

SUPPLY CHAIN INFORMATION FOR ABSORBENT HYGIENE PRODUCTS

***BASIC INFORMATION YOU NEED TO KNOW ABOUT
THE PRODUCT SAFETY AND REGULATORY REQUIREMENTS
FOR PLACING ABSORBENT HYGIENE PRODUCTS ON THE MARKET
IN THE EUROPEAN UNION***



IMPORTANT

**THIS IS A DOCUMENT THAT MAY BE AMENDED,
EXPANDED OR OTHERWISE MODIFIED IN THE FUTURE.**

This is a guidance document to the Absorbent Hygiene Products industry which in no manner replaces individual company responsibility and the applicable legislative framework in force. The information is provided in good faith by EDANA and whilst we endeavour to keep our regulatory and technical information up-to-date and correct, we make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability or availability with respect to the document. Any reliance the user places on such information is therefore strictly at the user's own risk. In no event will EDANA be liable for any loss or damage.

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

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List of abbreviations

AHP:	Absorbent Hygiene Product
BfR:	German Federal Institute for Risk Assessment
BPR:	Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22/05/2012 concerning the making available on the market and use of biocidal products
CAS:	Chemical Abstracts Services
CLP:	Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.
CMR:	Substances which are classified as carcinogenic, mutagenic, toxic for reproduction
CPR	Cosmetic Products Regulation EC 1223/2009
ECHA:	European Chemicals Agency
ED:	Substances which are classified as endocrine disruptors
GLP:	Good Laboratory Practice
GPSD:	General Product Safety Directive 2001/95/EC as amended
INCI:	International Nomenclature of Cosmetic Ingredients
ISO:	International Organization for Standardization
IUPAC:	International Union of Pure and Applied Chemistry
MDR:	Medical Devices Regulation (EU) 2017/745
REACH:	Regulation (EC) No. 1907/2006 of 18/12/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS:	Safety Data Sheet
SVHC:	Substances of Very High Concern

Introduction

The purpose of this Guidance is to present EDANA's interpretation on the minimum safety and regulatory requirements pertaining to the placing absorbent hygiene products (AHPs)¹ on the EU market. In addition to the information needed to ensure the **regulatory compliance** of AHPs and their raw materials, it builds on best practices, **EDANA minimum voluntary standards, guidelines**, as well as information needed to address issues of public perception about the safety of AHPs. This document has been developed by EDANA member companies in the supply chain for AHPs. It targets EU market; however, it touches upon requirements outside the EU for explanation and comparison. This document does not address information requirements pursuant to the technical or environmental performance of AHPs² or their raw materials.

EDANA regards this document as a recommendation of "what are the essential information requirements" with the aim of complying with the current regulatory landscape for these products, and thereby to encourage improved product stewardship in the full supply chain.

The document distinguishes between two categories of information requirements, and divides them into two sections:

Chapter 1 - The 'Upstream' Part establishes the **minimum information which AHP manufacturers would need from their raw material suppliers** following existing EU regulations in order to ensure the regulatory compliance of finished AHPs. While Chapter I identifies the basic requirements, it is not intended to impose a format in which AHP manufacturers should request the information, nor does it exclude these manufacturers from requesting additional information as per their individual company procedures.

Chapter 2 - The 'Downstream' Part establishes the **minimum requirements for manufacturers of 'finished' AHPs** as they are placed on the market, established by EU regulations.

In addition, the document outlines a limited number of other elements, pieces of legislation not directly applicable to AHPs but which the industry complies with by analogy, guidelines or standards which are voluntary for observation, but are publicly known to be applied by many companies and retailers in the EU.

An **Annex** in the form of a Conformity Declaration³ lists example of such requirements.

¹ AHPs (Absorbent Hygiene Products) are single-use products made from nonwovens and other raw materials: diapers for baby and adult incontinence (also called 'nappies'); pads/inserts for adult incontinence; nursing pads, armpit pads; feminine hygiene products (e.g., menstrual tampons, napkins, pads and panty liners (sometimes collectively referred to as 'femcare,' 'fempro,' 'feminine hygiene' or 'sanitary protection' products). When used for light incontinence, the product must meet the same standard applicable to Heavy incontinence).

² <https://www.edana.org/how-we-take-action/international-standards/nonwovens-testing-guidelines-for-finished-products>; <https://www.edana.org/how-we-take-action/edana-sustainability-initiatives/sustainability-reports>

³ Please note that this declaration is not an official EDANA position, it rather gives an indication of the sort of information that suppliers can be requested to provide to manufacturers; information which in some cases go beyond regulatory requirements

Chapter I: the ‘Upstream’ Piece

Regulatory Requirements and Related Guidelines

This chapter provides guidance for suppliers outlining the information they are expected to provide following EU regulatory requirements which will help AHP manufacturers to comply with their regulatory obligations. (see **Chapter 2**).

To document regulatory compliance, sections 1 and 2 below outlines the basic information, legal obligations that suppliers and other parties involved in the supply chain are expected to provide. To illustrate potential additional requests, section 3 further elaborates on additional guidance that could potentially apply and **optional information** that a raw material supplier may be asked to provide. Several of the below elements include footnotes that explain the reasoning for requesting the respective information.

1. General information

- **Material trade name / ‘Supplier Code’**
- **Supplier name** including details of main contact person
- **Material type**: e.g., airlaid nonwoven, superabsorbent polymer, closure system, fluff pulp etc.
- **Material category** under article 3(1-3) of **REACH Regulation**⁴: i.e., substance⁵, mixture⁶ or article⁷
- **Intended End-Use**: e.g., absorbent hygiene product (for menstrual protection, incontinence care etc.)
- **Data sheet**
- **Specific composition** is needed in order to carry-out an exposure calculation and a risk (and quality) assessment on the chemical composition/profile of the finished product and its constituents, namely:
 - a) All intentionally used ingredients, *including finishing agents, processing aids, crosslinkers, binders, metal catalysts, preservatives, other additives etc.*, that are expected to be present in the raw material at the time of sale/supply to the AHP manufacturer. For each

⁴ Needed in order to check which section(s) of the Regulation apply to the material. E.g., Annex XVII of REACH could apply to almost every material category, whereas Article 33 only applies to articles.

