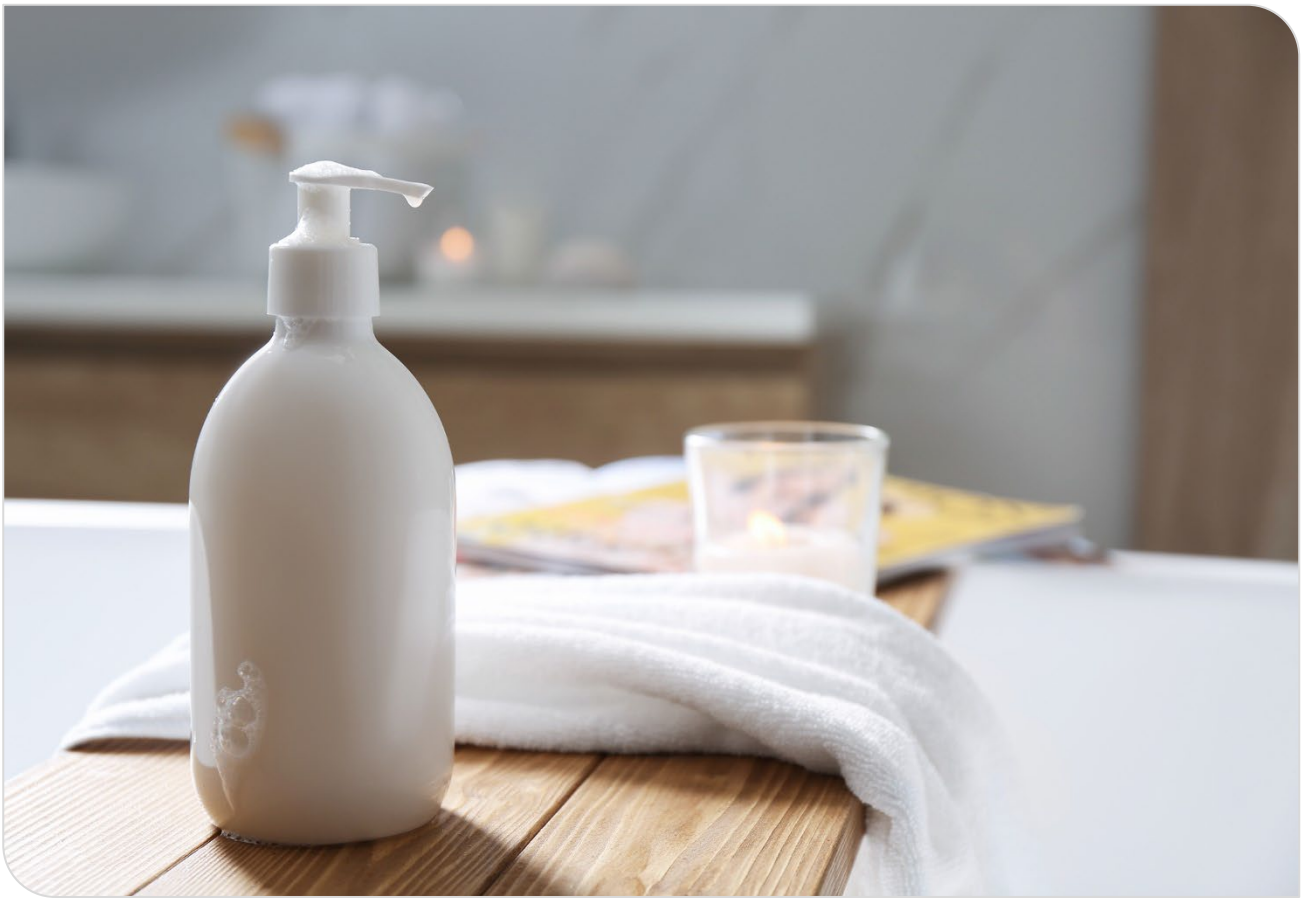
Nordic Ecolabelling for

Cosmetic products



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CONSULTATION

Nordic Ecolabelling

Content

090 Cosmetic products, version 4.0, Date

Contact information

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:

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1 Summary

This background document contains a brief description of the product group, the impact of cosmetic products on health and the environment, and background to the requirements set out in the criteria document.

The product group comprises all the products covered by the EU Cosmetics Regulation 1223/2009 with subsequent amendments, including wet wipes. Also, animal care, sex lubricants and medical lubricants are included even though they are not covered by the Cosmetics Regulation.

Cosmetic products affect the environment over the whole of their life cycle, but life cycle assessments show that the selection of ingredients has a higher environmental impact than the water and energy consumption from the manufacturing of ingoing substances and the cosmetic product. The impact from the ingredients is both from the raw material phase and the end-of-life phase. After use, cosmetic products and their ingoing substances can end up in the environment, and risk harming aquatic organism and the ecosystem. Properties, like biodegradability, bioaccumulability and aquatic toxicity are therefore of great importance for all ingredients.

As cosmetic products are being applied directly to the body, and for leave-on products being completely absorbed into the body, properties like carcinogenic, toxic to reproduction, and allergenic/sensitising are of great importance too.

Packaging also has a high impact on the environment from the consumption of energy and fossil resources, and it is therefore important to lower the total amount of packaging being used, and to ensure that the packaging is designed for recycling. Emissions of hazardous, non-degradable and/or bioaccumulative substances in the environment, which place a burden on treatment works and/or recipients.

This version of the criteria contains a number of changes compared with version 3. The main changes in this version are as follows:

- Palm oil/palm kernel oil must be RSPO certified with trace level Mass Balance or higher
- The new EUH hazard classes for endocrine disruptors, PBT/vPvB, and PMT/vPvM are added to the prohibited classifications along with H410, M>1.
- Updated definition on microplastics and endocrine disruptors.
- The exemption for anaerobic degradation of surfactants for emulsifiers is removed
- A limit of 1,0 ppm for 1,4 dioxane impurity in surfactant active matter is introduced
- Requirement for amount of allergenic fragrance in the product is adjusted to the updated list of regulated fragrances in the Cosmetic Regulation.

- In the requirements for environmentally hazardous substances, surfactants are no longer exempted.
- CDV must be calculated based on the DID list 2023 or later versions.
- Wet wipes can no longer contain plastic fibres.
- Medical examination lubricants are now included in the product group.
- New requirements have been introduced for primary packaging made from rigid and flexible plastic, paper-based materials, and aluminium, concerning the packaging's recyclability and design for recycling.
- Glass is no longer permitted as a packaging material.

For full list of changes, see section 6 Changes compared to previous generation.

2 Environmental impact of cosmetic products

The table below shows an overall analysis of the product group in terms of RPS (Relevance, Potential and Steerability). Relevance is assessed based on which environmental problems the product group causes and how extensive those problems are. Potential is assessed in terms of potential for reducing the environmental impact. Steerability is assessed based on the extent to which the Nordic Swan Ecolabel can contribute to a positive change and how this can be verified. The analysis is prepared based on available life cycle assessments and other relevant publications[1,2,3,4].

Table 1 Analysis of the product group in terms of RPS

Lifecycle stages	Area and assessment of R, P, S (high, medium or low)	Comments
Raw materials		
	Fossil oil or plant materials (palm oil etc.) for production of chemical raw materials R: High P: Medium S: High	R is high due to a large consumption of energy and fossil resources, and non-sustainable extraction of renewable raw materials. P is medium. There is no potential for minimising the use of fossil resources for chemical raw materials, due to the lack of available renewable raw materials, but there is a potential for excluding plastic fibres in wet wipes and for minimising the negative impacts of extraction of palm oil. S is high as requirements for RSPO certified palm oil origin can be set together with a supply chain policy and code of conduct and plast fibres in wet wipes can be prohibited.

[1] Herron, S., Life Cycle Impact Study of Leave-on Skin Care Products, 2013, www.sustainabilityconsortium.org

[2] Koehler, A. et. a., Comparing the Environmental Footprints of Home-Care and Personal-Hygiene Products: The Relevance of Different Life-Cycle Phases, 2009, Environ. Sci. Technol, 43, 8643–8651

[3] Cosmetics Design Europe, Croda announces RSPO certification for cosmetics ingredient factories in India and Brazil, 2014, Cosmetics Design Europe

[4] Secchi, M. et. al., Assessing eco-innovations in green chemistry: Life Cycle Assesment (LCA) of a cosmetic product with a bio-based ingredient, 2016, Journal of Cleaner Production, 129, 269-281.

	Plastic and other packaging raw materials R: High P: High S: High	R is high due to a large consumption of energy and fossil resources. P is high as the use of too much packaging and non-compatible packaging components is widespread, so there is a potential to limit the total amount of packaging and to promote design for recycling. S is high as requirements can be set for the total amount of packaging, the type of packaging and the combination of packaging materials that enables emptying and recycling.
	Materials used for transportation (pallets, wrapping etc) R: Low P: Low S: Low	R is low due to limited consumption of energy and fossil ressources. P and S is low due to the lack of available information about the transportation materials being used and how they are selected.
Production/distribution		
	Water and electrical consumption for production of packaging and cosmetic product R: Medium P: Medium S: Low	R is is medium due to consumption of energy and fossil ressources. P is medium as there is a potential to limit the use on non-renewable energy and to lower emissions from production. S is low as the production facilities often manufacture both Nordic Swan Ecolabelled and non-Nordic Swan Ecolabelled products on the same production line.
	Process chemicals used for cleaning and maintaning machinery R: Low P: Low S: Low	R is is low due to limited use of hazardous chemicals P is low as the difference in available suitable process chemicals is low. S is low as the production facilities often manufacture both Nordic Swan Ecolabelled and non-Nordic Swan Ecolabelled products on the same production line.
	Transportation from production to retail and to consumers R: Medium P: High S: Low	R is medium due to consumption of fossil ressources for fuel and particulate matter and emissions from distribution vehicles P is high as there is a potential to limit the use on non-renewable energy and to lower emissions from trucks. S is low as distribution is carried out by external companies transporting both Nordic Swan Ecolabelled and non-Nordic Swan Ecolabelled products.
Use phase		
RPS: High	Water and electrical consumption when using the cosmetic product R: Low P: Low S: Low	R is high due to the use of water and consumption of energy and fossil ressources for heating of water. P is medium as the use of water can be minimsed, but there is limited potential for the consumers to limit the use of non-renewable energy for heating of water. S is low as energy resources used for heating of water is not controlled by the consumers.
	Exposure of chemicals harmfull to health R: High P: High S: High	R is high due to consumers being exposed to chemicals that are harmful to health P is high as the is a potential to limit or exclude ingredients with negative impact on health, like allergens, endocrine disruptors and microplastic which are not sufficiently regulated by the Cosmetic Regulation. There is also a potential to limit overdosing and thereby minimising the exposure. S is high as requirements to prohibit or strongly limit problematic substances can be set. The amount of products used can be limited by clear instructions for use, and for some product types requirements for maximum dosage pr. pump stroke can be set.
End of life		
RPS: High	Water and electrical consumption for waste water treatment R: Medium P: Low S: Low	R is is medium due to consumption of energy and fossil essources. P is low as there is no potential for the licensees to limit the use on non-renewable energy. S is low as the sewage treatment plants are run by the public sector and they handle waste from both Nordic

		Swan Ecolabelled and non-Nordic Swan Ecolabelled products together.
	Packaging disposal (incineration, reuse or recycling) R: Medium P: High S: High	R is medium due to consumption of energy and fossil resources. P is high as the use of too much packaging and non-compatible packaging components is widespread, so there is a potential to limit the total amount of packaging and to promote design for recycling. S is high as requirements can be set for the total amount of packaging, the type of packaging and the combination of packaging materials that enables emptying and recycling.
	Product emissions from use (degradability and toxicity to aquatic organisms) R: High P: High S: High	R is high as cosmetic products and their ingredients can all end up in the environment affecting biodiversity, even though they might take different routes. Cosmetic products therefore risk harming both aquatic organism and the ecosystem, depending on the intrinsic properties of the ingredients. P is high as there is a potential to reduce the content of environmentally hazardous ingredients like, substances toxic to aquatic organism, non-degradable substances, microplastics, endocrine disruptors etc. S is high as requirements to prohibit or strongly limit problematic substances can be set.

Cosmetic products affect the environment over the whole of their life cycle, but life cycle assessments show that the selection of ingredients has a higher environmental impact than the water and energy consumption from the manufacturing of ingoing substances and the cosmetic product[2,3,5]. The impact from the ingredients is both from the raw material phase and the end-of-life phase.

Both renewable and non-renewable organic ingredients are used for cosmetic products, as well as raw materials that are synthesised from both renewable and non-renewable sources. In the long term, the amount of non-renewable materials is limited since they are extracted from fossil oil. Renewable materials, on the other hand, are replenished through natural processes, but it is important that they are produced sustainably to reduce their environmental impact. Possible negative effects of non-sustainable production of renewable materials include the use of environmentally harmful pesticides, genetic modification and use of land that was originally a key biotope, such as rainforest, or that could have been used for food production.

After use, cosmetic products and their ingoing substances can end up in the environment, and risk harming aquatic organism and the ecosystem. Properties, like biodegradability, bioaccumulability and aquatic toxicity are therefore of great importance for all ingredients.

As cosmetic products are being applied directly to the body, and for leave-on products being completely absorbed into the body, properties like carcinogenic, toxic to reproduction, and allergenic/sensitising are of great importance too.

Packaging also has a high impact on the environment from the consumption of energy and fossil resources, and it is therefore important to lower the total amount of packaging being used, and to ensure that the packaging is designed for recycling.

3 Other labels

Type 1 ecolabels

EU Ecolabel[5]

The EU Ecolabel was established in 1992. It has publicly available criteria that includes both leave-on and rinse-off products. The criteria exclude certain problematic ingredients and classifications, and have similar CDV, aNBO and anNBO requirements to the Nordic Swan Ecolabel. The criteria also include requirements on packaging and sustainable sourcing of palm oil.

Good Environmental Choice (Bra Miljöval)[6]

Good Environmental Choise (Bra Miljöval) was established in 1990 by the Swedish Association for Nature Conservation. It has publicly available criteria for chemical products and approval for all types of cosmetic products can be given through this document. The criteria exclude certain problematic ingredients and classifications. The criteria also include requirements on water content and packaging, and general requirements governing the companies that manufacture these products.

Other private labels

Asthma Allergy Nordic[7]

Asthma Allergy Nordic was established in 2018 as is a nordic label when the national Asthma Allergy associations in the nordic countries joined forces. The focus is solely minimising the risk of developing skin allergies. It has publicly available criteria and labels cosmetic products, but products are still assessed on a case-by-case basis by allergy experts. Perfumes and allergens are not permitted.

AllergyCertified[8]

AllergyCertified was launched in 2014 as a competitor to the Nordic Asthma and Allergy Association labelling systems. AllergyCertified is a global label. Products are assessed on a case-by-case basis by allergy experts. The complete criteria for awarding the label are not publicly available but fragrances and allergens are not permitted.

Ecocert COSMOS Organic[9]

Ecocert was established in France in 1991 and since 2011 part of the COSMOS standard for organic products. COSMOS is a European standard for organically certified cosmetics, that is used in more than 70 countries. Behind COSMOS are

[5] https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel-home_en
[6] www.bramiljoval.se
[7] www.asthmaallergynordic.com
[8] www.allergycertified.com
[9] www.ecocert.com/en/certification-detail/natural-and-organic-cosmetics-cosmos

five organic labelling schemes that together have created one common organic label to help obtain the Ecocert COSMOS Organic label. 95% of the product's plant-based ingredients must be organic, while at least 20% of all ingredients must be organic (10% for rinse-off products).

Vegan[10]

The Vegan trademark was established in 1990 and covers cosmetic products. According to The Vegan Trademark they are the oldest, largest, and original vegan verification scheme, managed by a team of vegan experts to give brands and consumers alike confidence in their purchasing decisions. The criteria are not publicly available.

4 Requirements and their justification

This chapter presents new and revised requirements, explains the background to them, the chosen requirement levels and any changes compared with version 3. The appendices referred to are those that appear in the criteria document "Nordic Swan Ecolabelling of cosmetic products".

4.1 Definition of the product group

All cosmetic products covered by the EU Cosmetics Regulation with subsequent amendments, such as skin care products, hair care products, decorative cosmetics, perfumes, and hygiene products can be Nordic Swan Ecolabelled.

According to the Regulation, "cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours. Wet wipes are included in the definition of the product group, as the liquid on the wipe is intended for functions as described above. Washing up liquid with added skin protection, perfumed toilet paper or tissues with lotion, for example, do not meet the above criteria and are not included in the definition.

Mix-it-yourself products (cosmetics kits), in which all the ingredients together with instructions for mixing the product are sold as a combined unit/single product are covered by the Cosmetics Regulation and can be Nordic Swan Ecolabelled.

Wet wipes can be Nordic Swan Ecolabelled even if there is only lotion in the product, which is covered by the Cosmetics Regulation. Animal care products can be Nordic Swan Ecolabelled although these are not covered by the Cosmetics Regulation.

[10] https://www.vegansociety.com/the-vegan-trademark

Lubricants for medical purposes (such as medical examinations with or without e.g. an ultrasound probe) as well as lubricants marketed as “sex products” (such as lube, anal creams, and orgasm gels) can be Nordic Swan Ecolabelled when their formulations are similar to cosmetic products. Lubricants for medical purposes are part of the scope of the Medical Device Regulation, which can also be the case for “sex products”.

Products covered by the Biocides Regulation 528/2012 cannot be Nordic Swan Ecolabelled. Products that are marketed as being antibacterial, antimicrobial, antiseptic and/or disinfectant or claim to have ingredients that have these properties cannot be Nordic Swan Ecolabelled, as this does not comply with the Biocides Regulation 528/2012.

4.2 Other definitions

For the purpose of this document, the following definitions shall apply.

