About Nordic Swan Ecolabelled

Cosmetic products



Version 3.9

Background to ecolabelling
01 December 2020

Nordic Ecolabelling

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090 Cosmetic products, version 3.9, 01 December 2020

This document is a translation of an original in Swedish. In case of dispute, the original document should be taken as authoritative.

Addresses

In 1989, the Nordic Council of Ministers decided to introduce a voluntary official ecolabel, the Nordic Swan Ecolabel. These organisations/companies operate the Nordic Swan 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 and the impact of cosmetic products on health and the environment, a market overview 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 and animal care products (not covered by the Cosmetics Regulation).

Nordic Swan Ecolabelling has come to the conclusion that the most relevant environmental parameters for cosmetics are:

- emissions of hazardous, non-degradable and/or bioaccumulative substances in the environment, which place a burden on treatment works and/or recipients,
- the amount of packaging material and
- extraction of raw materials

Setting criteria on the toxicity and degradability of the ingoing substances, the amount of packaging and sustainable extraction of raw materials can reduce the burdens on our external environment.

There are also certain health-related problems associated with cosmetic products, such as allergies and unnecessary exposure to substances that may be harmful to health. The criteria also cover these aspects.

This version of the criteria contains a number of changes compared with version 2. The main changes in this version are as follows:

- New information and policy requirements on renewable raw materials
- New substances added to the list of prohibited substances
- Ban on nano UV filters with exemption to nano TiO_2
- Restriction on aluminium in leave on products
- Stricter packaging requirements
- New requirement on the residual amount of the product in the container after use
- CDV can be calculated based on the DID list from 2014 or 2016

For full list of changes, see Table 3 Overview of changes to criteria for cosmetics version 3 compared with previous version 2 in chapter 5.

With the help of the above, the environmental benefits from version 2 to version 3 can be summed up as new substances on the list of prohibited substances, plus a total ban on nanomaterials med undantag till TiO_2 som UV-filter guaranteeing better cosmetics from an environmental and health point of view. Stricter packaging requirements restrict the use of packaging material and improve resource efficiency. A new requirement on the emptying level limits waste, leading to environmental benefits. Sustainable extraction of raw materials is a major global issue with a huge environmental impact and an information requirement and a policy requirement bring attention to the issue.

2 Basic facts about the criteria

Products that can be labelled

All cosmetic products covered by the EU Cosmetics Regulation 1223/2009 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 product group, as the liquid on the wipe is intended for functions as described above. These can be labelled with the Nordic Sean Ecolabel even if the wipe is not covered by the Cosmetics Regulation. Washing up liquid with added skin protection, perfumed toilet paper or tissues with lotion, for example, do not meet the above criteria and are normally not covered by the definition of cosmetic under the Cosmetics Regulation or Nordic Swan Ecolabelling criteria for cosmetic products.

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.[1]

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. Sex products with formulations similar to products within the Cosmetic Regulation such as lube, anal creams and orgasm gels can be Nordic Swan Ecolabelled although they are not covered by the Cosmetic Regulation.

Products covered by the Biocides Regulation 528/2012 cannot be Nordic Swan Ecolabelled. These are often marketed as antibacterial, antiseptic and/or disinfecting. It is the agencies in the Nordic countries who decide whether a product is a biocide or not – but irrespective of this, such products will not be able to be Nordic Swan Ecolabelled because we do not permit the addition of biocides for purposes other than to preserve the product.

Justification for Nordic Swan Ecolabelling

To achieve environmental gains, each individual requirement must be relevant to the inherent environmental problems of the product group. There must also be a proven potential to differentiate between the environmentally better products and others (there must be a difference and it has to be large enough that it “pays” to set the requirement). There must also be scope to steer the environmental problem in question via ecolabelling requirements.

These three parameters are to be seen together and as such are referred to as Relevance-Potential-Steerability, RPS. Choosing the requirements that together have the greatest

[1] (EU, 2013)

relevance, potential and steerability in terms of the product's life cycle achieves the greatest environmental gain.

Nordic Swan Ecolabelling believes that there are many different products and players in the cosmetics industry and that they differ in various ways, which means that Nordic Swan Ecolabelling can separate out the best products in environmental terms.

Nordic Swan Ecolabelling has carried out a quantitative MECO analysis (i.e. summarising the impact of materials, energy, chemicals, etc. on the basis of a total evaluation of the products, from production of raw materials to waste, plus transport). The MECO analysis helps to evaluate what the relevant health and/or environmental impacts are linked to materials, energy and chemicals (and other substances) in the different life cycle phases of cosmetic products. The evaluation is based on studies of the literature plus Nordic Swan Ecolabelling's knowledge of the products, their constituents and production. It has been divided into rinse-off cosmetics and leave-on cosmetics, which have different usage patterns. The MECO analysis for the two product types differs in the production, usage and waste phases. The two MECO analyses are set out in a table in Appendix 2.