⁵ REACH Regulation defines a substance as “a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition”.

⁶ Under REACH Regulation a Preparation/mixture is defined as “a mixture or solution composed of 2 or more substances (see above for definition of substance)”.

⁷ REACH Regulation defines an article as “an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”.

ingredient, also provide where applicable⁸:

- i. Name of original manufacturer
- ii. CAS number and designation (often the IUPAC nomenclature of organic chemistry and for cosmetic ingredients the International Nomenclature of Cosmetic Ingredients (INCI) name)
- iii. Function of the ingredient in the material
- iv. Any self-classification or harmonised hazard classifications under the [CLP Regulation](#) (including CLP hazard statements, where applicable)
- v. Concentration range of the ingredient in the material (percentage of total weight)⁹
- vi. If known, the above details of any known ‘ingredients of the ingredient’ based on sub-supplier information, including the original manufacturer

In addition, the [Safety Data Sheet](#) (SDS) will also include information about hazardous components that may be present in concentrations equal to or greater than the concentration limits, as described in annex II of REACH and the [ECHA Guide on Safety data sheets and Exposure scenarios](#).

It is understood that this ‘sub-supplier’ information may be confidential and thus not available to the company completing the questionnaire. In such cases, the company completing the questionnaire should put their customer in touch with the sub-supplier. This sub-supplier should be briefed on the information requirements to be (pre)-prepared.

- b) All additional constituents that are known or likely to be present in the product, *including monomers, residuals, impurities, other traces etc.* For each constituent, give, if applicable:
- i. The relevant CAS number and designation
 - ii. The source/origin of the constituent, if known
 - iii. Any hazard classification (including hazard statement) under the CLP Regulation and the United Nation’s Globally Harmonized System of Classification and Labelling ([GHS](#))
 - iv. Concentration of the constituent in the material (percentage of total weight)
 - v. Details of testing procedure used, including frequency of testing and the results

2. [Legal obligations](#)

Compliance with the REACH Regulation

The following need to be disclosed:

- a) All substances that are intended to be released from the material under normal or reasonably foreseeable conditions of use¹⁰.
- b) All known concentrations of candidate Substances of Very High Concern (SVHCs, as listed in the current version of the [Candidate List for Authorisation](#)) that are present in the

⁸ Some information is covered in the Safety Data Sheet and some of the listed information may be proprietary, and in many cases falling under specific confidentiality agreements, e.g., in relation to data sharing

⁹ Needed in order to check compliance with regulatory limits on the total concentration of certain chemicals in finished products and to allow for performing an exposure-based risk assessment (EBRA).

¹⁰ Substances intentionally released from articles may in certain circumstances be subject to registration requirements under REACH Article 7(1)

material.¹¹ Where exact concentrations are unknown, confirm whether the substance is present at a concentration above 0.1% weight/weight in each component¹²

- c) All substances in the Annex XIV [Authorisation List](#) that you incorporate into the material or otherwise use to create the material, and confirm that you have valid authorisations from the European Commission to use the substances for this use
- d) Declare that the material complies with all applicable requirements of the [Annex XVII](#) ‘Restrictions List’).

Companies should not underestimate the importance of REACH Annex XVII, nor the amount of work potentially required in order to check compliance with its provisions. Annex XVII is subject to several updates each year and its provisions can take several forms, including but not limited to:

- *Requirements to ‘not use’ certain substances (or categories thereof) in specific mixtures or articles*
- *Requirements to not place on the market mixtures or substances that contain certain substances above a given threshold (which can be much lower than the 0.1% threshold for SVHC)*
- *Restrictions on specific uses of the above substances in specific industries and end-uses*
- *Restrictions that are subject to change in the future*

Compliance with the Biocidal Products Regulation (BPR) (EU) 528/2012

Suppliers are requested to:

- a) Identify any ingredients that meet all of the following criteria:¹³
 - i. Are [substances](#) or [mixtures](#) as defined under REACH, **and**
 - ii. Consist of, contain or generate one or more active substances¹⁴ **and where** the substance/mixture is intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism (by means other than mere physical or mechanical action).
- b) For all substances/mixtures meeting the above three criteria, indicate the current **approval status**¹⁵ for active substance/product-type combination ([listed in BPR Annex V](#)).
- c) Comply with the provisions for ingredients that may be considered as treated articles¹⁶ (for further information see the [EDANA Guide to the BPR](#)).

A biocidal product (consisting of, containing, or generating a relevant substance) cannot be made available on the EU market if the substance supplier or product supplier is not

¹¹ Needed in order to check whether the finished product will have obligations under REACH Articles 7(2) and 33

¹² Following the ruling of the EUs Court of Justice, there is a requirement to look at each component of a complex article in relation to the 0.1% SVHC concentration as presented in <http://curia.europa.eu/jcms/upload/docs/application/pdf/2015-09/cp150100en.pdf>

¹³ Ingredients meeting all of these criteria may be ‘biocidal products’ under the BPR, leading to further obligations in the supply chain

¹⁴ Active substance: A substance or a micro-organism that has an action on or against harmful organisms

¹⁵ <http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>

¹⁶ Materials treated with or intentionally incorporating active substances and/or biocidal products may be ‘treated articles’ under the BPR, leading to further obligations

included in the Article 95¹⁷ list (for the product-type (PT) to which the product belongs). Biocidal active substances which are called in situ generated active substances are generated from one or more precursors at the place of use. For such substances, specific requirements apply¹⁸.