Definition	Description
Rinse-off product	A cosmetic product marketed as intended to be removed with water after use in normal conditions. This includes products that according to the usage instructions are rinsed off with water immediately after use (e.g. shampoo, conditioner, soaps, shaving cream, bath foam and scrubs, cleansing products/gels, hair treatments and peels). Solid shampoo/conditioner and shower bars are also included. Note that toothpaste is considered rinse-off but must meet requirement O19 Biodegradability and aquatic toxicity instead of O17 aNBO and O18 CDV.
Leave-on product	A cosmetic product marketed as not intended to be removed with water after use in normal conditions. This includes products stay on the skin (e.g. creme, lotion, perfumes). Products that according to the usage instruction are rinsed off with cotton wool, cotton pads etc. are also included (e.g. cleansing lotion, eye make-up remover). Note that lubricants are considered leave-on.
Ingoing substances	All substances in the cosmetic product including additives (e.g., preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g., formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoing substances.
Impurities	Residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the cosmetic product in concentrations less than 100 ppm for rinse-off products and 10 ppm for leave-on products if no other limit is stated in the requirement. Impurities in the raw materials exceeding concentrations of 1000 ppm are always regarded as ingoing substances, regardless of the concentration in the cosmetic product. Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines. The impurity limits apply to each individual substance that is excluded, i.e., Impurities with the same classification in different raw materials shall not be summed up to comply with the limit. The same contaminants in different raw materials also do not need to be summed.
DID-list	The DID-list (Detergent Ingredient Database) part A contains information on toxicity and degradability of several substances that are used in cosmetic products. If an ingoing substance is included on the DID-list, the data from the DID-list must be used for calculations of the amount of aerobic/anaerobic non-biodegradable organics, the critical dilution value and biodegradability and toxicity. If a substance is not included on the DID-list, or data is missing, the methods described in part B of the DID-list must be used. For this criteria generation, the DID-list dated 2023 or later versions apply. See further details in Appendix 6. The DID-list can be obtained from the Nordic Ecolabelling websites.
Wet wipes	Pre-wetted cloths of non-wowen fabric, where the lotion is covered by the EU Cosmetic Products Regulation.
Animal care product	Any product intended to be placed in contact with animal hair or skin to clean them or to improve the condition of it, such as shampoos and conditioners for animals
Sex lubricants	Lubricants with formulations similar to cosmetic products, that are marketed as “sex products” (such as lube, anal creams, and orgasm gels).
Medical lubricants	Lubricants with formulations similar to cosmetic products, that are marketed for medical purposes such as medical examinations with or without e.g. an ultrasound

4.3 General requirements

The requirements in the criteria document and accompanying appendices apply to all ingoing substances in the Nordic Swan Ecolabelled product. Impurities are not regarded as ingoing substances and are exempted from the requirements.

O1 Description of the product

The applicant must give detailed information on the cosmetic products to which the application relates. The following information is required:

- Description of the product
- A complete recipe for the product. The recipe must, if possible, include for each ingoing substance:
  - Trade name
  - Chemical name
  - INCI name (International Nomenclature of Cosmetic Ingredients)
  - Amount (both with and without solvents, e.g., water)
  - CAS No. and/or EC number
  - DID number for substances that can be placed in the DID-list dated 2023 or later versions*
  - Function

If a raw material consists of several substances, data for all ingoing substances is to be stated in the recipe.

** DID list: "Detergents Ingredients Database" list, see Appendix 6 for a detailed description.*

Description of the product, e.g., label or other documentation.

Complete recipe in line with the requirement, Nordic Ecolabelling's calculation sheet for cosmetic products can be used.

Safety data sheet for each raw material in line with prevailing legislation in the country of application, e.g., Annex II to REACH (Regulation 1907/2006/E2EC).

Background to requirement O1

A description of the product (e.g., label) and its areas of use is required to assess whether the product falls within the product group definition. Nordic Ecolabelling needs to know the complete formulation, with all ingoing raw materials. This is necessary to control the individual requirements below and make the calculations necessary in respect of each requirement.

The requirement is unchanged compared to generation 3 of the criteria.

O2 SCCS

Recommendations from the EU's Scientific Committee on Consumer Safety, SCCS Opinions[11], must be complied with where there is an unambiguous conclusion from SCCS. In cases where there is a direct conflict with other

[11] https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs_en

requirements in this criteria document, it is always the most restrictive requirement that applies.

Appendix 1 or equivalent declaration completed and signed.

Background to requirement O2

The EU's Scientific Committee on Consumer Safety (SCCS) has published many opinions on cosmetic products. Their opinions are based on thorough examination of available scientific information and particular attention should therefore be paid to them and they should be complied with.

The SCCS opinion of perfume allergens is no longer exempted, but otherwise the requirement is unchanged compared to generation 3 of the criteria.

O3 Supply chain policy and code of conduct

The license holder must have a) supply chain policy and b) a code of conduct for responsible sourcing of minerals and renewable raw materials* used in the Nordic Swan Ecolabelled cosmetic product. The supply chain policy and code of conduct must be both public and communicated to the supply chain. Licensees that are micro companies with maximum 10 employees are exempted.

a) The supply chain policy must include the following:

- A policy statement committing the licenses to respect human rights and the environment within its operations and supply chain; this includes a commitment to support suppliers' compliance with the supplier code of conduct by engaging in responsible purchasing practices.
- Commitment to comply with all appliable local, national- and international environmental laws and regulations, as well as all applicable health and safety regulations.
- A description for governance processes in place for due diligence; this includes routines for assessing biodiversity and deforestation risk along the whole supply chain.

b) The supplier Code of Conduct must inform all suppliers along the whole supply chain what is expected of them with respect to the Licensee's own supply chain policy regarding human rights and protecting the environment.

** Renewable raw materials compose of biomass and that can be continually replenished for example wood, crops, marine products, organic waste or be recycled raw materials*

Submit supply chain policy according to the requirement or reference to info on webpage.

Submit supplier code of conduct according to the requirement or reference to info on webpage.

Submit information on how the supply chain policy and supplier code of conduct are public and communicated to the supply chain.

Background to requirement O3

Supply chain management is the handling of the entire process of turning raw materials into a final product. Supply chain policy reflects the companies' requirements and responsibilities for saucing raw materials along the whole supply chain. This applies both to renewable raw materials and minerals like for instance MICA. The policy must describe how the company sees to respect human rights, compliance with local and international laws and regulations (environmental, health and safety) along the whole supply chain. The policy must also describe the governance processes in place for due diligence especially for assessing biodiversity and deforestation risk in the supply chain.

The licensee must in addition also present its supplier code of conduct that defines and describes what is expected and required of all suppliers in the supply chain. The supply chain policy and code of conduct must be both public and communicated to the supply chain.

The requirement for supply chain management reflects new EU legislation, e.g., due diligence directive (draft proposal) and new forest deforestation legislation, and how commodity companies work today. The EU due diligence directive applies at first hand to companies with +250 employees. Nordic Ecolabelling supports the new legislation but recognizes that this can be a huge workload for small businesses. Companies with less than 10 employees are therefore exempted from the requirement.

This is a new requirement in generation 4.

O4 Certified raw materials from oil palms

If renewable raw materials from palm oil are used in the product, the palm oil/palm kernel oil must be RSPO certified. This also includes by-products, residues, and waste fractions from palm oil industries, such as palm fatty acid distillate and palm effluent sludge. Tracability must be ensured by Mass Balance, Segregated, or Identity Preserved. Book and Claim are not accepted. The requirement does not include raw materials < 1% in the final product.

- A valid RSPO Supply Chain certificate from all relevant raw material manufacturers/suppliers.
- The manufacturer of the Nordic Swan Ecolabelled product must submit invoices/delivery notes/order confirmation that the palm oil purchased is RPSO certified and information about traceability system (Mass Balance, Segregated or Identity Preserved accepted).
- In cases where the applicant is RSPO chain of custody certified: a third party-controlled balance sheet showing RSPO certified raw materials being accounted/recorded to the Nordic Swan Ecolabelled product(s).
- Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O4

Palm oil plantations are often established at the expense of tropical rainforest and other protected areas. This is one of the biggest threats to biodiversity in Southeast Asia, leading to the loss of valuable species, habitats, ecosystems, and landscapes. Hence, palm oil is part of EU´s Regulation on deforestation-free products.

Palm oil is widely used as an ingredient in chemical substances and therefore difficult to exclude in NSE products. Therefore, if palm oil is used in the product the palm oil/palm kernel oil, including by-products or residues, must be RSPO certified. Traceability must be ensured by Mass Balance, Segregated, or Identity Preserved. Book and claim are not accepted as there are no link between the claim for certified palm oil and the product itself.

The manufacturer or supplier of palm oil must present a valid RSPO chain of custody certificate. The certificate/RSPO schemes ensures and controls the flow of certified claims throughout the supply chain. The manufacturer of the Nordic Swan Ecolabelled product must submit invoices/delivery notes/order confirmation that the palm oil purchased is RSPO certified. The type of traceability (Mass Balance, Segregated or Identity Preserved) must be apparent from the documentation.

In cases where the applicant is RSPO chain of custody certified, the applicant must present a third party-controlled balance sheet showing RSPO certified raw materials being accounted/recorded to the Nordic Swan Ecolabelled product(s). This to ensure that RPSO raw materials (credits) are used in the Nordic Swan Ecolabelled product(s).

This is a new requirement in generation 4.

O5 Classification of ingoing substances

Ingoing substances must not be classified with the hazard codes described in the table below.

Table 2 Classification of ingoing substances

Hazard class	Hazard class and category	Hazard code
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 or 2	H300
Hazardous to aquatic environment	Aquatic Chronic 1	H410, M>1******
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

* Including all combinations of stated exposure routes and stated specific effect. For example, H350 also covers classification H350i.

** Titanium dioxide (CAS No. 13463-67-7) is exempted from the requirement until 2024-12-31 on the following conditions:

- The product must not be loose powder, spray form, toothpaste, or lip products (lip balm, lipstick, lip gloss, lipliner, and similar)
- Titanium dioxide in powder form must be added in a closed system, in a suspension or by means of a method that promotes a "low dust" working environment e.g., using protective equipment which heavily reduce the dust or completely remove the dust from the raw materials (e.g., exhaust ventilation, personal protective equipment and clear safety instructions)

*** The following substances are exempted:

- Enzymes that are in liquid form or in solid form as granulates (including stabilisers in the enzyme raw material) and not used in spray products.
- Fragrance can be included in the final product according to the fragrance requirements O8-O10
- Tocopherol and tocopherol acetate (DID No. 2618)
- Amidoamines in betaine raw materials, such as cocamidopropyl betaine (CAPB): max. 1% of the betaine active content in the raw material, e.g., max. 0.3% amidoamine in raw materials with 30% betaine.

**** Only applies to lip products, toothpaste, oral hygiene products, and nipple cream. All other products are exempted.

***** See also O6 Excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances

****** M is the multiplying factor used for substances classified as chronic aquatic toxicity category 1, as stated in the CLP Regulation (EC) No 1272/2008.

Safety data sheet for all ingoing substances in line with prevailing European legislation (Annex II to REACH Regulation, 1907/2006/EC).

Appendix 1 or equivalent declaration completed and signed.

Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.

Background to requirement O5

Excluding carcinogenic, mutagenic, reproduction toxic (CMR), sensitizing substances and endocrine disruptors is an important parameter from a health perspective. For products that can be partly ingested, this also applies to substances that are fatel if swallowed. The list includes classifications that are

standard to include in all product groups if we do not get information that they are irrelevant, as we apply the precautionary principle. In that way we include unknown or new problematic ingoing substances or impurities that might be present in cosmetic products.

Enzymes and preservatives may be classified and labelled as H334 or H317. Enzymes can improve the efficacy of products at low washing temperatures and thus reduce energy consumption. Preservatives are necessary to ensure the quality and shelf life of products with a neutral pH. Nordic Ecolabelling considers the benefits of preservatives to outweigh the risk of the user being exposed to the product and thus to sensitizing preservatives.

We are aware that the classification of titanium dioxide is under discussion, but it is valid until the ongoing appeal case is settled. A temporary exemption for the use of titanium dioxide in cosmetic products applies until then. The exemption is limited to products that do not generate inhalation exposure or are known to be ingested to varying degrees. Lose powder products and spray products are excluded, as these are the ones generating the largest inhalation exposure according to SCCS/1617/2065. Pressed/compact powder products where the titanium dioxide is bound to an oil does not generate the same amount of dust during application and are thus included by the exemption. Spray products are defined as all types of sprays that can generate airborne particles (both mechanical (water) pump, mechanical spray pump and trigger pump). Lip products and toothpaste are also excluded from the exemption. According to SCCS/1661/23, genotoxicity from titanium dioxide cannot be ruled out in oral products and products that can be inhaled, and no safe limit for TiO_2 can be established in those products. Going forward, Nordic Ecolabelling will be following the development within titanium dioxide research closely.

Enzymes are used in toothpaste, for example. Enzymes that are in liquid form or in solid form as granulates and not used in spray products are not expected to cause allergies in the consumer as the ingredients of the enzyme are included in the product and do not exist as “free dust”, and they can therefore be exempted.

Tocopherol and tocopherol acetate are often used as antioxidants in leave-on products. Nordic Ecolabelling has been in dialogue with chemicals producers and experts in the allergy field and checked it with ECHA. In the light of this, tocopherol, and tocopherol acetate are judged not to be allergens, although certain raw materials suppliers classify them with H317.

Amidoamines up to 1% of the active betaine active content is allowed in betaine raw materials, as it is technically unavoidable and without risk in this concentration according to the Asthma and Allergy Nordic.

When classifying a substance as chronic aquatic toxicity category 1, it is mandatory to indicate an appropriate M-factor as stated in the CLP Regulation (EC) No 1272/2008. Nordic Ecolabelling has decided to not allow the most toxic substances in this category with M>1 (i.e., LC50 or EC50 < 0,1 mg/1).

The new CLP classifications is included 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. Additionally, the inclusion of PMT and vPvM substances is crucial due to their persistence, mobility, and potential impact on water quality. Nordic Ecolabelling aims for comprehensive hazard identification and protection of the environment and human health.

This requirement has been changed compared with generation 3 of the criteria, regarding inclusion of several EUH hazard codes.

O6 Excluded substances

The following substances or substance groups must not be present as ingoing substances in the Nordic Swan Ecolabelled cosmetic product.

Please note that exemptions to the definition of ingoing substances and impurities are specifically indicated in some cases.

- Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS No. 25013-16-5), alkylphenol ethoxylates (APEO), and other alkylphenol derivates (APD)

  An exemption is made for BHT (CAS No 128-37-0) in perfumes in the amount of ≤ 100 ppm, provided that the amount in the cosmetic product is ≤ 1 ppm.
- Bisphenols and bisphenol derivatives belonging to the group of 34 substances that have been identified by ECHA for further EU regulatory risk management that are known or potential enducrine disruptors for the environment of for human health, or that can be identified as toxic for reproduction[12]
- Benzalkonium chloride (CAS No. 63449-41-2)
- Boric acid, borates, and perborates
- Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and Diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts
- Halogenated and/or aromatic solvents*
- Microplastics**

  Exemption to the definition of ingoing substances and impurities: Applies to ingoing substances and impurities present at ≥ 0,010 % in the cosmetic rinse-off or leave-on product.
- Nanomaterials/-particles, as defined according to the Cosmetic Products Regulation ((EC) No 1223/2009)***

  Exemptions are made for:

  a) Synthetic amorphous silica (SAS) used as an abrasive in toothpaste.

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

b) Titanium dioxide (TiO_2) used as a UV-filter approved in SCCS opinion SCCS/1516/13; i.e. TiO_2 may not be photocatalytic, coating must be stable and TiO_2 may not be included in spray products

- Nitro musks and polycyclic musk compounds
- Organic chlorine compounds, hypochlorous acid and hypochlorite
- Parabens (4-Hydroxibenzoic acid and its salts and esters)
- PBT and vPvB substances in accordance with REACH Annex XIII, including substances under investigation according to the ECHA PBT assessment list https://echa.europa.eu/pbt/-/dislist/details/0b0236e1889ab857
- Per- and polyfluorinated substances (PFAS)
- Phthalates (esters of phthalic acid, CAS No. 88-99-3)
- Potential or identified endocrine disruptors, according to any of the following EU member state initiative "Endocrine Disruptor Lists":

  List I: https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu

  List II: https://edlists.org/the-ed-lists/list-ii-substances-under-eu-investigation-endocrine-disruption

  List III: https://edlists.org/the-ed-lists/list-iii-substances-identified-as-endocrine-disruptors-by-participating-national-authorities

  N.B. A substance which is transferred to one of the corresponding sublists 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 sublist II which were evaluated under a regulation or directive which doesn't have provisions for identifying EDs (e.g. the cosmetic products regulation). For those substances, ED properties may still have been confirmed or suspected. Nordic Ecolabelling will evaluate the circumstances case-by-case, based on the background information indicated on sublist II.
- Quaternary ammonium compounds, which are not aerobically or anaerobically biodegradable**** (such as DTDMAC, DSDMAC, DHTDMAC and DADMAC).
- Salicylic acid (CAS No. 69-72-7) and its salts (CAS No. 824-35-1 / 18917-89-0 / 59866-70-5 / 54-21-7 / 578-36-9 / 2174-16-5), benzyl salicylate (CAS No. 118-58-1), and ethyl-hexyl salicylate (CAS No. 118-60-5)
- Siloxanes

  Exemptions are made for linear siloxanes in in leave-on products.
- Silver, colloidal silver and nanosilver
- Substances on the REACH Candidate list of SVHC substanceshttps://www.echa.europa.eu/candidate-list-table
- Titanium dioxide (TiO_2, CAS No. 13463-67-7)

  Exemptions apply until 2024-12-31 for product that are not loose powder, in spray form, toothpaste, or lip products (lip balm, lipstick, lip gloss, lipliner, and similar)

  Titanium dioxide in powder form must be added in a closed system, in a suspension or by means of a method that promotes a "low dust" working

environment, e.g. using protective equipment which heavily reduces the dust or completely removes the dust from the raw materials (e.g. exhaust ventilation, personal protective equipment and clear safety instructions).

