Nordic Ecolabelling for **Sanitary products**



Generation 7.0 • 09 January 2025 – 10 March 2025 **Consultation**



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Appendix 1 Overview of forms for declarations and documentation Appendix 2 Analysis and test laboratories Appendix 3 Directions for raw material standards and certification schemes

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Contact informatio

In 1989, the Nordic Council of Ministers decided to introduce a voluntary official ecolabel, the Nordic Swan Ecolabel. These organisations/companies operate the Nordic Ecolabelling system on behalf of their own country's government. For more information, see the websites:

Denmark

Ecolabelling Denmark info@ecolabel.dk www.svanemaerket.dk

Finland

Ecolabelling Finland joutsen@ecolabel.fi https://joutsenmerkki.fi/

Sweden

Ecolabelling Sweden info@svanen.se www.svanen.se Iceland Ecolabelling Iceland svanurinn@ust.is www.svanurinn.is

Norway Ecolabelling Norway info@svanemerket.no www.svanemerket.no This document may only be copied in its entirety and without any type of change. It may be quoted from provided that Nordic Ecolabelling is stated as the source.

1 Environmental communication guideline for Nordic Swan Ecolabel sanitary products

The Nordic Swan Ecolabel on disposable sanitary products and reusable menstrual cups signifies that products meet strict environmental and health requirements. Reduced environmental and health impact is achieved by prohibiting harmful chemicals and imposing strict requirements on the production of the constituent materials which are responsible for the most significant environmental effects over the product' life cycle.

Nordic Swan Ecolabel single-use sanitary product:

- Made with responsibly sourced renewable raw materials, through requirements ensuring traceability and a high percentage of certified raw material. Wood raw material is at minimum 70% certified and cotton organically cultivated.
- Fluff pulp manufactured in an in a climate- and energy efficient way, with reduced energy consumption and reduced emissions of greenhouse gases.
- Fluff pulp and regenerated cellulose meet strict limits on emissions into air and water.
- Use materials with lower environmental impact such as renewable and recycled materials in both the product and packaging.
- Meet strict requirements concerning chemicals that are hazardous to health and harmful to the environment, including, for example, restrictions on phthalates, PFAS, as well as identified and potential endocrine disruptors on up-to-date lists from EU and national authorities.
- Contain no fragrances or lotions

Nordic Swan Ecolabel reusable menstrual cups

- Meet strict requirements concerning chemicals that are hazardous to health and harmful to the environment, including, for example, restrictions on siloxanes.
- Emissions into air and water are limited during manufacturing, including limits for emission of greenhouse gases in production of silicones.

The overall environmental impact in the lifecycle of the product group and where ecolabelling can have the greatest effect is described in the chapter 6 "Environmental impact of the sanitary products".

2 What can carry the Nordic Swan Ecolabel?

The product group "Sanitary products" covers disposable products with an absorbent and/or protective function for bodily fluids and faecal matter. The function of the products may furthermore be to facilitate bodily cleansing of such fluids or to facilitate the removal of products applied intentionally to the body, such as cosmetics. Disposable products for both private and professional use in health care sector can be ecolabelled. The product group covers also reusable menstrual cups as the product type fulfils the same function.

Products included are:

- Breast pads, children's diapers, incontinence care products, (panty-liners, formed diapers and diapers with tape strips), sanitary towels (pads and panty-liners), tampons, cotton buds, cotton pads, cotton wool, sauna underlays, bibs, plasters, compresses, mattress covers/protectors, draw sheets, bed linen, wash cloths (except paper cloths), surgical gowns, patient gowns/patient covers, surgical masks and caps.
- Reusable menstrual cups made of silicone or other elastomers.

Relevant disposable sanitary products in addition to those specified above may be included in the product group upon request. This applies only to products made of materials for which requirements are imposed in the criteria. Nordic Ecolabelling will decide which new products may be included in the product group.

Following products are out of scope of these criteria:

- Disposable products like bed linen marketed toward other user segments than health care, like tourism.
- Serviettes, wet wipes, dry wipes, paper towels or wash cloths made of paper, disposable gloves and toothpicks. Many of these products can, however, be labelled under other criteria for the Nordic Swan Ecolabel (NSE) or the EU Ecolabel, such as serviettes under Nordic Swan Ecolabel for Tissue Paper and products or wet wipes under NSE for Cosmetic Products.
- Reusables such as wash cloths, cloth baby diapers and cloth pads etc., these products can be ecolabelled under the criteria for the Nordic Swan Ecolabel for Textiles, hide/skins and leather, or the EU Ecolabel criteria for textile products.
- Products with added cosmetics, medication/medicines and disinfecting substances.
- Other similar products that have a function other than absorbing and/or protecting against bodily fluids/faecal matter or cleansing of cosmetic products. Please contact Nordic Ecolabelling for more information.

3 How to read this criteria document

Each requirement is marked with the letter O (obligatory requirement) and a number. All requirements must be fulfilled to be awarded a licence.

The text describes how the applicant shall demonstrate fulfilment of each requirement. There are also icons in the text to make this clearer. These icons are:

- ☆ Upload
- **Q** Requirement checked on site

All information submitted to Nordic Ecolabelling is treated confidentially. Suppliers can send documentation directly to Nordic Ecolabelling, and this will also be treated confidentially.

4 Summary

Nordic Swan Ecolabel Criteria for Sanitary Products have been revised from generation 6 to 7. Focus points during the revision have been requirements for raw materials which from a life cycle perspective, have the most significant environmental impact. Therefore, strict requirements are imposed on energy, climate and chemical use in the manufacturing of the ingoing raw materials. Transition to less energy-intensive materials such as renewables rather than fossil materials is also promoted. The criteria also impose strict requirements on the chemicals in manufacturing of sanitary product. Given that sanitary products come into close contact with the body and many of the products are intended for young children, there is high relevance to set requirements that decrease potential exposure to chemicals harmful to health.

The Criteria have been expanded with the reusable menstrual cups made of silicone and other elastomers, as they fulfil the same function as disposable options. This is in line with the latest revision of EU Ecolabel absorbent hygiene products. The reusable menstrual cup has been reported to have substantially lower environmental impact than the single-use menstrual products. In the beginning of the revision, an analysis was conducted whether disposable sanitary product should continue to be Nordic Swan Ecolabelled or if reusable should be promoted instead. Disposable products are, however, commonly used today and needed due to different user experience. The analysis concluded that disposable products should continue to be Nordic Swan Ecolabelled, providing there is a clear environmental difference between Nordic Swan Ecolabel products contra similar non-ecolabelled products in the market. There remains a considerable potential for improving disposable products by maintaining the ecolabel and enforcing requirements for the raw materials phase.

Therefore, Nordic Ecolabelling has continued to set detailed requirements concerning the constituent materials such as fluff pulps and regenerated cellulose and strict requirements for chemicals used during manufacturing of ingoing raw materials and sanitary products. The structure of the criteria have also been clarified by e.g. merging certain requirements into one. This is mainly done to improve the user experience and future licensing.

5 Requirements and justification of these

5.1 Definition of the product group

The current Nordic Swan Ecolabel criteria for sanitary products, generation 6 has comprised of disposable sanitary products. The Nordic Swan Ecolabel aims to reduce unnecessary consumption of disposable products. Although sanitary products are single-use and cannot currently be recycled, Nordic Ecolabelling is open to labelling disposable products in the hygiene sector, in order to support and enhance the environmentally best disposable products on the market. In this

generation 7 of the criteria, the product group is extended to cover reusable menstrual cups made of silicone and other elastomers. The menstrual cups comprise reusable flexible cups or barriers worn inside the body to retain and collect menstrual fluid. They are usually made from stable materials which allows them to be washed and reused for up to 10 years. More information about Nordic Swan Ecolabel and single-use contra reusable products can be found from the chapter 6.

The product group definition describes the types of disposable products that can be Nordic Swan Ecolabelled: it focuses on the type of function that the product has (absorbent, protective and removing). The definition also makes it clear what is being absorbed, protected or removed (bodily fluids and faecal matter, or cosmetics). Both products for private and professional use in health care sector can be ecolabelled. However, products with added cosmetics, medication/medicines, disinfecting substances and similar cannot be ecolabelled in this product group.

Products that may have a similar function but a different use such as disposable bedlinen in hotels are excluded as well as disposable washing clothes for kitchen or other cleaning, as the criteria for sanitary products encompass only products for personal hygiene. Nordic Ecolabelling does not wish to promote disposable articles in such use and refers to the Criteria for Textiles for labelling of reusable bedlinen. In general, related reusables such as wash cloths, textile diapers and mesh pants can be ecolabelled under the criteria for the Nordic Swan Ecolabel for Textiles, Hide/skins and Leather. This is also applied to hybrid products combining both reusable and disposable parts: the textile part shall fulfil the Criteria for Textiles and the disposable part the Criteria for Sanitary Products.

Examples of other products that cannot be ecolabelled under the Criteria for Sanitary Products, but may be under other Nordic Ecolabelling Criteria are following:

- Wet wipes for personal use (Criteria for Cosmetic Products).
- Dry wipes, serviettes and paper wash cloths (Criteria for Tissue Paper and Tissue Paper Products).
- Reusable wash cloths, cloth baby diapers, cloth pads and period underwear (Criteria for Textiles).
- Microfibre cloths for cleaning (Criteria for Supplies for Microfibre Based Cleaning).

Upon request, relevant disposable sanitary products in addition to those specified in the product group definition may be included in the product group. This applies only to products made of materials for which requirements are imposed in the criteria. Nordic Ecolabelling will decide which new products may be included in the product group.

5.2 Definitions

Additional components (A)	Components belonging to the sanitary product that are removed before use of the product. Examples include release paper, a plastic film around a tampon or a sanitary towel or an applicator for tampons.
Additive/additives in polymer	Substances added or incorporated in components, materials or the final products in order to improve or preserve some of its properties. Additives in polymers are chemical raw materials added to improve polymer performance, functionality and aging properties. Examples of additives are plasticizers, flame retardants, antioxidants, light/heat/thermal stabilizers, pigments, antistatic agents and acid removers.
Binders	An adhesive substance, generally a high polymer in a solid form (powder, film, fibre) or as a foam, or in a liquid form (emulsion, dispersion, solution) used for bonding the constituent elements of a web or enhancing their adhesion, in order to provide the nonwoven fabric cohesion, integrity and/or strength and additional properties (According to Edana's definition). Traditional nonwoven binders are plastic polymers in the form of an aqueous latex (colloidal dispersion).
Biobased plastic	Biobased plastic can be defined as polymer produced from renewable resources. It is therefore an alternative to conventional plastics based on fossil resources. The biomass currently originates mainly from plants grown specifically to be used as feedstock to substitute fossil resources, such as sugarcane, cereal crops, oil crops or non-food sources like wood. Other sources are organic waste and by-products, such as used cooking oil, bagasse and tall oil. Plastics can be fully or partially made from biobased feedstock. Biobased plastics can be both biodegradable and non-biodegradable.
Chemical product	A substance or a mixture of substances.
Colourant/ colourant substance	General term grouping both pigments and dyes. Colourant is a generic term including pigments, which are insoluble in the medium (the vehicle or the binder), or dyes, which are soluble in the medium. The colouring effect is due to "chromophore groups" being part of the structure of these substances. Chromophore groups absorb specific wavelength areas of the visible light spectrum.
Colour/colouring/ colouration	General term for colouring process, adding colour to a material e.g. such as dyeing. Does not include printing.
Colour formulation	Chemical mix that includes at least one colourant. Product sold by manufacturer that is used for printing, dyeing, shading or colouring of materials.
Component	Is made out of one or several materials and chemical products that together fulfil a desirable function in the sanitary product. For example: a non-woven layer, an outer barrier film or an absorbent core of fluff pulp and super absorbents.
Dissolving pulp	Highly bleached chemical pulp from coniferous or non-coniferous wood, rags, cotton linters, etc., of special quality, with very high alpha cellulose content (usually 90 percent and over) readily adaptable for uses other than papermaking. They are used principally as a source of cellulose in the manufacture of products such as man-made fibres (textiles), cellulosic plastic materials, lacquers, explosives, etc. according to CEPI's definitions.
Dye	Colourant/Colourant substance that is dispersed in a medium in which it is soluble.
Dyeing	Process of colouring a material, see also colour/colouring/coloration.
Ingoing substances	All substances in the chemical product regardless of amount, including additives (e.g. preservatives and stabilisers) in the raw materials of the chemical product. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine, in situ-generated preservatives) are also regarded as ingoing substances.
	N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance are also regarded separately. UVCB stands for unknown or variable composition, complex reaction products or of biological materials.

Impurities	Residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg). Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products and detergents for production equipment and carry-over from other or previous production lines.
Material	Means the materials constituting different components of sanitary product, such as fluff pulp, cotton or polypropylene (PP) or super absorbent polymers (SAP). A material type can be used in more than one component.
Master batch	A preparation of one or more polymers which encapsulate a high concentration of ingredients like colorants, fillers, fibres or stabilizers that influence the physical properties of the final preparation. A master batch is intended to be blended with a polymer and not used to make an article as such (According to Plastics Europe).
Nonwoven	Fibrous assembly, primarily planar, which has been given a designed level of structural integrity by physical and/or chemical means, excluding weaving, knitting or papermaking (ISO 9092:2019).
Paper	Paper in these criteria for sanitary products is a generic term covering all paper and board types relevant to sanitary products and it's packaging such as tissue paper, release paper and board used in packaging.
Phthalates	Esters of phthalic acid (orthophthalic acid / phthalic acid /1,2- benzene dicarboxylic acid).
Pigment	A coloured or white substance that is insoluble and finely divided. Used to colour or to deluster a fibre, fabric or plastic (Edana). TiO_2 is an example of an inorganic pigment.
Plastic materials	Also referred to as 'plastics', means polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006, to which additives or other substances may have been added, and which are capable of functioning as main structural components of final products and/or packaging, with the exception of natural polymers that have not been chemically modified.
Polymer	Polymer is defined according to the EC No 1907/2006.
Printing ink	Mixtures of colourants with other substances which are applied on materials to form a graphic or decorative design.
Regenerated cellulose	Regenerated cellulose fibres, also known as man-made cellulose fibres, means fibres produced from the raw material cellulose which include viscose, modal, lyocell, cupro and triacetate.
Recyclability	Means the amount (mass or percentage) of an item available for recycling.
Recycled content	Means the amount of an item (volume or mass) that is sourced from post- consumer and/or post-industrial recycled material.
Recycled material	 Recycled material is defined in the requirement according to ISO 14021, which applies the following two categories: 1. Pre-consumer/commercial is defined as material that is diverted from the waste stream during a manufacturing process. Excluded is reutilization of materials such as rework, regrind or scrap generated in a process and capable of being reclaimed within the same process that generated it. 2. Post-consumer/commercial is defined as material generated by households or commercial, industrial, or institutional facilities in their role as end-users of a product that can no longer be used for its intended purpose. This includes materials from the distribution chain.
	constitute a sales unit consisting of products and packaging to the final user or consumer at the point of sale. Sales packaging does not include transport packaging, information sheet and additional components.
Sanitary product (S)	Refers to the product used, i.e. excluding additional components, information sheets and sales packaging. S = the weight of the materials in the sanitary product.

5.3 Overview of the requirements

Structure of the requirements

Sanitary products

The requirements and triviality limits are based upon the percentage of the weight (weight-%) of the individual materials in the disposable sanitary product. Many of the material requirements are divided into different levels of stringency and come into force when specific limits of weight-% are exceeded. The weight-% of a specific material is calculated as the total weight of the material type (in the sanitary products and in the additional components, see 5.2 Definitions) divided by the weight of the sanitary product and additional components in a pack (excluding the weight of information sheets and sales packaging). The weight of the sanitary product (S) and additional components (A) are, in the criteria, hereafter referred to as (S+A).

Reusable menstrual cups

Reusable menstrual cups consist of one main material and therefore the calculation described for disposable sanitary products is not applied to menstrual cups. Requirement relevant to menstrual cups in these criteria are following O1, O3-O6, O7-O9, O10, O12, O14, O15, O37-O39, O40, O43, O45-O46, O47-O48.

Overview of the requirements

The table below provides an overview of which requirements the different material types will have to fulfil in the product. "Product manufacturer" means the manufacturer of the final product, covering both disposable sanitary product and reusable menstrual cup.

Requirement area	Requirement/Material	Req. no	Responsibility for documentation	Form		
Product and packaging						
Description of the	General requirements	01	Product manufacturer	Form 1		
product and packaging	Material composition	02	Product manufacturer	Form 1		
	PVC	O3	Product manufacturer	Form 4		
	Packaging	04- 06	Product manufacturer	Form 18		
Chemicals in production						
General chemical requirements	Classification, CRM- substances and other excluded substances	07- 09	Supplier of chemical product	Form 2a		
Specific chemical requirement	Silicone, applies to silicone added to other materials or silicone for coating	010	Producer of the product for silicone treatment	Form 3		
	Adhesives/Binders	011	Producer of the adhesive/binder	Form 2b		
	Fragrances and skin care preparations	012	Product manufacturer	Form 4		
	Odour control substances	013	Product manufacturer, supplier of chemical product	Form 4, form 2a		

Table 1 Overview of the requirements.

Requirement area	Requirement/Material	Req. no	Responsibility for documentation	Form
	Medicaments and antibacterial agents	O14	Product manufacturer	Form 4
	Colouration and printing	O15 - O16	Product manufacturer, supplier of colourants/printing inks	Form 2c, form 2d, form 2e
	Ма	aterials		I
Wood/fibre raw material	Forbidden and restricted tree species	017	Product manufacturer, supplier of wood, pulp and paper	Form 6
	Traceability and certification	O18	Product manufacturer, supplier of wood, pulp and paper	Form 6
Cellulose-based pulp/fluff	General, applies when ≥1.0 weight-% or more	O19	Pulp and fluff pulp producer	Form 5
	Production, applies when 10.0 weight-% or more	O20	Pulp and fluff pulp producer	Application tool
Paper	General, applies when ≥1.0 weight-% or more	O21	The paper manufacturer	Form 7
	Tissue paper, applies when 10.0 weight-% or more	O22	The paper manufacturer	Application tool
Cotton	Bleaching, applies when ≥1.0 weight-% or more	O23	Supplier of the cotton	Form 9
	Fibre raw material, applies when 5.0 weight-% or more	O24	Supplier of the cotton	Form 9
	Additives, applies when 5.0 weight-% or more	O25	Supplier of the cotton	Form 9, form 2a
Regenerated cellulose	Bleaching, applies when ≥1.0 weight-% or more	O26	Producer of regenerated cellulose	Form 10
	Production, applies when 10.0 weight-% or more	027	Producer of regenerated cellulose	Form 10
Plastic/ Polymer	 a) Forbidden substances, applies when plastic contained in components make up ≥1.0 weight-% or more b) B) Additives, applies when 5 weight-% or more 	O28	 a) Plastic manufacturer or test done in the supply chain b) Plastic manufacturer 	Form 11a Form 11b
Polyurethane/elasta ne	Applies when 5.0 weight- % or more	O29	Manufacturer of plastic/polymer	Form 12
Polyamide	Applies when 5.0 weight- % or more	O30	Manufacturer of plastic/polymer	Form 13
Bio-based polymers	Applies when 5.0 weight- % or more	O31	Manufacturer of polymer	Form 1
Recycled plastic	 a) Forbidden substances in additional components and packaging, applies when 1.0 weight-% or more b) Food contact grade in 	O32	Manufacturer of polymer	Form 14a Form 14b Form 2a
	the sanitary product, applies when 1.0 weight-% or more			

Requirement area	Requirement/Material	Req. no	Responsibility for documentation	Form		
	c) Additives, applies when 20.0 weight-% or more					
SAP	Residual monomers, applies when 1.0 weight-% or more	O33	Manufacturer of SAP	Form 15		
	Additives, applies when 10.0 weight-% or more	O34	Manufacturer of SAP	Form 15, form 2a		
Nonwoven	Materials	O35	Manufacturer of nonwoven	Form 16		
	Additives	O36	Manufacturer of nonwoven	Form 2a		
Silicones and elastomers in	Emissions of dust and chlorides	O37	Manufacturer of silicones/elastomers	Form 20, Form 21		
menstrual cups	Emissions of copper and zinc	O38	Manufacturer of silicones/elastomers	Form 20		
	Emissions of CO ₂	O39	Manufacturer of silicones/elastomers	Form 20		
	Manufacturin	g of fin	al product			
Material efficiency		O40	Product manufacturer	Form 19		
Product requirements						
Synthetic polymers used in single-use products	 a) share of bio-based or recycled polymers b) Restricted fossil-based polymers c) Energy consumption, applies when 5.0 weight-% or more 	O41	a-b Product manufacturer c Manufacturer of component			
Impurities in final product	Impurities in final product	O42	Product manufacturer			
Performance	Quality and function	O43	Product manufacturer			
Tampons	Aerobic microorganisms	O44	Product manufacturer			
Menstrual cups	Instructions for use	O45	Product manufacturer			
Information	On packaging	O46	Product manufacturer			
Quality and regularity						
Customer complaints		047	Product manufacturer			
Traceability		O48	Product manufacturer			

5.4 Product and packaging

This chapter contains product specification such as description of the final product and its packaging, material composition and manufacturing process. Requirements are applied both to sanitary products and reusable menstrual cups.

O1 Description of the product

The applicant must provide a description of each product, the manufacturing processes, as well as information about packet sizes. The following information must be provided for all components of the sanitary product, any additional components, product information sheets and sales packaging:

- Function (as outer layer, foil around each product, absorbing part, elastic around the legs, information sheet, sales packaging etc.)
- Weight of component
- Constituent materials (e.g. fluff pulp, PP, PET)
- Chemical products that are added to the product (e.g. adhesives)
- Supplier/manufacturer (with the trade name of components they deliver, company name, production site and contact person)

The production chain with suppliers for the sanitary product and additional components must be illustrated by i.e. a flowchart.

Description in line with the requirement including e.g. product data sheets and flowcharts to describe the production process. Template in Appendix 1, form 1 can be used to describe the composition.

O2 Material composition

1. Composition

The applicant must state

- a) The different material types in the sanitary product (S) and additional components (A)* in terms of amount and percentage by weight of (S+A).
- b) The material types in the sales packaging.

2. Threshold values

Following threshold values apply

- The requirements that must be fulfilled is determined by weight-% of the specific material related to the total weight of the sanitary product + additional component (S+A).
- Materials for which no requirements are imposed in the document, and which are not explicitly prohibited, may each make up a maximum of 2.0 weight-% of (S+A), but not exceed 5.0 % weight-% totally.

*See section 5.2 Definitions.

3. Recycled material

Recycled material is not allowed in the sanitary product (e.g. in cotton, paper and fluff pulp) with the exemption of recycled plastic. Recycled material is, however, allowed in additional components, e.g. in tape or release paper that shall be removed before use and in sales packaging.

For requirement for recycled plastic in the sanitary product, additional component and sales packaging, see O32.

Recycled material is defined in line with ISO 14021. See section 5.2 Definitions for more information.

4. **Bio-based plastics**

If bio-based polymers are used in the sanitary product, additional component or sales packaging, superior environmental benefit¹

¹ Superior environmental benefit must be based on LCA- analyses and follow <u>JRC Publications Repository - Life</u> <u>Cycle Assessment (LCA) of alternative feedstocks for plastics production (europa.eu)</u>

compared to fossil-based counterparts must be shown, quantified by an independent third party.

For requirement for bio-based polymers in the sanitary product, additional component and sales packaging, see O31.

- Description of the product showing compliance with the threshold values in the requirement. The template in Appendix 1, form 1, can be used to document the composition of the product.
- **1** If recycled material is used, specify what kind of material it is and where it is used (in the sanitary product, additional component or sales packaging).
- If bio-based plastics are used, enclose an independent third-party certification, based on methodology to assess the impacts of biobased plastics compared to fossil-based plastics.

Background to O1-O2 Description and material composition of the product

The requirements O1 and O2 have been set to provide an overview of the licensed product and it's sales packaging. This will make it easier to determine which requirements have to be fulfilled for the raw materials. Unlike in the previous generation 6, the requirement O2 includes also requirements for recycled and biobased polymers in the final product and its packaging. Thus, several requirements are now combined into a single requirement describing the material composition. Compared to the previous generation, a triviality limit for specific material types present in quantities of maximum 1.0 weight-% has been removed.

Composition and threshold values

For a Nordic Swan Ecolabelled sanitary product, 100% of the contents must be stated, and 95 % by weight of the materials, components and constituent substances in the sanitary product and the additional components must meet the requirements in the criteria. This means that 5.0% may consist of materials with no requirements, with a maximum of 2.0% by weight of each material type. This may be materials such as silk, rubber or latex. Similarly, the composition of sales packaging must be specified so it later in the document becomes clear which requirements apply to each material type.

The weight-% of a specific material is calculated as the total weight of the material type in the sanitary product (S) and in the additional components (A) divided by the total weight of the sanitary product and additional components in a pack (excluding the weight of information sheets and sales packaging). This represents the total weight required for the product to be usable. The weight of the materials in the sales packaging is not included in (S+A). The calculation is preferable done per single product unit.

Recycled material

Use of recycled material in the sanitary product itself is limited as recycled material may contain substances that can be harmful for health and environment. As the product most often is in direct contact with the body such substances are not wanted in the final product. However, recycled plastic can be used if the plastic fulfils the requirement set to recycled plastic for food contact in EU regulation nr. 2022/1616, see closely O32 for specific requirements set for recycled plastics. Recycled plastic in contact with food is more regulated than e.g.

recycled paper by legislation. Use of recycled material in additional components, like in release paper that are removed before use is, however, allowed.

Recycled material is defined according to ISO 14021 which contain definitions of "post-consumer" and "pre-consumer" materials. Recycled materials can be postconsumed material like discarded plastic products and packaging from the enduser as households or commercial, industrial or institutional facilities or be preconsumed material like reprocessed production scrap. Rework, regrind or scrap generated in a process and capable of being reclaimed within the same process that generated it is not considered as recycled material. This means that reuse of plastic from the use of the plastic material, and that is sent back to the producer of the plastic is considered pre-consumed. Cuttings from the plastic production that are used again in the same process are not considered as pre-consumer.