Compliance with the Medical Devices Regulation (MDR) EU 745/2017 (if applicable)

AHPs that are classified as medical devices (e.g., incontinence products) must comply with the requirements of the [Medical Devices Regulation \(MDR\)](#). Under MDR, the use of restricted substances (CMR cat 1A and IB and/ or ED substances) in medical devices above a concentration of more than 0.1% w/w (Annex I, Chapter II Section 10.4) is only allowed when proper justification and clarification are provided to support that there were no alternatives available or that the risk associated with these alternatives outweigh the risk for use such substances in addition to a risk-benefit analysis¹⁹.

Not only hazardous substances need to be controlled in medical devices. In general, materials should be carefully selected to ensure they are appropriately biocompatible for their intended clinical use. Special attention shall be given to nanomaterials in the design and manufacture of medical devices with the aim to reduce, as far as possible, any risks linked to the size and the properties of nanoparticles which are or can be released into the user's body. Devices incorporating or consisting of nanomaterials fall under the highest risk class, class III, if they present a high or medium potential for internal exposure and should be subject to stricter evaluation procedures.

Authorities presume conformity with the general safety and performance requirements in cases where harmonized standards²⁰ are applied. An important standard in this context is the ISO 10993 (Biological evaluation of medical devices) series and especially its following subsets:

- a) [ISO 10993-1 \(Evaluation and testing within a risk management process\)](#)²¹
- b) [ISO 10993-10 \(Tests for irritation and skin sensitization\)](#) (if skin compatibility testing is conducted)
- c) [ISO 10993-17 \(Establishment of allowable limits for leachable substance\)](#)
- d) [ISO 10993-18 \(Chemical characterization of materials\)](#) to identify the material and its chemical constituents. For identifying degradation products, also use

¹⁷ https://echa.europa.eu/documents/10162/1276600/pg_on_bpr_4_art95_list_active_substances_en.pdf/b1792913-70b6-4742-ae8a-517b08d9da14?t=1640075212276

¹⁸ <https://echa.europa.eu/regulations/biocidal-products-regulation/in-situ-generated-active-substances>

¹⁹ See as example SCHEER Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties

²⁰ https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

²¹ Part 7.1 requires that materials used to manufacture medical devices are compatible with biological tissues, cells and body fluids, taking account of the intended purpose of the device

- e) [ISO 10993-9 \(Framework for identification and quantification of potential degradation products\)](#) and
- f) [ISO 10993-13 \(Identification and quantification of degradation products from polymeric medical devices\)](#)
- g) [ISO 10993-5 \(Tests for in vitro cytotoxicity\)](#) – compliance with this standard is sometimes asked for raw materials, including those supplied for products that are not Medical Devices.
- h) [10993-23 \(Biological evaluation of medical devices — Part 23: Tests for irritation\)](#)

Raw materials suppliers are expected to assist their customers by supplying available information for their materials if relevant.

Compliance with Cosmetics Product Regulation EU 1223/2009 (where applicable)

Please note that fragrances and lotions are sometimes used in AHPs and they need to meet the requirements of the [Cosmetic Products Regulation](#). When fragrances or perfumed oils are used in AHPs, it is advised that they comply with the International Fragrances Industry (IFRA) Code of Practice

Compliance with Packaging and Packaging Waste Directive (for packaging materials)

For the purpose of this document, the max conc. limit for heavy metals must not exceed 100 ppm of total lead, cadmium, hexavalent chromium, and mercury in all packaging and packaging components²². Compliance with instructions is demonstrated by testing or based on results calculated from heavy metal testing in packaging materials.

3. Related Voluntary Guidelines

Manufacturers may ask suppliers to provide further **optional** information, certification or testing depending on the material and subject to a case-by-case assessment. Such information is additional to the above requirements and is based on specific guidelines that a manufacturer has chosen to apply rather than legal obligations.

- Examples of such possible additional requirements are voluntary codes of practice/certification schemes (list not exhaustive):

[EDANA Stewardship Programme](#)
[California Proposition 65 list](#)
[STANDARD 100 by OEKO-TEX®](#)

²² <https://eur-lex.europa.eu/eli/dir/1994/62/oj>

[Nordic Ecolabelling criteria for sanitary products](#)

[Blauer Engel.](#)

[EU Ecolabel criteria for absorbent hygiene products](#)

- Technical specifications, including a brief history of the material's use in AHPs and other product sectors might be required, e.g., whether the material was developed specifically/mainly for AHPs and/or has been used in AHPs in the past or mainly used for more technical (non-AHP) purposes. Compliance with food contact material legislation, the framework to which is Regulation (EC) 1935/2004, may be used to support the risk assessment.
- Alignment with the **BfR²³ Guidelines for the Evaluation of Personal Sanitary Products** can be used to demonstrate compliance of substances for which there are no harmonised EU regulations. In the field of some plastics or colorants, cellulose and wood pulp, **BfR Recommendations on Food Contact Materials** can be used as a reference. The list of substances in scope is available online as [BfR Database](#).
- When printing inks are used, specific recommendations exist²⁴.
- For rayon staple and cotton used in the manufacture of tampons the purity requirements of the **European Pharmacopoeia for non-sterile sanitary cotton made from cotton** and **European Pharmacopoeia 10.0, 01/2008:0034 corrected 6.0 Viscose wadding, absorbent** for viscose can be used as a reference
- Certification that materials do not contain hazardous chemicals or comply with the **EDANA Stewardship Programme Codex** may be requested as part of the qualification process.

Any approach to manage and control chemicals of concern should be primarily based on safety considerations and on the applicable regulatory requirements, for potential claims or company reputation might be required. Suppliers may be requested to support these efforts.