- Triclosan (CAS No. 3380-34-5)

* Solvents are defined as in Commission Directive 1999/13/EC: organic substances with a vapour pressure of at least 0.01 kPa at 20 °C

** Microplastics are synthetic polymer microparticles as defined in REACH Regulation ((EC) No 1907/2006), Annex XVII, Entry no. 78: Synthetic polymer microparticles: polymers that are solid, and which fulfil both of the following conditions:

a) are contained in particles and constitute at least 1% by weight of those particles; or build a continuous surface coating on particles.

b) at least 1% by weight of the particles referred to in point (a) fulfil either of the following conditions:

(i) all dimensions of the particles are equal to or less than 5 mm.

(ii) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3.

The following polymers are excluded from this designation:

a) polymers that are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted, which are not chemically modified substances.

b) polymers that are biodegradable as proved in accordance with Appendix 15 [to REACH, Regulation (EC) No 1907/2006].

c) polymers that have a solubility greater than 2 g/L as proved in accordance with Appendix 16 [to REACH, Regulation (EC) No 1907/2006].

d) polymers that do not contain carbon atoms in their chemical structure.

N.B. The following "Conditions of restriction" paragraphs apply: 1 (concentration limit in mixtures), 2 (definitions), 3 (particle size limits). The remaining points do not apply, e.g. 4 (Paragraph 1 shall not apply to the placing on the market of:), 5 (derogations), e.g. 5 (b) "synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry".

*** Nanomaterials/-particles is defined as insoluble or biopersistent and intentionally manufactured materials with one or more external dimensions or an internal structure in the region of 1-100 nm. Nordic Ecolabelling reserves the right to adopt a newer definition, should the Cosmetic Products Regulation ((EC) No 1223/2009) implement an adjusted definition.

**** According to test method 301 (A-F) or 310 in OECD guidelines for testing of chemicals or other equivalent methods evaluated by an independent body and controlled by Nordic Ecolabelling.

Recipe.

Appendix 1 or equivalent declaration completed and signed.

Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.

Background to requirement O6

There are several problematic substances and substance groups that are difficult to exclude through general requirements concerning the product's chemistry. Nordic Ecolabelling has compiled a list of the substances that must not be present as ingoing substances in labelled products. The aim of the list is to prohibit substances that are not excluded through other requirements but are associated with environmental and health hazards. Some substances are included in the list for the sake of clarity, even though they are prohibited under other requirements. The list includes substances that are standard to include in all product groups if we do not get information that they are irrelevant, as we apply the precautionary principle. In that way we include unknown or new problematic ingoing substances or impurities that might be present in cosmetic products.

Alkylphenols (AP), alkylphenol ethoxylates (APEO) and other alkylphenol derivates (APD)

Alkylphenols is a group of mainly non-ionic surfactants that are produced in large volumes and their use leads to widespread release to the aquatic environment. APEOs are highly toxic to aquatic organisms and degrade to more environmentally persistent compounds (APDs). Ethoxylated nonylphenol and several other alkylphenols are included in the Candidate List due to endocrine disrupting properties. Other alkylphenols are polyalkylated phenols such as butylated hydroxytoluene (BHT) and butylated hydroxyanisole (BHA) which have antioxidant properties. An exception is made for BHT in perfumes with the limit of ≤100 ppm provided that the amount in the cosmetic products does not exceed 1 ppm. This exemption is made since BHT is used to ensure the stability of the perfume mixture which can affect the stability of the entire product.

Bisphenols and bisphenol derivatives

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, 34[12] substances were identified in need for further regulatory risk management in EU[13].

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

Benzalkonium chloride

Benzalkonium chlorides (BACs) is part of a group of chemicals with wide applications due to their antimicrobial properties against bacteria, fungi and viruses. There is a risk that frequent and widespread use of BACs in commercial products can generative selective environments for microbes and contribute to resistance to antibiotics. Furthermore, there is a risk to consumer exposure due to their toxicity and allergenic properties.

Boric acid, borates, and perborates

Boric acid, borates and perborates have many uses, such as stain removal, oxidizing and bleaching agents. In cosmetic products they are used as oxidisers and buffers in oral hygiene products and as whiteners. They are classified as toxic to reproduction and poses a risk to consumers.

Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and Diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts.

Ethylenediaminetetraacetic acid (EDTA) and diethylenetriamine pentaacetate (DTPA) is used in many products such as liquid soaps and other 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).

Halogenated and / or aromatic solvents

Halogenated solvents are harmful to health, often not readily biodegradable and can have negative effects on the earth's ozone layer. Some halogenated solvents are suspected of causing cancer.

Microplastics

Microplastics[14] are very small fragments of plastic material, less than 5 mm. They can be harmful to health and the environment due to their size, surface properties and resistance to degradation. They have been found at sea in sediments, sludge from water treatment plants, agricultural soil, Arctic Sea ice as well as Antarctic freshwaters. Microplastics have been detected in various aquatic organisms across the food chain, from zooplankton to vertebrates, and in organisms in the soil. Currently, there are insufficient scientific knowledge and disagreement about the effects of microplastics, especially under natural

[14] Nordic Swan Ecolabel webtext: https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/chemicals-nano-microplastic/microplastics/

conditions. Nordic Ecolabelling applies the precautionary principle and strives to limit the use of microplastics where possible.

In cosmetics microplastics are used for example for exfoliation and cleansing (microbeads) and for opacity control, smooth and silky feeling, illumination of the skin and viscosity control.[15] They can be used both in rinse-off and leave-on products, in for example shampoos, soaps, lotions, lipstick and powders and as a carrier for other ingredients.[16]

Nordic Ecolabelling is concerned about consequences when microplastics are released into the environment, for example through bathing and showering, and laundering of towels, clothes and linen soiled with cosmetic products. Thus, we do not apply the derogations in paragraph 5 of Annex XVII to the REACH Regulation (EC) No 1907/2006 when excluding microplastics. Also, substances added for film-forming/water-repellent purposes in sunscreen products are no longer exempt from our exclusion of microplastics. However, it is still possible to use film-formers for waterproof sunscreen and other leave-on products, if the substances are biodegradable and/or have a solubility higher than 2 g/L. It is important to emphasize that it is NOT the intention to rule out ecolabelled waterproof sunscreen.

Nanomaterials/-particles

Nanomaterials are a diverse group of materials under the size of 100 nm. 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 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[17,18]. Nordic Ecolabelling takes these concerns seriously and applies the precautionary principle to exclude potentially hazardous nanomaterials from products.

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[15] Lamprini A. et al. Worldwide actions against plastic pollution from microbeads and microplastics in cosmetics focusing on European policies. Has the issue been handled effectively? Marine Pollution Bulletin Volume 162, January 2021, 111883. https://doi.org/10.1016/j.marpolbul.2020.111883.

[16] European Chemicals Agency (2019) Annex XV Restriction Report. Proposal for a restriction.

[17] UNEP (2017) Frontiers 2017 Emerging Issues of Environmental Concern. United Nations Environment Programme, Nairobi. https://wedocs.unep.org/bitstream/handle/20.500.11822/22255/Frontiers_2017_EN.pdf?sequence=1&isAllowed=y

[18] SCCS (2019) Guidance on the Safety Assessment of Nanomaterials in Cosmetics. SCCS/1611/19. https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_233.pdf

Synthetic amorphous silica (SAS) is an intentionally manufactured silicon dioxide (SiO_2) form that is extensively used in cosmetic products. Almost all toothpaste on the market contains SAS (hydrated silica) as an abrasive in the form of nanoscale particles which form aggregates[19]. It is transparent and can be used in both gel toothpastes and white and coloured toothpastes, and it is compatible with fluoride[20]. SAS is a nanomaterial under the Cosmetics Regulation and is exempted from the requirement due to a lack of alternative substances.

Nano titanium dioxide (TiO_2) is an effective physical UV filter often used in sunscreen. Reports from the Danish Environmental Protection Agency from 2015 find that the current use of nano titanium dioxide does not constitute an environmental risk in Denmark but that it must be monitored further so that we do not encounter environmental problems at a later date[21,22]. We choose to approve the use of TiO_2 as a UV filter as long as SCCS opinion SCCS/1516/1337 is followed, and the UV filter is thus not photocatalytic, and the coating is stable. Nano UV filters can still not be used in spray products, in line with the SCCS recommendation.

Nitro musks and polycyclic musk compounds

Nitro musks and polycyclic musk generally have undesirable properties regarding both health and the environment. Some such compounds are already excluded from use via the requirement concerning CMR substances.

Organic chlorine compounds, hypochlorite and hypochlorous acid

Organic chlorine compounds, hypochlorite and hypochlorous acid are sometimes used as disinfecting and antibacterial substances and as bleaching agents. Organic chlorine compounds can be, or lead to the formation of, toxic and bioaccumulative substances that are difficult to break down. Chlorine-based bleaching agents generally have undesirable health and environmental properties. Hypochlorous acid is not classified, and hypochlorite have the classification Very toxic to aquatic life (H400) and thus, they are not covered by the general requirement concerning environmentally hazardous substances.

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[19] Enax, J.; Meyer, F.; Schulze zur Wiesche, E.; Fuhrmann, I.C.; Fabritius, H.-O. Toothpaste Abrasion and Abrasive Particle Content: Correlating High-Resolution Profilometric Analysis with Relative Dentin Abrasivity (RDA). Dent. J. 2023, 11, 79. https://doi.org/10.3390/dj11030079

[20] Lippert F.An introduction to toothpaste: Its purpose, history and ingredients. Monogr Oral Sci. 2013;23:1-14

[21] Miljøstyrelsen (2015). Environmental assessment of nanomaterial use in Denmark. Environmental project No. 1788, 2015. From http://www2.mst.dk/Udgiv/publications/2015/10/978-87-93352-71-1.pdf

[22] Miljøstyrelsen (2015). Environmental effects of engineered nanomaterials, Estimations of Predicted No Effect Concentrations (PNECs). Environmental project No. 1787, 2015. From http://www2.mst.dk/Udgiv/publications/2015/09/978-87-93352-70-4.pdf

However, both pose an environmental risk due to the possibility of organic chlorine compounds forming.

Parabens (4-Hydroxibenzoic acid and its salts and esters)

Parabens (4-Hydroxibenzoic acid and its salts and esters) have a widespread use as preservatives in cosmetic products. Several parabens are identified- or under evaluation for being endocrine disruptors. Because of the structural similarities among parabens, they can be expected to have equivalent endocrine disruptive properties and therefore there is a ban on this group of substances.

PBT and vPvB substances in accordance with REACH Annex XIII

PBT and vPvB are abbreviations for substances that are persistent, bioaccumulative and toxic, and very persistent and very bioaccumulative, respectively, in accordance with REACH Annex XIII. This means that they are not biodegradable and that they accumulate in living organisms. Based on these adverse characteristics they pose a threat to the environment and human health. They are prohibited in all Nordic Swan Ecolabel products.

Per- and polyfluorinated substances (PFAS)

Per- and polyfluorinated substances (PFAS) are used in many types of products due to their water and dirt repellent properties. 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, shorter chain compounds (2–6 carbon atoms) have been discovered in nature. The substances in this group are suspected to be endocrine disruptors, carcinogenic and to have a negative impact on the human immune system. Perfluorooctanoic acid (PFOA), Ammonium pentadecafluorooctanoate (APFO) and certain fluoro acids are included in the Candidate List due to being reprotoxic, as well as having PBT properties.

Phthalates (esters of phthalic acid)

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

Potential or identified endocrine disruptors

Endocrine disruptors (EDs) are chemicals that alter the functioning of the endocrine (hormone) system and consequently cause adverse health effects. 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. By excluding both identified and prioritised potential EDs which are under evaluation, Nordic Ecolabelling ensures a restrictive policy on EDs.

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.

Quaternary ammonium compounds, which are not aerobically or anaerobically biodegradable (such as DTDMAC, DSDMAC, DHTDMAC and DADMAC)*

Quaternary ammonium compounds (QACs) are usually surface-active agents where some of them precipitate or denature proteins and destroy micro-organisms. QACs are toxic to a lot of aquatic organisms including fish, daphnids, algae, rotifer and microorganisms employed in wastewater treatment systems.

Salicylic acid and its salts, benzyl salicylate, and ethyl-hexyl salicylate

Salicylates are commonly used substances in cosmetic products. Salicylic acid is used for anti-dandruff, hair conditioning, preservative, and skin conditioning. Benzyl salicylate and ethyl-hexyl salicylate are mainly used as UV absorber and UV filter. The group of substances are suspected endocrine disruptors.

Siloxanes

Siloxanes are substances that have a widespread use in cosmetic products, such as skin care, hair care and make-up. The most commonly used siloxanes in cosmetic products are the cyclic siloxanes cyclotetrasiloxane (D4), cyclopentasiloxane (D5) and cyclohexasiloxane (D6) and the linear polydimethylsiloxane (PDMS) also known as dimethicone. The cyclic siloxanes D4, D5 and D6 are toxic to human health and the environment having PBT and/or vPvB properties, whereas dimethicone is not considered toxic or bioaccumulative. However, there is a concern that over time, dimethicone will slowly degrade into smaller units exerting the same properties as the cyclic siloxanes[23]. Therefore, the use of both cyclic and linear siloxanes is prohibited with the exemption for leave-on products, where linear siloxanes can be used as the products are intended to stay on the skin and not be rinsed off released directly into the wastewater.

[23] Danish Environmental Protection Agency, Survey, and risk assessment of siloxanes in cosmetic products, Survey of chemical sub-stances in consumer products No. 185, June 2021

Silver, colloidal silver and nanosilver

Silver is antibacterial agent used in various consumer products, typically in nano form, where it has a greater effect per total amount of silver. Silver is hazardous to health with since it is classified as reprotoxic and under assessment for endocrine disruptive properties. In addition, silver is extremely hazardous to the environment, classified H400 and H410 with an M factor of 10-1000 depending on particle size.

Substances on the REACH Candidate list of 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 act ahead of the legislation and ban the substances before they are subject to authorisation and restriction in accordance with REACH.

Titanium dioxide

Titanium dioxide is used as white pigment or opacifying agent in cosmetic products such as make-up, skin- and hair care, oral care, and sunscreen. Titanium dioxide is classified as a suspected carcinogen through inhalation (Category 2). This classification has been annulled by the European Court of Justice in November 2022, the annulment was appealed, and the case is still pending. The classification continues to apply until the appeal is settled. According to SCCS/1661/23, genotoxicity from titanium dioxide cannot be ruled out in oral products and products that can be inhaled, and no safe limit for TiO_2 can be established in those products.

Until the appeal is settled TiO_2 is prohibited for use in loose powder, sprays, toothpaste, and lip products (lip balm, lipstick, lip gloss, lipliner, and similar) based on the current SCCS opinions on TiO_2 in cosmetic products. Other products which are not expected to be inhaled or likely to be ingest are exempted until 2024-12-31. After this a re-evaluation for TiO_2 will be made.

In addition, to ensure that the TiO_2 risks that give rise to its classification are controlled, an assessment of the process and procedures on the handling and conditions of TiO_2 in powder form regarding to the occupational safety and health needs to be documented by the raw material producer to reduce worker exposure to dust.

Triclosan

Triclosan is an antibacterial agent used in different products such as toothpaste and deodorants. An antibacterial agent is a substance 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. 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. Furthermore, they can harm bacteria that are necessary for the treatment of water at water treatment plants. Therefore, products containing antibacterial agents should be avoided.

O7 Surfactants

All surfactants in the Nordic Swan Ecolabelled cosmetic product, irrespective of their function in the product must meet the following requirements:

- Be readily biodegradable (aerobically) and anaerobically biodegradable in line with the testing methods in Appendix 6.
- Impurities of 1,4-dioxane (CAS No. 123-91-1) must not exceed 1,0 ppm in the surfactant active matter.
- Sodium lauryl sulphate (SLS) is not allowed in toothpaste.

Reference to the DID* list dated 2023 or later versions. Substances not on the DID list must be calculated based on the guidance in part B of the DID list and associated data must be presented.

**DID list: "Detergents Ingredients Database" list, see Appendix 6 for a more detailed description.*

Appendix 1 or equivalent declaration completed and signed.

Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O7

Surfactants are found in high volumes in liquid soap, shampoo, and conditioner. Surfactants are often hazardous to aquatic organisms and unlike laundry and cleaning products, which are covered by the Detergent Regulation[24], there are no legal requirements on rapid degradability of surfactants in cosmetic products. A condition on rapid aerobic degradability and anaerobic degradability of surfactants is therefore considered relevant for this product group.

Sodium lauryl sulphate (SLS) is prohibited for use in toothpaste since studies have shown that SLS is irritating to the oral mucous membrane[25] and can

[24] Regulation (EC) No 648/2004, 2004

[25] Healy CM, Cruchley AT, Thornhill MH, Williams DM. The effect of sodium lauryl sulphate, triclosan and zinc on the permeability of normal oral mucosa. Oral Dis. 2000 Mar;6(2):118-23.

contribute to slower healing of recurrent oral aphthous ulcers (RAU)[26]. Furthermore, a scoping review of available literature regarding the side effects of SLS used in toothpastes reported that possible effects of SLS included mucosal desquamation, irritation or inflammation of oral mucosa or the dorsal part of the tongue and ulcerations[27], which further supports the assumption of SLS's ability to irritate the oral cavity. Based on current knowledge this requirement is therefore relevant from a health perspective.

Sodium lauryl sulphate is added to toothpastes to generate more foam and is the most common foaming (and cleaning) agent in toothpastes. Nordic Ecolabelling does not permit the substance in toothpastes because there are alternatives available that are less irritating.

