

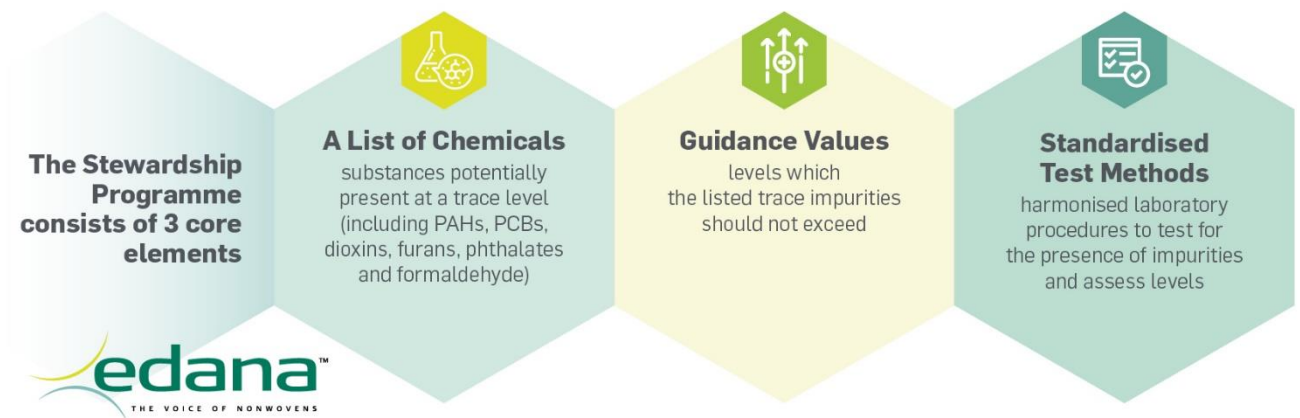


The EDANA  
Stewardship  
Programme  
for Absorbent  
Hygiene  
Products

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**The Codex  
Document**

## The Codex™ is composed of 3 elements



The EDANA Stewardship Programme  
for Absorbent Hygiene Products



## 1. A list of chemicals potentially present as impurities at trace levels

The list of trace impurities covers chemical substances that are not intentionally used to manufacture absorbent hygiene products (AHPs) but that may be present in trace amounts. Trace impurities have a long history of being tracked within the membership of EDANA and/or are subject to regulatory scrutiny, ongoing investigation by competent authorities or general consumer concern.

Chemicals or classes of chemicals involved in this industry effort include PAHs, PCBs, dioxins, furans, phthalates and formaldehyde.

**See annex 1: Codex™ list and values**

## 2. Guidance values, these are the levels not to be exceeded for each substance listed in the Codex

The guidance values will not be exceeded when Absorbent Hygiene Products are investigated for the potential presence of certain chemical substances.

The guidance values may evolve over time if new scientific data and insights are available or regulatory limits are updated.

The development of guidance values follows a tiered approach. The guidance values do not affect the requirement to have the necessary safety assessments for individual products to comply with the [General Product Safety Directive 2001/95/EC](#).

**See annex 1: Codex™ list and values**



### **3. Relevant test methods to determine the presence of substances at trace level and to check that the amount of possible trace impurities in products does not exceed the defined guidance values**

The relevant test methods, corresponding to the different trace impurities, check that the presence of these impurities in a product are below the guidance values. These test methods will be based on experimental extraction/exposure settings that are geared to real life usage conditions and address the respective sample preparation in detail. The new test methods will be added to the existing catalogue of Nonwoven Standard Procedures (NWSP).

To check compliance with the Codex, AHP manufacturers are recommended to have their products tested against the newly developed, validated and endorsed NWSP method in any independent laboratory, working according to Good Laboratory Practice (GLP), who can demonstrate its ability to meet the analytical requirements described in the NWSPs.

**See annex 2: Description of the EDANA Test method to Assess Trace Chemicals in Absorbent Hygiene Products**



Dioxin and Dioxin-like Furans and Polychlorinated Biphenyls		PAHs	Phenols	Phthalates	Pesticides	Organotin	Formaldehyde	Metals	
Dermal penetration based on dermal absorption estimates and toxicity profiles of the substance **		60% to 10%							<1% to <0.01%
Dibenzo-p-dioxins (PCDDs):		DIPCBs:	Bisphenol A	DINP	Glyphosate	Monobutyltin	Total	Antimony	
2,3,7,8-TCDD		Non-ortho PCBs:	Nonylphenol-di-ethoxylate	DEHP	AMPA	Dibutyltin		Cadmium	
1,2,3,7,8-PeCDD		PCB 77	Nonylphenol	DNOP	Quintozene	Tributyltin		Chromium	
1,2,3,4,7,8-HxCDD		PCB 81		DIDP		Triphenyltin		Lead	
1,2,3,6,7,8-HxCDD		PCB 126		BBP		Dioctyltin		Mercury	
1,2,3,7,8,9-HxCDD		PCB 169		DBP		Monooctyltin			
1,2,3,4,6,7,8-HpCDD		Mono-ortho PCBs:		DIBP					
OCDD		PCB 105		DIHP					
Dibenzofurans (PCDFs):		PCB 114		BMEP					
2,3,7,8-TCDF		PCB 118		DIPP					
1,2,3,7,8-PeCDF		PCB 123		DnPP					
2,3,4,7,8-PeCDF		PCB 156		DnHP					
1,2,3,4,7,8-HxCDF		PCB 157							
1,2,3,6,7,8-HxCDF		PCB 167							
1,2,3,7,8,9-HxCDF		PCB 189							
2,3,4,6,7,8-HxCDF		Hexachlorobenzene							
1,2,3,4,6,7,8-HpCDF									
1,2,3,4,7,8,9-HpCDF									
OCDF									
Proposed reference value/Regulatory reference	2ng/kg sum TEQ of the detected congeners of ( PCDDs, PCDFs and DLPCBs	0,2 mg/kg (PAHs)	0,02% (BPA) 10mg/kg (Nonylphenol and Nonylphenol-di-ethoxylate)	0,01%	0,5 mg/ kg	2ppb (TBT) 10 ppb (other organotin)	16mg/kg	Sb: 30mg/kg ; Cd: 0,1mg/kg; Cr: 1mg/kg; Pb: 0,2mg/kg; Hg: 0,02 mg/kg	
Analytical method	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	Recommendation BfR/German BauA AFPs	REACH Annex XVII entry 66 Oeko-Tex-Standard 100, annex 4	Oeko-Tex® Standard 100 (Appendix 6)	Oeko-Tex® Standard 100 (Appendix 4& 6)	EDANA guideline	Oeko-Tex® Standard 100 (Appendix 4 & 6)	Oeko-Tex® Standard 100 (Appendix 4 & 6)	
	<b>**the dermal penetration classification is in general and specific values would apply where data exists</b>								
	EDANA NWSP 360 parts 1-3								