- Supplier may be requested to specify the general status²⁵ of the raw material, indicating whether it is e.g.:
 - i. Animal derived
 - ii. Kosher
 - iii. Halal

²³ German Federal Institute for Risk Assessment

²⁴ <https://www.eupia.org/our-commitment/eupia-exclusion-policy-for-printing-inks-and-rel>

²⁵ To date, for some of these concepts there are no legally binding definitions (e.g., vegan), also available standards or requirements for products/ ingredients to be labelled are subject to various certification schemes (e.g., for halal, kosher)

- iv. Organic
- v. Vegan
- vi. Plant-derived
- vii. Third party certified and/ or tested

- Region specific requirements:

US Consumer Product Safety Act (CPSA)^[4]:

Please note that the raw material may not be covered specifically by CPSA requirements, but it needs to be compliant with the scope of the CPSA i.e., safe use of raw material in consumer products.

California Proposition 65^[5]:

It is noted that California Proposition 65 may be difficult to cope with, therefore further detailed explanatory comments are necessary for acceptance of compliance.

Chapter II: The ‘Downstream’ Piece

Minimum Regulatory Requirements for Finished AHPs

Absorbent Hygiene Products are considered to be **articles under REACH** and their safety requirements are covered by general (‘horizontal’) EU legislation applicable to multiple consumer goods, notably:

- The [General Product Safety Directive 2001/95/EC \(GPSD\)](#),
 - [Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\)](#)
 - [Regulation 528/2012 concerning the Making Available on the Market and Use of Biocidal Products \(BPR\)](#)
 - [Regulation on medical devices \(MDR\) EU 745/2017](#) for AHPs that are classified as medical devices (such as adult incontinence products like diapers, pads/inserts).
- *N.B. In addition to the present European legal framework, certain regulatory requirements relevant for AHPs do exist at national level, either in the EU Member States and furthermore in non-EU Member States.²⁶ Manufacturer are encouraged to check national requirements applicable to each product type. A voluntary standard, EDANA Stewardship Programme, developed to address consumer perceived safety concerns in the light of possible presence of trace substances, represents a helpful addition to current regulatory initiatives in setting minimum guidance values for certain trace substances in absorbent hygiene products.*

The General Product Safety Directive (GPSD) ²⁷

AHPs are not subject to sector-specific EU legislation (e.g., toys, cosmetics, medical devices). The regulatory framework applicable to AHPs consists in the General Product Safety Directive (GPSD). 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. *Products must comply with this definition.* Art. 3 of GPSD describes how a conformity assessment is performed in order to establish the safety of the product. Manufacturer can rely on national legislation, EU standards and other references. Where suitable standards do not exist, the GPSD allows other elements to be taken into account in assessing the safety of the product, i.e.:

- *European standards pursuant to the product*
- *Community technical specifications*
- *Codes of good practice*

²⁶ It is out of the scope of this document to include requirements at national level

²⁷ Currently under revision – new proposal for a Consumer Product Safety Regulation is available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0346&qid=1628522210573>

- *State-of-the-art and consumer expectations*

EDANA has an established track record of developing voluntary codes of good practices, some of them in the sense of Article 3. 3) (d) of GPSD. Examples include the [EDANA Stewardship programme for AHPs](#), [Tampons Code of Practice](#), [EDANA's test methods](#),

Obligations of producers and distributors

In addition to the basic requirement to place only safe products on the market, manufacturers must inform consumers of any risks associated with the products they supply (e.g., absorbency for tampons /TSS warnings, suffocation warning for children). Manufacturers must take appropriate measures to prevent such risks and be able to trace unsafe products.

To comply with the GPSD requirements, such measures include a rigorous in-house risk assessment of the overall product and its chemical constituents. This assessment identifies any risks pursuant to the product and leads to the implementation of risk management measures. The results of this activity are typically stored in an in-house product dossier which can be presented to Member State authorities in the event of enforcement actions.

Note: Risk assessment elements may also be covered by companies' obligations under the REACH Regulation. As 'Downstream Users' of chemicals, AHP manufacturers must ensure that the human health risks from exposure to these substances are managed, and this includes exposure at all stages of the substance's life cycle (including the life-cycle of articles). [See Part B below](#).

Obligations of Member States

Under the GPSD, Member States are obliged to enforce the requirements on producers and distributors. They must appoint the authorities in charge of [market surveillance](#) and enforcement. In addition to the power to impose penalties, the Directive gives the surveillance authorities a wide range of monitoring and intervention powers.

Exchange of information via a rapid alert system

The Directive provides an exchange for a rapid alert system – the [Safety Gate](#) between Member States and the Commission. The system ensures that the relevant authorities are rapidly informed of dangerous products. Subject to certain conditions, rapid alert notifications can also be exchanged with non-EU countries. In the case of serious product risks, the Directive provides for temporary decisions to be taken on EU-wide measures.

Emergency measures

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. Such decisions at EU level can be taken:

- where the Member States have different approaches to dealing with the risks posed by such dangerous products;
- where urgency is required due to the risk posed by the product, and where no other Community laws deal with that risk;

- where such Decisions are the most effective way of eliminating the risk.

A decision of this kind is only valid for a maximum of one year. Such decisions have been on non-compliance with requirements for certain chemicals like phthalates or dimethyl fumarate (DMF) on products such as toys or textiles, not for AHPs.

The REACH Regulation

The [REACH \(Registration, Evaluation, Authorization and Restriction on Chemicals\) Regulation](#) entered into force on 1 June 2007 to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals. It is complementary to other environmental and safety legislation but does not replace sector specific legislation (for example, legislation on cosmetics or medical devices). REACH gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances, including substances in mixtures and substances in articles. Manufacturers and importers are required to gather information on the properties of their chemical substances, which is aimed at allowing their safe handling, and to register the information with the European Chemicals Agency (ECHA).

REACH: Registration

REACH requires all manufacturers and importers of chemicals to identify and manage the risks linked to the substances they manufacture and market. Those companies who manufacture or import substances in quantities of 1 tonne or more per year per legal entity, must submit registration dossiers to ECHA. However, if a company places articles with intentionally released substances on the EU market, then that 'articles manufacturer' may also have to submit a registration dossier for those intentionally released substances.