Impurities of 1,4-dioxane is limited because of its toxic and environmental hazardous properties. 1,4-dioxane is an SVHC and meets the classification of carcinogenic, because of this, SCCS recommend that trace levels should not exceed 10 ppm in the final cosmetic product[28]. However, foremost it is of concern because of its PMT properties, leaning to easy distribution in the aquatic environment eventually ending up in drinking water. Because of this, the state of New York limits the amount of 1,4-dioxane to 1 ppm in rinse-of products and 10 ppm leave-on products[29] and the German competent authority for Reach has a proposal for restriction under Reach to limit trace levels of 1,4-dioxane to 1,0 mg/kg in the surfactant active matter. This is because the impurity of 1,4 dioxane is mainly present in organic surfactants. The German proposal targets the surfactant raw materials as the manufacturing is identified as the major source of emissions.

The requirement has changed since the previous version. The exemption on anaerobic degradability for surfactants used in toothpaste, emulsifiers, and emollients is removed. Nordic Ecolabelling concludes that there are enough anaerobic degradable surfactants available, and therefore there is no need for an exemption.

O8 IFRA

All fragrances in the Nordic Swan cosmetic products must be added in line with the IFRA's guidelines. The IFRA's (International Fragrance Association) guidelines can be read at https://ifrafragrance.org/.

IFRA certificate according to the current amendments to the IFRA standards.

[26] Herlofson BB, Barkvoll P. Sodium lauryl sulfate and recurrent aphthous ulcers. A preliminary study. Acta Odontol Scand. 1994 Oct;52(5):257-9.
[27] Kasi SR, Özcan M, Feilzer AJ. Side effects of sodium lauryl sulfate applied in toothpastes: A scoping review. Am J Dent. 2022 Apr;35(2):84-88.
[28] SCCS (Scientific Committee on Consumer Safety), Opinion on the Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products, 15 December 2015, SCCS/1570/15
[29] Environmental Conservation (ENV) CHAPTER 43-B, ARTICLE 37, SECTION 37-0117 Prohibition of cosmetic products and personal care products containing 1,4-dioxane or mercury, The New York State Senate, 2023

- Appendix 1 or equivalent declaration completed and signed.

Background to requirement O8

IFRA stands for the "International Fragrance Association" and represents the fragrance industry. The association conducts safety assessments of fragrance substances and provide public standards/guidelines for the use of these. The requirement for compliance with IFRA's guidelines[30] ensures that the manufacture, handling, and use of fragrances in the products meets specific standards in terms of prohibited substances, restricted use, and purity. IFRA's guidelines support the industry in offering products that are safe for consumers and for the environment. The guidelines apply to the manufacture and handling of all fragrance materials for all applications and contain the complete IFRA standards. Note that the requirement on IFRA guidelines is one of several requirements that must be included to protect the consumer, see also requirements O9 and O10 on regulation of fragrances.

O9 Fragrance free products for babies and children

Fragrance substances/perfumes/flavourings/aromas/fragrance substances in plant extracts must not be added to baby and children's products*.

Exemption: Flavourings are allowed in children's toothpaste, see requirement O20 Oral products: Flavourings, colours, and preservatives.

** Baby/children's products are products that are marketed for or have words such as infant, baby and/or children or pictures of children under the age of 12 years on the label.*

- Recipe.
- Appendix 1 or equivalent declaration completed and signed.
- Label.

Background to requirement O9

The requirement covers products marketed for babies or children, e.g., with the word "babies", "baby", "barn", "kids" or "child". Children up to the age of 12 are considered children in this context. Products marketed as family products or towards teenager are not covered by this requirement. The main argument is that children are more sensitive than adults and tend to have fewer opportunities to choose their own products. Thus, the purpose of the requirement is to reduce the risk of babies and children developing allergies to fragrances.

However, an exemption is made for flavourings in children's toothpaste where aromas for use in food are allowed. This is covered in requirement O20 Oral products: Flavourings, colours, and preservatives and ensures that the flavourings that are used in children's toothpaste are approved in terms of health. Nordic Ecolabelling considers it important to have an ecolabelled option for parents to enable an environmentally sound choice, as toothpaste in these

[30] Guidance for the use of IFRA Standards, The International Fragrance Association, 2023

criteria also must fulfil requirements on toxicity (requirement O5 Classification of ingoing substances), limitation on the use of environmentally hazardous substances (requirement O16) and a prohibition of the use of SLS, a known irritant to the oral cavity (requirement O7 Surfactants).

O10 Fragrance allergens

All fragrance substances/ flavourings/aromas/fragrance substance in plant extract in the Nordic Swan Ecolabelled cosmetic products must meet the following requirements:

- Substances with the hazard statement H317 and/or H334 or fragrance allergens listed in Annex III of the Cosmetic Regulation may be included at a maximum of 0.001% (10 ppm) in leave-on products and a maximum of 0.01% (100 ppm) in rinse-off products.
- The following fragrance allergens are prohibited: Oak moss extract (Evernia prunastri) and Tree moss extract (Evernia furfuracea).

Appendix 1 or equivalent declaration completed and signed.

Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Fragrance allergens list.

Background to requirement O10

This requirement limits the amount of fragrance allergens in products rather than prohibit the use of them, because fragrance-free cosmetics have a low demand on the market. Prohibiting fragranced products would most likely have a negative effect on the market presentation of the brand, which would be disproportionate compared with the limited impact that fragrances in Nordic Swan Ecolabelled products have on the environment. Particularly because the amount of environmentally hazardous substances (including fragrances) is strictly limited in requirement O18 Environmentally hazardous substances.

The aim of the requirements is to provide as much protection against new allergies in the society as possible. Nordic Ecolabelling has decided that it is appropriate to go further than the legislation in terms of both limiting sensitising substances and declaring them.

In 2023, the Cosmetic Regulation included 54 new fragrance substances that must be declared on the packaging when the concentration exceeds 0,01% in rinse-off products and 0,001% in leave-on products, leading to a total of 80 substances that are subjected to declaration[31]. These substances are adopted from the EU Scientific Committee on Consumer Safety (SCCS) opinion on fragrance allergens in cosmetic products from June 2012[32]. SCCS refrains from recommending maximum limits for the content of the fragrance substances in

[31] Regulation (EC) No 1223/2009, 2009.
[32] SCCS (Scientific Committee on Consumer Safety), opinion on fragrance allergens in cosmetic products, 26-27 June 2012

cosmetic products but however states that the general limit of 100 ppm is tolerated by most consumers and wishes to guard against the development of new allergy sufferers both within generally tolerant and sensitive people.

Nordic Ecolabelling do not distinguish between fragrance substances that are subject to declaration and fragrance substances that meet the classification H317 (may cause sensitisation by skin contact) or H334 (may cause allergy or asthma symptoms or breathing difficulties if inhaled), therefor the requirement includes all these substances. This is because allergies, particularly contact allergies to fragrances, constitute a growing problem and there is every reason to minimise the risk of increasing the number of sensitised consumers.

Nordic Ecolabelling consider a fragrance to be substances intended to perfume a product. If a fragrance without sensitising substances were to be used by another function, it can be accepted. However, all fragrance substances subject to declaration are a fragrance irrespective of their function in the product. If a product has instructions on the packaging such that it can be seen either as leave-on or rinse-off, the product is a leave-on in relation to the content of fragrance substances. Toothpaste is considered as a rinse-off products.

The criteria have changed since the previous version. All fragrance allergens and natural extracts added to the Cosmetic Regulation in 2023 are now covered by this requirement, which is 48 more substances than in the previous criteria version. Of these 48 substances, 29 are to be classified, leaving 19 substances not previously regulated. However, many of these substances are already regulated by requirement O16 Environmentally hazardous substances because they are to be classified as hazardous to the aquatic environment or requirement O5 Classification of ingoing substances because they are sensitising. Thus, the inclusion of these new fragrance substances is not a major change to the previous version. The substances Chloroatranol and Atranol are prohibited for use in cosmetics by the cosmetic regulation. These two are the main components of Oak moss extract (Evernia prunastri) and Treemoss extract (Evernia furfuracea) and therefore their use is prohibited in Nordic Swan Ecolabelled products.

O11 Organic colorants

All organic colorants in the Nordic Swan Ecolabelled cosmetic product must meet the following requirements:

- Must not bioaccumulative line with the testing methods in Appendix 6, having a BCF (bioconcentration factor) < 500 or log Kow (logarithmic octanol-water partition coefficient) <4. Alternatively, the colorant must be approved for use in food.
- Carbon black is prohibited.

Appendix 1 or equivalent declaration completed and signed.

Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O11

Nordic Ecolabelling carried out a study in 2023 of 103 colorants approved for use in cosmetics (equivalent to 33% of the approved colours in Annex IV of the Cosmetic Regulation at the timepoint)[33], which showed that several of these colorants lack data for bioaccumulation and meet the classification of hazardous to aquatic organisms. Relevant environmental requirements can and should therefore be introduced for colorants to prevent the use of colorants with unknown environmental data.

A study carried out in 2003 by Nordic Ecolabelling showed that colorants approved for use in food do not constitute a major environmental problem. When colourants are approved for use in food, their safety is evaluated by the European Food Safety Authority (EFSA). The evaluation discusses absorption, distribution, metabolism, and excretion (ADME) in line with various animal tests. Based on the ADME study and other toxicity data, such as gene toxicity or sensitisation, EFSA establish ADI (Acceptable Daily Intake) values for the colorants approved for use in food. Nordic Ecolabelling relies on the EFSA's evaluation that it is likely that highly bioaccumulating colours will not be approved for use in food. Therefore, based on our own study described above where log Kow or BCF values were lacking, we also accept E-numbers as documentation of low bioaccumulation potential.

In addition, requirement O16 Environmentally hazardous substances also exclude the use of more environmentally hazardous colorants. The BCF and log Kow values are used as indicators for bioaccumulation in line with the definitions in the CLP Regulation for classification of chronic aquatic toxicity[34].

Carbon black is prohibited because it is suspected of being carcinogenic. It is part of the ECHA Community Rolling Action Plan (CoRAP) where it is to be evaluated for carcinogenicity and IARC considers that carbon black is possibly carcinogenic to humans (group 2B)[35].

The requirement only covers organic colorants as bioaccumulation cannot be used for inorganic compounds. Inorganic colorants can therefore be used in Nordic Ecolabelled cosmetics if they meet our requirements on classification and toxicity.

O12 Preservatives

All preservatives in the Nordic Swan Ecolabelled cosmetic products must be:

- Readily aerobically degradable in line with the testing methods in Appendix 6.
- Not bioaccumulative in line with the testing methods in Appendix 6, having a BCF <500 or log Kow <4.

[33] Regulation (EC) No 1223/2009, 2009
[34] Regulation (EC) No 1272/2008, 2008
[35] IARC, Carbon Black, Titanium Dioxide, and Talc. Lyon. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 93 2010.

- Documentation showing that the substance is readily aerobically degradable. Safety data sheet in line with prevailing European legislation (Annex II to REACH Regulation, 1907/2006/EC) or reference to the DID* list dated 2023 or later versions can be used.

  **DID list: "Detergents Ingredients Database" list, see Appendix 6 for a more detailed description.*

- Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O12

This requirement is set to protect the environment and human health from substances with unknown toxicity and behaviour in the environment. Preservatives are included in most cosmetic products with the aim of preventing bacterial growth and extending shelf life. Nordic Ecolabelling carried out a study in 2023 of all preservatives approved for use in cosmetics listed in Annex V[36]. The study showed that several preservatives lack data for persistence and bioaccumulation, and many meet the requirements for classification of hazardous to aquatic organisms.

The requirement has changed since the previous version as it now requires that preservatives must not be bioaccumulative but also must be readily aerobically degradable. The addition of a requirement on aerobically degradable is made because persistence is considered the biggest cause of concern when looking at the environmental impact of chemicals and bioaccumulation alone is not enough since it mainly prevents bioaccumulation in humans and organisms[37]. This is described by Ian R. Cousins et. al, where they emphasise that persistence alone is a sufficient basis for regulation of a chemical. This is because the release of persistent chemicals leads to increasing concentrations in the environment that can cause known and/or unknown effects. In addition, it can take up to several decades to reverse the contamination.

Since the use of preservatives is common in most cosmetic products and they are often hazardous to the environment, both biodegradation and bioaccumulation are relevant requirements to protect the environment and human health. Especially, since environmental data is not available for all of them. In addition to this requirement, the choice of preservative is limited by the requirements on classification and toxicity (requirements O4 and O5).

O13 UV filter

All UV filters in the Nordic Swan Ecolabelled cosmetic product must meet the following requirements:

[36] Regulation (EC) No 1223/2009, 2009
[37] Ian T. Cousins et al. Environ. Sci.: Processes Impacts, 2019,21, 781-792

- UV filters may only be added to leave-on products and only to protect the user, not the product.
- All organic UV filters contained in the product must not be bioaccumulative in line with the testing methods in Appendix 6, having a BCF <500 or log Kow <4 or must have a lowest toxicity with NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l.

Nano UV filters, with exemption to nano TiO_2, are prohibited under requirements O6 Excluded substances.

Appendix 1 or equivalent declaration completed and signed.

Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O13

UV filters can be divided into two types: Physical organic filters such as titanium dioxide and chemical organic filters. UV filters can be problematic from an environmental and health point of view, but they also provide protection against the sun and thus reduce the risk of skin cancer.

UV filters should only be used to protect the user, not the product. The reason is that certain products on the market contain UV filters for reasons that could be described as debatable (for example deodorants in metal holders or shampoos and soaps)[38]. In addition, UV filters used to protect the user are the only filter covered by Annex VI to the Cosmetics Regulation.

To minimize the environmental impact, UV filters must not be bioaccumulative or toxic to aquatic organisms. A NOEC/EC_x/EC/LC50 value is sufficient but the lowest available value must be used. If Nordic Ecolabelling has access to a lower value than that on e.g. a safety data sheet, this one will be used instead.

For substances where logKow >4 and where the acute toxicity for the aquatic environment cannot be measured due to low water solubility, other tests should be considered. Such tests can include studies of chronic toxicity, with a test concentration under the solubility of the substances which results in a concentration without observed effect (NOEC). A sediment toxicity test should also be considered for substances potentially capable of being deposited or absorbed in sediments to a significant extent, or if log Kow is >3.

The requirement is unchanged compared to generation 3.

O14 Residual monomers in polymers

For each synthetic polymer in the Nordic Swan Ecolabelled cosmetic product, the quantity of residual monomers in newly produced polymers and its classifications must be stated. The polymer raw material may not contain more than 100 ppm residual monomer in of each classification listed in the table below.

[38] (Öko-Test 2009a), (Öko-Test 2009b), (Forbrugerrådet Tænk Kemi, 2015)

Table 3 Classification of monomers

Hazard class	Hazard class and category	Hazard code
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
Specific target organ toxicity	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Acute toxicity	Acute Tox. (oral) 1 Acute Tox. (oral) 2 Acute Tox. (dermal) 1 or 2 Acute Tox. (dermal) 3 Acute Tox. (inhalation) 1 Acute Tox. (inhalation) 2	H300 H301 H310 H311 H330 H331
Endocrine disruption for human health*	ED HH 1 ED HH 2	EUH380 EUH381

* Other potential or identified endocrine disruptors, as defined in requirement O6 Excluded substances are also restricted according to this requirement.

Appendix 1 or equivalent declaration completed and signed.

Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O14

Residual monomers in polymers can cause negative health effects, for example due to the allergic and carcinogenic properties of the monomers. Monomers are often very reactive substances, and the risk is considered so great that it necessitates a separate requirement to further limit the level of residual monomers in the polymer.

Monomers tend to reduce over time, as many monomers are volatile compounds. The requirement relates to the newly produced polymer since it is important to reduce the impact at source and to this end it is most practical for the polymer manufacturer to perform the analysis. The limit of 100 ppm of residual monomers in polymers with classification according to the table in the requirement is based on licensing data.

Compared to the requirements in generation 3, specific target organ toxicity classifications have been added and the environmental classifications H410 and H411 have been removed, as the relevance of this requirement is primarily health based.

O15 Aluminium

In Nordic Swan Ecolabelled cosmetics products, aluminium (corresponding to % elemental Al) may be present at the maximum concentration limits stated for each product type in the table below.

If a product type is not included in the table, the following maximum limit applies: 17.5%

Table 4 Maxiumum concentration limits of Aluminium in specific product categories.

Product category	Conentration (%) limits Alumunium
After Shave	2.5
Bar Soap	4
Body Lotion	3.81
Body Spray	1.18
Deo Gel	6.18
Deo RollOn	5.63
Deo Stick	7.73
Deo Wipes	0
Deo Spray	4.88
Deo Spray (anti-perspirant)	3.24
Eau de Parfum, Eau de Toilette	0.05
Eye Shadow	43.62
Eyeliner	15.76
Face Moisturizer	10.59
Hair Spray	0.15
Hair Styling	6.7
Hand Cream	0.86
Lip Care Products	0.606
Lip Stick	14.62
Liquid Hand Soap	0.89
Liquid Make Up Foundation	23
Make Up Remover	10.59
Mascara	3.13
Mouthwash	0
Conditioner	7.14
Shampoo	7.14
Shaving Products	0.094
Shower Gel	0.89
Sun Screen Lotion	8.403
Sun Screen Spray	0.332
Talc	2
Toothpaste	3.18

- Formulation and calculation of aluminium content corresponding to elemental Al
- Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O15

Aluminium is a known systemic toxicant at high doses. The SCCS have evaluated the safety of aluminium in cosmetics for several product categories, including aggregated exposure of cosmetic products. The opinion conclude maximum concentration limits for several products categories and these limits have been adopted by the Nordic Ecolabelling[39].

Since SCCS has not set limit values for all leave-on products, Nordic Ecolabelling asked an external consultant to make worst case safety calculations for make-up, as it is estimated that these products have the highest content of aluminium. The safety calculations were made by the Institute of Public Health in Norway in accordance with the method stated in the SCCS opinion on aluminium. The calculations were made for eyeshadow, blush, and facial powder. The conclusion is that the use of aluminium in these products can be considered safe at concentrations up to 17.5% for all three products. This limit value will therefore apply for all cosmetic products not mentioned in the SCCS opinion. Note that Aluminium Oxide is obliged to fulfil the requirement for nanomaterials (O6 Excluded substances).