The EDANA Stewardship Programme for Absorbent Hygiene Products



## Annex 2

### Description of the EDANA Test method to Assess Trace Chemicals in Absorbent Hygiene Products

The method presented here is the result of a development process aiming for an industry wide harmonised approach that is relatively easy to adopt, robust (repeatable and reproducible) and reflects consumer relevant aspects. It is currently undergoing final validation with external laboratories, and feedback is welcome during this process. The final first version of this methodology is foreseen for autumn 2020. For clarity herein, we define what is meant by those requirements as:

- *Easy to adopt.* Any laboratory with state-of-the-art analytical equipment and well-trained staff can run the method in a transparent and accessible manner.
- *Validated.* The method is proven to deliver reliable results within the operating parameters of the method (considering variable environmental background levels).
- *Robust.* the method delivers the same result independent of the operator or the laboratory that is running the test. In effect, the method is repeatable and reproducible within a proven level of uncertainty.
- *Reflects consumer relevance.* The product is tested under circumstances that reflect aspects of typical consumer usage.

A thorough exploration of options has led to a method that consists of three distinct parts: sample preparation, analyte extraction and analytical instrumental analysis. Each of these aspects of the overall method is discussed below.

#### 1. Sample preparation

A necessary starting point of any overall assessment method is to define some means of bringing a fluid of choice into contact with an article (or portions of an article) to extract possible trace chemicals. A range of approaches were considered. The intent of the sample preparation (as for the analyte extraction) is to capture as many aspects as possible that reflect consumer usage while enabling a procedure that is straightforward, scalable, and robust, and does not introduce factors (e.g. very high pressure) that clearly don't reflect consumer use.



The EDANA method is based on a milling process, in which the product to be tested is milled in its entirety. All components are taken into account. The homogeneity of milled samples is assessed by measuring the amounts of defined markers in series of sub-samples and the result is a pre-requisite for the further extraction and analytical steps. A milled sample is an over-exaggeration of a full product since it has a larger surface area and thus an extraction method would always extract more from a milled sample. Although the milling process is requirement based, EDANA also provides details of equipment, brand and model, cutting rotor type and speed, duration of the milling per step and the mesh of the sieves used in the outlet of the mill as a practical guidance. Attention is also given to the type of sample containers in order to avoid unintentional contamination of the sample.

## 2. Analyte extraction

The next step of the overall method is that a specimen of the milled, homogenized sample is extracted in an excess of extraction liquid. Based on the intent to test in a consumer relevant way, scientific experts from the industry decided to use aqueous solutions that mimic urine and menses as the extraction fluid of choice for baby diapers, adult incontinence products and feminine hygiene products. Based on literature review, various potential compositions for these solutions were selected, and experiments were devised to elucidate the differences between them, if any, in terms of extraction performance.

It is important to emphasize that there is no standard “synthetic urine,” because the composition of baby urine *itself* depends on variables like age and health of the baby, feeding habits and cultural differences. Extraction composition tests revealed that the precise composition of the synthetic urine did not have a significant impact on the results. It was therefore decided to work with a synthetic urine recipe (saline/urea mixture in water) that every laboratory can easily make and that is least influenced by contamination of its component ingredients. This choice contributes to the robustness of the overall method without impacting the extraction performance. Similar work to identify the optimal composition of menses is ongoing.

Another range of tests was performed to assess the influence of the key extraction parameters including the incubation time, incubation temperature, type of agitation and the extraction ratio (this is the amount of extraction liquid per gram of dry sample). These tests were all repeated multiple times per combination of parameters to allow statistical evaluation and fact-based decision taking.

## 3. Analytical instrumental analysis

The analytical instrumental analysis for testing trace chemicals in aqueous solutions is based on standard laboratory methods and detection techniques (GC-MS, GC-ECD, HPLC, etc.) that have reached



a high level of sophistication. Using these well known, validated and routine analytical techniques in the EDANA procedures contributes to the goal of releasing an AHP testing method that can be executed by a wide range of laboratories throughout the world.

However, these methods often allow a certain degree of variability in their execution in a lab. The EDANA method provides more specific instructions for the reporting of results and potential corrections based on results in blanks. This helps ensure that each laboratory's work is as comparable as possible to minimise uncertainty and reliably report test results with the correct limit of quantification (LOQ).

For more information contact us: [www.edana.org](http://www.edana.org)



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