Bio-based plastics

There is also a new requirement stating that if bio-based polymers are used in the sanitary product, additional component or sales packaging, superior environmental benefit² compared to fossil-based counterparts must be shown. This must be quantified by an independent third party and based on framework developed by the Commission's Joint Research Centre for LCA of alternative feedstocks for plastic production^{3,4}. EU Ecolabel has introduced similar requirement for absorbent hygiene products⁵. The requirement is also in line with the EU Taxonomy for sustainable investments stating that if renewable feedstock is used in manufacturing of plastics, greenhouse gas emissions must be lower than those originating from fossil fuel feedstock.

O3 Chlorinated plastic, product and packaging

Chlorinated plastic e.g. polyvinyl chloride (PVC), polyvinyl dichloride (PVDC), must not be included in the product, additional components or in the sales packaging.

Declaration from the manufacturer that the types of plastic, according to the requirement, are not included. Appendix 1, form 4 may be used.

Background to O3 Chlorinated plastic, product and packaging

The requirement is set to ensure that chlorinated plastics such as PVC (polyvinyl chloride) and PVDC (polyvinyl dichloride) are not included in the product, components or product's packaging. The environmental impact of PVC is associated primarily with emissions of harmful organic chemicals from the entire production chain, use of endocrine disrupters such as phthalates as plasticizers

² Superior environmental benefit must be based on LCA- analyses and follow <u>JRC Publications Repository - Life</u> <u>Cycle Assessment (LCA) of alternative feedstocks for plastics production (europa.eu)</u>

³ Nessi, S., Sinkko, T., Bulgheroni, C., Garcia-Gutierrez, P., Giuntoli, J., Konti, A., Sanye Mengual, E., Tonini, D., Pant, R., Marelli, L. and Ardente, F., Life Cycle Assessment (LCA) of alternative feedstocks for plastics production, EUR 30725 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-38144-0, doi:10.2760/693062, JRC125046. JRC Publications Repository - Life Cycle Assessment (LCA) of alternative feedstocks for plastics production (europa.eu)

⁴ Commission recommendation - establishing a European assessment framework for safe and sustainable by design.PDF

⁵ <u>Commission Decision (EU) 2023/... of 12 September 2023 establishing the EU Ecolabel criteria for absorbent</u> hygiene products and for reusable menstrual cups (notified under document C(2023) 6024)

in soft PVC and challenges with waste management during production and end of life. The requirement for packaging is applied only for sales packaging.

O4 Sales packaging, material

Sales packaging* made of

- paper/cardboard/board, must meet the requirement O21.
- plastic must contain a minimum of 35% of recycled plastic** and meet the requirement O3. Virgin plastic shall fulfil O28 part a), bio-based plastic O31 and recycled plastic O32 part a).

Sales packaging made of plastic must be made of mono-materials***.

* Sales packaging means the packaging that stays with the Nordic Swan Ecolabelled product all the way to the customer. See also Definitions 5.2.

** Additional component such an individual packaging around the single product (e.g. plastic wrapping around tampons) is exempted from recycled content.

*** A mono-material is defined as material components that are not composed of multiple material types, e.g. the same plastic type and cardboard are mono-materials.

- The sanitary product manufacturer shall enclose a description of the material composition of the packaging e.g. in the form of technical data sheets.
 Declaration from the manufacturer(s) of the packaging can be used as part of the documentation.
- Documentation from the producer of the sanitary product as in the referred requirements showing that the requirements are fulfilled. Appendix 1, form 18 may be used.

O5 Recycling

It must be possible to recycle* the main material** in the sales packaging via the existing waste and resource systems in the Nordics today.

* Incineration for energy recovery is not considered as material recycling. Biodegradable/compostable/oxo-degradable plastics cannot be recycled at today's recycling facilities.

** The main material is defined as the material that makes up 95 wt-% or more of the total packaging.

The sanitary product manufacturer shall demonstrate compliance with the requirement by enclosing a description of the main material in the packaging and how the material can be recycled in existing waste and resource systems in the Nordic region. Appendix 1, form 18 may be used. Declaration from the manufacturer(s) of the packaging can be used as part of the documentation.

O6 Information on recycling

The packaging shall carry information on how it can be sorted for recycling. This information shall be stated using text or symbols.

The sanitary product manufacturer shall enclose sample of information printed on the product's exterior packaging.

Background to O4-O6 Packaging and recycling

The requirement for packaging is updated. The environmental impact of packaging is usually small compared to that of the raw materials used in the sanitary product itself. Therefore, there has only been a few requirements on packaging in the previous generation, consisting mainly of a ban on PVC and unwanted chemical substances in the packaging or during its manufacturing. Recycled material in the packaging has, however, been fostered in the generation 6 by setting an alternative requirement for content of recycled material (a minimum of 20%). The requirement for recycled content in plastic packaging is made compulsory in the generation 7. Sales packaging must contain a minimum of 35% of recycled plastic. An individual packaging around the single packed product such as tampons is not covered by the requirement for recycled content. The new Packaging and Packaging Waste Regulation (PPWR) sets a minimum recycled content in plastic packaging from 2030. Packaging for contact sensitive products such as absorbent hygiene products shall contain a minimum of 10% of recycled content recovered from post-consumer plastic waste, if made from plastic materials other than polyethylene terephthalate (PET). The percentage is 30% for contact sensitive packaging made from PET as the major component.

There is a new design for recycling requirement that plastic packaging must be made of mono-materials. Material requirements for virgin plastic remain almost the same as in the previous version. Virgin plastic shall not contain certain harmful chemicals (O28a). If recycled or bio-based plastics are used in packaging, then relevant requirements (O32 and O31)) for these must be fulfilled. These requirements have been updated, for more information, see closely the relevant requirements that are referred to.

For paper-based packaging, the requirement is extended to cover general requirements for paper (O21). In addition to chemical requirements banning e.g. fluorinated chemicals, the producer of paper-based packaging must be Chain of Custody (CoC) certified by the FSC/PEFC schemes.

To foster circular economy, new requirements have been introduced for recycling and concerning the information how it should be sorted for recycling. The waste stage is affected by many factors, such as the sorting options in each country or local authority, and how the consumer ultimately sorts the waste. However, Nordic Ecolabelling can generally encourage greater recycling of packaging by setting requirements that support recycling options. These requirements also prepare manufacturers for future Packaging and Packaging Waste Regulation (PPWR)⁶.

5.5 Chemicals

The chemical requirements are split into two sections: general chemical requirements and function-specific requirements.

The general chemical requirements O7, O8, O9 apply for all chemical products added during the manufacture (assembly) of the sanitary products. These requirements are also applied to chemical products used in some specific materials/fibres/components/additional components used in the sanitary

⁶ Proposal approved by EU Parliament 24 April, <u>https://www.europarl.europa.eu/plenary/en/home.html</u>

products. The reference to these requirements is given in the relevant material requirements later in the document.

023/7.0

Definitions for constituent substances (ingoing substances and impurities) are given in 5.2 Definitions above.

5.5.1 General chemical requirements

O7 Chemical products, classification

Chemical products used in the production (assembly) of sanitary products, components/materials must not be subject to a classification requirement specified in Table 2. Classification in line with the Regulation on classification, labelling and packaging of substances and mixtures (Regulation (EC) no 1272/2008).

Table 2	Classification	of chemical	products	CLP Re	gulation	1272/2008.
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Hazard class	Hazard class and category	Hazard code
Hazardous to aquatic environment	Aquatic Acute 1 Aquatic Chronic 1-4	H400 H410, H411, H412 H413
Carcinogenicity	Carc. 1A or 1B Carc. 2	H350 H351 [*]
Germ cell mutagenicity	Muta. 1A or 1B Muta. 2	H340 H341
Reproductive toxicity	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
Acute toxicity	Acute Tox. (oral) 1, 2 Acute Tox. 3 Acute Tox. 4	H330, H310, H300 H331, H301, H311 H332, H312, H302
Specific target organ toxicity	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Aspiration hazard	Asp. Tox 1	H304
Skin corrosion/irritation	Skin Corr 1A/B/C	H314
Endocrine disruption for human health**	ED HH 1 ED HH 2	EUH380 EUH381
Endocrine disruption for the environment**	ED ENV 1 ED ENV 2	EUH430 EUH431
Persistent, Bioaccumulative and Toxic properties** Very Persistent, Very Bioaccumulative properties**	PBT vPvB	EUH440 EUH441
Persistent, Mobile, and Toxic properties Very Persistent, Very Mobile properties	PMT vPvM	EUH450 EUH451

*Titanium dioxide (CAS 13463-67-7) is exempted from the requirement when used as a pigment. It cannot be used in powder or spray form.

**See also O9 Other excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.

The producers of the chemical products are responsible for the classification.

- Duly completed and signed Appendix 1, form 2a, Declaration of chemical products, in the criteria document. To be completed by the producer of the chemical product.

O8 Chemical substances, classification

This requirement applies to chemical substances in chemical products used in the production (assembly) of sanitary products and components/materials.

The chemical products must not contain substances that are or may degrade into substances that are subject to a classification requirement specified in Table 3. Classification in line with the Regulation on classification, labelling and packaging of substances and mixtures (Regulation (EC) no 1272/2008).

Table 3 Classification of substances CLP Regulation 1272/2008.

Hazard class	Hazard class and category	Hazard code
Carcinogenicity	Carc. 1A or 1B	H350
	Carc. 2	H351 [*]
Germ cell mutagenicity	Muta. 1A or 1B	H340
	Muta. 2	H341
Reproductive toxicity	Repr. 1A or 1B	H360
	Repr. 2	H361
	Lact.	H362
Endocrine disruption for human health**	ED HH 1	EUH380
	ED HH 2	EUH381
Endocrine disruption for the environment**	ED ENV 1	EUH430
	ED ENV 2	EUH431
Persistent, Bioaccumulative and Toxic properties**	РВТ	EUH440
Very Persistent, Very Bioaccumulative properties**	vPvB	EUH441
Persistent, Mobile, and Toxic properties	PMT	EUH450
Very Persistent, Very Mobile properties	vPvM	EUH451

*Titanium dioxide (CAS 13463-67-7) is exempted when used as a pigment. It cannot be used in powder or spray form.

**See also O9 Other excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.

Duly completed and signed Appendix 1, form 2a, Declaration of chemical products, in the criteria document. To be completed by the producer of the chemical product.

O9 Prohibited substances

Chemical products used in the production (assembly) of sanitary products, components/materials and additional components must not contain substances from the list below.

- Substances on the REACH Candidate list of SVHC*.
 D4, D5 and D6 in silicone polymer have an own requirement, see O10.
- Organotin compounds

- Phthalates
- CMIT (CAS no. 26172-55-4)
- Alkylphenols, alkylphenol ethoxylates (APEO) and alkylphenol derivatives (APD). Alkylphenol derivatives are defined as substances that release alkylphenols when they break down. An exception is made for:

- sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole.

- Perfluorinated and polyfluorinated alkylated substances (PFAS)
- Halogenated organic compounds. An exception** is made for:

- halogenated organic pigments that meet the European Council's "Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food", point 2.5.

- Flame retardants
- Volatile aromatic carbons (VAC)
- Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and Diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts
- 34 bisphenols⁷ that have been identified by ECHA for further EU regulatory risk management that are known or potential endocrine disruptors for the environment or for human health, or that can be identified as toxic for reproduction.
- Nanomaterials***
 - An exemption is made for pigments.
- Substances evaluated by the EU to be Persistent, Bioaccumulative, and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated, but which meet these criteria.Endocrine disruptors: Substances on the EU member state initiative "Endocrine Disruptor Lists", List I, II and III, see the following links:
 - <u>https://edlists.org/the-ed-lists/list-i-substances-identified-as-</u> <u>endocrine-disruptors-by-the-eu</u>
 - <u>https://edlists.org/the-ed-lists/list-ii-substances-under-eu-investigation-endocrine-disruption</u>
 - <u>https://edlists.org/the-ed-lists/list-iii-substances-identified-as-</u> <u>endocrine-disruptors-by-participating-national-authorities</u>

A substance which is transferred to one of the corresponding sub lists called "Substances no longer on list", and no longer appears on any of List I-III, is no longer excluded. The exception is those substances on sub list II which were evaluated under a regulation or directive which doesn't have provisions for identifying EDs (e.g., the Cosmetics Regulation, etc.). For those substances, ED properties may still have been confirmed or suspected. Nordic Ecolabelling will

⁷ Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed – restriction https://echa.europa.eu/documents/10162/c2a8b29d-0e2d-7df8-dac1-2433e2477b02

evaluate the circumstances case-by-case, based on the background information indicated on sub list II."

- Preservatives that are bioaccumulative in accordance with Appendix 2 (BCF >500 / logKow >4).
- Antibacterial agents (e.g. nanosilver and triclosan)****

* The Candidate List can be found on the ECHA website: <u>https://echa.europa.eu/candidate-list-table</u>

** Perfluorinated and polyfluorinated alkyl substances are covered by their own bulletin and are not included in the exemption.

***Nanomaterials/-particles are defined according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01).2: 'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

****An antibacterial agent is a chemical/product that inhibits or stops growth of microorganisms such as bacteria, fungi or protozoa (single-celled organisms). The requirement does not apply to preservatives used to preserve the chemical product, so-called in-can preservatives.

Background to the O7-O9 General chemical requirements

The general chemical requirements are updated in line with the Nordic Ecolabeling's guidelines for chemicals. The requirements are divided into three specific requirements. The first concerns classification of the chemical products used, while the next two concern chemical substances that are included in these chemical products. The latter two requirements place special emphasis on substances that are considered to be Substances of Very High Concern (SVHC). Certain specific chemical groups such as phthalates, organotin compounds and flame retardants are also covered.

The requirements apply to chemical products and chemical substances used in production of hygiene products, components, materials and additional components. Responsibility for documenting compliance is specified in each requirement and may not always be the chemical supplier.

Chemical products and chemical substance classifications

The Nordic Swan Ecolabel has included the new CLP classifications to align with the European Green Deal's goal of a toxic-free environment. This inclusion reflects the need to establish hazard identification for endocrine disruptors and addresses criteria for environmental toxicity, persistency, mobility and bioaccumulation. By incorporating these classifications, Nordic Swan Ecolabel ensures that the criteria relate to up-to-date scientific understanding and regulatory compliance. Additionally, the inclusion of PMT and vPvM substances is crucial due to their persistence, mobility and potential impact on water quality. The Nordic Swan Ecolabel aims for comprehensive hazard identification and protection of the environment and human health.

Titanium dioxide, TiO₂

Exceptions are allowed for colouration with TiO_2 , see closely background for O15.

Prohibited substances list

The list of prohibited substances has been expanded with the following substances: CMIT (CAS no. 26172-55-4), Volatile aromatic carbons (VAC), Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and Diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts, 34 bisphenols, and nanomaterials. The motivation for each substance on the list can be seen below.

REACH Candidate list of Substances of Very High Concern, SVHC

The Candidate List identifies substances of very high concern which fulfil the criteria in article 57 of the REACH Regulation (EC 1907/2006). The list includes carcinogenic; mutagenic; and reprotoxic substances (CMR, categories 1A and 1B in accordance with the CLP Regulation); and PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) substances (as defined in REACH Annex XIII). In addition, two more substance groups are included if they are of equivalent level of concern (ELoC) as the ones previously mentioned. These are endocrine disruptors and substances which are environmentally hazardous without fulfilling the requirements for PBT or vPvB. Based on these adverse characteristics, Nordic Ecolabelling prohibits substances on the Candidate List. This means that we take action ahead of the legislation and ban the substances before they are subject to authorisation and restriction in accordance with REACH.

Organotin compounds

Organotin compounds are harmful and toxic to the aquatic organisms at low concentration and have been linked to adverse effects in humans, such as reproductive toxicity and therefore many of these compounds are listed as substances of very high concern.

Organotin compounds are regulated in Annex XVII, point 20 of REACH. Subsection 6a states that dioctyltin (DOT) must not appear at more than 0.1% by weight of tin in feminine hygiene products, for example. A report from 2005 written by Risk & Policy Analysts Limited (RPA), on behalf of the European Commission,⁸ states that organotin compounds have been reported in products that include diapers and feminine hygiene products. According to the report, organotin has historically been used as a catalyst in polymer production, as a stabiliser in polymers and as a biocide in various products.

Phthalates

Several phthalates are identified as endocrine disruptors and some of them are classified as reprotoxic. For these reasons several phthalates are included in the

⁸ Risk assessment studies on targeted consumer applications of certain organotin compounds, Final Report -September 2005 prepared for the European Commission by Risk & Policy Analysts Limited (RPA)

Candidate list. Based on their hazardous properties, phthalates pose a threat to the environment and human health and there is a ban on this group of substances. The exclusion of phthalates covers esters of phthalic acid (orthophthalic acid / phthalic acid /1,2- benzene dicarboxylic acid) or commonly known as ortho-phthalates.

5-Chloro-2-methyl-2H-isothiazol-3-one, CMIT

CMIT (CAS no. 26172-55-4) is a type of isothiazolinones which are commonly used as biocides. In generation 6 of the criteria, there was an exemption for CMIT. For generation 7 of the criteria, CMIT is on the list of forbidden substances due to its potential to cause skin sensitizing.

APEO

APEOs and its derivatives are a large group of different substances commonly used in products containing polymers, e.g. adhesives. The non-ionic APEO group of surfactants are produced in large volumes and their uses lead to widespread release to the aquatic environment. APEOs are highly toxic to aquatic organisms and degrade to more environmentally persistent compounds (alkylphenols). Ethoxylated nonylphenol and several other alkylphenols are included in the Candidate List due to endocrine disrupting properties. Exception in the requirement applies to phenolic antioxidants that are sterically hindered with a molecular weight> 600g/mole.

Halogenated organic substances and Perfluorinated and polyfluorinated alkylated substances (PFAS)

Halogenated organic compounds is a large group of organic substances that contain halogenated substances such as chlorine, bromine, fluorine, or iodine that are harmful to both the environment and human health. They are often carcinogenic, highly toxic to aquatic organisms and very persistent to degradation.

Per- and polyfluoroalkyl substances (PFAS) are used in many types of products due to their water and dirt repellent properties. PFASs are defined as fluorinated substances containing at least one fully fluorinated methyl or methylene carbon atom (without any H / Cl / Br / I atom attached to it), i.e., with a few listed exceptions, all chemicals with at least one perfluorinated methyl group (-CF3) or a perfluorinated methylene group (-CF2-) is a PFAS as described in OECD 2021. These compounds constitute a group of substances that have highly problematic intrinsic hazardous properties. They are extremely persistent and accumulate in the body. They are spread all over the globe, from the large oceans to the Arctic, and are found in e.g. wild birds and fish and their eggs. Also, short-chain compounds (2-6 carbon atoms) have been discovered in nature. The substances in these groups are suspected to be endocrine disruptors, carcinogenic and to have a negative impact on the human immune system. PFOA (perfluorooctanoic acid), APFO (ammoniumpentadecafluorooctanoate) and certain fluoro acids are included in the Candidate List due to being reprotoxic, as well as having PBT properties.

Flame retardants

Flame retardants are suspected of contributing to a number of unwanted health effects. Several of the substances are suspected of causing birth defects, cancer,

and endocrine disrupting effects. Many of them are on the EU candidate list under REACH. Many brominated flame retardants are persistent and bio accumulative chemicals that can now be found dispersed in nature. The focus on phasing out brominated flame retardants has led to the use of alternatives such as phosphorus and nitrogen-based flame retardants. Nordic Ecolabelling is not aware of any use of flame retardants in sanitary products.

Volatile aromatic carbons, VAC

Volatile aromatic compounds (VAC) are defined as aromatic compounds whose boiling point is max 250°C, measured at a standard pressure of 101.3 kPa. Volatile aromatic compounds (VACs) have a chemical structure with one or more benzene rings within the molecule, e.g. toluene, benzene and xylene. Some VACs are very stable and have a specific impact on the environment and human health, including damage to DNA. They are used as additives in plastics or as monomers in production of binders for paints (e.g., styrene).

Ethylenediamine tetraacetate, EDTA and Diethylenetriamine pentaacetate, DTPA

Ethylenediaminetetraacetic acid (EDTA) and diethylenetriaminepentaacetate (DTPA) is used in many products, such as detergents, liquid soaps, and cosmetics to improve stability. EDTA, DTPA and their salts are not readily degradable, furthermore, they are both classified toxic for reproduction and poses a risk to consumers. For EDTA, the EU's risk assessment states that under the conditions at municipal water treatment plants, EDTA is either not broken down or only breaks down to a slight degree. To-date in Europe, EDTA has been replaced in virtually all consumer products by readily biodegradable alternatives such as MGDA (methylglycine diacetic acid) and GLDA (glutamic acid diacetic acid).

Bisphenols

Several bisphenols with the general bisphenol structure and 'bisphenol derivatives' which have constituents with structural properties common to bisphenols are now prohibited. Based on the potential for widespread use and available information on potential endocrine disruptors, reproductive toxicity and PBT/vPvB properties, 34⁹ substances were identified in need for further regulatory risk management in EU¹⁰.

Nanomaterials

Nanomaterials are a diverse group of materials, defined in these criteria according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01).2. Due to their small size and large surface area nanoparticles are often more reactive and may have other properties compared to larger particles of the same material. Further, different sizes, shapes, surface modifications and coatings can also change their physical and chemical properties. Nanoparticles can cross biological membranes and thus be taken up by cells and organs. One of the main concerns are linked to free nanoparticles, as

⁹ Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed – restriction https://echa.europa.eu/documents/10162/c2a8b29d-0e2d-7df8-dac1-2433e2477b02

¹⁰ Annex XV restriction report https://echa.europa.eu/documents/10162/450ca46b-493f-fd0c-afec-c3aea39de487

some of these – when inhaled – can reach deep into the lungs, where the uptake into the blood is more likely.

There is concern among public authorities, scientists, environmental organisations, and others about the insufficient knowledge regarding the potential detrimental effects on health and the environment. Nordic Ecolabelling takes these concerns seriously and applies the precautionary principle to exclude potentially hazardous nanomaterials from products.

Pigments are finely ground, insoluble particles that are used to give products a specific colour. There are no substitutes that can fulfil pigments' function as colourants, and many pigments consist partly or entirely of nanoparticles. It is generally more efficient to use pigments with smaller particles than larger ones to obtain the same colour. Thus, nano-sized pigments are exempted.

Endocrine disruptors

Endocrine disruptors (EDs) are chemicals that alter the functioning of the endocrine (hormone) system and consequently cause adverse health effects. The term potential EDs is used for chemicals with properties that make them suspected to be EDs. The hormone system regulates many vital processes in living organisms and when normal signalling is disturbed, adverse effects may result. EDs raise high concern for their risk of causing serious negative impact on the environment as well as on human health specifically. Special concern is raised for effects on reproduction and development and about possible links to increases in public health diseases. While effects in wildlife populations have been confirmed, evidence is pointing to effects also in humans.

Harmonised scientific criteria for the identification of EDs are missing across different pieces of EU legislation. Few EDs have been identified in the legislation so far, compared to the numbers of potential EDs. Under these circumstances, the Nordic Swan Ecolabel excludes identified and potential EDs listed by the EU member state initiative "Endocrine Disruptor Lists" at www.edlists.org. The initiative is a voluntary collaboration, compiling and presenting a single repository of information about the current status of substances identified as EDs or being under ED evaluation in the EU.

A substance listed on any of List I; II; and/or III is excluded in the product group. List I contain substances identified as EDs at EU legislative level; List II contains substances under EU legislative ED evaluation; and List III is for substances considered by a national authority to have ED properties. All listed substances are excluded from all raw materials and products unless otherwise specified in the requirement, meaning that substances listed with reference to e.g., the Cosmetics Regulation are not only excluded from cosmetics.

The requirement concerns the main lists (List I-III) and not the corresponding sub lists called "Substances no longer on list". A substance which is transferred to a sub list is thus no longer excluded, unless it also appears on any of the other main lists I-III.

The lists are dynamic, and the companies are responsible for keeping track of updates in order to keep labelled products compliant with the requirement throughout the validity of the licences. Nordic Ecolabelling acknowledges the challenges associated with new substances being introduced on particularly List II and III, and in some cases also List I. We will evaluate the circumstances and possibly decide on a transition period on a case-by-case basis.

By excluding both identified and prioritised potential EDs which are under evaluation, the Nordic Swan Ecolabel ensures a restrictive policy on EDs.

Antibacterial agents

An antibacterial agent is a chemical/product that inhibits or stops growth of microorganisms such as bacteria, fungi, or protozoa (single-celled organisms) and can be applied on a treated article or constituent in a chemical product. For treated articles, the antibacterial agents usually disappear after a few washes and are released to the environment where they can cause adverse effects.

It is suspected that some antibacterial agents are contributing to the increasing resistance to antibiotics in society. Consequently, the bacteria are developing new methods of resisting the effects of the antibiotic. This, in turn, can lead to certain diseases becoming more difficult to treat. Antibacterial agents such as triclosan, triclocarban and silver are examples. Triclosan has been banned for use in human hygiene products since 2016¹¹ in EU. Furthermore, antibacterial agents can harm bacteria that are necessary for the treatment of water at water treatment plants. Therefore, antibacterial-treated articles or products containing antibacterial agents should be avoided.

The requirement specifies that in-can preservatives used to preserve the chemical product are excluded. However, deliberately adding chemicals with antibacterial effects to the sanitary product is not permitted (see also O14).

5.5.2 Function-specific chemical requirements

This section contains specific requirements for chemical products and chemical substances that may be used in the manufacture of sanitary products or added to the constituent components. The definition of constituent substances and impurities is given in Definitions 5.2.

O10 Silicone

The following requirements must be fulfilled when silicone is used on a material/component/additional component of the sanitary product or if silicone is used in a reusable menstrual cup:

- Solvent-based silicone coatings must not be used.
- Organotin catalysts must not be used in the production of the silicone polymer.
- Octamethyl-cyclotetrasiloxane, D4, (CAS no. 556-67-2), decamethyl cyclopentasiloxane, D5, (CAS no. 541-02-6) and dodecamethyl cyclohexasiloxane, D6, (CAS no. 540-97-6) must not form part of the product.
 - For silicone chemical products used in disposable sanitary products, impurity concentrations must not exceed 1000 ppm on

¹¹ COMMISSION IMPLEMENTING DECISION (EU) 2016/110 of 27 January 2016 not approving triclosan as an existing active substance for use in biocidal products for product-type 1.