REACH: Evaluation

Substances registered may be subject to evaluation by ECHA and the Member States. Evaluation looks at various aspects of registration **dossiers** and can result in a variety of consequences for registrants. At the most basic level, authorities may ask registrants to update aspects of their dossiers, or even to implement stricter risk management measures than they currently do. Further, depending on the hazard profile of the substance and its exposure to humans and the environment, authorities may use evaluation as a basis for more directly regulating that substance in specific products.

REACH: Authorisation

REACH also foresees an authorisation system, aimed at ensuring that Substances of Very High Concern (SVHCs)²⁸ are adequately controlled, and progressively substituted by safer

²⁸ The properties of these substances are defined in Article 57 of REACH: carcinogenic, mutagenic or toxic to reproduction (CMRs category 1 and 2), persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), or for which there is evidence for similar concern (e.g., endocrine disruptors)

substances or technologies, or only used where there is an overall benefit for society of using the substance. Via a system of prioritisation, SVHCs are added to the [Candidate List for Authorisation](#) and possible inclusion in Annex XIV of the Regulation. Once on the candidate list, various information obligations, to ECHA and within the supply chain, may apply if those substances are present in any component of an article in quantities greater than 0.1% weight by weight. Further, if present in mixtures in quantities greater than 0.1% weight by weight, it is mandatory to prepare a [Safety Data Sheet \(SDS\)](#) mentioning the substance's name.

Further, once a substance moves beyond the Candidate List to be listed in Annex XIV, and after an applicable 'sunset date,' EU-based companies must submit an application to the European Commission for authorisation to continue using the substance. Applications for authorisation can be quite burdensome to make, and the burden of evidence required to be granted an authorisation is quite high. Overall, the Authorisation system is designed to encourage EU industry to phase out, wherever possible, the use of Annex XIV substances altogether. At present, substances on Annex XIV which have passed the sunset date do not require Authorisation if contained in or intentionally released from imported articles.

REACH: Restriction

Under REACH, authorities may also impose specific restrictions on the manufacture, use or placing on the market of chemical substances causing an unacceptable risk to human health or the environment. They are listed in [Annex XVII](#) of REACH, and include various restrictions on substances in mixtures, as well as substances in articles like AHPs. Various existing restrictions were carried over from legislation existing before REACH.

'Main Obligations' for AHP Manufacturers under REACH

Apart from the specific elements above, there are other 'typical' REACH obligations for AHP manufacturers. Finished AHPs are considered articles under REACH and manufacturers are obliged to generate rigorous information about the potential presence of substances of very high concern (SVHC) and comply with the relevant Annex XVII restrictions. When SVHC substances are added to the [Candidate List](#), manufacturers are required to:

- **Notify ECHA** (the European Chemicals Agency):
 - a. if the article contains such a substance 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 ("Once an article, always an article.")²⁹

The notification must be submitted to ECHA no later than 6 months after the inclusion of the

²⁹ Bergkamp, Lucas ; Herbatschek, Nicolas: The "Once an Article, Always an Article" Approachy, European Journal of Risk Regulation 2015 N° 1 p.155-164 (EN)

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%.
 - Provide the same information to any consumer within 45 days of receipt of a request.
- c. Notify via the SCIP database. The notification, established under the Waste Framework Directive (WFD) is required for articles as such or in complex objects (products) placed on the market if they contain substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% weight by weight (w/w). The SCIP database ensures that the information on articles containing Candidate List substances is available throughout the whole lifecycle of products and materials, including at the waste stage. The information in the database is then made available to waste operators and consumers.

The Biocidal Products Regulation (BPR) and treated articles

Under BPR, biocidal products shall not be placed on the market unless either the active substance supplier or the biocidal product supplier are listed as such for the relevant product type(s) on the Article 95 list, managed by ECHA. While for the nonwovens industry the range of products placed on the market as biocidal products remains relatively small, rules for treated articles (contained in chapter XII /Article 58) may apply to AHPs.

Treated articles are defined in Article 3(1) of the BPR as “*any substance, mixture or article which has been treated with or intentionally incorporates, one or more biocidal products*³⁰”. However, if the product has a primary biocidal function, the provisions of the BPR applicable to biocidal products apply. In all other cases, the products will be regulated under the provisions applicable to treated articles, namely:

- A treated article may not be placed on the EU market unless all active substances in biocidal products are:
 - Included in the Article 95 list in accordance with Article 9(2) under BPR for the relevant product type (PT) and use
 - Or included in Annex I
 - And any conditions or restrictions specified therein are met

- Certain labelling requirements apply to treated articles

³⁰ « Any substance or mixture, in the form in which it is supplied to the user [...] consisting of, containing or generating one or more active substances [...] with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism [...] by any means other than mere physical or mechanical action. »

<https://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

- If a claim is made on biocidal properties of the treated article containing a biocidal product, or
- If required in the clearance of the active substance

For more detailed information refer to the [EDANA Guide on BPR](#)

The Medical Devices Regulation (MDR)

AHPs which are classified as medical devices falls under MDR requirements. The CE marking and a corresponding declaration of conformity indicate that the medical device complies with the applicable EU regulations and the product can move freely within the entire European Economic Area. Post-market surveillance by the Competent Authorities and a medical device surveillance and vigilance system by manufacturers guarantee the safety of the products which are placed on the market. MDR Annex II Section 4 (for Technical Documentation) requires manufacturers to demonstrate conformity with the applicable general safety and performance requirements of Annex I.

Products designed and manufactured according to applicable harmonised European standards the references to which are published in the Official Journal of the European Union benefit from a presumption of conformity with the relevant legal requirements. It is still possible to deviate from these harmonised standards, but manufacturers who do so must justify this and provide proof that their individual approach is at least as good as the official one. For biological evaluation of a medical device the ISO 10993 series as harmonised EN standards exist. Those standards are flexible and describe the safety assessment of a medical device by experts. The general framework is described in EN ISO 10993-1 which is recommended reading for experts in the supply chain of medical devices. Other harmonised standards apply, e.g., on Quality Management.