The limit values have changed compared to generation 3.

4.4 Biodegradability and aquatic toxicity

O16 Environmentally hazardous substances (C_{total})

The total weighted quantity of ingoing substances classified as environmentally hazardous according to Regulation 1272/2008/EEC (C_{total}) in the Nordic Swan Ecolabelled cosmetic products must not exceed the limits indicated in the table below, when calculated as the total weighted quantity:

$$C_{total} = 100 \cdot C_{H410} + 10 \cdot C_{H411} + C_{H412}$$

C_{H41X} is the fraction of the product, measured in percentage by weight, made up of the H410, H411 or H412 classified substances.

Ingoing substances must not be classified with the hazard code H410 if the associated multiplying factor as described in the CLP Regulation (EC) No 1272/2008 M>1 according to requirement O5 Classification of ingoing substances.

Table 5 Limit values for total weighted quantity of environmental hazards

Type of product	C_{total} (wt. %)
Liquid soap, shower gel	10.0
Other cosmetic products	2.0

Calculation of the weighted quantity (percentage by weight) of H410, H411, and H412 classified substances. If data is missing on a substance, it is assessed

[39] SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of aluminium in cosmetic products - Submission IV, preliminary version of 14 44 December 2023, SCCS/1662/23

according to a worst-case scenario (H410). Nordic Ecolabelling's calculation sheet for cosmetic products can be used.

- Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.

Background to requirement O16

Substances that are toxic to the environment and are also not readily biodegradable or substances that are chronically toxic (H410, H411 and H412) constitute a potential problem for the aquatic environment. Most ingredients in cosmetic products eventually end up in the aquatic environment through the wastewater system, either directly when they are used or after they have been used (rinsing in the shower). Some products are also released directly into the environment during use (e.g. sunscreen and hair care products). Nordic Ecolabelling has thus identified a need to limit environmentally harmful substances by means of a limit value calculation by a weighted method where the classification H410 is limited the most. The requirement excludes or limits, e.g. certain fragrance blends, colours, and high content of any hazardous impurities in cosmetic ingredients.

Including the M factor in the calculation have been considered, but instead the most toxic H410 substances with M-factor > 1 is completely prohibited. It is expected almost exclusively to be ingredients in perfume raw materials that have M > 1 and alternative perfume raw materials exist.

From 1 December 2012 the CLP Regulation changed the criteria used as its basis for classification as environmentally hazardous. This meant that many surfactants which were not previously classified as environmentally hazardous now needed to be, and they were therefore at that time exempted from the requirement, as surfactants have an important irreplaceable function in many cosmetic products. Surfactants are no longer exempted in this criteria version, but to mitigate the negative consequences, a separate limit value is introduced for the products where licence data has showed that it is needed.

Compared to generation 3, zinc compounds in zinc creams are no longer exempted from the calculation, as there are alternatives available to zinc creams and surfactants are also no longer exempted. H410 substances with M-factor > 1 is now completely prohibited.

Rinse-off products

O17 aNBO (aerobic non-biodegradable organics) and anNBO (anaerobic non-biodegradable organics)

Organic substances in the Nordic Swan Ecolabelled cosmetic product that are not readily biodegradable according to Appendix 6, must not exceed the limits indicated in the table below. For foam soap it is permitted to choose between

applying the limits per active content or per dose. The unit used shall be the same as in O18 CDV.

Surfactants must be biodegradable, see requirement O7 Surfactants.

Exemption to the definition of ingoing substances and impurities: Impurities in raw material ≤ 1.0 w% will not be included in calculations.

Table 6 Limit values for aNBO and anNBO

Type of product	aNBO (mg/g AC*)	anNBO (mg/g AC*)
Solid hand soap, shampoo bar, conditioner bar, shower bar.	5	5
Other rinse-off products	14	14

Type of product	aNBO (mg/dose**)	anNBO (mg/dose**)
Foam soap	2.5	2.5

** Active content (AC) refers to the amount (weight) of all organic substances in the product excluding the water content of the ingredients. Abrasives in handwash and exfoliants are not included. However, see requirement O6 Excluded substances for requirements on microplastics.*

*** One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designed for the product. If the product is not sold with a particular dispenser, a standardised dose of 0.75 g is used*

- Calculation of the quantity (mg) of aNBO and anNBO/g AC or mg/dose for the product. Nordic Ecolabelling's calculation sheet for cosmetic products can be used.
- Reference to the DID list 2023 or later versions. For substances not on the DID list or for which data is missing on DID-list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented. See Appendix 9 for further details on biodegradability, toxicity, potential for bioaccumulation and bioavailability.

Background to requirement O17

Restrictions on the content of organic substances that are not rapidly and anaerobically biodegradable reduce the total level of non-degradable organic substances to a minimum for Nordic Swan Ecolabelled rinse-off products. The limit values are based on data from existing Nordic Swan Ecolabel licences. For liquid soap, shampoo etc. the limit is lowered from 15 to 14 mg/g AC compared to generation 3.

The limit is lower for solid products compared to other rinse-off products because they have very high levels of active content. All solid products are included in this category compared to generation 3 where it was only solid soap.

Foam soaps have found it difficult to meet the requirements per active ingredients (AC) even though they are better for the environment from a functional unit perspective. Therefore, for foam soap it is permitted to choose between applying the limits per active content or per dose. The unit used shall be

the same as in the CDV requirement. A dose is defined as the largest amount that the dispenser for which the product is sold produces, or the maximum dose from the product's pump mechanism. If a dose cannot be determined (if the product is not sold for a particular dispenser or does not have a pump) a standard dose of 0.75 g can be used.

O18 Critical dilution volume (CDV)

The Nordic Swan Ecolabelled cosmetic product's critical dilution volume (CDV) must not exceed the threshold values in the table below. CDV is calculated according to the formula:

$$CDV_{chronic} = \Sigma(DF_i \cdot C_i / TF_i \text{ (chronic)})$$

DF_i is the degradation factor for substance i.
C_i is the amount in l of substance i per g active content or per dose
TF_i is the toxicity factor for substance i.

The calculation of CDV is based on information provided regarding the toxicity and biodegradability of the individual substances in an aquatic environment and must be obtained from the DID list 2023 or later versions. For substances not on the DID list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented.

For foam soap it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in O17 aNBO and anNBO.

For concentrated products incl. powder products, which must be mixed with water by the consumer before use, the calculation is carried out on the use solution.

Exemptions to the definition of ingoing substances and impurities: Impurities in raw material ≤ 1.0 w% will not be included in calculations.

Table 7 Limit values for CDV

Type of product	$CDV_{chronic}$ (l/g AC*)
Solid hand soap, shampoo bar, conditioner bar, shower bar.	2000
Other rinse-off products	9000

Type of product	$CDV_{chronic}$ (l/dose**)
Foam soap	1000

** Active content (AC) refers to the amount (weight) of all organic substances in the product excluding the water content of the ingredients. Abrasives in handwash and exfoliants are not included. However, see requirement O6 Excluded substances for requirements on microplastics.*

*** One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designed for the product. If the product is not sold with a particular dispenser, a standardised dose of 0.75 g is used*

Calculation of the $CDV_{chronic}$ l/g AC or l/dose for the product. Nordic Ecolabelling's calculation sheet for cosmetic products can be used.

Reference to the DID list 2023 or later versions. For substances not on the DID list or for which data is missing on DID-list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented. See Appendix 9 for further details on biodegradability, toxicity, potential for bioaccumulation and bioavailability. If chronic values are available, they must be used instead of acute ones.

Background to requirement O18

CDV is a theoretical value which considers the toxicity and aquatic degradability of each substance. Chronic data must be used because it better describes the environmental impact. When chronic data is unavailable, acute data can be used combined with higher safety factors. The limit values are based on data from existing Nordic Swan Ecolabel licences. For liquid soap, shampoo etc. the limit is lowered from 12000 to 9000 mg/g AC compared to generation 3.

The limit is lower for solid products compared to other rinse-off products because they have very high levels of active content. All solid products are included in this category compared to generation 3 where it was only solid soap. For foam soap it is permitted to choose between applying the limits per active content or per dose, as described in the background text for the aNBO/anNBO requirement.

The water content of the product in relation to the CDV value has been studied, and it varies from 50% to 95% depending on the product type, but can within the same product type, e.g. conditioner, vary considerably (75% to 92%). There is no clear correlation between water content and CDV value. It is therefore judged that the environmental benefit would be relatively small if a requirement on the water content in liquid products were introduced in relation to the advantages of the CDV requirement.

Leave-on products

O19 Biodegradability and aquatic toxicity

At least 96% by weight of the total content of organic ingoing substances in the Nordic Swan Ecolabelled cosmetic product must be:

- Readily biodegradable (OECD 301 A-F), and/or
- Lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioaccumulative (log Kow < 4 or BCF < 500), and/or
- Lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or
- Lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol).

Exemptions to the definition of ingoing substances and impurities: Impurities in raw material ≤ 1.0 w% will not be included in calculations.

UV filters are exempted.

Surfactants must be biodegradable, see requirement O7 Surfactants.

- Calculation of the quantity (percentage by weight) of substances that fulfil the listed requirements. Nordic Ecolabelling's calculation sheet for cosmetic products can be used.
- Reference to the DID list 2023 or later versions. For substances not on the DID list or for which data is missing on DID-list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented. See Appendix 9 for further details on biodegradability, toxicity, potential for bioaccumulation and bioavailability. If chronic values are available, they must be used instead of acute ones.

Background to requirement O19

Most leave-on products are washed off the body and clothes and therefore end up to a certain extent in the aquatic environment via wastewater treatment. Many environmentally problematic ingredients are commonly used in leave-on cosmetics. For instance, long chained vegetable oils or paraffin, that are not rapidly biodegradable. This also applies to many binders, polymers, siloxanes, and waxes. It is therefore important to set requirements on degradability and/or toxicity/bioaccumulation potential. The limit value is based on data from existing Nordic Swan Ecolabel licences and is raised from 95% 96% compared to generation 3.

In addition to readily degradable substances, substances are approved which have

- low chronic toxicity and potential degradability or
- low chronic toxicity and are not bioaccumulating or
- low chronic toxicity and low bioavailability

Molar weight > 700 g has been chosen as the limit value for bioavailability. An examination of the literature[40] judged the opportunity to estimate bioaccumulation potential based on molecular size and solubility. According to this examination, substances with a molar weight > 600 g/mol cannot have a bioconcentration factor > 300.

However, a certain amount of uncertainty prevails regarding high molecular hydrophobic substances due to a lack of data. The combination of a limit value for molar weight with a requirement of low toxicity is not expected to lead to harmful effects because a molar weight > 700 g/mol will probably prevent a high accumulation level, even if a substance has a high log Kow value.

UV filters in sun products are exempt from the requirement because they are needed in sun products in amounts greater than 5% and in many cases, they will not meet this. However, requirement O13 UV filter ensures that the most environmentally problematic UV filters are excluded by requiring them not to be

[40] fff

bioaccumulating and have a lowest toxicity of NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l.

Note that the requirement does not apply to products containing 100% inorganic raw materials.

4.5 Specific additional requirements relating to certain product types

Lip products, toothpaste, oral hygiene products, and nipple cream

O20 Flavourings, colours and preservatives

Flavourings, colours, and preservatives in Nordic Swan Ecolabelled lip products, toothpaste, oral hygiene products, and nipple cream must meet the following requirements:

- Must be approved for use in foodstuff under Regulation 1333/2008 for food additives and Regulation (EC) No 1334/2008 for flavourings.
- Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in lip care products must comply with the recommendations by Cosmetic Europe for mineral oils: https://cosmeticseurope.eu/download/N08vNnB0TUhMbWpwQmlqVk9UZzdwZz09
- Water-soluble Zinc salts in mouthwash is only allowed up to 0,1%.

☐ Appendix 1 or equivalent declaration completed and signed.

☐ Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

☐ Flavourings: Specification of FL-number*.

** FL-numbers are available at the European Commission's Food flavourings database https://ec.europa.eu/food/food-feed-portal/screen/food-flavourings/search and Annex I of Regulation (EC) No 1334/2008.*

Background to requirement O20

This requirement is set to protect human health by only allowing flavourings, colours and preservatives that are approved for food. This is because consumers are exposed to lip products, toothpaste, and oral hygiene products via the mouth. Nipple creams are included since babies can be exposed during breastfeeding.

By only allowing flavourings that are approved for food their safety has been evaluated by the European Food and Safety authority (EFSA) which conduct a risk assessment based on exposure, metabolism, and toxicity of the ingredient.

Mineral hydrocarbons (mineral oils or waxes) are used as ingredients of cosmetic lip care products and the safety have been discussed. With respect to potential oral exposure, Cosmetics Europe recommends that only particular mineral hydrocarbon fractions for which an Acceptable Daily Intake (ADI) has been identified, should be used in cosmetic lip products. This recommendation applies

to all mineral hydrocarbon fractions, i.e. mineral oils and microcrystalline waxes or mixtures thereof, which meet specifications ensuring a safe use in cosmetic lip care products.

Water-soluble Zinc salts in mouthwash is limited to 0,1% based on the scientific opinion of SCCS[41]. The Cosmetic Regulation does not have a specific limit for mouthwash, only a limit of 1% for oral products, which is why the Nordic Ecolabelling adopts the opinion of the SCCS.

O21 Fluoride

Nordic Swan Ecolabelled toothpaste and mouthwash products must contain fluoride in line with the national recommendations on fluoride content.

- Recipe.
- Appendix 1 or equivalent declaration completed and signed.

Background to requirement O21

The market for fluoride-free toothpaste is growing with products which are marketed as "natural"; however, it is well know that toothpaste without fluoride does not prevent dental caries when compared to fluoride toothpaste[42]. In addition, all the Nordic countries respective dental organisations recommend that both adults and children use fluoride toothpaste for a caries preventing effect. Therefore, the Nordic Ecolabelling requires that toothpaste and mouthwash must include fluoride to ensure performance of the products.

Decorative cosmetics and hair dyes

O22 Heavy metals in colourants

Traces of the following heavy metals cannot exceed the following limits in the Nordic Swan Ecolabelled decorative cosmetic product or hair dye product:

- Arsenic 1 ppm
- Antimony 1 ppm
- Cadmium 1 ppm
- Chromium 10 ppm
- Cobalt 1 ppm
- Lead 1 ppm
- Mercury 1 ppm
- Nickel 10 ppm

Colours that are approved for use in food in Regulation 1333/2008 may be used without further documentation of the metals listed above.

[41] SCCS (Scientific Committee on Consumer Safety), Opinion on water soluble zinc salts used in oral hygiene products - Submission I, preliminary version adopted on 7 March 2017, final version adopted on 21-22 June 2018, SCCS/1586/17

[42] Walsh T, Worthington HV, Glenny AM, Marinho VC, Jeroncic A. Fluoride toothpastes of different concentrations for preventing dental caries. Cochrane Database Syst Rev. 2019 Mar 4;3(3):CD007868

In addition, the following requirement applies to decorative cosmetics:

- Bismuth Oxychloride (CAS No. 7787-59-9) is prohibited.

Analysis results and/or material specification of the colourant.

Appendix 2 or equivalent declaration completed and signed with calculations of the amount of the specific metals in the Nordic Ecolabelled product.

Alternatively, test report showing that the quantities in the Nordic Ecolabelled product meet the requirement.

Specification of E-number for colorants approved for food. Appendix 2 can be used.

Background to requirement O22

The aim of this requirement is to protect consumers from unnecessary exposure to toxic heavy metals which are unavoidable in pigments as they are naturally occurring. All heavy metals except Chromium and Nickel are hazardous to the environment, in addition many of them are carcinogenic, mutagenic, toxic to reproduction and sensitising.

The use of the heavy metals Arsenic, Antimony, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel is prohibited by Annex II in the Cosmetic Regulation (EC) 1223 / 2009 (with exemption for special use of Mercury in Annex V). However, trace levels are allowed without specific limits, hence the Nordic Ecolabelling sees a need to limiting the amount of these heavy metals. The requirement only covers decorative cosmetics and hair dyes since other products such as soap and lotion are not considered relevant, as they contain very small amounts of colours in comparison.

The Food and Drug Administration (FDA) have previously shown that trace levels of these heavy metals can vary from zero ppm to thousands ppm in decorative cosmetics, while in lotions, they are mostly below detection limits. Furthermore, these results showed that trace levels of Nickel and Chromium, in many cases where higher than the other metals[43]. This is also shown in colourants data from the industry where trace levels of these metals are found in higher concentrations, generally in ranges between 10 to 200 ppm. Therefore, to enable the labelling of decorative cosmetics and hair dyes a higher limit for these heavy metals are needed.

The main concern for the public regarding Nickel and Chromium are their sensitisation properties. And to make sure the amount is not too high in the product; the Nordic Ecolabelling have adapted the limit of 10 ppm from a study by Basketter et al. This study suggest that the majority of individuals will rarely react to irritants in levels below 10 ppm in the final product[44].

[43] FDA's Testing of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content, The Food and Drug Administration (FDA) 2014

[44] Basketter et. al. Nickel, chromium, and cobalt in consumer products: revisiting safe levels in the new millennium. Contact Dermatitis. 2003 Jul;49(1):1-7

The use of the Bismuth chloride oxide (BiClO) is to provide a shimmering effect to the make-up. This pigment is prohibited since it can be irritating for sensitive consumers and there is a demand of Bismuth-free make-up on the market. In addition, according to the ECHA's summary of classification, approximately 15% of notifiers classify bismuth chloride oxide as a respiratory, skin and eye irritant (H335, H315 and H319).

Colourants approved for foods can be used because their safety have been evaluated by EFSA based on an exposure scenario in which they are "closer" to the body than cosmetic products. In addition, these colorants need to meet specific purity criteria in the Commission Regulation (EU) No 231/2012 where if relevant, certain heavy metals are limited.