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dry silicone basis e.g. without solvent/water (0.1% by weight, 1000 mg/kg dry silicone), with this limit applied to each substance individually. Chemical product is here defined as the ingoing silicone products (e.g. liquid silicones, silicone emulsions) to a multicomponent silicone formulation/silicone mixture.

 For silicone used in reusable menstrual cups, impurity concentrations of D4, D5 and D6 must not exceed 100 ppm in the silicone raw material. (0.01% by weight, 100 mg/kg), with this limit applied to each substance individually.

Nordic Swan Ecolabelled grease-proof paper meets the requirement for single use sanitary products.

Material safety data sheet for the product. Duly completed and signed Appendix 1, form 3, Silicone treatment and form 20 Silicones for menstrual cups. To be completed by the producer of the silicone products.

Background to O10 Silicone

Silicone is used primarily to achieve a grease- or water-repellent effect as a coating on materials or as an additive in materials.

The requirement applies where silicone is used, for example as a silicone release coating on paper or plastic component. The limit value for impurities of octamethylcyclotetrasiloxane (D4, CAS 556-67-2), decamethylcyclopentasiloxane (D5, CAS 541-02-6) and dodecamethyl cyclohexasiloxane, D6, (CAS no. 540-97-6) has been adjusted from 800 ppm in a coating bath of silicone emulsions to 1000 ppm on a dry silicone basis per commercial product/chemical product. This limit applies to each substance separately. Although the new limit might seem less stringent, it represents a significant tightening due to revised definitions. The updated limit value aligns with the Criteria for Grease-proof paper, adopted 2023. Revisions to definitions and wording have been made to improve clarity and avoid misunderstandings.

In practice, component manufacturers (e.g. release liner or tape producers, who are customers of Silicone chemical suppliers) typically purchase various raw materials from silicone suppliers and blend them in-house. This process results in a silicone mixture (or formulation), which is then cured onto the component (release liner/tape). The new limit values are applied to the silicone chemical products delivered from the silicone producer to the component manufacturer, rather than to the final silicone formulation or mixture.

The requirement has also been updated to include limit values for impurities of D4, D5 and D6 for silicone used in reusable menstrual cups. The limit values are based on the EU Ecolabel criteria for Reusable Menstrual Cups¹².

¹² COMMISSION DECISION (EU) 2023/1809 of 14 September 2023 - establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups (notified under document C(2023) 6024)

For more information on the requirement concerning silicone, see the background document about the criteria for grease-proof paper¹³ and the final technical report for EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups¹⁴.

O11 Adhesives/Binders

The requirement applies to adhesives/binders used in the sanitary product, components/materials and additional components. The requirement also applies to e.g. adhesive on tape release paper and binders in nonwoven.

- Adhesives/binders must not contain colophony (rosin). Modified colophony derivatives that are not classified as sensitizing are allowed.
- Formaldehyde generated during the production process of polymer dispersion may amount to no more than 250 ppm (0.025%) measured in newly produced polymer dispersion.

Hotmelt adhesives are exempted.

• The content of free formaldehyde in the ready-to-use adhesive must not exceed 10 ppm (0.001%).

Hotmelt adhesives are exempted.

The adhesive/binder must fulfil the general chemical requirements O7-O9.

Information on sampling, methods of analysis and analysis laboratories is provided in Appendix 2.

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Declaration from the producer of adhesive/binder that the adhesive/binder does not contain colophony. Results of analysis of the formaldehyde content of the adhesive/binder. Duly completed and signed Appendix 1, form 2b may be used.

Background to O11 Adhesives/Binders

The requirement has not been changed in this version of the criteria. However, phthalates are not explicitly banned in this requirement anymore because phthalates are already in the list of forbidden substances in O9. Rosin is prohibited because it can cause contact allergies. Rosin is derived from the resin of pine trees. The mixture contains several allergens and can cause a rash after prolonged skin contact. According to the website of Astma-Allergi Danmark¹⁵, the use of rosin is especially pronounced in plasters, sticky bandages and cosmetics, and may also go by the following names: colophony, abietin, abietic acid, methyl abietate or abiethyl alcohol. It is allowed to be used in adhesives based on derivatives of colophony if they are not classified as sensitizing.

The requirement that the content of formaldehyde must not exceed 250 ppm in newly produced polymer dispersion and the restriction to 10 ppm in the ready-touse adhesive have been set because formaldehyde is carcinogenic and may cause allergic reactions. The limit value of 10 ppm has been applied to the ready-to-use adhesive to simplify the analytical procedure. Hotmelts are, however, exempted from this requirement, since formaldehyde is not relevant for hotmelt adhesives.

 ¹³ About Nordic Swan Ecolabelled Greaseproof paper – Supplementary Module, version 5.0, 14 December 2023.
 ¹⁴ Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously

Absorbent Hygiene Products) - Final Technical Report: Final criteria, JRC Science for policy report.

¹⁵ Astma-Allergi Danmark. Kolofonium. https://www.astma-allergi.dk/viden-om/kontakteksem/allergiskkontakteksem/limstoffer/kolofonium/ (from 9. December 2024)

O12 Fragrances and skin care preparations

This requirement applies to sanitary products and menstrual cups.

Fragrance or other scents (e.g. essential oils and plant extracts), lotion, skin care and/or moisturising preparations must not be added to the final product, additional components or to the constituent materials/components.

Background to O12 Fragrances and skin care preparations

The ban on fragrances and skin care preparations remains unchanged in this revision. However, the requirement is now also applied to reusable menstrual cups. Fragrance and other scents in the form of essential oils, plant oils and plant extracts must not be included in the final product. Fragrances may contain allergens or CMR substances. To avoid unnecessary effects on health from these types of substances, the use of fragrance and scents is entirely prohibited. This is also applied to skin care preparations. Moisturising and skin care preparations might include aloe vera, chamomilla recutita, glyceryl stearate and protolatum (Vaseline). Allergens and carcinogens can occur in lotion preparations. Since lotion and skin care or moisturising preparations are not necessary for the function of the sanitary products, this type of additive is excluded from use on health grounds.

The requirement shall be documented by a declaration from the producer of the final product even if potential additives to materials can be done earlier in the supply chain. These substances are not added to the product or its components intentionally without agreement with the manufacturer.

O13 Odour control substances

Odour control substances are permitted only in incontinence care products.

If used, the substances must fulfil the general chemical requirements O7-O9.

Odour control substances with the classifications H332, H373, H400 and H410 are permitted under the following conditions:

- The incontinence care product must not be a so-called heavy incontinence product, that is designed for more severe incontinence.
- The odour control substance shall be encased/encapsulated in or bound by/attached to the superabsorbent so that there is not a risk of migration during normal use.
- The total content of odour control substance(s) shall be maximum 1.5 weight-% of the superabsorbent material.
- In the case of sanitary products that are not incontinence care products, the producer of the sanitary product must declare that the requirement is fulfilled. Appendix 2, form 4 may be used.
- If odour control substances are used, documentation from the producer of the chemical product showing that O7-O9 are fulfilled. Duly completed and signed appendix 1, form 2a can be used.

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If the odour control substance(s) are classified with H332, H373, H400 and/or H410:

- description from the producer of the incontinence product of the type of incontinence product.

- declaration from the producer of the superabsorbent material that the odour control substance(s) are encased/encapsulated in or bound by/attached to the superabsorbent and do not risk of migrating under normal use.

- declaration from the producer of the superabsorbent material that the total content of the odour control substance(s) are maximum 1.5% by weight in the superabsorbent material.

Background to O13 Odour control substances

As in the previous version, odour control substances are prohibited in sanitary products, with the exception of incontinence care products. The criteria specify that any odour control substances must fulfil the general chemical requirements O7-O9. Odour control substances classified as H332, H373, H400 and/or H410 are, however, permitted. These classifications are only allowed for products designed for lighter incontinence such as pads and panty liners. The delimitation is made as odour inhibitors are an important part of the function of such products for people who have an active everyday life.

O14 Medicaments and antibacterial agents

Sanitary products containing chemical substances designed to prevent bacterial growth, alleviate or cure illness, sickness symptoms and pain or to alter bodily functions cannot be ecolabelled.

Lactic acid bacteria added to tampons are exempted from the requirement, see also requirement O44.

The manufacturer must declare that the requirement is fulfilled. Duly completed and signed Appendix 1, form 4 may be used.

Background to the O14 Medicaments and antibacterial agents

To avoid any doubt about the extent to which a product with added medication or disinfecting substances is effective and meets the health requirements set for the product in question, Nordic Ecolabelling has chosen to entirely prohibit medicaments in ecolabelled sanitary products. In this context, medicaments mean chemical substances/products designed to prevent, alleviate or cure illness, sickness symptoms, pain and bacterial growth or to alter bodily functions (cf. definition in Section 2 of the Cosmetics Directive). This definition also extends to chemical substances such as silver compounds (healing). Antibacterial agents are also named in the title of the requirement, to make it absolutely clear that the addition of antibacterial agents to the sanitary product is not permitted.

Lactic acid bacteria added to tampons are exempted from the requirement. These are currently added in one type of tampon to maintain the pH balance in the vagina. Lactic acid bacteria occur naturally in the body and are therefore not considered a medicament, see also requirement O44.

O15 Colouration

Materials/components in the final products must not be coloured. The requirement does not apply to additional components, information sheet or sales

packaging. The requirements apply to the sanitary product and its components if a component constitutes 1 weight-% or more of (S+A). The following exemptions apply:

- 1. Tampon strings can be coloured.
- 2. Titanium dioxide in polymers and fibres of regenerated cellulose are allowed in all sanitary products, independent if the material is in contact with the skin or not.
- 3. Materials/components considered to have a special function* may be coloured if the material is not in contact with the skin.
- Exceptions may be granted in the case of certain special products for use in hospitals and nursing homes^{**} independent if the material is in contact with the skin or not. This is subjected to agreement with Nordic Ecolabelling.
- 5. Material in incontinence products for adults and children over 5 years, excluding women's hygiene products like panty liners, may be coloured, independent if the material is in contact with the skin or not.
- 6. Reusable menstrual cups. Colourants in the reusable menstrual cup shall not exceed 2% of total weight of the cup.

* An example of a special function can be colouring of breast pads to reduce the visibility of the product through white or light-coloured clothing and plasters.

** e.g. as a guidance to the personnel to differ on sizes or to use the product in the correct way. This is always a subject to an agreement with Nordic Ecolabelling.

If colouration is allowed the colourant (which is a generic term including pigments, which are insoluble in the medium (the vehicle or the binder), or dyes, which are soluble in the medium, see also 5.2 Definitions) must fulfil the following requirements:

- The colourant (pigment/dye) must not be based on* the following metals: aluminium, silver, arsenic, barium, cadmium, cobalt, chromium, copper, mercury, manganese, nickel, lead, selenium, antimony, tin or zinc.
 - Exceptions: Copper in phthalocyanine pigment/dyes and aluminium in aluminosilicates are allowed.

*"Based on" refer to cases where the metal is covalently bound to the other constituents/elements of the pigment/dye and is not regarded as an impurity.

- The colourant (pigment/dye) must not contain fluorinated substances.
- The colourant (pigment/dye) must meet the chemical requirement O7 in this criteria document.
- The colourant (pigment/dye) that may release one or more of the aromatic amines listed in Regulation (EC) No 1907/2006 Annex XVII, Appendix 8, must not be used (E.g. Azo dyes, which by reductive cleavage of one or more azo groups).

In addition to the requirements above the following applies:

• If the colourant (pigment/dye) is used to colour plastic materials the colourant must comply with the BfR's (Federal Institute for Risk Assessment) recommendations: "IX. Colorants for Plastics and other Polymers Used in Commodities"

- If the colourant (pigment/dye) is used to colour cellulose material it must comply with the BfR's recommendation XXXVI. Paper and board for food contact, from February 2023 or later versions.
- If colouring is performed using a colour formulation, the colour formulation must meet the requirement O16 for printing inks, except committing to the EuPIA Exclusion Policy listed on the website (www.eupia.org) 6th Edition 2024 or later versions or comply with the Swiss Ordinance Annex 10.
- Declaration from the producer of the sanitary product that neither the product nor the materials/components have been coloured. Appendix 1, form 4 may be used.
- For exemptions related to specialised products for hospitals/nursing homes or where the colouration has a special function, a detailed description of that function is required. In the case of incontinence products for adults and children over the age of five, the type of coloured product must be specified.
- Declaration from the producer of the reusable menstrual cup that colourants in the reusable menstrual cup shall not exceed 2% of total weight of the cup. Appendix 1, form 4 may be used.
- The producer/supplier of the colourant or masterbatch must declare that the requirements are fulfilled. Duly completed and signed Appendix 1, form 2d for colourants (pigment/dyes) and form 2e for colourant formulation can be used. Material safety data sheet must be submitted.

O16 Printing inks

Materials/components in direct contact with the skin must not be printed on.

The requirements apply to the sanitary product and its components if a component constitutes 1 weight-% or more of (S+A). The requirement does not apply to additional components, information sheet or sales packaging. The printing inks for printing on the sanitary products/components/materials must fulfil the following requirements:

- Colourant (pigment/dye) used in the print ink must not be based on* the following metals: aluminium, silver, arsenic, barium, cadmium, cobalt, chromium, copper, mercury, manganese, nickel, lead, selenium, antimony, tin or zinc.
 - Exceptions: Copper in phthalocyanine pigment/dyes and aluminium in aluminosilicates are allowed.

*"Based on" refers to cases where the metal is covalently bound to the other constituents/elements of the pigment/dye and is not regarded as an impurity.

- The printing ink must comply with the chemical requirements O7 O9 in this criteria document.
- Substances that may release one or more of the aromatic amines listed in Regulation (EC) No 1907/2006 Annex XVII, Appendix 8, must not be used (E.g. Azo dyes, which by reductive cleavage of one or more azo groups)

- The levels of ionic impurities in the print ink must not exceed the following limits:
 - o Antimony: 50 ppm
 - \circ Arsenic: 50 ppm
 - o Barium: 100 ppm
 - o Cadmium: 20 ppm
 - Chromium: 100 ppm
 - o Cobalt: 500 ppm
 - Copper: 250 ppm
 - Lead: 100 ppm
 - o Mercury: 4 ppm
 - o Nickel: 200 ppm
 - Selenium: 20 ppm
 - Silver, 100 ppm
 - Tin: 250 ppm
 - Zinc: 1 500 ppm.
- The printing ink must comply by committing to the EuPIA Exclusion Policy listed on the website (<u>www.eupia.org</u>) 6th Edition 2024 or later versions or comply with the Swiss Ordinance Annex 10.

The producer/supplier of the printing ink must declare that the requirement is fulfilled by means of material safety data sheets and duly completed and signed Appendix 1, form 2c.

Background to the requirements O15 Colouration and O16 Pringing inks

The requirements concerning colouration and printing inks are almost the same as in the previous generation, but have been clarified and simplified to ease the verification process. The requirements apply now for the sanitary product and the components in the sanitary product if the component makes up 1 weight-% or more of (S+A). As in the previous generation, the requirement does not apply to additional components, information sheet or sales packaging. The requirement for colouration is also applied to menstrual cups. However, colourants in the reusable menstrual cup shall not exceed 2% of total weight of the cup.

The ban on colouration of sanitary products has been set to minimise the presence of harmful colourants in products that come into close contact with the skin, and to avoid unnecessary colouration.

Exceptions may be made for special products used in hospitals and nursing homes, if there are justified reasons, such as the need for staff to differentiate between different sizes. For incontinence products, colouration is only allowed for incontinence products for adults and children over the age of five, excluding women's hygiene products like panty liners. Coloured products can reduce the stigma associated with incontinence by resembling regular underwear. Colouration is also allowed for children's incontinence products to help reduce embarrassment and protect self-esteem. Materials not in direct contact with the skin may be exempted if the colour serves a specific function, such as colouring the outer side of breast pads to make them less visible under white clothing. Tampon strings are also exempt, as colouring them helps users distinguish the string from the tampon without damage.

Exceptions are allowed for colouration with TiO_2 which is commonly used in polymers and regenerated cellulose to prevent a grey appearance. Nordic Swan Ecolabel is aware that the classification of titanium dioxide is under review. TiO_2 in inhalable powder form has been reclassified as Carcinogenic 2, but this was annulled by the European Court of Justice in November 2022. The annulment has been appealed, and the case is still pending. Since TiO_2 is not used in powder form and does not pose inhalation or ingestion risks, the exemption for TiO_2 is kept.

The majority of materials in sanitary products that are subjected to colouration are plastic based. Colouring these plastic materials is usually made by mixing pigments to a carrier resin to create a masterbatch. The carrier resin is a type of polymer that is compatible with the base polymer, e.g. the main plastic material. During the plastic manufacturing process, the masterbatch is added to the base polymer. The amount of masterbatch used is typically a small percentage of the total polymer mixture, as the pigments are highly concentrated.

The polymer in the master batch shall comply with the requirements set out for plastics (O28), while the specific pigment/dye requirements are detailed in this requirement. Pigments/dye must e.g. meet the requirements set out in O7 and the BfR's (Federal Institute for Risk Assessment) recommendations: "IX. Colorants for Plastics and other Polymers Used in Commodities" which e.g. contains purity requirements regarding metals. If the colourant (pigment/dye) is used to colour cellulose material it must fulfil the BfR's recommendation XXXVI. Paper and board for food contact, from February 2023 or later versions.

As mentioned above, when colouring a sanitary product, it usually means colouring a plastic material. However, if a cellulosic material is being coloured, it is typically made by using a colour formulation. If a colour formulation is used, it must meet the requirements of O16 for printing inks, except for committing to the EuPIA Exclusion Policy listed on the website (www.eupia.org) 6th Edition 2024 or later versions or compliance with the Swiss Ordinance Annex 10.

Printing on sanitary products, is usually applied to the backside of diapers, on the back of the release paper under panty-liners and incontinence care products. Printing is never allowed to materials in direct contact with the skin.

Printing inks must meet the chemical requirements set out in O7-O9 in this criteria document, metal purity limits and committing to the EuPIA Exclusion Policy listed on the website (www.eupia.org) or comply with the Swiss Ordinance Annex 10, which is a list of permitted substances for the production of printing inks in contact with foodstuffs.

5.6 Materials

This chapter includes requirements for different materials such as wood, fluff pulp, regenerated cellulose, paper, cotton and plastic used in final product.

5.6.1 Wood raw materials

The requirement for wood raw material in this chapter applies to components made from solid wood, such as the stick of a cotton bud but also wood/fibre raw material used in cellulose-based pulp, fluff pulp and paper. The requirement O17 and O18 are applied to wood in e g. cotton bud sticks irrespective of the quantity in the product whereas requirements for pulp and paper are applied if the fibre raw material is at minimum 10 weight-% in relation to total weight of the sanitary product and additional component (S+A).

O17 Prohibited and restricted tree species (wood, pulp≥ 10.0 weight-%, paper ≥ 10.0 weight-%)

Nordic Ecolabelling's list of restricted tree species* consists of tree species listed on:

- a) CITES (Appendices I, II and III)
- b) IUCN red list, categorized as CR, EN and VU
- c) Rainforest Foundation Norway's tree list
- d) Siberian larch from forests outside the EU

Use of tree species listed on a) CITES (Appendices I, II and III) is not permitted.

Tree species listed on either b), c) or d) may be used if they meet all of the following requirements:

- the tree species does not originate from an area/region where it is IUCN red listed, categorized as CR, EN or VU.
- the tree species does not originate from Intact Forest Landscape (IFL), as defined in 2002 <u>http://www.intactforests.org/world.map.html</u>.
- the tree species shall originate from FSC or PEFC certified forest/plantation and shall be covered by a valid FSC/PEFC chain of custody (CoC) certificate documented/controlled as FSC or PEFC 100% through the FSC transfer method or PEFC physical separation method.
- Tree species grown in plantation shall in addition shall in addition not originate from plantations established on areas converted from forest after 1994.

Exemptions

Eucalyptus and Acacia used for pulp and paper production are exempted from the list**.

* The list of restricted tree species is located on the website: Forestry requirements 2020 (nordic-swan-ecolabel.org)

** Regarding pulp, fibre raw material from eucalyptus/acacia must be a minimum of 70% certified (see also O18).

Enter the names of the tree species included in the product.

- 住 If species from the lists b), c) or d) are used:
- Yalid FSC/PEFC Chain of Custody certificate from supplier/applicant/manufacturer covering the specific tree species and documenting that the wood is controlled as FSC or PEFC 100% through the FSC transfer method or PEFC physical separation method.
- 업 The applicant/manufacturer/supplier shall document full traceability back to the certified forest unit and document the following:

- the wood does not originate from an area/region where it is on the IUCN Red List, categorised as CR, EN or VU.

- the tree species do not originate from an Intact Forest Landscape (IFL), as defined in 2002: <u>http://www.intactforests.org/world.webmap.html</u>

- for plantations, the applicant/manufacturer/supplier must document that the tree species do not originate from plantations established on areas converted from forest after 1994.

Background to O17 Prohibited and restricted tree species

Several tree species are restricted or not permitted for use in Nordic Swan Ecolabel products. Many of the restricted tree species are grown in countries which still have large areas of Intact Forest Landscape (IFLs). These are important to protect due to biodiversity and climate. A lot of these countries also have a high risk of corruption, and the national legislation related to environment, human rights and ownership to land are weak and/or not controlled by the authorities. Applying a precautionary approach, the use of listed restricted tree species must comply with strict requirements on origin, traceability and certification.

The list of **prohibited** species contains species on the CITES list while the list of **restricted** species contains species on the IUCN red list (categorized as critically endangered (CR), endangered (EM) and vulnerable (VU)), Rainforest Foundation Norway list and Siberian Larch (originated outside the EU). **Restricted** species can be used in Nordic Swan Ecolabelled products if certain strict conditions on origin, certification and traceability are met.

The requirement only applies to virgin wood and not wood defined as recycled material in accordance with ISO 14021. For more information about Nordic Swan Ecolabelling's approach on forest, click <u>here</u>.

O18 Traceability and certification (wood, pulp≥ 10.0 weight-%, paper ≥ 10.0 weight-%)

The requirement applies to wood/fibre raw material and bamboo used in the product/pulp/paper.

Species name

State the name (species name) on the wood/fibre raw material used in the product/pulp/paper.
Chain of Custody certification

All wood/fibre raw material and bamboo used in Nordic Swan Ecolabelled products must be covered by a valid Chain of Custody certificate in accordance with FSC/PEFC schemes.

The pulp and paper manufacturers and supplier(s) of the wood/fibre raw material must be Chain of Custody certified by the FSC/PEFC schemes.

Certified wood/fibre raw material and bamboo

A minimum of 70% by weight of all wood/fibre raw material and bamboo used in the Nordic Swan Ecolabelled product/pulp/paper must origin from forest managed according to sustainable forestry management principles that meet the requirements set out by FSC or PEFC schemes.

The remaining proportion of wood raw material must be covered by the FSC/PEFC's control schemes (FSC controlled wood/PEFC controlled sources).

The requirement must be documented as purchased amount of wood annually.

Certified wood raw material must be accounted/recorded to the pulp/paper/ production line. For paper labelled with FSC / PEFC or EU Ecolabel, no documentation is required, the requirement is considered to be met.

If several pulps are mixed, the certification percentage* must be fulfilled for the finished pulp in the product.

* Regarding individual pulp, fibre raw material from eucalyptus/acacia must be a minimum of 70% certified (see also O17).

- ☆ Valid FSC/PEFC Chain of Custody certificate from all suppliers/link to certificate in FSC/PEFC certificate database covering all wood raw material used in the product/pulp/paper.
- Documentation showing that the quantity of certified wood raw material is met and the remaining proportion is covered by FSC/PEFC's control schemes (FSC controlled wood/PEFC controlled sources). This shall be specified in e.g. invoices or delivery notes from suppliers.

Background to O18 Traceability and certification

Nordic Ecolabelling's requirements concerning raw material based on wood/fibre raw material including bamboo have focus on sustainable forestry and traceability of raw materials.

The many benefits that sustainably managed forests deliver to society include wood for materials and energy, protection against global warming, homes and livelihoods for local communities and indigenous peoples, support of biodiversity and protection of water and soil from pollution and erosion. By setting a requirement that wood raw material must originate from certified, sustainable managed forests, Nordic Ecolabelling is supporting the move towards more sustainable forestry practices. The requirement for wood/fibre raw material has been tightened. Certification percentage, a minimum of 70% is not only applied to wood raw material used in finalized product such as cotton buds but also to pulp and paper if the amount of pulp/paper is over 10 weight-% in the final sanitary product. The share of certification was 30% for pulp and 50% for paper in the previous generation of the criteria. The remaining proportion of wood raw material must meet the requirements of FSC controlled wood or PEFC controlled sources. The requirement limit, a minimum of 70% of all wood raw material, correspond to the FSC and PEFCs requirement limits for use of the respective labels on products, such as "FSC Mix" and "PEFC certified".

The pulp and paper manufacturers and suppliers of the wood/fibre raw material must be Chain of Custody certified by the FSC/PEFC's schemes. The requirement for Chain of Custody certification contributes to traceability in the supply chain within the FSC and PEFCs guidance and control systems for traceability.

There is a requirement that certified raw material must be assigned/allocated to the raw material used in Nordic Swan Ecolabelled product in the accounts for certified/non-certified material. This ensures that FSC/PEFC credits are used for the Nordic Swan Ecolabelled production and that the credits are "used up" and not sold twice. This will stimulate increased demand for certified wood raw material because more certified wood raw material must be purchased if the manufacturer wants to label other products, and not just thosed used in the Nordic Swan Ecolabelled products, with the FSC/PEFC logo. It should be noted that Nordic Ecolabelling approves both the percentage system and the credit system for accounting and sale of certified material.

Eucalyptus and Acacia used for pulp and paper production are exempted from the list of restricted tree species (O17). However, fibre raw material originating from Acacia and Eucalyptus plantations must be a minimum of 70% certified. This also applies if several pulps are mixed in the finished pulp. It is the user of the euca/acacia pulp who shall document, for instance based on invoice or delivery note, that the requirement of minimum 70% certified pulp are purchased on a yearly basis.

