on TDI of 0,15 mg/kg/day), elicitation threshold: 20,1µg/cm² (local effect)	ECHA (2019) Opinion on Annex XV restriction dossier - Substances used in single-use nappies
Heavy Metals			
Antimony	7440-36-0	RfD (oral): 4E-4 mg/kg/day	https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=6
Cadmium	7440-43-9	MADL - Oral: 4.1 µg/day or 5.9E-5 mg/kg/day	https://oehha.ca.gov/proposition-65/chemicals/cadmium
Chromium (VI)	7440-47-3	MADL: 8.2 µg/day or 1.2E-4 mg/kg/day	https://oehha.ca.gov/media/081210DraftMADLChromVI.pdf
Mercury (Hg)	7439-97-6	US EPA RFD (0.0001 mg/kg/day)	https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0073_summary.pdf#nameddest=rfd
Lead	7439-92-1	MADL: 0.5 µg/day or 7.1E-6 mg/kg/day	https://oehha.ca.gov/proposition-65/chemicals/lead-and-lead-compounds
Phenols			
Nonylphenol	25154-52-3	TDI: 0.005 mg/kg/d	https://www2.mst.dk/Udgiv/publications/1999/87-7909-566-6/pdf/87-7909-565-8.pdf

Bisphenol A	80-05-7	EPA RfD: 5E-2 mg/kg/day	https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=356
Phthalates			
Di(ethylhexyl) phthalate (DEHP)	117-81-7	NSRL: 310 (adult) µg/day or 4.43 E-3 mg/kg/day Dermal DNEL. Reprotox endpoint 0,72 mg/kg/day	https://oehha.ca.gov/proposition-65/proposition-65-list ECHA
Di-n-octyl phthalate (DNOP)	117-84-0	RfD: 4E-1 mg/kg/day	https://cfpub.epa.gov/ncea/pprtv/documents/OctylPhthalatediN.pdf
Di-iso-nonyl phthalate (DINP)	28553-12-0	NSRL: 146 µg/day or 2.1E-3 mg/kg/day	https://oehha.ca.gov/proposition-65/chemicals/diisononyl-phthalate-dinp
Butyl benzyl phthalate (BBP)	85-68-7	MADL 1200 µg/day or: 1.7E-2 mg/kg/day	https://oehha.ca.gov/proposition-65/proposition-65-list
Dibutyl phthalate (DBP)	84-74-2	MADL: 8.7 µg/day or 1.2E-4 mg/kg/day	https://oehha.ca.gov/proposition-65/proposition-65-list
Di-isodecyl-phthalate (DIDP)	26761-40-0 and 68515-49-1	MADL 2200 µg/day or 3.1E-2 mg/kg/day	https://oehha.ca.gov/proposition-65/proposition-65-list
Diisobutyl phthalate (DIBP)	84-69-5	ECHA DNEL: 0.21 mg/kg/d	https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/13519/7/1
Diisoheptyl phthalate (DIHP)	41451-28-9		No risk value assigned
Bis(2-methoxyethyl) phthalate (BMEP)	16501-01-2		No risk value assigned
Diisopentyl phthalate (DIPP)	605-50-5	ECHA DNEL (dermal): 0.07 mg/kg/d	https://echa.europa.eu/documents/10162/1564405/dipp_dnels_en.pdf/7e24c7a1-0248-9b6a-c6d9-c5ef33a62ad6?t=1486566703397
Dipentyl phthalate (DnPP)	131-18-0.		No risk value assigned
Di-n-hexyl phthalate (DnHP)	84-75-3		No risk value assigned
*The 2005 World Health Organization Re-Evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-Like Compounds; Toxic equivalency factor: estimates of compound-specific toxicity relative to the toxicity of an index chemical.			

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