The important parameters according to the MECO and life cycle analyses[2] are the extraction and production of raw materials, packaging, the usage phase and emission of chemicals in the usage and waste phases. Transport is normally a minor impact. The impact is described in more depth of the different phases below using the RPS tool.

Relevance

Relevance is assessed based on which environmental problems the product group causes and how extensive those problems are.

Raw materials

Most of the raw materials used in cosmetic products are organic substances. Inorganic raw materials are also used, e.g. salts, alkalis, TiO2 and mineral pigments but with fewer variations and in smaller quantities. Cosmetic products use both renewable and non-renewable organic raw materials. There are limited amounts of non-renewable materials because they are extracted from fossil oil while renewable raw materials are re-established through natural processes. The fact that renewable raw materials are re-established is an important argument for promoting the use of renewable raw materials, i.e. it is relevant to introduce requirements encouraging the use of renewable materials.

Renewable raw materials also have an environmental impact, however, and questions relating to palm oil are one of the most important and most relevant issues regarding renewable raw materials. Approximately 70–80% of all cosmetics in the world contain palm oil. [3] Other vegetable raw materials that can be used as an alternative also have their problems; the harvest for palm oil is much higher than for other vegetable oils, it is 4–9 times more productive than other vegetable oils. [4] It is therefore appropriate to set requirements for the production of vegetable raw materials.

[2] (Herron, June 18 2013), (Annette Koehler, 2009)
[3] (Cosmetics Design Europe, 2014)
[4] (WWF, 2016)

Packaging

Packaging is a relevant environmental burden in cosmetics, and for some products it is more relevant than the product itself. This naturally primarily concerns products with more packaging than contents. There are many examples of cosmetic products that use more packaging than necessary, e.g. small amounts of cream sold in heavy glass jars or so called luxyry products with both palsitc and paper wrapping, and it is therefore relevant to set requirements on packaging in terms of the amount and the materials used.

Manufacture of ingoing substances and cosmetics

Manufacturing ingoing substances and products consumes energy in the factories. Life cycle assessment of cosmetic products shows that the manufacture of ingoing substances in cosmetic products or the manufacture of the cosmetic product does not account for the dominant environmental impact in the life cycle of the product.[5] Raw materials producers state that the part of the life cycle of the product that accounts for the greatest environmental impact differs from product to product based on production processes, e.g. drying and fermenting demand energy.

Even if the environmental impact from the manufacture of cosmetics/ingoing substances is not the dominant environmental impact in the product's life cycle, it can sometimes be thought to be relevant because cosmetics are manufactured in large amounts.

Use phase

Cosmetics can contain over 26 000 substances and constituent parts according to the European Commission's inventory of cosmetic ingredients.[6] The overall relevance of the product group in terms of chemicals requirements is based on the fact that the Cosmetics Regulation does not contain requirements on the use of the substances that may impact on the environment (toxic, persistent or bioaccumulative). Nor does it exclude the use of allergens, for example. There is currently no definition of endocrine disruptors in the EU and therefore nor are these extensively limited/prohibited in cosmetic products. Nor are there any requirements that cosmetic products should be classified, e.g. in the same manner that laundry and cleaning products are classified.

Allergens are a major concern for many consumers, and are found in very many cosmetic products. Media attention is also often focussed on cosmetic products and their component substances, something which gives rise to concern among consumers. Large amounts of cosmetic products are sold, and these products can be used by consumers up to several times a day. Large amounts of cosmetic products are used, which also makes it relevant to set ecolabelling requirements for cosmetics. Sales of cosmetic products are high throughout the Nordic countries, amounting to a total of over EUR 4 800 million. [7]

When a cosmetic product is used, the amount that is used is relevant and in the product types where it is possible to steer the consumer towards using the "right dose", it is relevant to limit overdosing. This applies, for example, to liquid soap which can be dosed with a pump, ensuring that only products with a low environmental impact per functional unit (washing hands) are able to meet the requirement.

[5] (Herron, June 18 2013), (Annette Koehler, 2009)
[6] (European Comission, ei pvm)
[7] (TY, 2014), (Kosmetikkleverandørenesforening, 2012), (SPT, ei pvm), (KTF, KTF/Statistik, ei pvm)

A relevant environmental impact in the use of many cosmetic products is the consumption of hot water, due to the energy required to heat the water.