5.6.2 Cellulose-based pulp/fluff pulp

The requirements concerning cellulose-based pulp/fluff pulp are split into different levels, depending on the quantity in the product (weight-% in relation to total weight of the sanitary product and additional component (S+A)):

- Cellulose-based pulp/fluff pulp must fulfil requirement O19. This also applies to cellulose pulp that have been evaluated by Nordic Ecolabelling according to the "Basic Module for Paper Products", version 3 or later.
- If there is 10.0 weight-% or more of cellulose-based pulp/fluff in relation to the total weight of the sanitary product and additional component (S+A), requirements O17-O18 and O20 must also be fulfilled.

O19 Cellulose-based pulp/ fluff pulp, general requirements

State the name and type of the pulp/fluff pulp- manufacturer, trade name, production site, type of pulp (such as ECF, TCF, CTMP etc., market pulp or not).

The following requirements must be met:

- The producer of cellulose-based pulp/fluff pulp must be Chain of Custody (CoC) certified by the FSC/PEFC schemes.
- The cellulose-based pulp/fluff pulp must not be bleached with chlorine gas* (Cl₂).
- Optical brightener or fluorinated chemicals must not be added to the cellulose-based pulp/fluff pulp.
- The cellulose-based pulp/fluff must not have a growth inhibiting effect on microorganisms, under test method EN 1104.
- Chemicals added to the finished cellulose-based pulp/fluff pulp to provide specific properties** must fulfil the chemical requirements O1-O2*** in the Chemical Module, version 3 or later.

* The residual quantities created during the production of chlorine dioxide from chlorate are not defined as a component of chlorine gas bleaching.

** Softeners that contain quaternary Imidazoline (CAS no. 72749-55-4) are exempt from classification as Aquatic acute 1 H400, Aquatic chronic 1 H410, Aquatic chronic 2 H411 and Aquatic Chronic 3 H412 in the requirement O1 in the Chemical Module, version 3 or later.

*** Production chemicals used during the manufacturing of the pulp are not included in the requirement.

Ask the manufacturer/supplier of the chemical product to demonstrate compliance with the requirement in the web-based application tool, more information can be found from Pulp and Paper Declaration in the MSA Portal (nordic-swan-ecolabel.org).

- Duly completed and signed Appendix 1, form 5, Cellulose-based pulp/fluff pulp, general requirements. To be completed by the producer of the cellulose-based pulp/fluff pulp.
- The manufacturer of pulp/fluff pulp must present a valid FSC/PEFC Chain of Custody certificate / link to certificate in FSC/PEFC certificate database covering all wood raw material used in the pulp.
- - The pulp manufacturer shall submit a list of the chemical products added to the finished pulp/fluff pulp including trade name, manufacturer, function and amount used (kg/ADt). Product safety data sheets for chemical products shall be included upon request.
 - The manufacturer/supplier of the chemical product shall demonstrate compliance with the requirement in the web-based application tool.

Background to O19 Pulp, general requirements

The requirement for all pulps remains almost same as in the previous generation. The requirement is mainly associated with the use of chemicals in manufacturing. In addition to requirements for chemicals, pulp manufacturer(s) must be Chain of Custody (CoC) certified by the FSC/PEFC's schemes. The requirement for CoC certification contributes to traceability in the supply chain within the FSC and PEFC's guidance and control systems for traceability. Chemicals added to the finished pulp to provide specific properties must fulfil the chemical requirements O1 and O2 in the Chemical Module, version 3, to be in line with the general chemical requirements set for pulps. This has been changed from the previous generation, where chemicals had to fulfil chemical requirements set for sanitary products. This requirement only applies to chemicals added to pulp to provide specific properties associated with sanitary products, and during the fluffing of the pulp. This may mainly relate to debonding agents and softeners.

The pulp must not be bleached with chlorine gas (Cl₂) and optical brightener or fluorinated chemicals must not be added to the pulp. Bleaching with chlorine gas is no longer used in Europe, but the requirement remains in place to cover imported pulps. It is less common for fluorinated chemicals to be added to the pulp. Nordic Ecolabelling is, however, particularly concerned about the unnecessary use of fluorinated chemicals and therefore, the ban remains. In addition to these, the pulp must not have a growth inhibiting effect on microorganisms, under test method EN 1104. The use of chemicals intended to have an antibacterial effect is unnecessary in sanitary products, and residues of process chemicals are also undesirable.

O20 Cellulose-based pulp/fluff pulp, production requirements (≥10.0 weight-%)

The cellulose-based pulp/fluff pulp must fulfil the requirements O1-O6, O8-O16 in the Basic Module for Paper Products, version 3 and all the requirements in the Chemical Module, version 3, or corresponding requirements in later versions.

Fossil fuels

Fossil oil and coal must not be used as fuels* for production of process heat in the pulp/fluff pulp mill.

Necessary use of fossil oil e.g. in planned maintenance stops, emergency maintenance stops, as a reserve and tip fuel (peak load fuel) or at start-ups for regulation of the combustion temperature in a heat and co-generation boiler is allowed.

*Use of natural gas and liquefied petroleum gas (LPG) is allowed.

For the requirements concerning energy consumption and emissions, the following limits and reference values apply:

Energy

- \circ Pelectricity_total < 1.25
- \circ P_{fuel_total} < 1.25
- The reference values for cellulose pulp are found in the Basic Module, version 3 or later.
- The reference values for fluff pulp are El_{reference} = 780 kWh/ADt and Fuel_{reference} = 5900 kWh/ADt. For mechanical fluff pulp (CTMP) the reference values are El_{reference} = 1650 kWh/ADt and Fuel_{reference} = 900 kWh/ADt.

A more detailed description of documentation requirements and calculation methods is provided in the Appendix 4 of the Basic Module, version 3 or later, in which $P_{electricity}$ and P_{fuel} are also defined.

Emissions of greenhouse gases

• Emissions of greenhouse gases from fuels and electricity used for production of process heat must not exceed 350 kg CO₂/ADt. For mechanical fluff pulp (CTMP) the limit value for emissions of CO₂ is 100 kg CO₂/ADt.

For pulp comprising a mixture of chemical pulps and mechanical pulps, a weighted limit value is calculated based on the proportion of each pulp type.

Emissions to water and air

Emissions of AOX from production of pulp/fluff pulp must on average be ≤ 0.14 kg/tonne per pulp mixture. Emissions of AOX from the individual pulp must be ≤ 0.16 kg/tonne.

Total emission points must be \leq 4.0, and individual emission points must be \leq 1.3. The reference values in the Basic Module, version 3 or later shall be used*.

• $P_{emissions_total} = P_{COD} + P_P + P_S + P_{NOx} \le 4$

To calculate the individual emission scores for P_{COD} , P_P , P_S , and P_{NOx} and for reference values for difference pulp types, please refer to the Basic Module, generation 3 or later (Appendix 5, Table 5.1).

* For unbleached chemical pulp used in manufacturing of fluff pulp, the reference value of phosphorus is 0.03 kg/ADt.

- The pulp manufacturer shall demonstrate compliance with the requirement in the web-based application tool. For the calculation of the energy and emissions to water and air, the pulp manufacturer shall use the spreadsheet provided by Nordic Ecolabelling.
- If the pulp/fluff pulp has previously been approved by Nordic Ecolabelling, state the name of the pulp.

Background to O20 Pulp, production requirements (≥10.0 weight-%)

The requirement for manufacturing pulp/fluff pulp has been updated and follow the updated requirements in the Basic Module and the Chemical Module for Nordic Ecolabelling Paper Products, generation 3, as revised in 2020. If the amount of cellulose-based pulp/fluff pulp is 10.0 weight-% or more in the product, requirement for traceability and certification (O17-O18) in this criteria for sanitary products must also be met.

Environmental impact of sanitary products is highly related to raw materials used. Cellulose pulp/fluff pulps are one of those raw materials that may be used in sanitary products. During the recent years, the focus in updating Nordic Swan Ecolabel requirements for cellulose pulp-based products has mainly been on reduced energy and greenhouse gas emissions and these requirements for pulp/fluff pulp are also made more stringent than in the previous version of the Criteria for Sanitary Products.

Compared with current requirements for pulp/fluff pulp, the following key changes have been introduced:

• Reference values for manufacturing of fluff pulp - consumption of fuel and electricity - have been tightened. Regarding fuel, from 6 000 kWh/ADt to 5900 kWh/ADt and for electricity from 900 kWh/ADt to 780 kWh/ADt. The new reference values are based on the licence data available to Nordic

Ecolabelling. The values have also been compared with the reference values proposed for the EU Ecolabel's criteria for absorbent hygiene products.

- Reference values for the pulps in the Basic Module¹⁶, generation 3 have been tightened.
- There is a new requirement for ban on fossil oil and coal used for production of process heat in the pulp/fluff pulp mill.
- The requirement for emissions of greenhouse gases has been changed. The greenhouse gas requirement only encompasses fuels used for production of process heat and not electricity as in the previous generation. The limit value is now set to 350 kWh/ADt.

The background document to the Basic Module, version 3 provides comprehensive information on the energy requirement and Appendix 4 in the Basic Module describes the calculations in detail. Nordic Ecolabelling also provides a spreadsheet that is to be used for these calculations.

Requirement for emissions to air and water are also tightened:

• Regarding emissions to water and air, limit value for individual point score has been tightened from 1.5 to 1.3. The reference values for all emission parameters, namely COD, P, S and NOx have been updated in the Basic Module, version 3. The weighted average value of AOX released from the mixed pulps must not exceed 0.14 kg/ADt pulp. AOX emissions from each individual pulp must not exceed 0.16 kg/ADt.

Major changes in the Chemical Module¹⁷, version 3 also affect the manufacturing of pulp/fluff pulp:

- The requirement for classification of chemical products (O1) has been expanded with hazard class and hazard statement Aquatic Chronic 3 H412.
- There is a new requirement for prohibited substances (O2), such as substances on the Candidate list shall not be ingoing substances in chemical products used in the production of pulp. Subsequently, some former requirements are removed, such as the requirement concerning residual monomers, as these are now covered by the new requirement.
- The definition of ingoing substances and impurities in chemical products has been updated, the limit for impurities in the chemical product is 1000 ppm.

5.6.3 Paper

The paper requirements apply for different types of tissue paper, paper in tape or release paper (silicone paper), and other paper, which are commonly referred to as paper in this chapter, unless otherwise stated in the requirement.

¹⁶ Nordic Ecolabelling for paper products – Basic Module, version 3 <u>basic-module-3.1_005_tissue-paper-005_english.pdf</u>

¹⁷ Nordic Ecolabelling for paper products – Chemical Module, version 3 <u>criteria-document-chemical-module-</u> <u>3.4 005 tissue-paper-005 english.pdf</u>

The requirements are separated into different levels, depending on the quantity of paper involved:

- All types of paper used in sanitary products and additional components must fulfil O21.
- All paper types that account for 10.0 weight-% or more of (S+A) must fulfil requirement O17 and O18.
- Tissue paper that account for 10.0 weight-% or more of (S+A) must fulfil O22.

Each paper type (e.g. tissue paper, release paper, paper in tape and air-laid) shall be summarized separately and only if the individual paper type reaches 10.0 weight-% or more the requirement must be fulfilled.

O21 Paper, general requirements

State the name, grade, grammage and manufacturer of the paper. The following requirements must be met:

- a) The producer of the paper must be Chain of Custody (CoC) certified by the FSC/PEFC schemes.
- b) The paper must not be bleached with chlorine gas* (Cl₂).
- c) The paper must not be coated or treated with fluorinated chemicals. Requirement also applies to fluorinated chemicals in the pulp.
- d) If the paper is coated with silicone, requirement O10 must be fulfilled.
- e) The paper must not have a growth inhibiting effect on microorganisms, under test method EN 1104.

*The residual quantities created during the production of chlorine dioxide from chlorate are not defined as a component of chlorine gas bleaching.

- Documentation from the paper manufacturer of paper showing that the requirements are fulfilled. Duly completed and signed appendix 1, form 7 may be used for the declaration.
- Paper manufacturer must present a valid FSC/PEFC Chain of Custody certificate /link to certificate in FSC/PEFC certificate database covering all wood raw material used in the paper.
- If the paper is coated with the silicon, manufacturer of silicone products shall complete and sign Appendix 1, form 3, see also O10. If the paper is Nordic Swan Ecolabelled, the certification number must be submitted.

O22 Tissue paper (≥10.0 weight-%)

Tissue paper must fulfil requirements in the criteria for Nordic Ecolabelling for Tissue Paper and Tissue Products, version 6 or later.

The tissue paper manufacturer shall submit documentation demonstrating compliance with the requirement with the aid of the web-based application tool. If the tissue paper is already Nordic Swan Ecolabelled, the certification number must be submitted.

Background to O21 Paper, general requirements and O22 Tissue paper

The requirements for paper are separated into different levels, dependent on the amount of paper in the product.

All types of paper in sanitary products and additional components (S+A) must fulfil O21. Paper must not be coated with fluorine compounds or have fluorine added to the cellulose pulp. If the paper is coated with silicone, requirement O10 must also be fulfilled. The requirement concerning microbial activity remains unchanged. The paper's microbial activity gives an indication of whether the paper contains antimicrobial agents.

The paper manufacturer(s) must be Chain of Custody certified by the FSC/PEFC's schemes. The requirement for Chain of Custody certification contributes to traceability in the supply chain within the FSC and PEFC's guidance and control systems for traceability.

If the product contains 10.0% by weight of paper or more, the requirements for wood raw material must be fulfilled, to be in line with the Nordic Ecolabelling guidelines for forestry¹⁸. In this revision the, the limit of certification has been increased from 50% to 70% in paper, see closely requirement O18.

Regarding requirements for paper manufacturing (O22), the requirement has been changed to have focus only on tissue paper. Tissue paper is most widely used paper type in the sanitary products, apart from release paper that is especially used as an additional component in e.g. pads. In the previous generation, release paper was, however, exempted from the manufacturing requirements. More information on the requirements for the tissue paper can be found in the "Background document for the Tissue Paper and Tissue Products, version 6¹⁹. See also chapter 6 for environmental benefit in the background for sanitary products.

5.6.4 Cotton

The requirements for cotton depend on the quantities involved (weight-% in relation to total weight of sanitary products and additional components (S+A). Cotton must fulfil O23. If cotton makes up 5.0 weight-% or more of (S+A), the requirements O24 and O25 must also be fulfilled.

O23 Cotton, bleaching with chlorine gas

The cotton and other natural cellulosic seed fibres must not be bleached with the aid of chlorine gas (Cl₂).

 Declaration from the cotton and other seed fibre producer/supplier showing that the requirement is fulfilled. Duly completed and signed Appendix 1, form 9 may be used for the declaration.

O24 Cotton, raw fibre (≥5.0 weight-%)

The cotton and other natural cellulosic seed fibres of cellulose must be organically cultivated*.

Tampon strings are exempted from the requirement.

*Organic cotton means cotton fibre that is certified as organic or transitioning to organic according to a standard approved in the IFOAM Family of Standards,

¹⁸ <u>https://www.nordic-swan-ecolabel.org/pulp-paper-declaration-portal/what-can-be-declared/forestry-requirements/forestry_requirements_2020/</u>

¹⁹ Nordic Ecolabelling background for Tissue Paper and Tissue Products, version 6 <u>https://www.nordic-swan-ecolabel.org/criteria/tissue-paper-005/</u>

such as Regulation (EU) 2018/848, USDA National Organic Program (NOP), APEDA's National Programme for Organic Production (NPOP), China Organic Standard GB/T19630. Also approved are GOTS, OCS 100, OCS blended (shares that are not organic must meet other relevant requirements in this criteria) and DEMETER and certification as "transitioning to organic cultivation". The certification body must have the accreditation required for the standard, such as ISO 17065, NOP or IFOAM.

- ♀ Valid certificate showing that the cotton and other seed fibres in the Nordic Swan Ecolabelled product were organically cultivated in line with the standards in the requirement. If the supplier is the holder of GOTS certification, the requirement must be documented with a transaction certificate showing that the goods supplied are GOTS certified.
- O25 Cotton, additives (≥5.0 weight-%)

Additives added to cotton must fulfil the chemical requirements O7-O9.

- Duly completed and signed Appendix 1, form 9 from the supplier of cotton.
- If chemicals are added, a list of the added chemicals and material safety data sheets must be submitted. Duly completed and signed Appendix 1, form 2a) can be used to document O7-O9.

Background to O23-O25 cotton and other cellulosic seed fibres

The requirements for cotton have not been changed in this version except that the requirements now apply to other cellulosic seed fibres as well. All cotton or other cellulosic seed fibres more than 5.0 % by weight in sanitary products and additional components must be organically cultivated. The requirement is strict but steerable for the manufacturers. Cultivation of cotton is linked to serious health and environmental problems caused by use of pesticides, fertilisers, irrigation water and monocultures^{20,21}. Nordic Ecolabelling has chosen to require organic cotton for most of the products that carry the Nordic Swan Ecolabel. This is in line with Nordic Ecolabelling's view of organic farming as a means of sustainably protecting soil, water resources and biodiversity.

The ban on bleaching with chlorine gas (O23) in manufacturing aims at minimising the negative effects on the environment caused by chlorine (e.g. prevention of the formation of dioxins and other highly carcinogenic pollutants). If additives are added in manufacturing of cotton, then they shall fullfill the general requirements O7-O9 for chemicals. The requirement is applicable to both raw cotton and cotton manufacturing in the supply chain.

5.6.5 Regenerated cellulose

The requirements for regenerated cellulose depend on the quantities involved (weight-% in relation to total weight of sanitary products and additional components (S+A)).

• Regenerated cellulose must fulfil O26.

²¹ Kooistra K, Termorshuizen A, Pyburn R (2006) The sustainability of cotton – consequences for man and the environment. Wageningen University & Research, report no. 223.

²⁰ https://issuu.com/pan-uk/docs/cottons_chemical_addiction_-_update?e=28041656/62705601

• If regenerated cellulose makes up 10.0% by weight or more of (S+A), then requirement for forestry O17-O18 and production O27 must also be fulfilled.

O26 Regenerated cellulose, bleaching

Pulps used to manufacture regenerated cellulose fibres shall not be bleached using chlorine (Cl₂) gas.

Residual amounts of chlorine gas formed during the production of chlorine dioxide from chlorate are excluded.

The annual average for the measured emissions adsorbable organic halogens (AOX) and organically bound chlorine (OCl) must not exceed:

• 0.14 kg/ADt in the wastewater from each pulp manufacturing (AOX)

and

• 150 ppm in the finished regenerated cellulose fibres (OCl)

Information on sampling, methods of analyses and analysis laboratories is provided in Appendix 2.

- A Manufacturer of the regenerated cellulose shall enclose information on the trade name, production site and the manufacturer of the pulps used in manufacturing regenerated cellulose.
- Regarding pulps used in manufacturing regenerated cellulose, declaration that
 - Chlorine gas is not used.
 - The requirement for AOX is fulfilled including test results, method of analysis, test frequency and the compliance of laboratory with the laboratory requirements. Appendix 1, form 10 can be used.
- Declaration from the manufacturer of the regenerated cellulose that the requirement for OCl in the finished fibre is fulfilled including test results, method of analysis, test frequency and the compliance of laboratory with the laboratory requirements. Appendix 1, form 10 can be used.

Background to the O26 Regenerated cellulose, bleaching

The requirement has been updated by tightening the limit value for emissions of adsorbable organic halogens (AOX) to water from 0.15 to 0.14 kg/ADt. This requirement is applied to pulps used in manufacturing of regenerated cellulose fibres. Otherwise, the requirement is the same as before.

Cellulose pulp must not be bleached with chlorine gas. Chlorine gas is no longer used in Europe but may still be used in some parts of the world. Chlorine gas is an effective bleaching agent, but it causes considerable emissions of organochlorine substances. There are good alternative bleaching methods for pulps. Bleaching can be done total chlorine free (TCF) or by using elemental chlorine free (ECF) process. If ECF is used, then the annual average emissions of AOX in cellulose pulp production shall not exceed 0.14 kg/ADt which is the same as in the EU Ecolabel. When bleaching with chlorine dioxide, residues may arise as a by-product, and these are therefore exempt from the requirement. In addition to AOX emissions of pulps, organically bound chlorine (OCI) shall be analysed in the actual finished regenerated cellulose fibre. The amount shall not exceed 150 ppm in the fibre. Manufacturer of the regenerated cellulose shall enclose information of the pulps used in manufacturing. Manufacturer also compiles information from the pulp producers regarding emissions of AOX and sends it to Nordic Ecolabelling. Alternatively, pulp manufacturer can send the information directly to Nordic Ecolabelling.

O27 Regenerated cellulose, production requirements (≥10.0 weight-%)

Part a) or b) must be fulfilled:

a) Closed loop processes

At least 50% of the regenerated cellulose fibre production must be based on "closed loop"* processes such as the lyocell process or similar closed processes. The rest of the fibres must live up to part b).

* "Closed loop" is defined here as processes with a high degree of recycling of chemicals that are included (>99%) or processes without release of chemicals.

or

b) Emissions to water and air

Emissions of chemical oxygen demand (COD) from the production of dissolving pulp and regenerated cellulose fibres must not exceed a combined total* of 30 kg/ADT of regenerated cellulose.

Sulphur emissions to air from regenerated fibre production must not exceed more than 16 g/kg of regenerated cellulose fibre expressed as an annual average.

Zinc emissions to water from regenerated fibre production must not exceed 0.05 kg Zn/kg of regenerated cellulose fibre, expressed as an annual average.

*Combined total shall be calculated as the sum of the emissions from dissolving pulp manufacturing and subsequent production of regenerated cellulose fibres, taking into account the mixture of pulps used. If several pulps are used, then the calculations shall include the weighted average of the COD emissions of all pulps in the pulp mix.

The quantity of oxygen depleting substances may also be stated as the equivalent quantity of total organic carbon (TOC). Information on sampling, methods of analysis and analysis laboratories is provided in Appendix 2.

- Part b). Duly completed and signed Appendix 1, form 10 from the producer of
regenerated cellulose fibres including test results, method of analysis, test
frequency and the compliance of laboratory with the laboratory requirements.

Background to the requirement O27 Regenerated cellulose, production

The requirement for manufacturing of regenerated cellulose has been updated. There is a new alternative requirement a) that at least 50% of the regenerated cellulose fibre production must be based on "closed loop" processes such as the lyocell process. The rest of the fibres must live up to requirements for emissions to air and water (b). All limit values for emissions have been tightened, namely sulphur emissions to air and chemical oxygen demand (COD) and zinc emissions to water. As for pulp and paper, the requirement is applied only when the material is included with 10.0% by weight or more in the sanitary product (S+A). The requirements for forestry are also applied when the amount of regenerated cellulose is over 10.0 weight-% in the sanitary product, see closely O17-O18.

The requirements regarding the production of regenerated cellulose have been tightened in this generation of the criteria. The purpose is to promote the more environmentally friendly manufacturing methods such as the lyocell process with more than 99% recycling rate for chemicals used or processes without the use of chemicals. This limits emissions of harmful chemicals to air and water. Other newly developed processes can be approved as "closed loop" after the assessment of Nordic Ecolabelling.

Man-made cellulose fibres (MMCF), also known as regenerated cellulose fibres are produced by the chemical sulphite pulping process, more specifically by the dissolving pulp process. By far, the most common MMCF is viscose fibre²². Regenerated cellulose fibre is based on cellulose fibres, made from raw materials such as wood, bamboo and cotton (cotton linters). Emissions of COD originating from manufacturing of cellulose pulp may be substantial. Therefore, the requirement for COD is set for both manufacture of the ingoing pulps and subsequent production of the regenerated cellulose fibres. The limit value for COD has been decreased from 45 kg/ADt to 30 kg/ADt in this revision and is based on the EU's Reference Document on Best Available Techniques (BATreports)²³ and data from licensing. Instead of measuring COD, total organic carbon (TOC) may be measured, if there is a correlation between the two values for the production process. This is to avoid mercury which is used in the COD analysis.

The manufacture of regenerated cellulose fibres also generates emissions of sulphur to air and zinc to water if closed loops are not applied. The requirement concerning emissions of sulphur to air has been decreased from 20 to16 kg/ADt and regarding zinc, the limit value 0.05 g/kg in EU Ecolabel is applied. The requirement set in these criteria are applied to stable fibres because they are usually used as raw material in nonwovens of sanitary products.

5.6.6 Plastic

Polymers/plastic materials that are subject to requirements when used in sanitary products, additional components and sales packaging are: polyethylene (PE), polypropylene (PP), polyester (PET), polyamide (PA), ethylene vinyl acetate (EVA) and polyether/polyurethane (e.g. elastane, spandex, foam) and bio-based polymers.

Other polymers may be included together with other materials for which no requirements have been set, up to a maximum of 5.0% by weight, with maximum 2.0% by weight for each material type, see O2. This means, for example, that silicone materials may be used in small quantities, even though no silicone polymer requirement has been set. However, if silicone is used as an additive in other materials or as a coating, requirement O10 must be fulfilled. If silicone is used as a raw material in menstrual cups, then requirements O37-O39 are applied.

²² European Man-made Fibres Association https://www.cirfs.org/

²³ Reference Document on Best Available Techniques in the Production of Polymers, August 2007 <u>https://eippcb.irc.ec.europa.eu/sites/default/files/2019-11/pol_bref_0807.pdf</u>

Process and auxiliary chemicals, such as spinning additives and machine oils are exempt from the requirements.

For definitions of polymers, plastics and components, see Definitions 5.2.

O28 Plastic in components

a) Substances in plastic components

The requirement includes plastic contained in components (e.g. film, foil or foam).

The following substances must not be present in the polymer apart from impurities*:

- 1. halogenated organic compounds including perfluorinated and polyfluorinated alkylated substances (PFAS)
- 2. phthalates
- 3. organotin compounds
- 4. compounds based on lead, cadmium, chromiumVI and mercury

Polyester: The amount of antimony in polyester, measured as an average value on an annual basis, must not exceed 260 ppm (recycled polyester is exempted).

Information about test methods and analysis laboratories is provided in Appendix 2.