Related guideline

Depending on the composition of the finished product, specific legislation applies.

- Compliance with **Cosmetic Products Regulation**³¹ is required when fragrances and lotions are used in AHPs.
- When **inks** are used, specific **recommendations**³² are available.
- EDANA Stewardship Programme CODEX, the industry voluntary standard addresses trace chemicals. The Codex outlines voluntary maximum guidance value of certain trace chemicals and a harmonized consumer relevant test method to test AHPS should the manufacturer wish to confirm its product complies with the voluntary standard. The manufacturers can individually go beyond this standard and apply deeper limits of substances with perceived safety concerns.

³¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20211001>

³²<https://www.eupia.org/our-commitment/eupia-exclusion-policy-for-printing-inks-and-rel>

Annex

I. Example of a Conformity Declaration ³³

For raw materials in Absorbent Hygiene Products: baby diapers and feminine hygiene products, breast pads and incontinence products)

Scope of Conformity Declaration (CD):

It is mandatory for the finished product manufacturer [please add client name] to have its raw materials checked for compliance rules and information duties laid down in the various pieces of legislation as far as applicable for the respective raw materials.

Consumer articles must not endanger human health and therefore have to be safe as laid down in the legally binding European Directive for General Product Safety and in national legislation, when applicable³⁴.

Furthermore, legal provisions of horizontal legislation for specific product type (e.g., Medical Devices Regulation (MDR), Biocidal Products Regulation (BPR) must be followed. Additionally, the EU Regulation concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) requires downstream user to fulfil certain obligations for finished articles³⁵.

Besides the legal obligations, also non-legal requirements must be observed or need to be taken into account in particular when triggered by the safety perception expressed in public domain.

Please fill in this questionnaire³⁶ for compliance, comment on non-compliance and attach documents as necessary; please also indicate the type of proof. Since it is difficult to formally cover all aspects of legal compliance and safety of a raw material into one short, formatted document efforts should be taken to fill in this questionnaire as adequate as applicable; explanatory comments are highly appreciated.

Please have the document signed by the responsible (contact) person!

³³ Please note this is provided as a guidance and does not constitute the official EDANA opinion. All suppliers are advised to request similar examples from their customers.

³⁴ US Consumer Product Safety Act (CPSA) [4] and more specifically California Proposition 65.

³⁵ All references can be found at the end of the Annex.

³⁶ See below example of key information that could be included in such a questionnaire

II. Example of key information for communication in the supply chain

The objective of this section is to establish a list of questions to provide information needed for communication in the supply chain. This document is NOT a list of criteria to define what are substances of concern. This document is also NOT a list of criteria to define which products should be substituted, nor is exhaustive. It can be adapted by each AHP manufacturer according to their needs.

Suppliers are requested to provide the information below to ensure that companies that distribute AHPs are in compliance with regulatory requirements and meet customer needs, namely:

- Compliance with specific material-related legislation;
- Chemical composition (per product and/or component);
- The presence or absence of specific substances and certain material properties;
- Detailed information³⁷ about the origin of materials
- Compliance with customer specific material related requirements, such as social aspects and/or excluding certain sources or harvesting/manufacturing methods
- Information on specific tests related to product safety

Suppliers may use their own template if it contains all the requested information.

The declaration needs to cover 100% (w/w) of all substances (“recipe”) present in the product, including impurities of concern.

II.1. General information

Name of Raw Material

[If raw material is a composite material/chemical mixture and/or finishing agent/technical auxiliary etc., please specify.]

CAS Number(s) & percentage (%)

[(if applicable) including solvents, additives, by-products, and impurities] and CLP/GHS classification of all stated substances...

Type of Raw Material:

[Please specify intended use of raw material in hygiene product]

Topsheet		Dyestuff/ink	
Back sheet film		Adhesive/glue	

³⁷ For instance, from which species, manufacturing process (or recycling), regions, country, or company the material originates

Elastic ear		Release paper	
Front ear		Soft sides	
ADL		Removal string (tampons)	
Absorbent core (fluff/SAP/airlaid/viscose/cotton)		Perfume	
Frontal tape		Lotion	
Closure tape		Tissue	
Back sheet nonwoven		Other (please specify:	
Cuff			

Supplier Name:

Supplier Address:

Manufacturing Country(ies)/Region(s)/ Site(s):

Does direct skin contact take place due to the intended use of the raw material? Yes No

Are tests on biocompatibility performed on this product? Yes No

If yes, are ISO 10993-1/5/10/11 certificates, HRIP tests or other relevant skin irritation tests or other biological tests available for cases where direct skin contact from raw material is intended? Please provide certificate

Has raw material been tested with experimental animals? Yes No

If yes, please provide year, rationale and any further explanation for testing.

Add section 3 of SDS (if data can be transferred electronically)

Contact Person:

Date:.....

(Name and address, including telephone number and e-mail)

II.2. Legal obligations

This section covers compulsory legal obligations. It should be noted that requirements need to be fulfilled as if they would directly apply for a raw material for use in AHPs. Raw materials which do not fulfil these obligations, must not be placed on the market. Compliance is to be guaranteed by the supplier. In case of non-compliance, Manufacturer [please add client name] may have to withdraw the finished product from the market.

Note, if you do not know, whether your supplier's raw material may fulfil the criteria in the below tables please ask for your suppliers written statement. If you do not get it, mark "no" in respective column and comment accordingly.