O23 Hair dyes

The following hair dyes are prohibited in Nordic Swan Ecolabelled hair dye products:

- Lawsone (CAS No. 83-72-7)
- Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (CAS No. 928659-47-5 and CAS No. 73793-79-0)
- Hair dyes judged to be sensitising and/or allergenic by the SCCS is prohibited even if they do not meet the classification of H317 and/or H334

Appendix 1 or equivalent declaration completed and signed.

Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O23

Lawsone (CAS No. 83-72-7) and Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (CAS No. 928659-47-5 and CAS No. 73793-79-0) are prohibited based on SCCS opinions, suggesting that both have mutagenic potential[45,46], and their use is not regulated by the Cosmetic Regulation.

In addition, hair dyes which are suggested to be sensitising and/or allergenic by the SCCS are prohibited to limit the risk of sensitisation and allergies of hair dye products. Examples of such dyes are methylimidazolium propyl p-phenylenediamine HCl (CAS No. 220158-86-1)[47].

[45] SCCS (Scientific Committee on Consumer Safety), Opinion on Lawsonia inermis (henna), 19 September 2013, corrigendum 12 November 2021

[46] SCCS (Scientific Committee on Consumer Safety), Opinion on Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165), preliminary version of 20-21 June 2019, final version of 30-31 October 2019, SCCS/1608/19

[47] SCCS (Scientific Committee on Consumer Safety), Opinion on hair dye Methylimidazoliumpropyl p-phenylenediamine HCl (A166), preliminary version adopted on 29 July 2019, final version adopted on 30-31 October 2019, SCCS/1609/19

Wet Wipes

O24 Wipe material

Wipe carrier material used in Nordic Swan Ecolabelled wet wipes must meet the following requirements:

- Must not be based on fossil raw materials and must be plastic free. Chemically modified natural polymers, and biodegradable/bio-based plastics are also considered plastic, as specified in the guidelines on the Single-Use Plastic directive[48].
- Wipe carrier material or fibre type must meet relevant requirements under one (not all) of the criteria documents listed in the table below. For cellulose-based pulp and fluff pulp used in carrier material of wipes, the requirements in the Appendix 7 can also be applied.

Table 8 Requirements for wipe carrier material.

Wipe carrier material	EU Ecolabel, Absorbent hygiene products 2023/1809/EU	Nordic Swan Ecolabel, Textiles version 5.4 or later	Nordic Swan Ecolabel, Tissue paper version 6.0 or later	EU Ecolabel Tissue paper 2019/70/EU
Regenerated cellulose*	Criterion 2,7	Fibres must be licenced or fulfil requirements O23-O27 O30-O31 O33-O41	***	***
Cellulose-based pulp/fluff pulp**	Criterion 1,7	***	***	***
Cotton and other natural cellulosic fibres	Criterion 3,7	Fibres must be licenced or fulfil requirements O14 O30-O31 O33-O41	***	***
Flax, bamboo, hemp and bast fibres	***	Fibres must be licenced or fulfil requirements O16-O17 O30-O31 O33-O41	***	***
Tissue paper made off cellulose-based pulp	***	***	Paper must be licenced	Paper must be licenced

[48] Commission guidelines on single-use plastic products in accordance with Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment (2021/C 216/01)

* 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.

** For cellulose-based pulp and fluff pulp, the requirements in the Appendix 7 can be applied as an alternative to the mentioned criteria document in the table.

*** The criteria document is not applicable to the material type, select another of the alternative criteria documents.

If wipe carrier material or fibre type is licenced or used in a licenced product, valid licence number must be stated. Otherwise, documentation for the relevant requirements in the chosen criteria document must be provided.

Background to requirement O24

Wet wipes are pre-wetted cloths of nonwoven fabric, where the lotion is covered by the EU Cosmetic Products Regulation (CPR). Environmental impact of wet wipes is highly related to raw materials used as carrier material in wipes. According to the RPS, there is relevance and potential for excluding plastic polymers in wet wipes and therefore, plastic fibres are no longer allowed in the wipe carrier material.

Wet wipes are mostly made with nonwoven technology consisting of only viscose or a mixture of viscose and plastic, but it is possible to manufacture wet wipes consisting of a mixture of viscose and other natural polymers. Nonwoven industry has recently had focus on increasing the use of materials made from renewable sources, fully biodegradable, recycled, or non-plastic alternatives where relevant[49]. This is partly driven by EU Directive (EU) 2019/9043[50] also known as the Single-Use Plastic (SUP) Directive, where any personal care product that is designed to be used once and contains plastic shall be marked with the “dead turtle” on the packaging[51].

Requirements set for relevant types of carrier materials can be found in the Nordic Swan Ecolabel and the EU Ecolabel Criteria for textiles, hygiene products and tissue paper. Carrier material in wipes shall meet the latest updates of these Criteria, presented in the table in the requirement. If the material in the wet wipe is included in several different criteria, the applicant can choose the criteria whose requirements they wish to meet. Compared to the previous criteria for Cosmetics, it is a significant tightening that wipe carrier material cannot be based on fossil raw materials and must be plastic free. Also, the reference to Nordic Swan Ecolabelled sanitary products, version 6 and EU Ecolabel for textile products 2014/350/EC are removed and will be re-introduced when these Criteria are updated. For cellulose-based pulp and fluff pulp, the requirements in the Appendix 7 can also be applied. More information about justification of

[49] https://www.edana.org/how-we-take-action/edana-sustainability-initiatives/edana-sustainability-vision23
[50] https://eur-lex.europa.eu/eli/dir/2019/904/oj
[51] Regulation (EU) 2020/2151 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R2151

requirements for carrier material and fibres can be found from relevant Nordic Swan Ecolabel Background documents and EU Ecolabel Final Technical Reports.

O25 Process water

Sensitising substances with H317 and/or H334 can be used in the process water of the wet wipe material production only if the concentration in the carrier material/wipe is < 0.10 ppm per sensitising substance.

Signed declaration of the use of sensitising substances in the process water for material in wet wipes. Appendix 3 can be used.

If sensitising substances are used, an analysis report is to be enclosed showing < 0.10 ppm for each sensitising substance.

Background to requirement O25

Through analysing wet wipes, Nordic Ecolabelling has become aware that substances such as MI (methylisothiazolinone), CMI (methylchloroiso-thiazolinone) and glutaraldehyde can be used in process water in the manufacture of non-woven and viscose. MI, CMI and glutaraldehyde are sensitising substances, and the Nordic Ecolabelling does not permit sensitising substances classified with H334 or H317 in cosmetic products, see requirement O5 Classification of ingoing substances.

To ensure that no sensitising substances are found in Nordic Swan Ecolabelled wet wipes, producers of all carrier materials/wipes must declare any use of sensitising substances classified with H334 or H317 in process water. If use of sensitising substances is declared, the carrier material/wipe must be analysed for the sensitising substance(s) concerned. An analysis must show a content of < 0.10 ppm of each sensitising substance.

O26 User information

Nordic Swan Ecolabelled wet wipes must be marked on the front side of the packaging with the following information:

- “Do not flush” pictogram defined in guidelines for the EU Single-Use Plastic (SUP) Directive:

- "Use re-usable washcloths instead of single-use products like wet wipes whenever possible"

Label or packaging sample

Background to requirement O26

Correct disposal of wet wipes ensures the best possibilities for recycling and reduces the risk of problematic substances being discharged into the environment.

According to the EU Directive (EU) 2019/904[52], also known as the Single-Use Plastic (SUP) Directive, wet wipes containing plastics must contain the following "dead turtle" marking on the packaging:

Nordic Ecolabelling no longer allows plastic fibres in the wipe carrier material, but for the sake of recognition and uniformity the "Do not flush" part of the logo is required on wet wipes.

To reduce the use of problematic single-use products like wet wipes, Nordic Ecolabelling has decided that wet wipes must carry an information text encouraging consumers to use reusable washcloths instead whenever possible.

Sunscreen products

O27 Efficacy and UV protection claims

The efficacy of Nordic Swan Ecolabelled sunscreen product's protection against UVB and UVA radiation must comply with the EU Commission Recommendation (2006/647/EC), Section 3 Minimum efficacy:

- UVB protection of minimum SPF 6
- UVA protection factor of minimum 1/3 of UVB SPF
- Critical wavelength of minimum 370 nm

Test methods

The test methods used to verify the efficacy shall be among those established by the European Committee for Standardization (CEN). The methods currently include:

- EN ISO 24444:2020 "Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF) (ISO 24444:2019)"
- EN ISO 24443:2021 "Cosmetics - Determination of sunscreen UVA photoprotection in vitro (ISO 24443:2021, Corrected version 2022-02)"
- EN ISO 24442:2022 "Cosmetics - Sun protection test methods - In vivo determination of sunscreen UVA protection (ISO 24442:2022)"

Currently under drafting:

- prEN ISO 23675 "Cosmetics - Sun protection test Methods - In Vitro determination of Sun Protection Factor"

Labelling

The labelling of the Nordic Swan Ecolabelled sunscreen product must comply with Section 4 Simple and meaningful claims of efficacy:

- Claims indicating the efficacy shall be simple, unambiguous, meaningful, and coherent with the results from the above-mentioned efficacy testing of the product.

[52] EU Directive (EU) 2019/904: https://eur-lex.europa.eu/eli/dir/2019/904/oj

- Claims on the protection efficacy shall be indicated by categories “low”, “medium”, “high”, “very high”, according to the SPF intervals tabled in the Commission Recommendation.
- The claimed SPF shall be one of the “labelled sun protection factor” tabled in the Commission Recommendation, in accordance with the results of the efficacy testing.
- The protection efficacy category shall be indicated at least as prominently as the SPF.

Test reports including description of the tests methods used and the results obtained.

Product label.

Background to requirement O27

Sunscreen products are commonly used and trusted by consumers to protect against the health hazards of excessive UV light exposure. It’s important that their efficacy is verified and claimed accurately in order not to mislead consumers, who could otherwise be put at an elevated health risk. Whereas the EU regulations on cosmetic products[53] and on cosmetic products claims[54] requires that all claims are substantiated and documented, Nordic Swan Ecolabelled products must also comply with the EU recommendation on efficacy of sunscreen products and the claims used[55]. This means that the recommendation, with suggestions on how to fulfil the cosmetic products regulation's Article 20 about product claims, must be followed. The efficacy of both UVB and UVA protection must be tested according to standardised methods, reach a minimum level, and be consistently communicated. The claims used must be accurate and clear and be accompanied by instructions on how to use the sunscreen product in order to obtain the claimed efficacy.

Products outside the scope of the cosmetic products regulation

O28 Animal care products

Nordic Swan Ecolabelled animal care products must meet the following requirements:

- Fragrance and colourants are prohibited
- The product shall comply with the following parts of the EU regulation on cosmetic products ((EC) No 1223/2009):
  - Article 14 Restrictions for substances listed in the Annexes

[53] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. ELI: http://data.europa.eu/eli/reg/2009/1223/oj.
[54] Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products. ELI: http://data.europa.eu/eli/reg/2013/655/oj.
[55] Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EC). ELI: http://data.europa.eu/eli/reco/2006/647/oj.

  - Article 15 Substances classified as CMR substances
  - Article 19 Labelling
  - Article 20 Product claims
- The product must not be classified as hazardous to the aquatic environment corresponding to any of the codes H400, H410, H411, H412 or H413, according to the EU CLP regulation ((EC) No 1272/2008).

Safety data sheet (MSDS) of the product in accordance with the EU REACH regulation ((EC) No 1907/2006, Annex II).

Appendix 1 or equivalent declaration completed and signed.

Product label.

Background to requirement O28

Animal care products include rinse-off products such as shampoo, conditioner, and cleanser as well as leave-on products such as sunscreen, much like the corresponding cosmetic products for human use. Products for animals are not covered by the Cosmetic Products Regulation though. There are no declaration/INCI requirements for animal products so animal owners do not know what the products contain. Nordic Swan Ecolabelling can therefore make a difference in declaring constituent substances in ecolabelled animal products, so benefitting both the owners and the animals.

Cosmetic products for animals are often rinsed into the wastewater system just cosmetic products for humans. Also, the user is exposed to the same chemicals. These products should therefore meet the same general requirements as ordinary cosmetic products.

Neither fragrances nor colours are permitted in cosmetics for animals. There is no functional reason or safety reason to add these substances to animal care products and therefore they are not permitted. Even though this argument could reasonably also apply to products aimed at humans, we consider that there are strong consumer needs that encourage the use of cosmetics with colours and fragrances.

Because the owner of the animal comes into contact with the product in the same way as with cosmetic products for humans, they must meet the same requirements as ordinary cosmetics in terms of ingoing substances and declaration of ingoing substances. In other words, we permit, for example, only the preservatives listed in the Cosmetics Regulation in the amounts listed (provided that they meet other requirements). The user's health is the justification behind the requirement.

Because animal care products are covered by CLP 1272/2008, the requirement includes that products may not be classified as environmentally hazardous.

In criteria generation 4 the requirement clarifies which parts of the CPR the products must comply with, including an addition of the obligations on claims.

O29 Sex lubricants

Nordic Swan Ecolabelled sex lubricant products must meet the following requirements:

- Fragrance and colourants are prohibited
- The product shall comply with the following parts of the EU regulation on cosmetic products ((EC) No 1223/2009):
  - Article 3 Safety
  - Article 8 Good manufacturing practise
  - Article 10 Safety assessment
  - Article 14 Restrictions for substances listed in the Annexes
  - Article 15 Substances classified as CMR substances
  - Article 19 Labelling
  - Article 20 Product claims
- The safety assessment must be conducted by a specialist with documented qualifications required for cosmetic product safety assessment. Additionally, in case the product manufacturer doesn't manufacture cosmetic products, the safety assessor must be an independent third party
- The product must not be classified as hazardous to the aquatic environment corresponding to any of the codes H400, H410, H411, H412 or H413, according to the EU CLP regulation ((EC) No 1272/2008).

In cases where the product is within the scope of the EU regulation on medical devices (MDR, (EU) 2107/745)), compliance with it must be shown. The product then doesn't need to comply with articles 3, 8, and 10 of the cosmetic products regulation.

Safety data sheet (MSDS) of the product in accordance with the EU REACH regulation ((EC) No 1907/2006, Annex II) (not for products within the scope of the MDR).

Safety assessment report and declaration of the qualifications of the safety assessor (not for products within the scope of the MDR).

EU declaration of conformity with the MDR (only for products within the scope of the MDR).

Appendix 1 or equivalent declaration completed and signed.

Product label (with CE conformity mark if the product is within the scope of the MDR).

Background to requirement 029

The lubricant “sex product” segment, with products such as lube, anal cream, and orgasm gel, is outside the scope of the cosmetic products regulation (CPR, (EC) No 1223/2009). This is because, for example, the products are not only used on e.g. the external genital organs but also internally. However, the product formulas are similar to cosmetic products. Moreover, in 2018 Nordic Ecolabelling compared different sex lubricants on the Nordic market and concluded that there are differences regarding health and environmental profiles. Thus, there’s a

potential to differentiate between the products by ecolabelling the more favourable products. The criteria for cosmetic products are suitable since the product formulas and their close-to-body applications are comparable. Therefore, the product group definition was extended in 2018 to include this additional product type.

Sex lubricants may or may not be within the scope of the EU regulation on medical devices (MDR, (EU) 2017/745*), depending on how they're marketed and claimed. If, for example, a product is recommended for use together with a condom it's within the scope of the regulation as an "accessory for a medical device". They may also be regarded as medical devices *per see*, in terms of constituting a "replacement or modification of the anatomy or of a physiological or pathological process or state", especially if they're recommended to help alleviate dryness of mucous membranes.

Since sex lubricants are not subject to the obligations of the CPR, and in some cases neither those of the MDR, the requirement includes reference to selected articles of the CPR that shall apply to the products. The ingoing substances must comply with the restrictions on substances, the products must be safe for human use and a safety assessment must be conducted to confirm it. Also, the products must be manufactured according to good manufacturing practise (GMP), labelled with a declaration of the ingredients for transparency towards the consumer, and the claims used must be clear, accurate and verified.

The safety assessment must be conducted by a specialist with the relevant documented qualifications needed (university level pharmacy, toxicology, medicine or similar). In addition, for companies who doesn't have internal experience in manufacturing of cosmetics, the safety assessor must also be an independent third party in order to strengthen the robustness of the assessment.

For sex lubricants which are within the scope of the MDR, a safety assessment according to the CPR is not required. Instead, for those products the EU declaration of conformity with the MDR and the CE marking of the product is requested as verification documentation. Compliance with MDR also replaces the need for compliance with some of the selected articles of the CPR.

Sex lubricant products which are not within the scope of the MDR fall within the scope of the EU CLP regulation ((EC) No 1272/2008) as chemical mixtures. The products must not be classified as hazardous to the aquatic environment, which is a standard requirement for Nordic Swan Ecolabelled chemical products.

Fragrances and colourants are excluded since the products are used on intimate and sensitive parts of the body.

In criteria generation 4 the requirement clarifies which parts of the CPR the products shall comply with. Moreover, that the safety assessor must have documented qualifications, in accordance with the CPR. The differentiation between sex lubricants which are medical devices or not is new in generation 4.

O30 Medical examination lubricants

Nordic Swan Ecolabelled medical lubricant products must meet the following requirements:

- Fragrance and colourants are prohibited
- The product shall be within the scope of, and compliant with, the EU regulation on medical devices (MDR, (EU) 2017/745)
- The product shall comply with the following parts of the EU regulation on cosmetic products (CPR, (EC) No 1223/2009) (where the CPR is stricter than the MDR, the former applies):
  - Article 14 Restrictions for substances listed in the Annexes
  - Article 15 Substances classified as CMR substances
  - Article 19 Labelling
  - Article 20 Product claims

EU declaration of conformity from the notified body, in accordance with the MDR.

Appendix 1 or equivalent declaration completed and signed.

Product label, with CE conformity mark.