* For definition of impurities, see Definitions 5.2.

The requirement shall be documented by a **declaration from the component manufacturer** based on knowledge gathered from and requirements made to its suppliers, or by use of a test. See explanation below:

- If test is used, the test can be performed by the producer of polymer/plastic or a part in the supply chain, e.g. a nonwoven supplier. If the test is performed by someone other than the polymer/plastic producer, the test must be done on the virgin plastic raw materials before the supplier receiving it has done any modifications, like adhesives or other additives. See Appendix 2 for information on test methods and laboratory for analysis.

b) Additives in plastics components (≥5.0 weight-%)

The requirement is applied to components of plastic included in the sanitary product and the additional components (S + A) by 5.0% by weight or more.

If the component manufacturer adds chemical products to the plastic component, they must meet O7-O9. Requirements can be confirmed with a declaration from the component manufacturer.

술 For part a),

-Declaration from the component manufacturer that the requirement is fulfilled. Appendix 1, form 11a can be used. Alternatively,

- Test report showing that the requirement is met.

For part b) Declaration from the component manufacturer that the requirement is fulfilled. Appendix 1, form 11b can be used.

Background to O28 Plastic in components

Requirement for plastic components remains the same as in the previous generation, except for minor editing. Background for forbidden substances and

requirements for additives can be found in O9. Regarding antimony in polyester, antimony trioxide (CAS no. 1309-64-4) is carcinogenic and the key catalyst in PET production. Nordic Ecolabelling wants to limit the content of antimony as it is a substance of concern. Therefore, a limit value is set at 260 ppm, as in the previous generation.

In the part a, forbidden substances in plastic components shall be declared by the component manufacturer or by the use of a test. A test can be carried out by a manufacturer of the plastic or later in the supply chain, for example, by nonwoven supplier. If the testing is done later in the supply chain, the pure plastic material must be tested, that is, the material that the supplier receives without further compilation with, for example, glue or other additives.

The responsibility for fulfilling the requirement throughout the supply chain is placed on the component manufacturer. Declaration by the component manufacturer must be based on knowledge gathered and requirements set to suppliers. Nordic Ecolabelling is aware that it is generally difficult to obtain information from the polymer producers and the plastics industry. The long supply chain makes it even more challenging. Requiring the component manufacturer's declaration to be based on ongoing discussions with suppliers helps to ensure that any changes in supply chain are included. Nordic Ecolabelling does not require documentation for the component manufacturer's dialogue with suppliers during licensing but may request this on audits.

Part b includes components of plastic included in the sanitary product and additional components (S + A) with 5% by weight or more. If the component manufacturer adds chemical products to the plastic component, these additives must meet the chemical requirements O7-O9. It is also clarified in the text that the requirement concerns chemical products added to the plastic component not additives added to the masterbatch, or the polymer production itself. As in part A, this can be confirmed with a declaration from the component manufacturer.

O29 Polyurethane/Elastane (≥5.0 weight-%)

The requirement includes elastane / polyurethane which accounts for 5.0 wt % or more relative to the total weight of the sanitary product and the additional components (S + A).

- a) A closed process must be used when using isocyanate in the production.
- b) Organotin compounds shall not be used.
- c) Fibre (as elastane and spandex)
- d) Emissions to air of aromatic diisocyanates during polymerisation and, if applicable, spinning must be less than 5 mg/kg of produced fibre, expressed as an annual average.
- e) PUR foam and thermoplastic PUR must fulfil "Criterion 2 Polyurethane (PUR) foam" in EU Ecolabel criteria for "Bed mattresses" (2014/391/EU).

Declaration from the polymer producer that the requirement is fulfilled. Duly completed and signed Appendix 1, Form 12 may be used in addition to test reports from the polymer producer.

Background to O29 Polyurethane/Elastane

Requirement for polyurethane/elastane remains the same as in the previous generation, except for minor editing. Elastane is a polyurethane elastomer. It is not used alone as a textile fibre but is incorporated into other materials to make them elastic. If elastane/polyurethane is used more than 5 weight- % in the product, then the requirements for manufacturing must be fulfilled. Organotin compounds can be used as catalysts in the polymerisation. Organotin compounds are very toxic, both for humans and animals (see closely O9), and a requirement is set that organotin compounds shall not be used. Requirements are also set for emissions of aromatic diisocyanates in the polymerisation and spinning. These compounds can cause allergic reactions in the eyes, lungs and skin in the event of emissions to the air. The requirement shall be documented through test reports and/or detailed information that shows that emissions of aromatic diisocyanates do not exceed 5 mg/kg produced fibre, or with a valid EU Ecolabel licence.

More information of the justification of the requirement can be found from the background of the previous generation 6. For organotin compounds, see also O9.

In addition to the manufacturing requirements, there is also additional requirement for PUR foams and thermoplastic PUR. PUR foam is used in wash cloths and thermoplastic polyurethane used in adhesive plaster. In these product types, a significant amount of PUR can be included. If these are used, then manufacture of PUR shall meet Criterion 2 in EU Ecolabel criteria for Bed mattresses²⁴. This includes requirements for biocides, plasticisers, heavy metals, monomers, organotin compounds, VOC emissions, total chlorine content and blowing agents.

O30 Polyamide (≥5.0 weight-%)

The requirement includes polyamide which accounts for 5.0 wt.% or more relative to the total weight of the sanitary product and the additional components (S + A).

Emissions of nitrogen dioxide (N_2O) to the air from the production of monomers must not exceed 9 g/kg caprolactam (for PA 6) or adipic acid (for PA 6.6), expressed as an annual average.

Detailed information and/or a test report from the polyamide producer showing that the requirement is fulfilled. Duly completed and signed Appendix 1, form 13 may be used.

Background to O30 Polyamide

Requirement for polyamide remains the same as in the previous generation, except for minor editing. The two commercial polyamide products (nylon) on the market are polyamide 6.6 and polyamide 6. Polyamide 6.6 is created through the polymerisation of adipic acid and hexamethylenediamine, while polyamide 6 is created through the polymerisation of melted ε -caprolactam. For PA 6 and PA 6.6, there is a requirement regarding emission of nitrogen dioxide to the air from the production of the monomers caprolactam (PA 6) and adipic acid (PA 6.6). This value is the same as in the previous generation.

²⁴ <u>COMMISSION DECISION - of 23 June 2014 - establishing the ecological criteria for the award of the EU Ecolabel</u> for bed mattresses - (notified under document C(2014) 4083) - (2014/391/EU) (europa.eu)

O31 Bio-based plastics: raw materials for bio-based polymers (≥5.0 weight-%)

Raw materials used in the production of bio-based polymer (granules) for the product and packaging must meet the following requirements:

Palm oil and soy

Palm oil, soybean oil, and soy flour must not be used for bio-based polymer.

Other raw materials

The origin of the raw materials shall be verified as either a) or b):

- a) Waste* or residual products** defined in accordance with (EU) Renewable Energy Directive 2018/2001. There must be traceability back to the production / process where the residual production occurred.
- b) Certified by one of the following certification schemes:
 - Bonsucro EU
 - ISCC EU or ISCC Plus
 - A standard/certification scheme that meets the requirements in Appendix 3.

Primary feedstock must in addition not be genetically modified***.

The supplier of the bio-based polymer must have a valid chain of custody (CoC) certificate according to the standard by which the raw material is certified. Traceability must at least be ensured by mass balance. Book and claim systems are not accepted.

* Waste as defined by EU Directive 2018/2001/EC.

** Residual products as defined by EU Directive 2018/2001/EC. Residues come from agriculture, aquaculture, fisheries, and forestry, or they can be processing residues. A processing residual product is a substance that is not one of the end products that the production process directly strives for. Residues must not be a direct target of the process and the process must not be changed to intentional production of the residual product. Examples of residual products are e.g., straw, husks, pods, the non-edible part of maize, manure, and bagasse. Examples of processing residues are e.g., raw glycerine or brown lye from paper production. Palm Fatty Acid Distillate (PFAD) or Palm Oil Mill Effluent (POME) from palm oil is not considered a residual/waste product and can therefore not be used.

*** Genetically modified organisms are defined in EU directive 2001/18/EC.

- Declaration by the manufacturer of the polymer, that palm oil (incl. PFAD (Palm Fatty Acid Distillate)) soybean oil and soy flour are not used as raw materials for the bio-based polymer. Duly completed and signed Appendix 1, form 17 may be used.
- For waste and residual products: Documentation from the polymer manufacturer which shows that the requirement's definition of waste and residual products is met, as well as traceability which shows where the residual product comes from.
- For certified raw materials (supplier): Indicate which certification system the raw materials are certified by. A copy of a valid CoC certificate/certificate number from the supplier.

- For certified raw materials: Documentation in form of invoices or delivery notes documenting the purchase of certified bio-based polymer for use in Nordic Swan Ecolabelled products.
- For certified raw materials: Declaration stating that the primary feedstock has not been genetically modified (this also applies to mass balance approach).

Background to O31 Bio-based plastics, polymers

The requirement for bio-based plastics is updated in line with the Nordic Ecolabelling guidelines for renewable raw materials. Threshold value when the requirement is applied, have been lowered from 20% to 5%, and is applied both to product and packaging.

Biobased plastic can be defined as polymers produced from renewable resources. It is therefore an alternative to conventional plastics based on fossil resources. The biomass currently originates mainly from plants grown specifically to be used as feedstock to substitute fossil resources, such as sugarcane, cereal crops, oil crops or non-food sources like wood. Other sources are organic waste and byproducts, such as used cooking oil, bagasse and tall oil.

Renewable raw materials can have a potential to give better environmental impact than fossil alternatives, but it depends on many parameters such as type of crop, where it is cultivated, cultivation conditions, land use change, further processing of the renewables and waste. Converting forest to cropland can have a huge impact on climate change and biodiversity. So, the possible benefits of replacing fossil-based raw materials with renewable raw materials will vary much and depend on responsible farming/forestry practices.

The establishment of palm oil and soybean plantations has led to vast areas of deforestation and destruction of natural habitats, thereby driving the loss of biodiversity in some of the world's most precious places like the Amazon and Cerrado in Brazil and Borneo in Indonesia²⁵. Voluntary certification schemes for palm and soy are not yet considered good enough (by Nordic Ecolabelling) to protect against deforestation, and palm oil, soybean oil and soy flour are therefore banned as raw materials for bio-based polymers. This also applies to waste or residual product from the palm oil production such as palm Fatty Acid Distillate (PFAD) or Palm Oil Mill Effluent (POME).

Other renewable raw materials must be a) waste or residual products from i.e., agriculture, fishing, forestry or processing residual product defined in accordance with (EU) Renewable Energy Directive 2018/2001 or b) certified according to approved certifications schemes. Certified virgin raw materials must also not be genetically modified.

Nordic Ecolabelling has so far recognised Bonsucro EU and ISCC RED/Plus as valid certification schemes. The supplier of the bio-based polymer must have a valid chain of custody (CoC) certificate according to the standard by which the raw material is certified. Traceability must at least be ensured by mass balance. Book and claim systems are not accepted. The ban on GMO also applies when mass balance is used i.e. that GMOs may not be included in the specific mass balance system.

²⁵ <u>https://www.worldwildlife.org/stories/deforestation-fronts</u> (May 2024)

Nordic Ecolabelling emphasizes the precautionary principle and discourage the use of GMOs that are commercially available today. Nordic Ecolabelling is concerned about the consequences when genetically modified plants, animals and microorganisms are propagated in nature. However, Nordic Ecolabelling is not against genetic engineering or GMOs as such, and we believe that GMOs should be assessed on a case-by-case basis. For more information on Nordic Swan Ecolabelling's approach on GMO: <u>https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/</u>

O32 Recycled plastic

For recycled plastics, following apply:

• Recycled material* is defined according to ISO 14021.

*See definition of recycled materials in section 5.2.

• Recycled plastic is traceable*.

*The traceability of recycled plastic must be documented by certification schemes EUCertPlast, RecyClass, Global Recycling Standard (GRS), Recycled Claim Standard (RCS) or ISCC, or other equivalent certification scheme that may be approved by Nordic Ecolabelling.

Or

a declaration from the manufacturer of plastic granulate/product enclosed with documentation of supply chain all the way from the production site of recycled plastic until granulate/plastic product. In addition, the manufacturer must disclose the primary sources of the recycled plastic (e.g. collected consumer packaging, residual waste from the manufacturer of xx product), as well as disclose the proportion of pre-consumer/commercial and/or postconsumer/commercial recycled plastic.

• If recycled plastic is used in a product or packaging, it should not be directly in contact with the skin or the product. This can be achieved using e.g. multilayer extrusion methods within the same polymer.

a) Additional components and sales packaging

Part a) applies to recycled plastic in additional components and sales packaging

• Recycled plastic must not contain polybrominated biphenyls or diphenyl ethers (PBB and PBDE), phthalates, organotin compounds, Bisphenol A, lead, cadmium, mercury or chromiumVI. Impurities up to 100 ppm are, however, permitted. See Table 1 in Appendix 2 for further specification of substances.

The requirement shall be documented by a test report, or a description and traceability to the source that verify that the given substances do not occur in the plastic. The requirement must be documented at the time of application, as well as when any change after the license has been granted e.g., when changing of the supplier of recycled plastic, significant changes to the sources of the recycled plastic, changes of treatment (e.g. washing or sorting) of the recycled plastic or similar.

b) Sanitary product

Part b) applies to the recycled plastic in the sanitary product.

• Recycled plastic must meet the requirements for recycled plastic materials and articles intended to come into contact with foods* and fulfil O3.

c) Sanitary product (≥5 weight-%)

Part c) applies if the recycled plastic constitutes ${\geq}5$ weight-% in the sanitary product.

• In addition to part b), chemicals added to the recycled plastic component must fulfil the requirements O7-O9.

*EU commission regulation (EC) No 2022/1616 on recycled plastic materials and articles intended to come into contact with foods. If it can be documented that the recycled material originates from a closed system, like recycling of PETbottles (e.g. if PET-granulate are used from this process or from bottles that no longer can be reused), it is not necessary to document that the requirement for recycled plastic in contact with food is met.

- Information on recycled plastic type(s) and weight % of recycled material in additional component/sales packaging/product.
- If recycled plastic is used, declaration confirming that is not in direct contact with the skin or in case of packaging, with the product.
- Third party certificate for traceability from accepted certification schemes or declaration from manufacturers including all information required.
- Part a) test report for the content of the substances in part a) of the recycled plastic. Duly completed and signed Appendix 1, form 14a can be used.
- Part b) Documentation showing that the recycled plastic material fulfils the requirements to recycled plastic in contact with food. Duly completed and signed Appendix 1, form 14b can be used.
- Part c) Declaration from the component supplier that the requirements O7-O9 are fulfilled. Appendix 1, form 2a can be used.

Background to O32 Recycled plastics

The requirement for recycled plastics has been updated. In line with circular economy, use of recycled plastics should be promoted in the product and packaging. Future legislation such as Packaging and Packaging Waste Regulation (PPWR)²⁶ will also increase content of recycled post-consumer plastic in packaging. Use of recycled plastic imposes, however, additional requirements on its origin, traceability and purity, to ensure its safe use. In the previous generation 6 of the criteria, some chemical requirements for recycled plastic were included. They are now clarified and updated with stricter traceability and certification requirements.

All recycled plastics must be defined according to the ISO 14021 and be traceable either by certification schemes such as EUCertPlast, RecyClass, Global Recycling Standard (GRS), Recycled Claim Standard (RCS), ISCC or other equivalent certification scheme that may be approved by Nordic Ecolabelling. Alternatively, a declaration from the manufacturer can be approved if supplemented with all

²⁶ Proposal approved by EU Parliament 24 April, https://www.europarl.europa.eu/plenary/en/home.html

documentation required. If recycled plastic is used in a product or packaging, it should not be directly in contact with the skin or in case of packaging, with the product. This can be achieved using e.g. multilayer extrusion methods within the same polymer. Barrier layers are especially important in contact-sensitive products such as sanitary products and its packaging made of recycled plastics because recycled materials can sometimes contain contaminants or substances that are not suitable for direct contact with skin. Using barrier layers in such packaging is essential for maintaining safety and minimizing the risk of migration of unwanted chemicals.

Additional components and sales packaging

Recycled plastic that are used in additional components and sales packaging must not contain polybrominated biphenyls or diphenyl ethers, phthalates, organotin compounds, lead, cadmium, mercury or chromiumVI. Impurities up to 100 ppm are, however, permitted. The requirement shall be documented by a test report, or a description and traceability to the source that substantiate that the given substances do not occur in the plastic.

The list of restricted substances has been updated with Bisphenol A, commonly found in plastics. Generation 7 of the criteria also specifies substances for polybrominated biphenyls, diphenyl ethers, phthalates, and organotin compounds. The specified phthalates are based on the OEKO-TEX Standard 100, Annex 5. The majority of phthalates specified is on the Candidate list and restricted by Regulation No 1907/2006 and No 2018/2005, Annex XVII, entries 51 and 52.

Requirements for Recycled Plastics in Sanitary Products

There have been no changes to the recycled plastic requirements for sanitary products since Generation 6. Generally, the Nordic Swan Ecolabel does not permit recycled plastics approved for food contact to be used in non-relevant products. However, sanitary products can be considered as contact-sensitive products²⁷ and therefore, require higher purity in their packaging materials. Thus, recycled plastic in sanitary product packaging must be approved according to EU Commission Regulation (EC) No 2022/1616 on recycled plastic materials and articles intended to come into contact with foods. There are strict requirements to traceability if the recycled plastic should be used in food contact and therefore a better system for controlling what kind of substances the plastic contain. For materials of recycled plastic this means that the recycling process must be preapproved. Basically, there are processes for recycling of PET that are approved today. Hence the mechanical recycled plastic available is limited. If it can be documented that the recycled plastic originates from a closed-loop system, like recycling of PET-bottles, no further documentation that the plastic is approved for food contact is necessary.

Just as for plastic components constituting ≥ 5 weight-% in the sanitary product, any chemicals added to the recycled plastic must comply with chemical requirements O7-O9.

²⁷ Proposal approved by EU Parliament 24 April, <u>https://www.europarl.europa.eu/plenary/en/home.html</u>

5.6.7 Superabsorbent polymers

All superabsorbent polymers (SAP) must meet O33. If SAP accounts for 10.0 weight-% or more of (S+A), requirement O34 must also be fulfilled.

O33 Superabsorbent polymers (SAP), residual monomers and extracts

- Superabsorbent polymers (SAP) may contain a maximum of 1000 ppm residual monomers (the total of unreacted acrylic acid and crosslinkers) that are subject to a classification requirement and have been allotted the risk or hazard phrases specified in requirement O7, Table 2.
- Acrylamide (CAS 79-06-1) must not be used as a monomer.
- SAP shall as a maximum contain 10.0 weight -% of water-soluble extracts*.

*Water-soluble extracts in SAP are monomers and oligomers of acrylic acid with a lower molecular weight than the one of SAP, and salts.

Information on sampling, methods of analysis and analysis laboratories is provided in Appendix 2.

- The producer of superabsorbent polymers must document the composition of the superabsorbent polymer by means of a product safety data sheet which specifies the full name and CAS number, and the residual monomers contained in the product classified in accordance with the above requirement and the quantities thereof.
- The producer of superabsorbent polymers must specify the quantity of watersoluble extracts in the superabsorbent. The methods of analysis must be described and the laboratories responsible must be stated. Appendix 1, form 15 may be used.

O34 Superabsorbent polymers, additives (≥10.0 weight-%)

Additives in superabsorbent polymers must fulfil requirements O7-O9.

- **Declaration from the producer of superabsorbent polymers that the requirement is fulfilled. Duly completed and signed Appendix 1, form 15 can be used.**
- If additives are used, a list of the additives and material safety data sheets shall be enclosed. Duly completed and signed Appendix 1, form 2a) can be used to document O7-O9.

Background to O33-O34 Superabsorbent polymers

Requirements for superabsorbent polymers (SAP) remain the same as in the previous generation, except for minor editing. SAP is a synthetic material, manufactured mainly by the polymerisation of acrylic acid with ammonium persulphate as an initiator and can absorb and retain huge quantities of liquids. It was reported that 1 kg of SAP can absorb up to 418 L of water and for this reason it is used to retain high amounts of fluids in baby, incontinence and menstrual products²⁸. Regarding the LCA-analysis of sanitary products, SAP has a significant impact on global warming potential (GWP). There is considerable relevance in setting requirements concerning constituent materials like SAP in sanitary products. However, the potential and steerability are low due to lack of

²⁸ Bachra., Y., Grouli, A., Damiri, F., Bennamara, A. and Berrada, M. 'A new approach for assessing the absorption of disposable baby diapers and superabsorbent polymers: A comparative study', Results in Materials, Vol. 8, Elsevier, 2020, pp. 100156.https://doi.org/10.1016/j.rinma.2020.100156

site-specific data and therefore, the requirement is the same as in the previous generation, focusing on harmful chemicals in SAP. See also chapter 6 for environmental impact of sanitary products.

The requirement for residual monomers and extracts in SAP is the same as in EU Ecolabel requirements for absorbent hygiene products²⁹. Amount of classified residual monomers is restricted to 1000 ppm and use of acrylamide as a monomer (CAS 79-06-1) is totally prohibited. Acrylamide is classified as mutagenic and carcinogenic, amongst other things³⁰. Water-soluble extracts in SAP are restricted to a maximum of 10.0 weight-%. Water-soluble extracts are mainly monomers and oligomers of acrylic acid with a lower molecular weight than the one of SAP, and salts.

If SAP accounts for 10.0 weight-% or more of sanitary product (S+A), then possible additives to SAP must fulfil chemical requirements O7-O9.

5.6.8 Nonwoven

Nonwoven may be produced from a variety of materials. The requirements concerning nonwoven therefore regularly refer to other requirements in criteria. The requirements applied are related to the amount of material in the sanitary product. The description of which material requirements apply can be found under the chapter 5.6 Materials.

O35 Nonwoven, general requirement

The producer of the nonwoven must specify the materials and additives used in the production and state the names of the suppliers. The materials must fulfil the requirements in the following chapters:

- 5.6.2 Fluff pulp/cellulose-based pulp
- 5.6.4 Cotton
- 5.6.5 Regenerated cellulose
- 5.6.6 Polymers as fibre or binder
- 5.6.7 Superabsorbent polymers (SAP).

If other materials are present and have requirements in the criteria, these must also be fulfilled.

The producer of the nonwoven must specify the materials and additives used in production and state the names of the suppliers. Documentation as in the referred requirements. Appendix 1, form 16 can be used.

O36 Nonwoven, additives

All additives used in the production of the nonwoven must fulfil the chemical requirements O7-O9.

Adhesives/binders must fulfil O11.

²⁹ Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197. <u>EU</u> Ecolabel - Personal and animal care products (europa.eu)

³⁰ https://echa.europa.eu/da/registration-dossier/-/registered-dossier/15534

Other process- and auxiliary chemicals (e.g. spinning additives and machine oils) are exempt from the requirement.

Process water: A substance that is classified as sensitising with risk phrase H317 and/or H334 can only be used in the process water if the residue in the nonwoven is <0.10 ppm for each sensitising substance.

Background to the O35-O36 Nonwovens

Requirements for nonwovens concerning materials and additives used in manufacturing are basically the same as before. However, requirements for raw materials these requirements are referring to have been updated, such as those for fluff pulp and regenerated cellulose, as well as general chemical requirements regarding additives (O7-O9).

Nonwovens are defined by ISO 9092 and CEN EN 29092. Nonwovens are widely used in baby diapers, feminine hygiene, adult incontinence and personal care products, in multiple components of the products, such as top sheet, acquisition/distribution layer and back sheet³¹. Main nonwoven technologies used in adsorbent hygiene products are airlaid, carded nonwovens and spunmelt³². Because nonwoven may be produced from a variety of materials, the requirements refer to the requirements for the constituent materials and to the chemical requirements if additives have been used during the manufacture of the nonwoven. Although the processes associated with the manufacture of nonwoven use energy and may generate emissions to water, no requirements concerning these have been included in this generation of the criteria. There are also no requirements concerning process chemicals such as spinning additives, but with the exception of requirement to sensitising substances in the process water. If allergenic substances are used in the process water, it should be declared that the content in the finished nonwoven is <0.10 ppm for each sensitising substance.

5.6.9 Silicones and elastomers used in menstrual cups

Requirements in this chapter are applied to production of raw materials - silicones and elastomers - used in reusable menstrual cups.

O37 Emissions of dust and of chlorides to air

1. Emissions of dust

1a) This requirement applies to silicones only.

The storage and handling of the elemental silicon raw material shall use at least one of the following techniques:

- Storing of elemental silicon in silos (after grinding).
- Storing of elemental silicon in covered areas protected from rain and wind (after grinding).

³¹ https://www.edana.org/nw-related-industry/nonwovens-in-daily-life/absorbent-hygiene-products

³² https://www.edana.org/nw-related-industry/nonwovens-in-daily-life/absorbent-hygiene-products

- Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding).
- Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.

1b) This requirement applies to both silicones and other elastomers.

The yearly average of channelled emissions of dust shall be below 5 mg/Nm3. The dust emissions should be continuously monitored.

Methods accepted are EN 15267-1, EN 15267-2, EN 15267-3, EN 15267-4, EN 13284-1 and EN 13284-2. For the production of silicones, the measurement shall cover grinding, storage and handling of elemental silicon as a minimum.

2. Emissions of chlorides

2a) This requirement applies to silicones only.

The off-gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process.

2b) This requirement applies to elastomers other than silicones. Polychlorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDF) emissions shall be below 0,01 ng TEQ/Nm3 (average over the sampling period). Monitoring of the PCDD/F emissions should take place every six months.

Methods accepted are EN 1948-1, EN 1948-2 and EN 1948-3.

A declaration of compliance from the raw material supplier

1a) describing the technique used on site.

1b) results of the dust measurements taken on site, together with the yearly average of the dust emission.

2a) details on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps.

2b) results of the PCDD/F emissions measurements of the treated gases.

Duly completed and signed Appendix 1, form 20 for silicones and form 21 for elastomers can be used.

O38 Emissions of copper and of zinc to water

This requirement applies to silicones only.