II.2.2.1. Information on substance Lists which are driven by the regulatory framework

Product contains any of the following substances above applicable limit values according to each regulation	Yes	No	Not applicable N/A	If yes, list substance(s) and content in % (w/w) or mg/kg	Type of proof available (T (Test report); F (Proof follows from the Formulation); D (Declaration of supplier(s)))	If “no” or “N/A” explain your choice
Substances on SVHC Candidate List according to Regulation (EC) No 1907/2006 (REACH)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Substances subject to authorisation according to Annex XIV of REACH Regulation (EC) No 1907/2006 REACH Annex XIV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Substances subject to restriction according to Annex XVII to REACH Regulation (EC) No 1907/2006 REACH Annex XVII	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B under CLP Regulation (EC) No 1272/2008, Annex VI part 3 . Note: this covers hazard statements H317, H340, H350, H360, H362,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Substances subject to the Stockholm Convention on Persistent Organic Pollutants (POPs) according to Regulation (EC) No 850/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Substances ³⁸ that are prohibited, restricted, or substances to be notified according to Biocides Regulation (EU) No 528/2012	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Cosmetics substances are prohibited, restricted, or Substances to be notified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

³⁸ substance/mixture present in the raw material representing a biocidal product (already authorized or in review process) in the meaning of Article 3(1)(a) and the biocidal product belong to Main Group 1; Product Types 1 (human hygiene) or 2 (disinfectants and algacides not intended for direct application to humans or animals)

Product contains any of the following substances above applicable limit values according to each regulation	Yes	No	Not applicable N/A	If yes, list substance(s) and content in % (w/w) or mg/kg	Type of proof available (T (Test report); F (Proof follows from the Formulation); D (Declaration of supplier(s)))	If “no” or “N/A” explain your choice
according to Cosmetic Products Regulation 1223/2009/EC						

If required, indicate applicable legislation:

	Yes	No	
Does the material conform to requirements for food contact or similar	<input type="checkbox"/>	<input type="checkbox"/>	Please indicate applicable legislation
Substances restricted in Directive 94/62/EC (Packaging and Packaging Waste)	<input type="checkbox"/>	<input type="checkbox"/>	Please list restricted substances and concentration in packaging

II.2.2.2. Obligation covering substances intentionally added

The section provides examples of substances present in AHPs which may be banned or restricted (in full or for specific uses) to a specified amount or a specified migration limit. When included in Annex XVII³⁹ to REACH, the substance is listed under an “entry number”, which is updated regularly.

Requirements	Yes	No	Type of proof available: T (Test report) F (Proof follows from the Formulation) D (Declaration of supplier(s)) is available	Comments on why criteria are not applicable may be made here)
Are the requirements of Annex XVII to REACH, entry 43 for azocolourants and azodyes fulfilled?				
Are the requirements of entry 01 of Annex XVII to REACH for Polychlorinated Terphenyls (PCTs) fulfilled?				

³⁹ [Substances restricted under REACH - ECHA \(europa.eu\)](#)

Requirements	Yes	No	Type of proof available: T (Test report) F (Proof follows from the Formulation) D (Declaration of supplier(s)) is available	Comments on why criteria are not applicable may be made here)
Are the requirements of POP Regulation for PentaChloro-Phenol (PCP) fulfilled?				
Are the requirements of entries 34 , 35 , 36 , 37 , 38 of Annex XVII to REACH fulfilled?				
Are the requirements of Annex XVII to REACH, entry 8 for Polybromobiphenyls, Polybrominatedbiphenyls (PBB) fulfilled?				
Are the requirements of entry 46 and 46a of Annex XVII to REACH for nonylphenol/ nonylphenol ethoxylates fulfilled?				
Are the requirements of entries 51 & 52 Annex XVII to REACH for phthalates fulfilled?				
Are the requirements of POP Regulation for PerFluorOctane Sulfonates (PFOS) fulfilled?				
Are the requirements of entry 50 of Annex XVII to REACH for Polycyclic Aromatic Hydrocarbons (PAH) fulfilled?				
Are the requirements for dioxins PCDDs and PCDFs fulfilled (Section 4 of ref. 7]				

II.2.2.3. Specific obligations according to applicable safety requirements

Note, the requirements listed in this chapter are applied to raw materials for the manufacture of absorbent hygiene products, although they may have been created for other sectors of use originally. Their fulfilment establishes an important safety standard because the exposure is relevant for direct skin contact. In bracket reference to the applicable legislative framework listed at the end of the document.

Requirements [Reference]	Criteria fulfilled?		Type of proof: T = Test report is available F = Proof follows from the formulation D = Declaration of supplier(s) is available	Comments on why criteria are not applicable may be made here)
	Yes	No		
Compliance with the German guidelines for the evaluation of personal sanitary products [ref. 10] for: <ul style="list-style-type: none"> spin finishes (if not in compliance, please provide proof for their biocompatibility/absence of relevant cytotoxicity (on delivered material). cellulose, wood pulp 				Note that for raw materials in direct contact with skin compliance is mandatory
For fiber finishes compliance with ref. 13 is recommended.				
Compliance with requirements for the manufacture of materials in contact with foodstuff [ref. 11; 12; 13] with regard to the listing of substances				
Quality criteria of cellulose for use in tampons according to [12]?				
Use of perfumes is according [ref. 9, 15]? Note, safety assessment has to be executed according to [ref. 15]; attention is drawn to presence of allergenic substances.				
Compliance with IFRA Recommendations [ref 15] for fragrances?				
No bleaching with elemental chlorine is performed [ref 16]				
Compliance with or assignment of Oeko-tex Standard 100, class I (baby) [ref. 17] can be shown?				
TAMC (Total aerobic microbial count): < 100 CFU/g TYMC (Total combined yeast/moulds count): < 100 CFU/g Absence of specific human pathogens, i.e. <i>E. coli</i> ; <i>Ps. aeruginosa</i> ; <i>St. aureus</i> ; <i>Cand. albicans</i> , <i>A. brasiliensis</i> Microbial quality criteria according to Ph. Eur. 2.6.12 / 2.6.13 for				

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Requirements [Reference]	Criteria fulfilled?		Type of proof: T = Test report is available F = Proof follows from the formulation D = Declaration of supplier(s) is available	Comments on why criteria are not applicable may be made here)
	Yes	No		
requirements for non-sterile products for dermal application [ref. 14]?				
Compliance of any colorants with applicable food contact material legislation requirements can be shown according to [ref. 12, 18 or 21] when applicable				
Are nanomaterials ⁴⁰ present in the composition?				
Is microplastic ⁴¹ present in a concentration equal to or greater than 0.01% w/w.				