Background to requirement O30

During the evaluation of criteria generation 3 ahead of the revision, lubricants used during medical examinations was identified as a product type for extension of the criteria product group definition, adding to the sex lubricants that were introduced during generation 3. The formulations of the respective product types are similar. Likewise, from a comparison of different medical examination lubricants on the Nordic market, the potential to ecolabel products that are favourable from an environment and health perspective is comparable. Such favourable products are desirable to differentiate, since the products are used in a healthcare setting in direct contact with the skin and mucous membranes of patients, including sensitive groups. Also, they are used in quite large volumes.

Medical examination lubricants are not cosmetic products but fall within the scope of the medical devices regulation (MDR). A safety assessment according to the cosmetic products regulation (CPR) in not requested, but an EU declaration of conformity with the MDR and the CE conformity marking of the product is requested as verification documentation. In addition, the requirement includes reference to selected articles of the CPR that shall apply to the products. The ingoing substances must comply with the restrictions on substances, the products must be labelled with a declaration of the ingredients for easy access transparency towards professional users and consumers, and the claims used must be clear, accurate and verified.

Fragrances and colourants are excluded since the products are used on intimate and sensitive parts of the body.

This is a new requirement in criteria generation 4.

4.6 Packaging requirements

Packaging is a focus area in circular economy, an one of the most important parameters in reducing the climate burden. Nordic Ecolabelling wants to set strict requirements on packaging to ensure the best possibilities for recycling and to reduce the material consumption and transport of packaging.

The packaging requirements target the primary packaging*. Only the packaging materials described in requirement O31 Packaging and materials can currently be used. Please note that glass packaging is no longer permitted. If you are interested in another packaging type (or e.g., another label type), please contact Nordic Ecolabelling to find out whether the criteria can be extended to include your format.

** In accordance with EU Directive 94/62/EC on packaging and packaging waste, the term "primary packaging" is defined as consumer packaging, i.e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of sale.*

O31 Packaging and materials

The following material types must be used in primary packaging*:

- Plastic (see requirements O32)
- Paper-based, e.g. cardboard and corrugated board (see requirements O33)
- Aluminium can be used only for the following types of products, if the container does not contain any other metals and is not based on aluminium alloys:
    - Product sizes < 100 ml
    - Spray bottles/propellant bottles for hairstyling products and shaving foam in all sizes

The following packaging and material types must not be used:

- Miniature bottles sold to the HoReCa sector**.
- Glass
- Metal

  Exemptions for:
    - Aluminium for the product types described above
    - Small metal parts, e.g. parts of a hand pump or sealing foil across small openings on e.g. tubes, are permitted up to 1% of the total weight of the packaging.
    - Decorative cosmetics up to 15% of the total weight of the packaging. Mirrors are not permitted as part of the packaging.

** In accordance with EU Directive 94/62/EC on packaging and packaging waste, the term "primary packaging" is defined as consumer packaging, i.e., packaging conceived to constitute a sales unit to the final user or consumer at the point of sale.*

*** Hotel, restaurant, and catering sector*

- Specification of materials, including description of all components (cap, pump, lid, etc.). Appendix 4 Declaration from the manufacturer/supplier(s) of the primary packaging component can be used as part of the documentation.
- Declaration from the applicant that products with a volume lower than 100 ml is not sold to the HoReCa sector. Appendix 1 can be used.
- If primary packaging of aluminium: Declaration that no other metals, alloys or labels are used. Appendix 4 Declaration from the manufacturer/supplier(s) of the primary packaging component can be used.
- If decorative cosmetic: Account of the content of metal in packaging for decorative cosmetics.

Background to requirement O31

The requirement specifies what material types may be used in primary packaging: Rigid and flexible plastic, paper-based (e.g. cardboard and corrugated board) and aluminium with some exemptions. Nordic Ecolabelling performed an internal comparative LCA study of the packaging material types most commonly used in primary packaging of cosmetic products, which showed that glass has an environmental impact fourfold that of plastic (PE, PP and PET). Therefore, the use of glass is no longer permitted as material in primary packaging in this generation of the criteria.

Very small (miniature-sized) bottles of products such as shampoo and wash soap use an unnecessary high amount of packaging in relation to the amount of product. They are unnecessary in hotel rooms as they are easily replaced by dispensers that are installed in the bathroom. We therefore wish to prohibit the Nordic Swan Ecolabelling of such small products. The prohibition concerns both rinse-off and leave-on products sold to the HoReCa (Hotel, Restaurant and Catering) sector.

The prohibition is not extended to smaller-sized products sold to consumers as these are either long-lasting at smaller volumes (e.g. lip balm, eye cream) or there are no alternatives to them (travel size products need to be less than 100 ml due to flight restrictions), and such sizes should be available on the market.

Aluminium spray/propellant bottles are commonly used for hair care products and shaving foam. Nordic Ecolabelling does not wish to exclude such packaging in situations where they are needed and thus exclude certain product types from Nordic Ecolabelling. Therefore, aluminium is allowed for spray/propellant bottles.

Nordic Ecolabelling performed an internal comparative LCA screening of the packaging material types that are most commonly used in primary packaging of cosmetic products. The screening showed that aluminium packaging for small product sizes perform well in comparison to plastic packaging for similar products given that the weight of the packaging is low. Therefore, aluminium is allowed for product sizes lower than 100 ml. The WUR requirement ensures that aluminium packaging of low weight is used.

Supply is the limiting factor on the market for recycled aluminium. In such cases, the EU defines a default allocation factor of 0.2[56], meaning that only 20% of the environmental benefit from recycling is allocated to the use of the recycled material (i.e. creating a demand), whereas the remaining 80% is allocated to recycling of the material (i.e. creating a supply). This means that the highest environmental benefit comes from ensuring conditions leading to recycling of the aluminium, rather than the use of recycled aluminium in new products. Thus, a mandatory requirement on the use of recycled aluminium is not set.

The container must consist of 100% aluminium; other metals and aluminium alloys are not permitted as other metals is at risk of being lost in the recycling process by being oxidized or leaving as slag, or it contaminates the recycled aluminium. Other materials should be avoided to the highest extent possible, therefore labels are prohibited[57].

Metal is not allowed because residues cause plastics to be rejected if there are metal detectors on the sorting line. Metal residues can also break down plastics and become a problem in production of the recycled plastic[58,59]. However, small pieces of metal which have a function when used as a metal part in a hand pump, or to protect the product such as sealing foil at small openings of e.g. tubes are permitted.

A majority of packaging for decorative cosmetics contain metal for various reasons. To provide an opportunity to ecolabel a wide range of products, up to 15 w% metal of the total weight of the packaging is permitted. However, mirrors are not permitted as they are considered unnecessary and contribute a lot of extra metal and weight to the packaging.

This is partially a new requirement.

O32 Plastic packaging: Recyclability and design for recycling

To enable recycling, the following is required:

- The main materials* in the primary packaging must be possible to recycle** in today's existing material recirculation systems in the Nordic countries.
- All parts of the packaging of products for domestic use that are comprised of different materials must be possible to be sorted separately without using a tool (including sorting into different plastic types). Mixed materials that cannot be separated must not be used.

  An exemption is made for small metal parts in pumps (e.g. springs) up to 1% of the total weight of the packaging, labels, pressurised containers (including airless) and packaging for decorative cosmetic products.

[56] https://environment.ec.europa.eu/system/files/2021-12/Annexes%201%20to%202.pdf (Accessed 2023-11-16)
[57] Metallförpackningar: En återvinningsmanual från FTI version 2.0 (Accessed 2023-12-12)
[58] Plastkretsen and FTI, Bättre förutsättningar för återvinning av plastförpackningar.
[59] http://www.plasticsrecycling.org/hdpe (Accessed 2023-11-24)

The primary packaging must have a design that enables material recovery, and therefore must meet the following requirements:

- The container and closure must be made from monomaterial of either polyethylene (PE), polypropylene (PP) or polyethylene terephthalate (PET). However, up to 5% of PE in PP material and up to 1% of PP in PE material is permitted from masterbatch. Recycled material, which is purchased as one type of polymer, e.g. PP, is considered monomaterial.

  An exemption is made for small metal parts in pumps (e.g. springs) up to 1% of the total weight of the packaging.
- For rigid plastic packaging: Packaging and closures must be compatible with each other, in accordance with the following:
  - PET packaging: PE or PP closure with a density < 1.0 g/cm^3.
  - PE packaging: PP/OPP-closures must not be used unless the following text or similar is stated on the packaging: "Take the cap/closure off prior to recycling to improve recycling".
- Pigments must not be added to PET. Coloured, recycled PET granulate where the pigment originates from the recycled material is allowed.
- Carbon black pigments must not be added to container or closure.
- Fillers (such as $CaCO_3$) must not be included in PE or PP containers or closures at a level that the density of the plastic exceeds 0.995g / cm^3.
- Barriers are not allowed in rigid plastic packaging. Barrier coatings in flexible plastic pouches can only be of EVOH (ethylene vinyl alcohol) and constitute max 5% of the total weight.
- Silicone is not allowed in closures.
- The primary packaging must not be surface treated with PFAS, either on the inside or on the outside.

Container means e.g., bottle, tube, jar, flexible plastic pouches including spout fixed to the plastic pouch.

Closure means e.g., cap, lid, pump, spout, dosing device, oblate, seal. Please note that a spout that is fixed to the container counts as part of the container.

** Labels, pumps, and spray nozzles are not considered main materials.*

*** Incineration with energy recovery is not considered to be material recycling. In case of doubt about the actual recyclability in the current Nordic systems, Nordic Ecolabelling may request the applicant to obtain additional substantiation about the recyclability from one of the Nordic Producer Responsibility organisations.*

Documentation showing that the primary packaging is recyclable: List the used materials in Appendix 4 and define how each component should be recycled.

Statement from one of the Nordic Producer Responsibility organisations, if specifically requested by Nordic Ecolabelling.

A picture/description of how the lid/pump can be taken apart without tools.

Packaging specifications (including all components, such as container and closure, label etc.) or certificate showing the materials used, component weights, density of PE or PP components, and which pigments have been added. Appendix

4 Declaration from the manufacturer/supplier(s) of the primary packaging component can be used as part of the documentation.

Label showing text regarding instruction to remove the cap before recycling, where applicable.

Background to requirement O32

The EU has adopted a circular economy action plan[60] that has a clear focus on recovery and recycling, particularly with regards to packaging material. Recyclability is an important step in shifting towards a circular economy. The requirement states that all parts of the packaging that consist of different materials must be possible to be separate without using a tool and sorted separately, so as to not hinder recycling. An exemption is made for certain packaging elements as they are difficult to separate from the rest of the primary packaging and there are no known alternatives to these.

The Nordic recycling manuals for plastic packaging[61] are the base for the requirement stating that plastic bottles/containers and closures must be made from PE, PP or PET. These are the best performing plastics from a recycling perspective. Biodegradable plastics are not suitable in today's recycling systems and can cause problems in the material recovery process. Up to 5% of PE in PP material and up to 1% of PP in PE material is permitted as it does not impair the recycling process. Nordic Ecolabelling has decided to accept EVOH to a maximum of 5% (in relation to the total packaging weight) as a barrier coating. This is in line with what the recycling companies recommend so that the recycling process is not adversely affected.

Colourless plastics have the highest recovery value. Dark colours result in a darker recycled fraction, which is not preferable. Carbon black causes problems in automated sorting plants, as the NIR (near infrared reflectance) detector cannot identify dark colours produced with carbon black. For PE and PP, carbon black is excluded from packaging and closures, to contribute to a visually lighter recycled fraction and to avoid issues with NIR-detection. For virgin PET, pigments are not accepted since there is no market for coloured PET packaging and coloured packaging is currently incinerated in Nordic recycling systems.

Fillers are restricted so that the HDPE or PP density does not exceed 0.995g/cm3. If the plastic becomes too dense, it sinks in the water bath in the recycling process and goes to incineration instead of material recovery.

Silicone is not allowed in packaging as it is difficult to remove in the recycling process and silicone impurities in the recycled fraction are problematic.

[60] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Closing the loop – An EU action plan for the Circular Economy, COM(2015) 614 final, https://eur-lex.europa.eu/resource.html?uri=cellar:8a8ef5e8-99a0-11e5-b3b7-01aa75ed71a1.0012.02/DOC_1&format=PDF (Accessed 2023-11-24)

[61] "Plastförpackningar – En återvinningsmanual från FTI, version 7.0

During the revision, it has come to our knowledge that surface treatment of the primary packaging with PFAS occurs in the industry. PFAS constitute a group of substances that have highly problematic intrinsic hazardous properties. They are extremely persistent and accumulate in the body. The substances in this group are suspected to be endocrine disruptors, carcinogenic and to have a negative impact on the human immune system. Therefore, such surface treatment is prohibited.

Nordic Ecolabelling wishes to set a requirement on a minimum amount of recycled material in plastic packaging to further promote circular economy. However, recycled plastic contains several problematic substances, many of which are hazardous to health, which can migrate into the product. Currently there is no established test protocol for the recycled PE and PP to show compliance for use in packaging for near-food applications, albeit there are developments in the industry, of which CosPaTox's project[62] shows the most promise. Until such testing protocols are established, Nordic Ecolabelling refrains from setting a mandatory requirement on recycled plastic material in primary packaging. Furthermore, the Cosmetic Regulation[63] mandates in article 3 that the cosmetic product shall be safe for human health when used under normal or reasonably foreseeable conditions of use, which in accordance with article 17 includes migration of substances hazardous to human health from the packaging into the product.

This is a new requirement.

O33 Paper-based packaging: Recycled material and design for recycling

To enable recycling of the cardboard and corrugated board packaging, the following is required:

- The main materials* in the primary packaging must be possible to recycle** in today's existing material recirculation systems in the Nordic countries.
- Cardboard packaging must contain at least 90% paper/paperboard.
- A minimum of 90% by weight of the wood raw material that is used in the paper/cardboard must be made of recycled material***.
- The remaining proportion of wood raw material (that is not recycled material) must be covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources).
- Two-sided plastic laminate is not permitted.
- PVC or plastic based on other types of halogenated plastics must not be used in the packaging (container and closure).
- Solid coloured cardboard is not permitted, except for white solid coloured cardboard, which is permitted.

** Labels, pumps, and spray nozzles are not considered main materials.*

[62] https://cospatox.com/the-project/ (Accessed 2023-11-24)
[63] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1223-20221217 (Accessed 2023-12-12)

*** Incineration with energy recovery is not considered to be material recycling. In case of doubt about the actual recyclability in the current Nordic systems, Nordic Ecolabelling may request the applicant to obtain additional substantiation about the recyclability from one of the Nordic Producer Responsibility organisations.*

**** Recycled material is defined in accordance with ISO 14021 in the following two categories:*

- Material in the pre-consumer phase: Material that has been taken from the waste flow during the manufacturing process. The exception is the re-use of material that is generated in a process, e.g., waste that can be recycled within the same process that generated it.
- Material in the post-consumer phase: Material generated by households or by trade, industry, or institutional facilities in their role as end-users of a product that can no longer be used for its intended purpose. This includes the return of materials from the distribution chain.

Description of the packaging from the packaging producer showing. Appendix 4 can be used:

- percentage (by weight) of paper/paperboard material, and percentage of recycled material in wood raw material
- percentage (by weight) of any barrier material; material type and description showing whether the barrier is one- or two-sided
- percentage (by weight) of other materials that might be present in elements such as closure, handles etc. and material type.

Declaration that any non-recycled wood raw material is covered by the FSC/PEFC control schemes.

Declarations that PVC and other plastic based on other types of halogenated plastics has not been used. Appendix 4 can be used.

Declarations that aluminium and other metals has not been used. Appendix 4 can be used.

If labels are used: Specification from the manufacturer showing that the label is made of paper and that the adhesive is water soluble.

Background to requirement O33

Legislation and infrastructure are in place for paper-/cardboard collection and recycling in the Nordic countries[64]. To promote the use of recycled materials and to save virgin resources, an obligatory requirement on the amount of recycled materials is introduced. The 90% and 70% recycled material requirement levels respectively, are based on current licence data as well as on further correspondence with stakeholders.

Two-sided plastic laminate is not allowed since the doble layer impedes the pulpability and leads to a low degree of fibre recovery. Specialized pulpers are required to obtain good fibre recovery for two-sided laminates. A significant

[64] http://norden.diva-portal.org/smash/get/diva2:1304371/FULLTEXT01.pdf (Accessed on 2020-12-06).

proportion of the Nordic board waste is currently not sent to such specialised facilities[65].

PVC and other halogenated plastics are excluded since they lead to adverse environmental impacts in waste handling. Aluminium is not essential in paper-based packaging within this product group.

Solid coloured material other than white is not permitted, as this may lead to discolouration of non-coloured fractions in the pulper.

This is a new requirement.

O34 Labels for all packaging materials: Design for recycling of packaging

To enable recycling of the packaging, the following is required for the labels*:

- Containers in polyethene (PE) and polypropene (PP): The label must be of the same material as the packaging.

  Cross-over labels are exempted from this requirement.
- Containers in polyethylene terephthalate (PET):
  - The label must be of PP or PE with a density < 1.0 g/cm^3.
  - The label must not cover more than 50% of the packaging surface for sizes ≤ 500 ml and 70% for sizes > 500 ml.**
- For aluminium packaging: Labels must not be used.
- For all plastic packaging: Paper labels must not be used.
- For paper/cardboard packaging: Paper labels can be used, but other types of labels must not be used. The label glue must be water soluble.
- Labels of polyvinyl chloride (PVC) and other halogenated plastics must not be used.
- Metallized labels/shrink film labels must not be used.
- Direct print on the container is not permitted except for date codes, batch codes and UFI (Unique Formula Identifier).

  An exemption is made for tubes, flexible plastic pouches, paper-based packaging and containers made from aluminium.

** Label means "traditional label", shrink film label/sleeve, direct print etc.*

*** The calculation of the percentage shall be based on the two-dimensional profile of the container i.e., the area of the top and bottom of the packaging and the sides of a box/ container/bottle/can shall not be included in the calculation. If the label on the front of pack and back of the packaging are of different size, the maximum percentage shall be fulfilled for each side separately. For a cylindrical bottle, the calculation can also be based on the three-dimensional profile excluding the bottom and top of the bottle.*

[65] Personal communication with Johannes Daae, Grønt Punkt Norge (January 2021).