The water effluents from the polydimethylsiloxane (PDMS) production step shall be pre-treated by precipitation or flocculation under alkaline conditions, followed by sedimentation and filtration. This shall include:

- a) dewatering of the sludge before disposal; and
- b) recovering of the solid metal residues in metal recovery plants.

The concentration of copper in the treated effluent shall be below 0,5 mg/l, while the concentration of zinc shall be below 2 mg/l.

A declaration of compliance from the silicone supplier describing the technique used on site. Duly completed and signed Appendix 1, form 20 can be used.

P Results for copper and zinc measurements in the treated effluent.

O39 Emissions of CO₂

This requirement applies to silicones only.

Emissions of CO_2 from the production of the silicone shall not exceed 6.58 kg per kg silicone, including emissions from the production of electricity (whether onsite or off-site).

 $\rm CO_2$ emissions shall include all sources of non-renewable energy used during the production of the silicone (whether on-site or off-site). $\rm CO_2$ emission factors for other energy sources can be found in Annex VI to Regulation (EU) 2018/2066, whereas the $\rm CO_2$ emission factors for grid electricity shall be calculated by factor 210 g $\rm CO_2/kWh$. However, if the greenhouse gas emission intensity of electricity generation given by European Environment Agency* indicates a higher emission calculation factor for the country where the manufacturing is located, this shall be used.

https://www.eea.europa.eu/en/analysis/indicators/greenhouse-gas-emission-intensity-of-1

Background to O37-O39 Silicones and elastomers in menstrual cups

Requirements for production of raw materials - silicones and elastomers - used in reusable menstrual cups are new in the criteria. Background for these requirements is presented only shortly as more information can be found from EU Ecolabel's Technical Report³³.

Requirement for emissions to air (O37) aims at minimising the emissions of dust and chlorides during production of silicon. Dust is emitted during i.e. elemental silicon grinding, storage and handling. Different measures such as filtering can be used to decrease these emissions. A Best Available Technique-Associated Emission Levels (BAT-AEL) for channelled emissions of dust in all chemical plants is 1-5 mg/Nm₃. Therefore, a 5 mg/Nm₃ dust emission level is set as a limit value (yearly average).

During silicone material production, chlorides emissions occur during the methyl chloride synthesis, the direct synthesis and the distillation process steps. The off-gases from these processes shall undergo thermal oxidation followed by scrubbing. Thermal oxidation step is to minimise the risk of polychlorinated dibenzodioxins/furans (PCDD/Fs) formation. Polychlorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDF) emissions shall be below 0,01 ng TEQ/Nm3 and is applied to elastomers other than silicones.

As it was not possible to retrieve detailed information on the production of TPE, requirement for emissions water applies to silicon menstrual cups only. Inorganic impurities in wastewater arise from the use of different catalysts and other additives during silicon production. The main inorganic compounds present in the wastewater are copper and zinc. To minimise the concentration of copper and zinc in the effluent, the wastewater from PDMS production can be treated in two

³³ Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197. <u>EU</u> Ecolabel - Personal and animal care products (europa.eu)

steps: a pre-treatment by precipitation/flocculation, and a sedimentation step to remove heavy metals.

The production of silicones is related to significant amounts of energy; therefore, GHG emissions are one of the most important sustainability parameters. This requirement (O39) thus aims at reducing the emissions of CO_2 occurring during the production of the raw material (silicone). CO_{2e} emissions related to electricity are calculated by factor 210 g CO_2/kWh . However, if the greenhouse gas emission intensity of electricity generation given by European Environment Agency indicates a higher emission calculation factor for the country in which the manufacturing is located, this shall be used. The factor of 210 g CO_2/kWh is based on Greenhouse gas emission intensity of electricity generation in Europe³⁴.

5.7 Manufacturing of the final product

Requirements in this chapter apply to the final product assembly site, concerning both disposables and reusable products.

O40 Material efficiency

The quantity of waste generated during the manufacturing and packaging of the final products which is sent to landfill or incineration without energy recovery, shall not exceed:

- a) 8% by weight for tampons; 4% by weight for all the other sanitary products.
- b) 4% by weight of the reusable menstrual cup.

The quantity of waste sent to landfill or to incineration without energy recovery shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc.). The final product and packaging are included in the calculation.

 Compliance with the above requirement by declaring quantity of waste not reused, recycled or going to the energy recovery, including

- the weight of the product and of the packaging
- all the waste streams generated during the manufacturing, and

- the respective treatment processing of the fraction of recovered waste and that disposed of to landfill or incineration.

Duly completed and signed Appendix 1, form 19, can be used.

Background to the requirements O42 Material efficiency

Requirement for material efficiency is new in the criteria. The main objective of this requirement is to limit the amount of waste that is sent to landfill or incineration from the final product manufacturing assembly site. The waste recovered for reuse, recycling or energy production is not targeted by this requirement.

In line with the Circular Economy Action Plan 2020, the design and production phases are among the key drivers to achieve circular economy objectives and

³⁴ https://www.eea.europa.eu/en/analysis/indicators/greenhouse-gas-emission-intensity-of-1

ensure that the resources used are kept within the EU economy for as long as possible. In line with this, the threshold for waste generated during the manufacturing and packaging of the products which is sent to landfill or incineration was set at 8 % w/w for tampons and 4 % w/w for all the other products. This quantity of waste, sent to landfill or incineration, shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc.) As incineration with energy recovery is preferable to simple landfilling, it is only incineration without energy recovery that is targeted by this requirement. For more information see closely EU Ecolabel's Technical Report³⁵.

5.8 Product requirements

O41 Synthetic polymers used in single-use products

For sanitary products, the following apply

- a) For children's diapers, incontinence care products, sanitary towels (pads and panty-liners), a minimum of 10% of the polymers in relation to the total weight of polymers in the product and additional component (S+A), must be bio-based and/or recycled.
- b) Wipes, wash cloths and tampons including applicator must not be based on fossil raw materials and must be plastic free.
- c) Manufacturing facilities producing plastic components and superabsorbent polymers (SAP) that represent > 5 w% of the product and additional component (S+A) must
 - Undergo energy audit and have an action plan (EN 16247 and action plan) or have an ISO 50001 certification or have an ISO 140001 certification together with section 6.3 in 50001.
 - Submit data on energy consumption* kWh/kg component.

Energy used in production processes specific to component/SAP manufacturing (e.g. for nonwoven formation, bonding, and finishing treatments) is calculated per kilogram of finished component material/SAP. The calculation encompasses all production activities within the manufacturing site boundaries and includes both electrical and thermal energy consumption.

- Parts a-b, the sanitary product manufacturer shall demonstrate compliance with the requirement by enclosing a product description.
- Part c, the component manufacturer must submit
 - ISO 50001 certificate or ISO 14001 certificate together with section 6.3 ISO 50001 or proof of an energy audit (according to EN 16247) together with an action plan.
 - $\circ~$ the energy consumption kWh/kg component (e.g. SAP, Plastic film or nonwoven).

³⁵ Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197. <u>EU</u> <u>Ecolabel - Personal and animal care products (europa.eu)</u>

Background to O41 Synthetic polymers used in single-use products

This is a new requirement set to promote plastic with lower environmental impact in single-use sanitary products.

For children's diapers, incontinence care products, sanitary towels (pads and panty-liners), which contain a high share of fossil-based polymers, a minimum of 10% of the polymers in relation to the total weight of polymers in the product and additional component (S+A), must be bio-based and/or recycled. This encourages a gradual shift from virgin fossil-based materials, balancing environmental ambition with what is practical and achievable in the market.

For wipes, wash cloths and tampons including applicator, where plastic film or components are not essential, these products must not be based on fossil raw materials and must be plastic free. This will exclude e.g. airlaid wipes with fossilbased binders, polyurethane foam wipes and tampons carrying the "death turtle" label under the Single-Use Plastics (SUP) Directive. This requirement does not apply to product types where plastic film is needed for functionality such as cover sheets, breast pads, patient and surgical gowns.

For manufacturing facilities producing plastic components and superabsorbent polymers (SAP) that represent > 5 w% of the product and additional component (S+A), they must have energy saving actions in place, either through energy audit with an action plan or with ISO certifications. To improve transparency, the manufacturer is to submit energy consumption data (kWh/kg component). The requirement is set to promote energy efficiency at the manufacturing site.

O42 Impurities in the final product

For the product types children's diapers, incontinence care products, sanitary towels (pads and panty-liners) and tampons the following requirement must be fulfilled:

- The final product shall be tested for impurities according to the Table 2 specified in Appendix 2.
- The applicant shall submit an analysis report or demonstrate compliance with the EDANA Stewardship Programme together with test results for total fluorine or be Oeko-tex Standard 100 certified.

Background to O42 Impurities in the final product

The requirement for impurities in the final product is new. Concerns have been raised about hazardous chemicals in sanitary products, such as those highlighted in the ANSES opinion from 2018³⁶. However, no health risks have been demonstrated^{37,38}. To enhance transparency regarding trace substances, EDANA introduced a voluntary Stewardship Programme³⁹, which identifies and sets

chemical-substances-in-feminine-hygiene-products.pdf

³⁶ ANSES Opinion on the safety of feminine hygiene products, Request No 2016-SA-0108. <u>https://www.anses.fr/en/system/files/CONSO2016SA0108EN.pdf</u>

³⁷ Committee for Risk Assessment (RAC) Opinion on an Annex XV dossier proposing restrictions on Substances in single-use baby diapers

https://echa.europa.eu/documents/10162/c374b7bb-b0e2-e01f-d55d-398dc270343f

³⁸ Kemikalieinspektionen, 2018. Survey of hazardous chemical substances in feminine hygiene products A study within the government assignment on mapping hazardous chemical substances 2017–2020. https://www.kemi.se/download/18.6df1d3df171c243fb2331064/1589120703821/report-8-18- survey-of-hazardous-

³⁹ https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products

Nordic Ecolabelling Consultation document

limits for trace substances that may be present in absorbent hygiene products. These substances include PAHs, DL-PCBs, dioxins, furans, phthalates, formaldehyde, heavy metals, pesticides, organotins and phenols. Companies participating in the program commit to ensuring that impurity levels do not exceed the established limits.

The proposed new requirement aligns with EDANA's recommendations while introducing an additional limit for total fluorine. Although the use of PFAS chemicals is already restricted (e.g. in the prohibited substance list O9), this limit has been added due to the persistence and widespread of these substances. Fluorinated chemicals can be used e.g. as lubricants in polymer processing industry⁴⁰.

The applicant can demonstrate compliance by either submitting a test report or demonstrate compliance with the EDANA Stewardship Programme, together with a separate test result for total fluorine. The applicant can also document the requirement by certifying the product under Oeko-tex Standard 100⁴¹. Oeko-tex standard 100 list of substances exceeds the one for EDANA, such as the inclusion of total fluorine but also lack some of the substances DL-PCBs, dioxins, furans which is connected to raw material contamination. Dioxins and furans can also be formed during chlorinated bleaching of cellulose.

O43 Performance

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The performance/quality of the final product must be satisfactory and must match that of equivalent products on the market.

In the case of products where an acknowledged test exists, this test must be used. The test may be a laboratory test, the applicant's internal quality test, a consumer test or a comparative test with an equivalent product.

In the case of diapers, sanitary products (sanitary towels and panty-liners), incontinence care products and breast pads, the performance test must as a minimum include absorption capacity and rewet under pressure (dryness on the outside).

In the case of tampons, the performance test must as a minimum encompass absorption capacity.

In the case of menstrual cups, both a consumer test and a performance test are required. The performance test must as a minimum include biocompatibility test, in accordance to ISO 10993 series or the USP Class VI standard.

If a consumer test is performed, a minimum of 10 users must be included and the users must be satisfied with the product. Documentation (test report or user report) of the performance of the product including, where applicable, tests of absorption capacity and rewet under pressure. The chosen test must be described and data attached.

⁴⁰The Danish Environmental Protection Agency, 2024. PFAS and fluorine-free alternatives in lubricants and construction products. <u>PFAS and fluorine-free alternatives in lubricants and construction products - use, emissions and socioeconomic analysis of a Reach-restriction</u>

⁴¹ https://www.oeko-tex.com/importedmedia/downloadfiles/OEKO-TEX_STANDARD_100_Standard_EN_DE.pdf

Background to O43 Performance

The requirement remains unchanged except that menstrual cups have been included in the requirement. In the case of menstrual cups, the performance test must as a minimum include biocompatibility test, in accordance to ISO 10993 series. No relevant biological effects in the studies performed for cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days) as indicated by ISO 10993 shall be detected. Alternatively, compliance with USP Class VI standard (acute systemic toxicity, intracutaneous toxicity and implantation test) can be reported. Technical tests shall be conducted for the material(s) used for the manufacturing of reusable menstrual cups.

It is in the interest of both licensees and Nordic Ecolabelling that Nordic Swan Ecolabelled products should have satisfactory performance characteristics.

Standard performance tests do not exist for most types of sanitary products. Manufacturers may accordingly use their own modified tests for children's diapers, sanitary towels, breast pads and other sanitary products. In other words, there is a certain degree of freedom in relation to documentation.

In its criteria for absorbent hygiene products from 2023, the EU Ecolabel has similar requirements but has specified testing practices required. These relate to absorption ability and protection against leakage e.g. for diapers and tampons, plus a skin dryness test using the TEWL method for baby diapers and feminine care pads, see closely Criterion 10. Fitness for use and quality of the product in EU Ecolabel⁴².

O44 Tampons

Tampons may as a maximum contain 1,000 aerobic microorganisms per gram of product.

Description of the test for aerobic microorganisms and a statement on the test results from the sanitary product manufacturer.

Background to O44 Tampons

The requirement has not been changed in the revision and has a limitation in relation to the content of aerobic microorganisms per gram of product. This requirement is set by hygienic reasons.

O45 Menstrual cups

The product shall be accompanied by instruction for its use. The manufacturer shall make sure that the user receives at least the following information:

- a) How to choose the right size of cup. Such information shall be placed where it can be accessed by the user before purchase (e.g. on the primary packaging).
- b) How to correctly wear the cup to avoid leakage and/or discomfort.
- c) How long to wear the cup before emptying it. Information on the longest wearing time shall be backed up by test studies. This information shall be given in a visible way, e.g. via a logo or in bold characters, and shall be placed both on the packaging and on the instructions for use.

⁴² Decision - 2023/1809 - EN - EUR-Lex (europa.eu)

- d) How to clean the cup before and after use during the same menstrual period, including, as a minimum, information about the importance of washing the hands, the need for boiling (yes/no, and if yes for how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. This information should be backed up by test studies.
- e) How to clean and store the cup between menstrual periods, including, as a minimum, information about the importance of washing the hands, the importance of boiling (and information on how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. This information should be backed up by test studies.
- f) How long it is possible to use the cup (the lifetime of the cup). It should moreover be stated that eventual discolouring of the cup has no influence on its lifetime and function.
- g) Information about the risk of developing toxic shock syndrome shall be provided.
- The applicant shall provide a sample of the information sheet and, if relevant, the packaging sold with the cup displaying the information for the user. The applicant shall also provide relevant tests/studies, e.g. biological risk assessments or toxicology studies, supporting the above requirements.

Background to O45 Menstrual cups

The requirement for information for the user regarding menstrual cups is new in the criteria. The manufacturer shall make sure that the user receives basic instructions how to user the product. The use phase of the menstrual cup is the most relevant life cycle phase, accounting for 96-99% of the impacts, depending on the impact category⁴³. While Ecolabel cannot set requirements to limit the impacts during the use phase, as the behaviour of the user is out of control, it is possible to make sure that the users receive the relevant information needed to correctly use the products. More information about the requirement can be found from the EU Ecolabel's Technical Report⁴⁴.

O46 Information on the sales packaging

Copy of the information on the sales packaging (artwork) for all the relevant languages must be submitted.

The absorption ability must be specified on the packaging in the case of product types where this is relevant. For diapers, sanitary products (sanitary towels and panty-liners), tampons and incontinence care products, for example, this information can be provided by means of clear details of the size (e.g. the weight of the child in kilos or pictograms/values indicating the absorption capacity of the product).

In the case of relevant products, consumers must be urged not to discard them down the toilet. This information can be stated using a pictogram. Relevant

⁴³ Sinkko T. Screening LCA study : Reusable Menstrual Cup in Europe. <u>https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2022-06/LCA%20screening%20study%20RMC_April%202022.pdf</u>

⁴⁴ Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197. <u>EU</u> Ecolabel - Personal and animal care products (europa.eu)

products include diapers, sanitary towels, panty-liners, tampons, cotton buds and reusable menstrual cups etc.

술 Sample of the packaging information.

Background to O46 Information on the sales packaging

The requirement concerning the information text on the products remains unchanged from the previous version of the criteria, except that reusable menstrual cups have been included.

The requirement concerning information that the products must not be discarded down the toilet applies to products such as cotton buds, diapers, sanitary towels, panty-liners, tampons and menstrual cups. Cotton buds get caught in the mechanical filters of wastewater treatment plants, creating problems. Disposal of sanitary products down the toilet causes blockages and build-ups in sewage pipes in many municipalities which, in turn, can lead to basement flooding and the discharge of pollutants into nature. Such information is not relevant to other, larger, products such as bed linen.

The other requirements applicable to the information text, such as the disclosure of information on the absorption of the relevant products and the specification of the size of the product are unchanged. This information is important to consumers, because they want products that perform satisfactorily from first use. The parameters that are of interest to consumers are the purpose of the product, if applicable the age or size of the consumer (this applies in particular to children's diapers) and the time at which the product is to be used.

5.9 Licence maintenance

The purpose of the licence maintenance is to ensure that fundamental quality assurance is dealt with appropriately.

O47 Customer complaints

The licensee must guarantee that the quality of the Nordic Swan Ecolabel product or service does not deteriorate during the validity period of the licence. Therefore, the licensee must keep an archive over customer complaints.

Note that the original routine must be in one Nordic language or in English.

알 Upload your company's routine for handling and filing customer complaints.

Background to O47 Customer complaints

Nordic Ecolabelling requires that your company has implemented a customer complaint handling system. To document your company's customer complaint handling, you must upload your company's routine describing these activities. The routine should be dated and signed and will normally be part of your company's quality management system.

If your company does not have a routine for customer complaint handling, it is possible to upload a description of how your company perform these activities. During the on-site visit, Nordic Ecolabelling will check that the customer complaint handling is implemented in your company as described. The customer complaints archive will also be checked during the visit.

O48 Traceability

Nordic Ecolabelling

Consultation document

The licensee must be able to trace the Nordic Swan Ecolabel products in the production. A manufactured / sold product should be able to trace back to the occasion (time and date) and the location (specific factory) and, in relevant cases, also which machine / production line where it was produced. In addition, it should be possible to connect the product with the actual raw material used.

You can upload your company's routine or a description of the actions to ensure traceability in your company.

Background to O48 Traceability

Nordic Ecolabelling requires that your company has implemented a traceability system. To document your company's product traceability, you must upload your company's routine describing these activities. The routine should be dated and signed and will normally be part of your company's quality management system.

If your company does not have a routine for product traceability, it is possible to upload a description of how your company perform these activities. During the on-site visit, Nordic Ecolabelling will check that the product traceability is implemented in your company as described.

6 Environmental impact of the sanitary products

Single-use versus reusable sanitary products

The Nordic Swan Ecolabel aims to reduce unnecessary consumption of disposable products. While sanitary products are typically single-use and currently cannot be recycled⁴⁵, alternative reusable options are emerging on the market, such as cloth baby diapers, menstrual cups, cloth pads and hybrid products combining both reusable and disposable parts.

Regarding environmental impact of single use versus reusable products, a comparative LCA study of disposable and reusable baby diapers showed that while disposable options obtain their highest environmental impact primarily during production and consumption of raw materials, reusable diapers' impacts are influenced more by use stage. Consumer behaviour including e.g. the choice of washing temperature and the energy efficiency of the washing machines significantly affect the environmental footprint of reusable diapers. Optimised reusable systems, which minimise energy and water consumption, tend to have lower environmental impact than single-use options⁴⁶.

In the evaluation of the generation 6 of the criteria, an analysis was conducted to determine whether disposable sanitary product should continue to be Nordic Swan Ecolabelled or if Nordic Ecolabelling should promote reusable products instead. The evaluation, based on Nordic Ecolabelling principles for disposables, concluded that disposable products should continue to be Nordic Swan

⁴⁵ Wegwerpluiers en incontinentiemateriaal (vlaanderen.be)

⁴⁶ Hoffmann, B. S., Morais, J. de S. and Fonseca Teodoro, P., 'Life cycle assessment of innovative circular business models for modern cloth diapers', Journal of Cleaner Production, Vol. 249, No 10, Elsevier, 2020, pp. 119364. https://doi.org/10.1016/j.jclepro.2019.119364

Ecolabelled, providing there is clear environmental difference between Nordic Swan Ecolabel products contra similar non-ecolabelled products in the market.

Secondly, Nordic Swan Ecolabel cannot control consumer choices such as whether consumers and purchasers choose disposable or reusable products, or how these products are used and disposed in the end-of life. Therefore, there remains a considerable potential for improving disposable products by maintaining the ecolabel and enforcing requirements for the raw materials phase. Disposable products are commonly used today and needed due to different user experiences. In addition, health related issues, have high awareness among consumers such as e.g. diapers that are close to the babies' skin. Labels on the products are needed and appreciated.

Regarding reusable alternatives, Nordic Ecolabelling has decided to expand the Criteria for Sanitary Products to include reusable menstrual cups made of silicone and other elastomers. Other reusables, such as wash cloths, cloth baby diapers and cloth pads are not covered under these criteria but can be Nordic Swan Ecolabelled under Nordic Ecolabelling criteria for textiles.

RPS for single-used products

The relevant environmental impacts found in the life cycle of sanitary products are set out in a MECO scheme (below). A MECO describes the key areas that have impact on the environment and health throughout the life cycle of the product – including consumption of materials/resources (M), energy (E), chemicals (C) and other impact areas (O). Nordic Ecolabelling establish criteria focusing on areas of the life cycle that have a high environmental impact – also called hotspots. An RPS tool is used to identify where ecolabelling can apply the greatest influence. In this context, R represents the environmental relevance; P is the potential to reduce the environmental impact and S is the steerability on how compliance with a requirement can be documented and followed up.

The criteria contain requirements aiming for areas of the life cycle with high RPS, offering the potential for notable environmental improvements. From a life cycle perspective, the raw materials used in disposable sanitary products have the most significant environmental impact. Key constituent materials that generate the greatest impact are fluff pulp, SAP and nonwovens. Relevant

lifecycle stages are presented in the following table below and are based e.g. for following references^{47,48,49,50,51,52,53,54,55,56}.

https://cdn.dal.ca/content/dam/dalhousie/pdf/science/environmental-science-program/Honours Theses/2015/ThesisWeir.pdf

⁴⁷ Cordella, M, Wolf, O, Schulz, M, Bauer, I, Lehmann, A, Development of EU Ecolabel Criteria for Absorbent Hygiene Products (formerly referred to as "Sanitary Products"). Preliminary Report – Final. European Commission, Joint Research Centre, 2013. Available here

https://doi.org/10.1007/s11367-013-0556-6

⁴⁸ Mirabella, N.; Castellani, V and Sala, S., 'Life cycle assessment of bio-based products: a disposable diaper case study', International Journal of Life Cycle Assessment, Vol. 18, Springer, 2013, pp. 1036–1047.