II.2.2.4. Obligations covering trace levels of substances

Note: products, which are placed on the market for consumers, have also to fulfil certain criteria with respect to criteria published and advocated by consumer protection organisations, competent authorities, by the media or by EDANA in the context of the Stewardship Programme for AHPs. Manufacturer [Please add client name] therefore does need assurance that all trace levels, listed below, are not exceeded. In brackets reference to the applicable legislative framework listed at the end of the document.

The below listed substances are not intentionally added during the manufacturing process above the specified limits (when applicable)	Criteria fulfilled?		Type of proof: T = Test report is available F = Proof follows from the Formulation D = Declaration of supplier(s) is available	Comments (Please provide clarifications if "yes" or on why criteria are not applicable)
	yes	no		
Formaldehyde < 0.5 mg/kg				

⁴⁰ MDR (EU) 2017/745, art 1 : « nanomaterial' means a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm ». Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials [MDR, Article 2(18)]. Related definitions on 'particle', 'agglomerate' and 'aggregate' are also included in the MDR [Article 2(19-21)]. The definitions on nanomaterial and the related terms were taken from Commission Recommendation 2011/696/EU on the definition of nanomaterials. Guidance on terms and concepts used in the definition can be found in a report from the European Commission's Joint Research Centre [ref 23]

⁴¹ <https://echa.europa.eu/documents/10162/b4d383cd-24fc-82e9-cccf-6d9f66ee9089>

Phthalates listed in Annex II of Cosmetics Regulation [ref. 9]?				
Trace level of certain (extractable) heavy metals: <ul style="list-style-type: none"> ■ Antimony (Sb): < 30 mg/kg ■ Arsenic (As): < 0.2 mg/kg ■ Chromium (Cr(VI)): < 0.5mg/kg ■ Lead (Pb): < 0.2 mg/kg ■ Mercury (Hg): < 0.02 mg/kg ■ Nickel (Ni): < 1.0 mg/kg 				
Polycyclic Aromatic Hydrocarbons (PAH) < 0.5 mg/kg [ref 22]				
1,3-Dichloro-2-propanol (DCP) and 3-Monochloro-1,2-propandiol (3-MCPD): Trace level for DCP < 2 µg/kg? Trace level for 3-MCPD < 12 µg/kg				
Organotin compounds: Trace level of TBT (Tributyltin) < 2 µg/kg? Trace level of DBT, TPhT, MBT, MOT, DOT < 10 µg/kg				
Colophonium and its derivatives				
Polyvinyl Chloride (PVC)				
Rubber latex				
Optical brighteners				
Derivatives from animal origin [19]				
1,3-Dichloro-2-propanol (DCP) and 3-Monochloro-1,2-propandiol (3-MCPD): Trace level for DCP < 2 µg/kg? Trace level for 3-MCPD < 12 µg/kg?				
Glyoxal (Ethandial) < 1.5 mg/dm ² ?				
Isothiazolinones (MIT, BIT or CIT)				
Derivatives from genetically modified organisms (GMO) [ref 20]				
Bisphenol A (BPA; CAS 80-05-7)				
Trace level of 26 potentially allergenic substances [ref 9]: < 1 mg/kg in the perfume?				
Majantol (CAS# 103694-68-4): < 1 mg/kg in the perfume?				

Supply Chain Information for Absorbent Hygiene Products

Nitromusk and polycyclic musk compounds: < 1 mg/kg in the perfume?				
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II.3. EDANA Voluntary Stewardship Programme CODEX

Please note that the guidance values hereunder apply to the finished product

(Class of) substances and their guidance values	Criteria fulfilled?		Type of proof available: T (Test report) (Proof follows from the Formulation) D (Declaration of supplier(s))	Comments on why criteria are not fulfilled may be made here)
	Yes	No		
Formaldehyde < 16 mg/kg?				
heavy metals: <ul style="list-style-type: none"> ▪ Antimony (Sb): < 30 mg/kg? ▪ Chromium (Cr): < 1mg/kg? ▪ Lead (Pb): < 0.2 mg/kg? ▪ Mercury (Hg): < 0.02 mg/kg? 				
Organotin compounds: Trace level of TBT (Tributyltin) < 2 µg/kg? Trace level of DBT, TPhT, MBT, MOT, DOT < 10 µg/kg?				
Polycyclic Aromatic Hydrocarbons (PAH) <0.01%				
Dioxin and Dioxin-like Polychlorinated Biphenyls < 2ng/kg sum TEQ of the detected congeners (combined PCDDs, PCDFs and DLPCBs)				
Glyphosate, AMPA, Quintozene < 0.5mg/kg				
Bisphenol A < 0,02%				
Nonylphenol-di-ethoxylate, Nonylphenol < 10mg/kg				

Date: _____

Signature: _____

Position: _____

Revision history table

Version	Status	Date of change
V1	Creation	October 2014
V2	Update	November 2016
V3	Update	August 2018
V4	Update	May 2022

References/Sources

Note: All references are to be checked for their latest amended version.

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- [12] BfR Recommendations for materials in contact with foodstuff: (in particular recommendations: III, VII, IX, XV, XXXVI and LIII); available at: [BfR Recommendations on Food Contact Materials - BfR \(bund.de\)](https://www.bfr.bund.de/SharedDocs/DE/PresseMitteilungen/2011/11_001.html)

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[14] European Pharmacopeia; available at: <http://www.edqm.eu>

[15] Code of Practice of the International Fragrance Association; available at:

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