- Label specifications showing the material used and density. Appendix 4 Declaration from the manufacturer/supplier(s) of the primary packaging component can be used as part of the documentation.
- Declarations that PVC and other halogenated plastics, aluminium and other metals have not been used. Appendix 4 can be used.
- For labels of different material on PET packaging: Calculation of label size compared to the surface of the container.
- Declaration from the applicant that direct print is not used except for date codes, batch codes and UFI.

Background to requirement O34

PE and PP containers should preferably have labels of the same plastic material in order to facilitate correct sorting by the NIR sensor. Other label materials could be accepted given that the packaging passes RecyClass' Washing quick test procedure. However, the washing temperature in procedure is set to 40°C, which is not compatible with the area of use for cosmetic products used in a shower or a warm bathroom, whereby we have not included this in the criteria. Therefore, PE and PP containers must have a label in the same plastic material. RecyClass are currently revising this test procedure and we will follow the process closely to see if it can be implemented in the criteria after the public consultation.

PET containers must have labels with density 1.0 g/ml). As a consequence, for the time being, cPET labels are not allowed. Nordic Ecolabelling will consider allowing cPET-labels with the appropriate specifications, if cPET labels become endorsed by EPBP (The European PET Bottle Platform) for PET bottles and/or by RecyClass (www.recyclass.eu). PET-G labels/shrink film labels are excluded on PET containers since PET-G is problematic in recycling in large quantities as it is not compatible with the PET commonly used for containers (A-PET).

If the NIR sensor at the sorting facility hits the label instead of the bottle, the bottle may end up in the rejected fraction. Therefore, labels and shrink film labels of different materials than the container must not cover more than 50% of the container surface for sizes ≤ 500 ml and more than 70% for sizes > 500 ml in accordance with RecyClass' guidelines.

PVC and other halogenated plastics are excluded since they lead to adverse environmental impacts in waste handling. Paper labels are excluded since they degrade the recycled material.

Metallized labels can be detected by metal detectors causing the packaging to be sorted to reject. Thin metal layers do not seem to possess major problems for the sorting or recycling, if the labels can be separated from the containers[66]. However, these metal materials will not be recycled, and single use of metal is not supportable from a resource point of view.

[66] https://www.epbp.org/design-guidelines/products (Accessed on 2023-11-24)

Direct printing on the container is restricted, as ink residues lower the quality of the recycled plastic. An exemption is made for date codes, batch codes and UFI (Unique Formula Identifier).

For paper-based packaging, direct print instead of labels is preferable in the recycling process. However, Nordic Ecolabelling has decided to allow paper labels, to provide for flexibility for the producers. For paper labels, water soluble adhesive is preferable in the recycling process[67].

This is a new requirement.

O35 Amount of packaging: Weight-Utility Ratio (WUR)

To limit the use of an unnecessarily large amount of material, the primary packaging must meet the following calculation. See more information and calculation examples in Appendix 5.

$$\frac{\sum(mf_i \cdot W_{material\_i}) - \frac{W_{pump}}{2}}{t} \leq a \cdot Vol_{product} + b$$

mf_i = Material factor for type of material divided into the following three materials:

$mf_{paper/cardboard} = 0.4$

$mf_{plastic} = 1.0$

$mf_{plastic\ laminate} = 1.0$

$mf_{aluminium} = 2.1$

$W_{material\ i}$ = Weight of the packaging component (including label + information sheet) in grams

W_{pump} = Weight of pump (if applicable) in grams.

t = Reuse factor ($t=1$ for packaging, which is not reused for the same purpose, $t > 1$ if the product is sold with a refill or for the purpose of multiple refills, e.g. $t = 5$ if the amount of refills is 4.)

$Vol_{product}$ = Volume of the product in ml

a and b are constants that vary for different packaging types:

Packaging type	a	b
Pump bottle incl."Airless"	0.05	22
Tube	0.1	6.4
Bottle	0.065	15
Jar	0.08	35
Stick + roll on	0.5	8
Wet wipes*	0.98	8
Propellant bottles	0.4	10
Solid soaps, shampoo etc.	0.025	0.4

[67] Personal communication with Cecilia Halling Linder, Fiskeby Board AB (December 2020).

For decorative cosmetics** the following applies:

$$\frac{\sum W_{packaging,i}}{W_{product,total}} \leq 0.9$$

$W_{packaging,\ i}$ = *the weight of the packaging component i*

$W_{product,\ total}$ = *the weight of the end product (packaging plus content)*

** Wet wipes use the same equation as above, but volume of the product is replaced by the number of wet wipes in the packaging.*

*** Decorative cosmetics are mascara, eye liner, eye primer, eyebrow pencil, eyeshadow, powder/blusher, concealer, primer, nail varnish, lipstick, lip gloss and similar products.*

- Declaration/documentation from the packaging manufacturer stating the type of material in the packaging components (e.g., closure (cap, spray nozzle etc.), bottle and labels). Appendix 4 can be used.
- Calculation of weight-utility ratio (WUR) and required documentation on reuse of the packaging component. Nordic Ecolabelling's WUR calculation sheet for cosmetic products can be used.
- If t >1: Documentation in the form of sales statistics or similar showing how many refills are sold per original packaging.

Background to requirement O35

Packaging often accounts for a relatively large proportion of a cosmetic product. Products with several layers are common, especially for luxury products. It is therefore important to limit the amount of packaging used in relation to the product's volume.

The requirement uses a formula that takes into account the volume of the product, the weight of the packaging, reusable/refillable packaging, and a potential pump to make correct dosage easier. The formula works by calculating the amount of packaging on the left-hand side, taking into account return figures and an eventual pump. On the right-hand side, the volume is taken into account by use of a linear equation with different constants. The constants differ for different packaging types such that there are different limits for, e.g. tubes and pump bottles, which ensures a stringent requirement for all packaging types.

The requirement has been changed since the last generation of the criteria. The equation on the right-hand side is now linear with new constants a and b, which will make the limit value more stringent than in the previous generation. The basis for determining the constants was data from current Nordic Swan Ecolabelled products (385 of them). All the data was entered in a diagram and the constants were determined iteratively considering that the requirements should be realistic but strict.

The limit value for wet wipes now relates to the number of wipes in the packaging, rather than the volume of the packaging, which will give a more

accurate representation of the amount of packaging used for a certain amount of product.

Furthermore, the element representing the amount of recycled material in the packaging has been removed due to the issues raised concerning recycled plastic in requirement O32.

The material factor value produces a rough "environment weight" of each material and have been revised in this generation of the criteria. They are estimated based on a simple screening[68] of the climate impact for 1 kg of cardboard, aluminium and plastic used as packaging material. The screening included both the production and waste management phase, in order to include potential climate impacts/benefits from recycling. All three materials were modelled as monomaterials, containing 0% recycled material, and were assumed to be sorted 100% for recycling by the consumer. The climate impacts of the materials were normalised according to the climate impact for plastic.

Below follows a description of all elements of the formula:

$\sum(mf_i \cdot W_{material\_i})$ limits the total weight of the packaging and includes the material factor (mf_i).

$\frac{-Weight_{pump}}{2}$ means that only "half" of the weight of a dosage pump is included in the calculation. This extra weight is allowed because correct dosage is an important aspect in the environmental burden of the products and a dosing pump can make correct dosing easier.

$\frac{1}{t}$ is included in the formula to encourage direct reuse of the packaging material, e.g. with the help of refill products. The reuse figure t is as standard 2 when refilling is offered, but if, for example, sales statistics can show that more refills are sold, a higher value can be used in the calculations. If, for example, two refills are sold for each product, t can be 3. A corresponding amount of refill packs must be included in the calculations to ensure that refills lead to a total reduction in the amount of packaging.

$a \cdot Vol_{product} + b$ describes the increase of packaging material as a function of the volume of the product. This is equivalent to the relative need for more packaging per volume for products with a small product volume, e.g. 20 ml cream, compared with 500 ml shampoo. The constants a and b are determined iteratively for different packaging types and have been changed compared with generation 3.

Decorative cosmetics are a type of product that differs considerably from creams, lotions, and shampoo. The requirement above has not taken into account the fact

[68] The screening was based on datasets from the Ecoinvent database and expert knowledge, and the circular footprint formula was used, together with suggested default allocation values from the EU, to allocate impacts between use of recycled material and recycling of material.

that such small products use a large amount of packaging in relation to their small product volume, therefore a separate formula is developed for decorative cosmetics. The formula has been changed somewhat; the element representing amount of recycled material has been removed and consequently the limit value has been set to 90% of the total weight of the product.

O36 Dosability / Dosing systems and emptying level

To avoid over-dosing, the following is required:

- For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press
- The following products must have an emptying level* of 90% or be able to be taken apart without tools in order to be able to empty the packaging further:
    - Bottles for conditioner and cream
    - Bottles with a pump, incl. dispenser bottles and bag-in-box dispenser systems

      Pump products with an "airless" system are exempted from this requirement

** Emptying level must be calculated according to the formula and taking into account the emptying methods in Appendix 5.*

For liquid hand soap: Description of dosing system and weighing results per full press.

For conditioner and cream bottles, bottles with a pump, incl. dispenser bottles, and bag-in-box products: Documentation of emptying level in accordance with Appendix 5 or a picture/description of how the lid/pump can be taken apart without tools.

Background to requirement O36

Over-dosing of the product increases its environmental impact but does not improve its efficiency. The requirement on dosability/dosing systems has been judged to be steerable only for liquid hand soap with a dispenser. The maximum dose at one press for liquid hand soap is related to the requirement O18 CDV.

If a large amount of product remains in the packaging when it is thrown away, this results in great product wastage. To reduce this wastage a requirement on the emptying level of the product was introduced. According to a report from the Institute for European Environmental Policy the following help to minimise waste: a large opening, transparent packaging, opportunity to turn the packaging upside down and it being easy to close[69].

It has been identified that the products with the lowest emptying level are:

- Viscous products in pump bottles
- Viscous products in tubes

[69] (Institute for European Environmental Policy, 2004)

- Viscous products in bottles, especially conditioner and skin cream

Instead of a general requirement on the emptying level, a requirement is therefore set that focuses on only these product and packaging types as far as possible.

Bottles for conditioner and cream, and bottles with a pump, incl. dispenser bottles must have an emptying level of 90%. Pump products with an "Airless" system or similar system, where there is a bag in the container and the content is sucked out when the pump is pressed, always meet the emptying level requirement and therefore do not to be documented in line with the requirement.

This requirement is unchanged compared to generation 3.

4.7 Disposal information requirements

Correct disposal of cosmetic products is an important factor in reducing the environmental impact.

O37 Disposal information

- All cosmetic products must have a label that includes the correct pictogram(s) in accordance with the common Nordic system of waste symbols, showing how the packaging should be sorted by the consumer. See details in the design guidelines for packaging: Unified pictogram system for recycling[70]. For products that are not sold in the nordic countries, national symbols or phrases can be used instead.
- The product types mentioned in the table below must bear the texts stated or equivalent information/pictogram on the label:

Table 9 Consumer information on label

Product	Cleansing lotion	Eye make-up remover	Nail polish	Nail polish remover	Aerosol spray cans
"Do not discard product, cotton wool or paper carrying this product in the lavatory or drain. Dispose in a waste bin instead"	X	X			
"Do not discard cotton wool or paper carrying this product in the lavatory or drain. Dispose in a waste bin instead"				X	
"Do not throw out-of-date/unwanted product in the lavatory, drain or waste bin. Please leave at a collection point for hazardous waste instead"			X	X	

[70] Design guidelines for packaging: Unified pictogram system for recycling: https://www.eupicto.com/media/khlbx4hb/eupicto_design-guidelines-for-packaging_final-5-skrivskyddad.pdf

"Do not discard product in a waste bin. Please leave at a collection point for hazardous waste instead"					X

Label or packaging sample

Background to requirement O37

Correct disposal of cosmetic products ensures the best possibilities for recycling and reduces the risk of problematic substances being discharged into the environment. The common Nordic system of waste symbols must be applied to indicate how to sort the packaging. See details in the design guidelines for packaging: Unified pictogram system for recycling. To increase the chance og correct sorting, the pictogram must be visible on the label. Reference to web pages or QR codes are not accepted.

To reduce the effects of paper/cotton and cosmetic products in the aquatic environment and wastewater treatment plants an information text is required about correct disposal of paper/cotton. Nail varnish and nail varnish remover contain solvents and should therefore be sorted as hazardous waste. Solvents used as a propellant in aerosols remain in the bottle when the product runs out and should therefore also be sorted as hazardous waste.

4.8 Licence maintenance

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

O38 Customer complaints

The licensee must guarantee that the quality of the Nordic Swan Ecolabelled 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.

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

Background to requirement O38

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.

O39 Traceability

The licensee must be able to trace the Nordic Swan Ecolabelled 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.

Upload your traceability routine or a description.

Background to requirement O39

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.

5 Areas without requirements

Performance/quality

A requirement on verification of the general product performance as well as any claimed specific effect was part of earlier generations of the criteria. The current criteria generation comprises efficacy testing of sunscreen products and declaration of fluorine content in toothpaste only. We have chosen to narrow the scope since the cosmetic products regulation[71] and the claims regulation[72] require that proof of effect is included in the Product information file and that all claims are substantiated. Market surveys by the European Commission[73] and the European Advertising Standards Alliance (EASA)[74] have shown about 90% overall compliance with the claims regulation's common criteria for claims.

[71] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. ELI: http://data.europa.eu/eli/reg/2009/1223/oj.
[72] Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products. ELI: http://data.europa.eu/eli/reg/2013/655/oj.
[73]REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on product claims made based on common criteria in the field of cosmetics, 19.9.2016 COM(2016) 580 final https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0580
[74] Cosmetics Europe and the European Advertising Standards Alliance: Cosmetics Advertising Audit, 2015.

Claims

According to the cosmetic products regulation, no claims shall be used to imply characteristics or functions which the products do not have. For claims on organic origin of products and ingredients, established ISO 14024 type I certification schemes such as Ecocert and COSMOS are available. Nordic Swan Ecolabel criteria do not require proof of verification assessment concerning sustainability aspects which are not part of the criteria. Verification of claims on claims on mild/gentle/sensitive products is also not part of criteria generation 4 since we consider the obligations of the CPR[51] and the claims regulation[52] sufficient, according to the section on Performance/quality above.

6 Changes compared to previous generation

Changes to the requirements for cosmetic products in criteria generation 4 compared with the previous criteria generation 3.

Table 10 Overview of changes to requirements for cosmetic products generation 4 compared with previous generation 3.

Proposed requirement generation 4	Requirement generation 3	Same requirement	Change	New requirement	Comment
O1 Description of product	O1	X			
O2 SCCS	O2		X		SCCS opinion on perfume allergens are no longer exempted
O3 Supply chain policy and code of conduct				X	
O4 Certified raw materials from oil palms				X	
O5 Classification of ingoing substances	O4		X		EUH hazards, H410 M>1 have been added.
O6 Excluded substances	O5		X		Definitions of microplastics and endocrine disruptors have been updated. A few new substance groups have been added.
O7 Surfactants	O6				Exemption on anaerobic biodegradability for emulsifiers and emollients is removed. 1,4-dioxane impurities are restricted to 1 ppm
O8 IFRA	O7	X			

O9 Fragrance free products for babies and children	O8	X			
O10 Fragrance allergens	O9				All allergens subject to declaration on the updated list in Annex III is included
O11 Organic colorants	O10		X		Carbon black is prohibited
O12 Preservatives	O13				Preservatives must now also be readily aerobic biodegradable
O13 UV filter	O14	X			
O14 Residual monomers in polymers	O15				H370-H373 is now also restricted
O15 Aluminium	O16		X		Limits adjusted to SCCS opinion
O16 Environmentally hazardous substances	O17		X		Limits adjusted. Zinc compounds and surfactants are no longer exempted.
O17 aNBO and anNBO	O18		X		Limits adjusted
O18 CDV	O19		X		Limits adjusted
O19 Biodegradability and aquatic toxicity	O20		X		Limit adjusted
O20 Oral products: Flavourings, colours, and preservatives	O22		X		Nipple cream is included, water-soluble Zinc salts in mouthwash is limited to 0,1%
O21 Oral products: Fluoride	O36		X		Toothpaste and mouthwash must contain fluoride
O22 Heavy metals in make-up and hair dye	O11		X		Arsenic and Antimony is added to the list
O23 Hair dyes	O23		X		Hydroxypropyl p-phenylenediamine and its dihydrochloride salt is prohibited
O24 Wet wipes: Wipe material	O24		X		Plastic fibres no longer permitted. Newer up-to date requirements
O25 Wet wipes: Process water	O24	X			
O26 Wet wipes: User information				X	

O27 Sunscreen products	O31, O35		X		Clarifications on test procedure and SPF claims
O28 Animal care products	O25a		X		Clarifications to which parts of the CPR to comply with
O29 Sex lubricants	O25b		X		Clarifications to which parts of the CPR to comply with
O30 Medical lubricants				X	
O31 Packaging and materials				X	
O32 Plastic packaging				X	
O33 Paper-based packaging				X	
O34 Labels				X	
O35 WUR	O26		X		Limits tightened. Material constants updated
O36 Dosability	O29	X			
O37 Disposal information	O32		X		Aerosol spray cans included
O38 Customer complaints				X	
O39 Traceability				X	

New criteria

In the next version of the criteria, the following should be reviewed:

- The possibility for setting a requirement for the maximum allowed content of raw materials based on fossils.
- The possibility for requiring that palm oil/palm kernel oil must be RSPO certified with traceability level Segregated or Identity Preserved, and no longer allowing Mass Balance (or Book and Claim).
- The possibility for setting a requirement for the maximum allowed content of viscose in wet wipes.

The possibility for setting a requirement for the use of recycled plastics for packaging.