⁴⁹ Arena, U., Ardolino, F. and Di Gregorio, F., 'Technological, environmental and social aspects of a recycling process of post-consumer absorbent hygiene products', Journal of Cleaner Production, Vol. 127, Elsevier, 2016, pp. 289-301. https://doi.org/10.1016/j.jclepro.2016.03.164

⁵⁰ Mendoza, J. M. F., Popa, S. A., D'Aponte, F., Gualtieri, D., Azapagic, A., 'Improving resource efficiency and environmental impacts through novel design and manufacturing of disposable baby diapers', Journal of Cleaner Production, Vol. 210, Elsevier, 2019, pp. 916-928. https://doi.org/10.1016/j.jclepro.2018.11.046

⁵¹ Cordella, M., Wolf, O., Schulz, M., Bauer, I., Lehmann, A., 'Evolution of disposable baby diapers in Europe: life cycle assessment of environmental impacts and identification of key areas of improvement', Journal of Cleaner Production, Vol. 95, Elsevier, 2015, pp.322-331. https://doi.org/10.1016/j.jclepro.2015.02.040

Khoo, S. C., Phang, X. Y., Ng, C. M., Lim, K. L., Lam, S. S. and Ma, N. L., 'Recent technologies for treatment and recycling of used

disposable baby diapers', Process Safety and Environmental Protection, Vol. 123, Elsevier, 2019, pp. 116-129. https://doi.org/10.1016/j.psep.2018.12.016

⁵² Khoo, S. C., Phang, X. Y., Ng, C. M., Lim, K. L., Lam, S. S. and Ma, N. L., 'Recent technologies for treatment and recycling of used disposable baby diapers', Process Safety and Environmental Protection, Vol. 123, Elsevier, 2019, pp. 116-129. https://doi.org/10.1016/j.psep.2018.12.016

⁵³ Mazgaj, M., Yaramenka, K. and Malovana, O., 'Comparative Life Cycle Assessment of Sanitary Pads and Tampons', 2006, GROUP 6, Royal Institute of Technology Stockholm. 22 Weir, C. S., In The Red: A private economic cost and qualitative analysis of environmental and health implications for five menstrual products. Master Thesis, Dalhousie University, 2015. Available at:

⁵⁴ Hait, A. and Powers, S. E., 'The value of reusable feminine hygiene products evaluated by comparative environmental life cycle assessment', Resources Conservation and Recycling, Vol. 150, Elsevier, 2019, pp. 104422. https://doi.org/10.1016/j.resconrec.2019.104422

⁵⁵ UNEP, 2021. Notten, P., Gower, A., Lewis, Y. Single-use menstrual products and their alternatives: Recommendations from Life Cycle Assessments. United Nations Environment Programme (UNEP), 2021. Available here (accessed 26/08/2021)

⁵⁶ Sinkko T., Tosches D., Pérez-Camacho M.N., Faraca G. (2022). Screening LCA study: Absorbent Hygiene Products in Europe (Updated April 2022). Available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2022-06/LCA%20screening%20study%20on%20AHP_update%20April%202022.pdf

Lifecycle stages	Area and assessment of R, P, S (high, medium or low)	Comments					
Raw materials							
	Wood based raw materials R: High P: High S: High	Wood-based raw materials used in sanitary products have a high RPS. While wood can be directly used as such in cotton buds, it serves as the main raw material for fluff pulps and regenerate cellulose. From an environmental point of view, it would be relevant to promote use of recycled fibres but as sanitary products are high quality products close to the skin, safety and quality aspects are of high priority. Recycled fibres may contain unknown substances and be polluted with substances that should not be present in the products. Therefore, only virgin wood fibres shall be used in Nordic Swan Ecolabel (NSE) sanitary products. In addition to the sanitary products, wood fibres can be used as raw material in cardboard packaging.					
		When virgin fibres are used, forestry operations can have a marked impact on forest life through e.g. loss of species and deterioration of ecosystems. There is high RPS to set requirements for origin and certification of fibre raw materials by using independent third-party certifications schemes such as FSC and PEFC. This is to ensure that fibres come from controlled sources and sustainably managed forests. Nordic Swan Ecolabel also set requirements for restricted tree species, to protect the forest as a habitat and preserve biodiversity. Regarding wood fibres in fluff pulps, regenerated cellulose and paper-based products, there are several key areas of environmental impact such as energy consumption, chemical use, emissions to water and air, and forestry practices.					
	Manufacturing – pulps R: High P: High S: High Manufacturing – paper	Production of pulp is energy intensive and generate emissions to water and air. Therefore, NSE sets requirements on fuel and electricity use, emissions of sulphur (S), NOx and greenhouse gases to air. Emissions to water such as chemical oxygen demand (COD), phosphorus (P) and adsorbable organically bound halogens (AOX) are also restricted. By setting requirements for these, Nordic Ecolabelling contributes to reduced climate impact, reduced acidification of the atmosphere and eutrophication of water sources.					
	R: High P: High S: High	Paper manufacturing is highly energy intensive. The generation and use of energy results in various environmental impact, see the pulp production above. It is, thus, highly important to focus on energy consumption when trying to reduce the environmental impact of the paper.					
	Polymers R: High P: Medium S: Medium	Plastic is extensively used in sanitary products and its production is energy and resource intensive. To reduce the impact, incorporating recycled plastic can reduce the climate impact compared to virgin plastic. However, recycled fibres may contain unknown substances and be polluted with substances that should not be present in sanitary products. Use of recycled plastic is allowed in the NSE sanitary product. but if it is used then it must meet the requirements for recycled plastics in contact with food. Recycled plastics can also be used in sales packaging to promote circular economy.					
		Fossil-based polymers , such as super absorbents (SAP) and polypropylene in nonwovens have a significant impact on global warming potential (GWP). There is considerable relevance in setting requirements concerning these constituent materials. However, the potential and steerability are low due to lack of site-specific data.					
		Bio-based polymers can be used instead of fossil-based polymers. Renewable materials contribute to sustainable development through reduced CO ₂ emissions and reduced use of materials from fossil sources. However, materials based on renewable raw materials are not automatically sustainable. There are several key problems concerning the cultivation and production of the renewable materials, such as land use in competition with food production, use of genetically modified organisms and energy and chemical use in the processes. Nordic Ecolabelling wishes to contribute to the "green shift" through increased use of bio-based materials but only if the environmental impact is lower than in the similar fossil-based polymers. In addition to the products, plastic can be used in the packaging.					
Chemicals harmful to health and environment R: High P: High S: High In manufacturing of raw materials, chemicals are used. Some chemicals may e.g. be activicing equirements for chemicals used in manufacturing of raw materials in order to reduce the use of harmful chemicals and to ensure that consumers are not exposed to these in the use stage. Manufacturing of sanitary product R: Low Production/distribution R Manufacturing of sanitary product R: Low Assembly of the final sanitary product requires mainly electricity. Some chemicals such as adhesives may also be used. R: Low Production/distribution S: Medium Assembly of the final sanitary product can be reduced through the manufacturers focus on a reduction in the weight of the product. and on optimizing the material composition of the products. The latter area is in here product composition can change the function or other properties of the product which comsumers appreciate. As main environmental impact comes from raw materials used, here are no requirements set for manufacturing of the final product. Quantity of wasts sen to landfill or incineration without energy recovery is limited. Regarding chemicals, see also chemicals in use phase below. Use phase Use phase Use phase Quality R: High S: High Given that sanitary products come into close contact with the body and many of R: high P: High S: High Quality R: High S: High Given that sanitary products come into close contact with the body and many of R: high P: High S: High Quality R: High P: High P: High P: High P:		Cotton R: High P: High S: High	A high RPS has been found for requiring 100% organic cotton for sanitary products – either 100% organic or transitioning to organic cultivation. The cultivation and harvesting of cotton are associated with serious environmental and health problems. This is largely due to the use of pesticides and other chemicals in production, but other factors, such as water consumption, can also have a major impact on the environment. The environmental and social consequences of using genetically modified (GMO) cotton plants in conventional cultivation are also a debated subject. By using organic cotton, GMO and use of harmful chemicals in cultivation can be avoided.				
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Production/distribution Manufacturing of sanitary product R: Low P: Low S: Medium Assembly of the final sanitary product requires mainly electricity. Some chemicals such as adhesives may also be used. The environmental impact of sanitary products can be reduced through the manufacturers focus on a reduction in the weight of the product, and on optimizing the material composition of the products. The latter area is, however, difficult for Nordic Ecolabeling to steer, because even small changes in the product composition can change the function or other properties of the products which consumers appreciate. As main environmental impact comes from raw materials used, there are no requirements set for manufacturing of the final product. Quantity of waste sent to landfill or incineration without energy recovery is limited. Regarding chemicals, see also chemicals in use phase below. Use phase Use phase Chemicals R: High P: High S: High Given that sanitary products come into close contact with the body and many of the products are intended for young children, there is high relevance to set requirements that decrease potential exposure to chemicals harmful to health such as CMR substances, allergenic substances, endocrine disrupting substances etc. in the final product. This is a be achieved by setting strict requirements for chemical products that are used in the production of the ingoing materials and the finaled sanitary product. Chemicals can be bandered subtances like acrylamide, residual monomers and water-soluble extracts in SAP can be either restricted or banned. Steerability is reasonably good as manufacturers are able to impose requirements on their suppliers and choose the best materials within each material type, can be. Quality R: High P: High S: High The large amount of wast		Chemicals harmful to health and environment R: High P: High S: High	In manufacturing of raw materials, chemicals are used. Some chemicals are not readily biodegradable and can bioaccumulate in organisms. Other chemicals may e.g. be carcinogenic and disruptive to endocrine functioning. There is high RPS to set strict requirements for chemicals used in manufacturing of raw materials in order to reduce the use of harmful chemicals and to ensure that consumers are not exposed to these in the use stage.				
Manufacturing of sanitary product Assembly of the final sanitary product requires mainly electricity. Some chemicals such as adhesives may also be used. R: Low The environmental impact of sanitary products: can be reduced through the manufacturers focus on a reduction in the weight of the product. The latter area is, however, difficult for Nordic Ecolabelling to steer, because even small changes in the product composition can change the function or other properties of the products which consumers appreciate. As main environmental impact of some from raw materials used, there are no requirements set for manufacturing of finalized sanitary product except those for chemicals and material efficiency in the manufacturing of the final product. Quantity of waste sent to landfill or incineration without energy recovery is limited. Regarding chemicals, see also chemicals in use phase below. Use phase Chemicals Given that sanitary products core into close contact with the body and many of the products are intended for young children, there is high relevance to set requirements that decrease potential exposure to chemicals harmful to health such as CMR substances, allergenic substances, endocrine disrupting substances etc. in the final product. This can be achieved by setting strict requirements for chemical products that are used in the products are integrol as manufacturers are able to impose requirements on their substances the best materials within each material type, so that both the raw materials and the product. Quality There is relevance to set requirements for quality of product such as tests for absorption and leakage protection. This is to ensure good quality and that the product fulfils the i			Production/distribution				
Use phase Chemicals Given that sanitary products come into close contact with the body and many of the products are intended for young children, there is high relevance to set requirements that decrease potential exposure to chemicals harmful to health such as CMR substances, allergenic substances, endocrine disrupting substances etc. in the final product. This can be achieved by setting strict requirements for chemical products that are used in the production of the ingoing materials and the finalized sanitary product. Chemicals can be banned such as fragrances and skin care preparations while unwanted substances like acrylamide, residual monomers and water-soluble extracts in SAP can be either restricted or banned. Steerability is reasonably good as manufacturers are able to impose requirements on their suppliers and choose the best materials within each material type, so that both the raw materials and the production conditions are among the best they can be. Quality R: High P: High S: High There is relevance to set requirements for quality of product such as tests for absorption and leakage protection. This is to ensure good quality and that the product fulfils the intended functions. By doing this, unnecessary consumption and production can be decreased. Therefore, requirements are set for the performance of the product. End of life The large amount of waste associated with disposable sanitary products is a major environmental problem. Sanitary products cannot be recycled nor composted due to hygienic reasons. Most of the sanitary products in the Nordic requirements to promote that materials in the product must be recycled is low. Materials in the product R: High P: Low S: Low There is high RPS for requirements stating that the packaging must be recyclable and guidance on the		Manufacturing of sanitary product R: Low P: Low S: Medium	Assembly of the final sanitary product requires mainly electricity. Some chemicals such as adhesives may also be used. The environmental impact of sanitary products can be reduced through the manufacturers focus on a reduction in the weight of the product, and on optimizing the material composition of the products. The latter area is, however, difficult for Nordic Ecolabelling to steer, because even small changes in the product composition can change the function or other properties of the products which consumers appreciate. As main environmental impact comes from raw materials used, there are no requirements set for manufacturing of finalized sanitary product except those for chemicals and material efficiency in the manufacturing of the final product. Quantity of waste sent to landfill or incineration without energy recovery is limited.				
Chemicals Given that sanitary products come into close contact with the body and many of the products are intended for young children, there is high relevance to set requirements that decrease potential exposure to chemicals harmful to health such as CMR substances, allergenic substances, endocrine disrupting substances etc. in the final product. This can be achieved by setting strict requirements for chemical products that are used in the production of the ingoing materials and the finalized sanitary product. Chemicals can be banned such as fragrances and skin care preparations while unwanted substances like acrylamide, residual monomers and water-soluble extracts in SAP can be either restricted or banned. Steerability is reasonably good as manufacturers are able to impose requirements on their suppliers and choose the best materials within each material type, so that both the raw materials and the production conditions are among the best they can be. Quality There is relevance to set requirements for quality of product such as tests for absorption and leakage protection. This is to ensure good quality and that the product fulfils the intended functions. By doing this, unnecessary consumption and production can be decreased. Therefore, requirements are set for the performance of the product. End of life The large amount of waste associated with disposable sanitary products is a major environmental problem. Sanitary products in the Nordic region are sent for incineration after use. Consequently, the RPS for requirements to promote that materials in the product must be recycled is low. Materials in the packaging R: High P: High P: High There is high RPS for requirements stating that the packaging must be recyclable and guidance on the disposal of it. See also materials above.			Regarding chemicals, see also chemicals in use phase below. Use phase				
Chemicals Given that sanitary products come into close contact with the body and many of the products are intended for young children, there is high relevance to set requirements that decrease potential exposure to chemicals harmful to health such as CMR substances, allergenic substances, endocrine disrupting substances etc. in the final product. S: High Si High S: High Si consected. Quality This can be achieved by setting strict requirements for chemical products that are used in the production of the ingoing materials and the finalized sanitary product. Chemicals can be banned such as fragrances and skin care preparations while unwanted substances like acrylamide, residual monomers and water-soluble extracts in SAP can be either restricted or banned. Steerability is reasonably good as manufacturers are able to impose requirements on their suppliers and choose the best materials within each material type, so that both the raw materials and the production conditions are among the best they can be. Quality There is relevance to set requirements for quality of product such as tests for absorption and leakage protection. This is to ensure good quality and that the production can be decreased. Therefore, requirements are set for the performance of the product. End of life Materials in the product on condition after use. Consequently, the RPS for requirements or products in the Nordic region are sent for incineration after use. Consequently, the RPS for requirements to promote that materials above. Naterials in the packaging R: High There is high RPS for requirements stating that the packaging must be recycled is low. Naterials in the packaging R: H							
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End of life Materials in the product The large amount of waste associated with disposable sanitary products is a major environmental problem. Sanitary products cannot be recycled nor composted due to hygienic reasons. Most of the sanitary products in the Nordic region are sent for incineration after use. Consequently, the RPS for requirements to promote that materials in the product must be recycled is low. Materials in the packaging There is high RPS for requirements stating that the packaging must be recyclable and guidance on the disposal of it. See also materials above.		Quality R: High P: High S: High	There is relevance to set requirements for quality of product such as tests for absorption and leakage protection. This is to ensure good quality and that the product fulfils the intended functions. By doing this, unnecessary consumption and production can be decreased. Therefore, requirements are set for the performance of the product.				
Materials in the productThe large amount of waste associated with disposable sanitary products is a major environmental problem. Sanitary products cannot be recycled nor composted due to hygienic reasons. Most of the sanitary products in the Nordic region are sent for incineration after use. Consequently, the RPS for requirements to promote that materials in the product must be recycled is low.Materials in the packaging R: High P: HighThere is high RPS for requirements stating that the packaging must be recyclable and guidance on the disposal of it. See also materials above.	End of life						
		Materials in the product R: High P: Low S: Low Materials in the packaging R: High P: High	The large amount of waste associated with disposable sanitary products is a major environmental problem. Sanitary products cannot be recycled nor composted due to hygienic reasons. Most of the sanitary products in the Nordic region are sent for incineration after use. Consequently, the RPS for requirements to promote that materials in the product must be recycled is low. There is high RPS for requirements stating that the packaging must be recyclable and guidance on the disposal of it. See also materials above.				

	Raw material	Production	Use	End of life
Material	Pulp, fluff pulp and regenerated cellulose - Sustainable managed forests, FSC/PEFC Cotton - Organic (fertilisers, pesticides) Fossil based synthetic polymers/plastic – SAP, PE, PP, PET Biobased plastic Recycled fibres not allowed except recycled plastic. Materials for packaging PE virgin and recycled, corrugated board. Water uses for all raw materials.	Choice of ingoing materials (weight, composition). Material efficiency and recycling of waste possible.	Product used close to skin.	Product disposed of after use, cannot be recycled or composted. Products either go to incineration or landfill (Eurostat). Handling of manufacturing and packaging waste Packaging could be recycled.
Energy	Pulp, fluff pulp – Fossil/biofuel, and internal produced electricity Regenerated cellulose, Cotton, fossil based synthetic polymers –fossil/biobased fuel and electricity	Electricity for assembling the product. Transport of products.	Transport of products for consumers/ professional use	Energy recovery from incineration of products. Landfill should be avoided. Transport of waste.
Chemicals	Pulp, fluff pulp – pulp processing chemicals, bleaching agents. Emissions to water (COD, AOX, P) and to air (NOx, CO ₂ , S) Regenerated cellulose – emission to water (COD, AOX, Zn, SO ₄) and air (S) Cotton and other plants – Pesticides SAP – emissions of HCI and HF Polyurethane (PUR)/Elastane emission of diisocyanate, DMAc	Adhesives, printing inks, Wetness indicator	Potential exposure to chemicals harmful to health. Acrylamide, residual monomers, water soluble extracts – SAP Formaldehyde – Adhesive D4, D5, D6 – Silicones Heavy metals – Print inks VOC, PAHs, PCDD, dioxins, furans, pigments, antibacterial agents Ban on fragrances and skin care preparations.	Potential exposure to chemicals to environment
Other	Sustainable sourced raw materials to maintain biodiversity and protect natural areas. Social and ethical challenges associated with working conditions outside of EU.		Good performance to reduce the number of products used and avoid unnecessary consumption	

MECO scheme for single used sanitary products:

RPS for reusable menstrual cups

Nordic Ecolabelling has decided to expand the Criteria for Sanitary Products, gen 7 to include reusable menstrual cups made of silicone and other elastomers, as they fulfil the same function as disposable options. The reusable menstrual cup has been reported to have substantially lower environmental impacts than the single-use menstrual products. This was shown to be the case across all impact categories and regardless of the material from which the menstrual cup was produced. Relevant lifecycle stages are presented in the following table and are based for following references 57,58,59,60,61,62,63. MECO scheme is not presented here but the reader is referred to have a closer look on LCA study⁶⁴, introduced during the revision of EU Ecolabel criteria.

Lifecycle stages	Area and assessment of R, P, S (high, medium or low)	Comments
		Raw materials
	Silicones R: High P: High S: High Thermoplastic elastomer R: High P: Medium S: Medium	Reusable menstrual cups can be made out of various materials, where medical- grade silicon and thermoplastic elastomer (TPE), are the most demanded types due to their hypoallergenic properties. <u>Silicones</u> There is high RPS to set requirements for silicones. When excluding the use phase which has the biggest environmental impact in the LCA analysis of silicone menstrual cups, and analysing only the other life cycle phases, the production of silicone contributes to 29% of the environmental impacts in terms of climate change. The production of silicones is related to significant amounts of energy; therefore, GHG emissions are one of the most important sustainability parameters. The other main environmental issues associated with the production of silicones are dust and chlorides emissions to air, as well as emission of copper and zinc to water. <u>Thermoplastic elastomers (TPE)</u> Being a type of elastomer, the production process of the raw material can be assumed to be roughly similar. Potential and steerability are, however, lower due to the lack of information. Requirements can, however, be set to emissions of dust and of chlorides to air.
	Wood raw materials in packaging R: High P: High S: High Plastic in packaging R: High P: High S: High	Menstrual cups are usually packed in a bag/pouch, placed in a box made of cardboard/paper or plastic, which constitutes the sales packaging. There is high RPS to set requirements for traceability of wood fibres. See also wood raw materials in the disposable sanitary products above. There is high RPS to set requirements for recycled plastic in the packaging in line with circular economy.
	Cotton	Most menstrual cups are sold within a cloth bag or pouch made of textile, usually cotton, that is considered an additional component and is used to store the cup when

⁵⁷ Weir, C. S., In The Red: A private economic cost and qualitative analysis of environmental and health implications for five menstrual products. Master Thesis, Dalhousie University, 2015. Available at:

Recommendations from Life Cycle Assessments. https://www.lifecycleinitiative.org/wp-content/uploads/2021/07/UNEP-LCI-Single-use-vs-reusable-Menstrual-

2022. https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2022-

https://cdn.dal.ca/content/dam/dalhousie/pdf/science/environmental-science-program/Honours Theses/2015/ThesisWeir.pdf

⁵⁸ Leroy, Y., Yannou, B., Murthy, L., Lallmahomed, A. and Yannou-Le Bris, G., Which hygienic products for which continent? Design for usage and sustainability', Proceedings of International Design Conference, DS 84, DESIGN, 2016, pp. 311-320.

⁵⁹ Hait, A. and Powers, S. E., 'The value of reusable feminine hygiene products evaluated by comparative environmental life cycle assessment', Resources Conservation and Recycling, Vol. 150, Elsevier, 2019, pp.104422. ⁶⁰ United Nations Environment Programme (2021). Single-use menstrual products and their alternatives:

Products-Meta-study.pdf ⁶¹ Sinkko, T., Screening LCA: Reusable Menstrual Cup in Europe, EUR (where available), European Commission, Ispra,

^{06/}LCA%20screening%20study%20RMC_April%202022.pdf ⁶² Vilabrille Paz, C., Ciroth, A., Mitra, A., Birnbach, M. and Wunsch, N. (2020) Comparative Life cycle assessment of menstrual products. GreenDelta GmbH, commissioned by einhorn products GmbH

https://einhorn.my/wp-content/uploads/2022/03/Comparative-Life-Cycle-Assessment-of-Menstrual-Products.pdf ⁶³ JRC Publications Repository - Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products) (europa.eu)

⁶⁴ Sinkko, T., Screening LCA: Reusable Menstrual Cup in Europe, EUR (where available), European Commission, Ispra

D. Lliab	not in use. See cleachy action in the dispersable conitary products above
к. підп	not in use. See closely couldn'in the disposable samilary products above.
P: High	Requirements for cotton bags are not set in the first generation of the criteria due to
S: Low	low steerability but shall be considered in the next revision.
<u></u>	
Chemicals harmful	Menstrual cups are not considered as medical devices and do not fall under the
to health and	Medical Device Regulation (Regulation (EU) 2017/745). As a
environment	result, they are not required to be manufactured from medical grade materials.
R: Hiah	Instead, it is, for example common to see menstrual cups made of food grade
D. High	silicone
г. ніўн	In manufacturing, additives are used. Some chemicals are not readily high-gradeble
S: High	In manufacturing, additives are used. Some chemicals are not readily biodegradable
	and can bloaccumulate in organisms. Other chemicals may e.g. be carcinogenic and
	disruptive to endocrine functioning. There is high RPS to set strict requirements for
	chemicals used in manufacturing of raw materials in order to reduce the use of
	harmful chemicals and to ensure that consumers are not exposed to these in the use
	phase.
	Production/distribution
 Manufacturing of	During the production of menstrual cups, the majority of environmental burdens are
menstrual cup	associated with a demand for energy usually electricity used for the moulding of the
D. Madium	cups. However, the potential for setting requirement is considered limited due to the
R: Mealum	lack of information on the consumption of energy per unit of product
P: Medium	ack of mornation of the consumption of energy per unit of product.
S: Medium	As main environmental impact comes from raw materials used (apart from use
	phase), there are no other requirements set for manufacturing of finalized menstrual
	cup except those regarding material efficiency in the manufacturing and additives,
	see the chemicals in use phase.
	Use phase
	According to the LCA analysis, the use phase is the meet relevant life evals phase
Use	According to the LCA analysis, the use phase is the most relevant life cycle phase,
R: High	accounting for 90-99% of the environmental impacts, depending on the impact
P: Low	category. Electricity required to boil the water to sternise the cup, soap production
S: Low	
	Possibilities for NSE to set requirements for use phase are limited. It is, however,
Chamieala	possible to make sure that the consumers receive the relevant information needed to
Chemicals	correctly use the menstrual cups, by setting requirement for information on the use of
R: High	the product.
P: High	Given that menstrual cups come into close contact with the body, there is high
S [.] High	relevance to set requirements for additives used in products. See closely use phase
	chemicals in the disposable sanitary products above.
Quality	There is relevance to set requirements for quality of product such as leakage
Dulliah	protection. This is to ensure good quality and that the product such as leakage
R. High	functions. By doing this unnecessary consumption and production can be
P: High	decreased. Therefore, requirements are set for the performance of the product
S: High	
	End of life
Materials in the	Among the environmental advantages of menstrual cups (compared to single-use
product	ones), waste prevention is one of the biggest factors. It has been estimated that the
R: Low	use of a menstrual cup results in a reduction of 99% of the waste that would be
P [.] Low	generated using single-use products.
Silow	The RPS for setting requirements is, however, rather low at the end of menstrual
J. LOW	cups life except guidance on the correct disposal of the product. Silicone rubber
	cannot be recycled by simple processes today. Thermoplastic elastomer can be
	recycled without problems.
Materials in the	There is high RPS for requirements stating that the packaging must be required
nackaging	and guidance on the disposal of it. See also materials above
packaging	and yuldahoe on the disposal of it. See also fildtellats above.
R: High	
P: High	
S: Medium	

7 Areas that are not subject to requirements

Other materials

There was a requirement O37 for other materials in the previous generation 6: the stick in cotton buds shall not be made of plastic or a blend of plastic and paper. This has now been removed since cotton bud sticks including plastics are covered by Directive EU 2019/904 on the reduction of the impact of certain plastic products on the environment. Cotton bud sticks shall not be placed on the market, except if they fall within the scope of Council Directive 90/385/EEC or Council Directive 93/42/EEC.

Incontinence care products in Performance O43

During revision, it was discussed to include a new requirement for incontinence care products in the requirement for Performance (O43). The aim of the requirement was to promote the effective use of incontinence care products by encouraging measures such as wetness indicators, incontinence care support services such as staff education, or digital monitoring solutions to reduce unnecessary consumption. However, after further evaluation, it was determined that the potential impact of this requirement in achieving the desired outcome was limited. Consequently, the requirement was not included in the Criteria.

8 Changes compared to previous generation

Table 4	Overview of changes to criteria for sanitary products, generation 7 compared with
	previous generation 6.

Proposed Gen. 7	Gen. 6	Same req.	Cha nge	New req.	Comment
				Product a	and packaging
O1 Description of the product	O1	х			Adjusted, no significant changes.
O2 Material composition	02, 013		x		Recycled material and bio-based plastics have been updated and merged to O2. If bio-based plastics is used, superior LCA compared to fossil-based feedstock must be shown. The exemption of requirements for specific material types under 1-w% of S+A has been removed.
O3 PVC	O26	Х			Adjusted, no significant changes.
O4 Packaging, raw materials	O38		Х		Plastic and paper packaging
O5 Packaging, recycling				Х	Packaging must be recyclable in the Nordic Countries
O6 Packaging, information				Х	Information how to sort the packaging

	Chemicals in production					
O7 Chemical products, classification	O3		x		Updated in line with the NSE guidelines for chemicals, it includes new CLP classifications to support the European Green Deal's goal of a toxic-free environment, addressing endocrine disruptors, environmental toxicity, persistency, mobility, and bioaccumulation. Endocrine disruption for human health: EUH380, EUH381 Endocrine disruption for the environment: EUH430, EUH431 Persistent, Bioaccumulative and Toxic properties: EUH440 Very Persistent, Very Bioaccumulative properties: EUH441 Persistent, Mobile, and Toxic properties: EUH450 Very Persistent, Very Mobile properties: EUH451	
O8 Chemical substances, classification	O4		Х		Updated in line with the NSE guidelines for chemicals, it includes new CLP classifications, see O7 classification above.	
O9 Prohibited substances	O5		x		The list of prohibited substances has been expanded with the following substances: CMIT (CAS no. 26172-55-4), Volatile aromatic carbons (VAC), Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and Diethylenetriamine pentaacetate (DTPA, CAS No. 67-43- 6) and its salts, 34 bisphenols and nanomaterials.	
O10 Silicone	O6		x		Limit values for each D4, D5 and D6 has been tightened from 800 ppm in the ready to use silicone mixture or the finished cured silicone to 1000 ppm on dry silicone basis on the ingoing silicone chemical products and aligns with the Criteria for Grease-proof paper, generation 5. For comparison, previous limit value of 800 ppm in a coating bath containing 10% dry silicone corresponds to a limit value of 8000 ppm in the ingoing silicone chemical product. Silicon cups have limit values aligned with EU Ecolabel for menstrual cups.	
O11 Adhesives/Bin ders	07		Х		Adjusted, no significant changes except phthalates removed since they are covered by O9.	
O12 Fragrances and skin care preparations	O8	х			Adjusted, no significant changes, except that silicon menstrual cups included.	
O13 Odour control substances	O9	x			Adjusted, no significant changes.	
O14 Medicaments and antibacterial agents	O10	X			Adjusted, no significant changes, except that silicon menstrual cups included.	
O15 Colouration	011		×		Adjusted and clarified with definitions. Chemical substance classifications (O8) and prohibited substances (O9) at the pigment level have been removed. Pigments must now comply with chemical classification (O7) and BfR's (Federal Institute for Risk Assessment) recommendations: "IX. Colorants for Plastics and other Polymers Used in Commodities" regardless of whether the coloured component is in contact with the skin. Silicon cups have a requirement aligned with EU Ecolabel for menstrual cups. Colourants in the reusable menstrual cup shall not exceed 2% of total weight of the cup.	
O16 Printing inks	012		x		A ban on printing on components in direct contact with skin has been added. Printing inks must comply with the EuPIA Exclusion Policy (6th Edition 2024 or later) or with the Swiss Ordinance Annex 10.	

			N	laterials
O17 Forbidden and restricted tree species	015, 018, 020		X	Updated with Nordic Ecolabelling's requirement concerning restricted tree species.
O18 Traceability and certification	015, 018, 020		x	Updated with Nordic Ecolabelling's requirement concerning certified wood.
O19 Cellulose- based pulp/fluff pulp, general	O14	x		Adjusted, no significant changes.
O20 Cellulose- based pulp/fluff pulp, production	O16		X	Reference value for energy and emissions to water and air have been tightened, airlaid removed. Fluff pulp $EI_{ref} = 900 \text{ to } 780 \text{ kWh/ADt}$ $FueI_{ref} = 6000 \text{ to } 5900 \text{ kWh/ADt}$ CO_2 emission 450 to 350 kg/ADt CTMP fluff pulp $EI_{ref} = 2000 \text{ to } 1650 \text{ kWh/ADt}$ $FueI_{ref} = 1000 \text{ to } 900 \text{ kWh/ADt}$ CO_2 emission 900 to 100 kg/ADt AOX 0.15 to 0.14 kg /ADt pulp mixture AOX 0.17 to 0.16 kg/ADt individual pulp
O21 Paper, general	O17	х		Adjusted, no significant changes.
O22 Tissue paper, production	019		X	Applicable only to tissue paper.
O23 Cotton, bleaching	O21	х		Adjusted, no significant changes, except that other natural cellulosic seed fibres included.
O24 Cotton, raw fibre	O22	х		Adjusted, no significant changes, except that other natural cellulosic seed fibres included.
O25 Cotton, additives	O23	х		Adjusted, no significant changes, except that other natural cellulosic seed fibres included.
O26 Regenerated cellulose, bleaching	O24		x	Limit values for AOX tightened from 0.15 to 0.14 kg/ADt.
O27 Regenerated cellulose, production	O25		×	Closed loop processes included as an alternative. Limit values for emissions to water and air tightened. S from 20 to 16 g/kg fibre COD from 45 to 30 g/kg fibre Zn from 0.2 to 0.05 g/kg fibre
O28 Plastics included in components	O27	х		Adjusted, no significant changes.
O29 Polyurethane/ elastane	O28	x		Adjusted, no significant changes.
O30 Polyamide	O29	х		Adjusted, no significant changes.
O31 Bio- based polymers	O30		X	Threshold value have been lowered from 20% to 5%. Updated with Nordic Ecolabelling's requirement for bio- based polymers.
O32 Recycled plastics	O31		X	The requirement has been clarified and updated with stricter traceability and certification requirements. Recycled plastic must not come into direct contact with

					the skin or, in the case of packaging, with the product. The list of restricted substances for recycled plastic has been updated to include Bisphenol A. The requirement now also specifies which substances must be included in the analysis of restricted impurities (Table 1 in the Appendix 2).
O33 SAP, residual monomers and extracts	O32	х			Adjusted, no significant changes.
O34 SAP, additives	O33	х			Adjusted, no significant changes.
O35 Nonwoven, general	O34	х			Adjusted, no significant changes.
O36 Nonwoven, additives	O35	х			Adjusted, no significant changes.
O37 Silicons and elastomers, emissions of dust and chlorides				x	Applicable to menstrual cups
O38 Silicons and elastomers, emissions of copper and zinc				×	Applicable to menstrual cups
O39 Silicons and elastomers, emissions of CO ₂				X	Applicable to menstrual cups
			Mar	nufacturin	ng of final product
O40 Material efficiency				Х	Applicable both to sanitary products and menstrual cups
			Pro	duct spec	cific requirements
O41 Synthetic polymers used in single-use products				х	Applicable to single-use sanitary products
O42 Impurities in the final product				х	Applicable to single-use sanitary products
O43 Performance	O39	х			Adjusted, no significant changes, except that silicon menstrual cups included.
O44 Tampons	O40	Х			Adjusted, no significant changes.
O45 Menstrual cups				х	User instructions, applicable to menstrual cups
O46 Information	O41	X			Adjusted, no significant changes.
Quality and reg	ularity				
O47 Customer complaints	O44			Х	
O48 Traceability	O47		Х		Updated and partly rewritten

	Removed requirement from gen. 6						
Other materials	O37		Removed because plastic sticks in cotton buds are covered by EU 2019/904.				
Responsible person and organisation	O42		Covered by application portal				
Documentatio n	O43		Covered by application portal				
Planned changes	O45		Covered by application portal				
Unplanned nonconformitie s	O46		Covered by application portal				
Take-back system	O48						
Legislation and regulations	O49		Covered by application portal				

9 Future criteria generation

This chapter will be updated after the finalization of the criteria.

10 Criteria version history

Nordic Ecolabelling adopted version 7.0 of the criteria for Sanitary products on DAY MONTH YEAR. The criteria are valid until DAY MONTH YEAR.

11 How to apply and regulations for the Nordic Ecolabelling

Application and costs

For information about the application process and fees for this product group, please refer to the respective national web site. For contact information see first in this document.

The application consists of an application form/web form and documentation showing that the requirements are fulfilled.

Licence validity

The Nordic Swan Ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be prolonged or adjusted, in which case the licence is automatically prolonged, and the licensee informed.

Revised criteria shall be published at least one year prior to the expiry of the present criteria. The licensee is then offered the opportunity to renew their licence.

On-site inspection

In connection with handling of the application, Nordic Ecolabelling normally performs on-site inspection visit/-s to ensure adherence to the requirements. For such an inspection, data used for calculations, original copies of submitted certificates, test records, purchase statistics, and similar documents that support the application must be available for examination.

Queries

Please contact Nordic Ecolabelling if you have any queries or require further information. See contact info first in this document. Further information and assistance (such as calculation sheets or electronic application help) is available. Visit the relevant national website for further information

Follow-up inspections

Nordic Ecolabelling may decide to check whether sanitary product fulfils Nordic Ecolabelling requirements during the licence period. This may involve a site visit, random sampling, or similar test.

The licence may be revoked if it is evident that sanitary product does not meet the requirements.

Random samples may also be taken in-store and analysed by an independent laboratory. If the requirements are not met, Nordic Ecolabelling may charge the analysis costs to the licensee.

Regulations for the Nordic Ecolabelling of products

When the Nordic Swan Ecolabel is used on products the licence number shall be included.

More information on graphical guidelines, regulations and fees can be found at <u>www.nordic-swan-ecolabel.org/regulations</u>

Appendix 1 Overview of forms for declarations and documentation

These forms apply for the producers of the sanitary product, additional components and sales packaging and their suppliers.

- Form 1, Material composition of the product and the packaging
- Form 2a, Declaration Chemicals
- Form 2b, Declaration Adhesive/binder
- Form 2c, Declaration Printing inks
- Form 2d, Declaration Colourants
- $\bullet\,$ Form 2e, Declaration – Colourant formulation
- Form 3, Silicone treatment
- Form 4, Other substances in the sanitary product and additional components
- Form 5, Cellulose-based pulp/fluff
- Form 6, Forestry requirements
- Form 7, Paper, general requirements
- Form 9, Cotton
- Form 10, Regenerated cellulose
- Form 11a, Plastic included in components
- Form 11b, Additives in plastic components
- Form 12, Elastane/Polyurethane
- Form 13, Polyamide
- Form 14a, Recycled plastic in packaging and additional components
- Form 14b, Recycled plastic in product
- Form 15, Superabsorbent materials
- Form 16, Nonwoven
- Form 17, Bio-based plastic
- Form 18, Sales packaging
- Form 19, Material efficiency
- Form 20, Silicones in menstrual cups
- Form 21, Elastomers in menstrual cups

Appendix 2 Analysis and test laboratories

Choice of analysis laboratory

The analysis laboratory shall fulfil the general requirements of standard EN ISO 17025 or have official GLP status.

Company's own laboratory may act as a test laboratory if:

- The manufacturer has a quality management system encompassing sampling and analysis and has been certified to ISO 9000.
- The test method for performance test is part of the quality system.
- Nordic Ecolabelling shall have access to all raw data from performance testing.

Formaldehyde in adhesives

The content of formaldehyde in adhesives can be determined with an appropriate method, e.g. HPLC, the Merckoquant method or other equivalent test method.

Absorbable organic halogens (AOX) and organic bounded chlorine (OCl)

AOX and OCl shall be tested using ISO 9562 or the equivalent EPA 1650C for AOX, and ISO 11480 for OCl. In the case of pulp manufacturers using chlorine dioxide for bleaching, the annual average value of AOX must be based on at least one representative 24-hour sample per week.

COD/TOC

COD: ISO 6060, ISO 15705, DIN 38409-01 or DIN 38409-44 Determination of the chemical oxygen demand (COD).

TOC may be used in place of COD if the applicant demonstrates how these two methods of analysis correlate with each other. The correlation coefficient must be based on a statistically significant number of measurements and be assessed by an independent party.

TOC: ISO 8245 Water quality. Guidelines for the determination of total organic carbon (TOC).

Determination of chemical oxygen demand is calculated as an annual average and based on at least one representative 24-hour sample per week unless the emission permit of the authorities prescribes some other means of calculation.

Zinc

Analysis of the zinc content of waste water: EN ISO 11885. SS 02 81 52, NS 4773, SFS 3047 or ISO 17294 (2023).

Emissions of zinc to water are calculated as an annual average and based on at least one representative 24-hour sample per week unless the emission permit of the authorities prescribes some other method of calculation.

Content of chemical substances in plastic (O32)

The test results may be submitted by the plastic producer or by a later part of the supply chain, for instance a nonwoven producer. The test must be performed on the "clean" material before adding any glue or other additives. The method of analysis and the detection limit must be stated.

Table 1. Overview of substance specifications for analysis of recycled plastic.

Substance/substance group	Max limit	Test method
Phthatalates	100 ppm	ISO 8124-6 or
1. Diethylhexyl-Phthalat (DEHP CAS no. 117-81-7)	each	similar method
2. Dimethoxyethyl-Phthalat (BMEP CAS no. 117-82-8)		
3. Dibutyl phthalate (DBP CAS no. 84-74-2)		
5. Dihexyl phthalate or Di-n-hexyl-Phthalat (DHP or DnHP CAS no. 84-75-3)		
6. Diisobutyl phthalate (DIBP CAS no. 84-69-5)		
7. Diisohexyl phthalate (DIHxP CAS no. 71850-09-4)		
8. Dipentyl phthalate (DPP or DnPP CAS no. 131-18-0)		
10. n-pentyl-isopentyl phthalate (CAS no. 776297-69-9)		
11. 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich		
(DIHP CAS no. 71888-89-6)		
12. 1,2-Benzenedicarboxylic acid, di-07-11-branched and linear alkyl esters		
13. Di(C6-C10)alkylphthalat / 1,2-Benzenedicarboxylic acid, di-C6-C10-alkyl		
esters (CAS no. 68515-51-5)		
14. Di(C6-C10)alkylphthalat (gemischt) / 1,2-Benzenedicarboxylic acid, mixed		
decyl and nexyl and octyl diesters (CAS No. 68648-93-1)		
16. Diisodecylphthalate (DIDP CAS no. 26761-40-0 and 68515-49-1)		
17. Diisononylphthalate (DINP CAS no. 28553-12-0 and 68515-48-0)		
18. 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (DHxP		
CAS no. 68515-50-4) 19. Diisooctyl phthalate (DIOP CAS no. 27554-26-3)		
20. Dipropyl phthalate (DPrP CAS no. 131-16-8)		
21. Dinonyl phthalate (DNP CAS no. 84-76-4)		
22. Diethyl-Phthalat (DEP CAS no. 84-66-2)		
23.Dimethyl-Phthalat (DMP CAS no. 131-11-3)		
Polybrominated biphenyls and diphenyl ethers	100 ppm	IEC 62321-6
PBB		or similar method
Dibromonbondiphenyl ether		
Tribromodinhenvi ether		
Tetrahromodinhenyl ether		
Pentabromodiphenyl ether		
Hexabromodiphenyl ether		
Heptabromodiphenyl ether		
Octabromodiphenyl ether		
Nonabromodiphenyl ether		
Decabromodiphenyl ether		
and		
PBDE		
Monobromodiphenyl		
Dibromophenyl ether		
Tribromobiphenyl		
Tetrabromobiphenyl		
Pentabromobiphenyl		
Hexabromobiphenyl		
Heptabromobiphenyl		
Octabromobiphenyl		
Nonabromobiphenyl		
UI Brom/Bromino Br	50 ppm	
	(00	
Organotin compounds, OTC	100 ppm	EN ISO 17353
Tributyitin (TBT)	Cault	or similar method
retrabutyitin		

Triphenyltin (TPT)		
Dioctyltin (DOT)		
Monooctyltin		
Tricyclohexyltin		
Metals	100 ppm	
Lead	each	
Cadmium		
Mercury		
chromiumVI		
Bisphenol A (CAS no. 80-05-7)	100 ppm	Adapted method based on EN ISO 11936 or similar method.

Superabsorbents Residual monomers in SAP

As a test method for residual monomers in SAP could NWSP 210.0.R2 (15) Polyacrylate Superabsorbent Powders- Determination of the Amount of Residual Monomers, EDANA Recommended Test method, be used.

Water-soluble extracts in SAP

As a test method could EDANA NWSP 270.0.R2 (15) Polyacrylate Superabsorbent Powders- Determination of Extractable Polymer Content by Potentiometric Titration be used.

Bioaccumulation

Unless otherwise proven, substances are considered bioaccumulating if log Kow \geq 4.0 in OECD test methods no. 107 or 117. Such a substance may be tested on fish in line with the OECD test methods 305 A-E*.

If the substance has a biological concentration factor (BCF) \geq 500 the substance is considered to be bioaccumulative, and if the BCF < 500 the substance is considered not to be bioaccumulative. If there is a measured BCF value, it is always the highest measured BCF that is used in assessing a substance's bioaccumulative potential.

OECD test method 107 cannot be applied to surfactants which have both fat and water-soluble properties. Based on what is known today, for such substances it must be demonstrated with a high degree of certainty that they and their degradation products do not pose any risk to aquatic organisms over a longer time perspective.

Data models (such as BIOWIN) are accepted, but if the results of the model calculations are close to the limit values, or if Nordic Ecolabelling has contrary data, more accurate information can be required.

If there is information on both BCF and log Kow, the value for the highest BCF measured shall be used.

Impurities in final product (O42)

List of restricted substances in line with the EDANA Stewardship Programme CODEX ver. 1.4 March 2023, with the addition of Total Fluorine, TF. Recommended test method to be use is EDANA NWSP 360 parts 1-3 or equivalent. For the total fluorine analysis, the following can be used: Method Nordic Ecolabelling Consultation

based on direct sample combustion with oxygen. The resulting HF is collected in an absorber solution and can then be analysed for the fluorine content using IC^{65} .

Group of substances	Substance name	Cas nr	Limit value
Dibenzo-p-dioxins (PCDDs):	2,3,7,8- tetrachlorodibenzo[b,e][1,4] dioxin; 2,3,7,8-TCDD	1746-01-6	2ng/kg sum TEQ of the detected congeners of PCDDs, PCDFs and DLPCBs
	1,2,3,7,8-pentachlorodibenzo-pdioxin; 1,2,3,7,8-PeCDD	40321-76-4	
	1,2,3,4,7,8- hexachlorodibenzo-p-dioxin; 1,2,3,4,7,8-HxCDD	39227-28-6	
	1,2,3,6,7,8- hexachlorodibenzo-p-dioxin; 1,2,3,6,7,8-HxCDD	57653-85- 7	
	1,2,3,7,8,9- hexachlorodibenzo-p-dioxin; 1,2,3,7,8,9-HxCDD	19408-74-3	
	1,2,3,4,6,7,8- heptachlorodibenzo-pdioxin; 1,2,3,4,6,7,8-HpCDD	35822-46-9	
	octachlorodibenzo-p-dioxin; OCDD	3268-87-9	
Polychlorinated Dibenzofurans (PCDFs):	2,3,7,8-tetrachlorodibenzofuran; 2,3,7,8-TCDF	51207-31-9	
	1,2,3,7,8-pentachlorodibenzofuran; 1,2,3,7,8-PeCDF	57117-41-6	
	2,3,4,7,8-pentachlorodibenzofuran; 2,3,4,7,8-PeCDF	57117-31-4	
	1,2,3,4,7,8-hexachlorodibenzofuran; 1,2,3,4,7,8-HxCDF	70648-26-9	
	1,2,3,6,7,8-hexachlorodibenzofuran; 1,2,3,6,7,8-HxCDF	57117-44-9	
	2,3,4,6,7,8-hexachlorodibenzofuran; 2,3,4,6,7,8-HxCDF	60851-34-5	
	1,2,3,7,8,9-hexachlorodibenzofuran; 1,2,3,7,8,9-HxCDF	72918-21-9	
	1,2,3,4,6,7,8-heptachlorodibenzofuran; 1,2,3,4,6,7,8-HpCDF	67562-39-4	
	1,2,3,4,7,8,9-heptachlorodibenzofuran; 1,2,3,4,7,8,9-HpCDF	55673-89-7	
	octachlorodibenzofuran; OCDF	39001-02-0	

Table 2. List of restricted substances.

⁶⁵ Testing Methods OEKO-TEX standard 100 & Organic cotton Edition 04.2024

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Dioxin-like Polychlorobiphenyls (DL-PCBs):	3,4,4',5-tetrachloro-1,1'-biphenyl; PCB 81	70362-50-4	2ng/kg sum TEQ of the detected congeners of PCDDs, PCDFs and DLPCBs
	3,3',4,4'-tetrachloro-1,1'-biphenyl; PCB 77	32598-13-3	
	2,3',4,4',5'-pentachloro-1,1'-biphenyl; PCB 123	65510-44-3	
	2,3',4,4',5-pentachloro-1,1'-biphenyl; PCB 118	31508-00-6	
	2,3,4,4',5-pentachloro-1,1'-biphenyl; PCB 114	74472-37-0	
	2,3,3',4,4'-pentachloro-1,1'-biphenyl; PCB 105	32598-14-4	
	3,3',4,4',5-pentachloro-1,1'-biphenyl; PCB 126	57465-28-8	
	2,3',4,4',5,5'-hexachloro-1,1'-biphenyl; PCB 167	52663-72-6	
	2,3,3',4,4',5-hexachloro-1,1'-biphenyl; PCB 156	38380-08-4	
	2,3,3',4,4',5'-hexachloro-1,1'-biphenyl; PCB 157	69782-90-7	
	3,3',4,4',5,5'-hexachloro-1,1'-biphenyl; PCB 169	32774-16-6	
	2,3,3',4,4',5,5'-heptachloro-1,1'-biphenyl; PCB 189	39635-31-9	
Formaldehyde	Formaldehyde	50-00-0	16 mg/kg
	Tributyltin (TBT)	688-73-3	2 ppb (0.002 mg/kg)
	Monobutyltin (MBT)	78763-54-9	10 ppb (0.01 mg/kg)
Ormonotino	Dibutyltin (DBT)	1002-53-5	
Organouns	Triphenyltin (TPT)	668-34-8	
	Dioctyltin (DOT)	15231-44-4	
	Monooctyl tin (MOT)	15231-57-9	
Heavy Metals	Antimony	7440-36-0	30 mg/kg
	Cadmium	7440-43-9	0,1 mg/kg
	Chromium	7440-47-3	1 mg/kg
	Lead	7439-92-1	0,2mg/kg
	Mercury	7439-97-6	0,02 mg/kg
Phenols	Bisphenol A	80-05-7	10 mg/kg
	Nonylphenol	25154-52-3	10 mg/kg
	Nonylphenol-di ethoxylate		10 mg/kg

Pesticides	Glyphoshate	1071-83-6	0,5 mg/ kg each
	Aminomethylphosphonic acid (AMPA)	1066-51-9	
	Quintozene	82-68-8	
	Hexachlorobenzene	118-74-1	
	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	71888-89-6	
	Bis-(2-methoxyethyl) phthalate (BMEP)	117-82-8	
	Diisopentylphthalate (DPP/DIPP)	605-50-5	
	Di-n-pentylphthalate (DnPP)	131-18-0	
	Di-n-hexylphthalate (DnHP)	84-75-3	
	Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	
	Dibutyl phthalate (DBP)	84-74-2	100 mg/kg each
	Benzyl butyl phthalate (BBP)	85-68-7	
	Diisobutyl phthalate (DIBP)	84-69-5	
Phthalates	Di-iso-decyl phthalate (DIDP)	26761-40-0 / 68515-49-1)	
	Di-isononyl phthalate (DINP)	28553-12-0	
	Di-n-octyl phthalate (DNOP)	117-84-0	
	DMP	131-11-3	
	DHNUP	68515-42-4	
	DCHP	84-61-7	
	DHxP	68515-50-4	
	DIHxP	71850-09-4	
	DIOP	27554-26-3	
	DPrP	131-16-8	
	DNP	84-76-4	
	1,2-benzenedicarboxylic acid, di-C6-10 alkyl esters	68515-51-5	
	1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters	68648-93-1]

РАН	Benzo(a)anthracene	56-55-3	
	Benzo(a)pyrene	50-32-8	0,2 mg/kg each
	Benzo(e)pyrene	192-97-2	
	Chrysene	218-01-9	
	Benzo(b)fluoranthene	205-99-2	
	Benzo(k)fluoranthene	207-08-9	
	dibenzo(a,h)anthracene	53-70-3	
	Benzo[j]fluoranthene	205-82-3	
	Benzo[g,h,i]perylene	191-24-2	
	Indeno[1,2,3-cd]pyrene	193-39-5	
	Phenanthrene	85-01-8	
	Pyrene	129-00-0	
	Anthracene	120-12-7	
	Fluoranthene	206-44-0	
	Naphthalene	91-20-3	
Fluorine	Total fluorine (TF)		100 mg/kg

Appendix 3 Directions for raw material standards and certification schemes

Nordic Ecolabelling sets requirements on the standards to which feedstock is certified. These requirements are described below. Each individual raw material standard or certification scheme is reviewed by Nordic Ecolabelling as to fulfilment of the requirements. When a raw material standard is revised, it is rereviewed.

Requirements on raw material standards

- The standard must balance economic, ecological and social interests and comply with the Rio Declaration's forestry principles, Agenda 21 and the Forest Principles, and respect relevant international conventions and agreements.
- The standard must contain absolute requirements and promote and contribute towards sustainable cultivation of raw materials. Nordic Ecolabelling places special emphasis on the standard including effective requirements to protect the forest from illegal felling and that the requirements protect the biodiversity of the forest.
- The standard must be available to the general public. The standard must have been developed in an open process in which stakeholders with ecological, economic and social interests have been invited to participate.

The requirements related to standards are formulated as process requirements. The basis is that if stakeholders agree on the economic, social and environmental aspects of the forestry standard, this safeguards an acceptable requirement level.

If a standard is developed or approved by stakeholders with ecological, economic and social interests, the standard may maintain an acceptable standard. Accordingly, Nordic Ecolabelling requires that the standard balances these three interests and that representatives from all three areas are invited to participate in development of the standard.

The standard must set absolute requirements that must be fulfilled for the certification of the forestry. This ensures that the forest management fulfils an acceptable level regards the environment. When Nordic Ecolabelling requires that the standard shall "promote and contribute towards sustainable cultivation", the standard must be assessed and revised regularly to initiate process improvement and successively reduce environmental impact.

Requirements on certification system

• The certification system must be open, have significant national or international credibility and be able to verify that the requirements in the forestry standard are fulfilled.

Requirements on certification body

• The certification body must be independent, credible and capable of verifying that the requirements of the standard have been fulfilled. The certification body must also be able to communicate the results and to facilitate the effective implementation of the standard.

The purpose of certification is to ensure that the requirements regarding raw material standards are fulfilled. The certification system must be designed to verify that the requirements of the forest standard are fulfilled. The method used for certification must be repeatable and applicable to forestry. Certification must be in respect to a specific raw material standard. The forest must be inspected prior to certification.

Requirements on Chain of Custody (CoC) certification

- Chain of Custody certification must be issued by an accredited, competent third party (as for forest certification).
- The system shall stipulate requirements regarding the chain of custody that assure traceability, documentation and controls throughout the production chain.

Documentation

Copy of raw material standard, name, address and telephone number to the organization who has worked out the standard and audit rapports.

References to persons who represents stakeholders with ecological, economic and social interests who have been invited to participate.

Nordic Ecolabelling may request further documents to examine whether the requirements of the forestry standard and certification system in question can be approved.