Waste phase

Cosmetic products and their ingoing substances can take different routes from the consumer to the surrounding environment after use. Some volatile ingredients evaporate to air from hair and skin, other ingredients disappear with the washing water when bathing/showering or washing clothes. Some ingredients are absorbed by the skin and finally disappear the natural way or are accumulated in the body. Some products (e.g. wet wipes, facial cleaning products and nail varnish remover) are likely to be disposed of with the household waste. Sunscreens partly end up in the sea/aquatic environment when people go swimming. It is therefore relevant to set requirements on the inherent characteristics of the substances included in the products, such as degradability and aquatic toxicity and to prohibit or reduce problematic substances such as microplastics.

There are also products on the market where an extremely large proportion of the product remains in the packaging and which are hard to empty without extra work, and a pair of scissors, for example. The requirement on the emptying level is therefore relevant in reducing the amount of waste. However, the emptying level reduces the environmental impact in all phases of the life cycle. Because the product is used to the very last drop, less raw ingredients, and energy in production and transport are needed.

Potential

Potential is assessed based on the potential environmental gains within the specific product group and for each area in the criteria where requirements are set.

Raw materials

There is potential to introduce requirements on renewable raw materials to safeguard their origin and their sustainable cultivation. Systems such as RSPO are currently available, which distinguish between raw materials production. Nordic Swan Ecolabelling experiences a desire both from consumers and certain licence-holders that Nordic Swan Ecolabelling should broaden this area and consider introducing requirements for renewable raw materials.

Packaging

There are major differences in both choices of material and amount of material in the packaging of cosmetic products. There is therefore potential for requirements on packaging. The majority of cosmetic products that are Nordic Swan Ecolabelled today have plastic packaging, but there are also other types of packaging on the market, e.g. glass and metal.

Manufacturing ingoing substances and cosmetics

Energy use and environmental impact from manufacturing are reduced by optimising processes and using renewable energy, for example.

We also have the potential to influence the production of ingoing substances when we set requirements on residues from the production of ingoing substances.

Use phase

Cosmetic products involve a large number of different substances. As cosmetic products are used directly on the body, it is relevant to set stringent health requirements such as avoiding or limiting substances that are sensitising, endocrine disruptors and similar. There is also potential for such requirements where the manufacturers of the products are able to select which raw materials are to be included in their products.

The potential for health benefits in the product group has been shown in a large number of tests carried out by the Finnish consumer organisation Kuluttaja, the Swedish Testfakta, the Danish consumer organisation Forbrugerrådet Tænk and the German magazine Öko-Test, which have also found differences between the products in recent years: In recent years Testfakta has found allergenic substances and parabens in skin lotions[8], and allergens in mascara[9]. The Finnish consumer magazine Kuluttaja compared BB and CC creams in 2014[10] and found sensitising fragrances in several products and in 2012 found the carcinogenic nitrosamine in one mascara.[11] The Danish consumer organisation Forbrugerrådet Tænk[12] has tested wrinkle cream. It found that 2 of the 14 products tested contained the preservative MI. They have also tested wet wipes,[13] children's sunscreen,[14] and found substances such as methylisothiazolinone and propylparaben in both and body lotions[15] and hand soap[16] and found undesirable ingoing substances in these too. In August 2014 Fremtiden i våre hender[17] in Norway carried out a test of deodorants. 13 of the 28 products tested were found to contain triclosan. An increased incidence of allergies in conjunction with the use, e.g. of fragrances and preservatives also indicates potential for differentiating products with a good health profile.

Nordic Swan Ecolabelling carried out a small survey of cosmetic products in stores during its evaluation of cosmetics in 2014 and found that non-Nordic Swan Ecolabelled products contain a large proportion of substances that Nordic Swan Ecolabelling excludes, which shows that it is relevant to exclude or limit the substances that have been found here.

These articles, tests and survey show that there is a difference between the products and thus potential. Similarly, the ban on microplastics is one way to differentiate Nordic Swan Ecolabelled products from non-Nordic Swan Ecolabelled products in the segments in which microplastics are used. This would enable Nordic Swan Ecolabelling to help to guide consumers to choose products that are best for the environment.

With regard to correct dosages, there is potential to make a difference as it is possible to choose different pumps and vary the viscosity of the products. However, it is hard to steer how the end consumer handles the products and, for example, how much shampoo they use.

[8] (Testfakta, 2015)
[9] (Testfakta, 2011)
[10] (Kuluttaja, 2014)
[11] (Kuluttaja, 2012)
[12] (Forbrugerrådet Tænk, u.d.)
[13] (Forbrugerrådet Tænk)
[14] (Testfakta, 2014)
[15] (Forbrugerrådet Tænk Kemi, 2015)
[16] (Forbrugerrådet Tænk Kemi, 2015)
[17] (Lindahl, 2014)

Unlike, e.g. detergents, there is little potential for concrete improvements in terms of hot water used in conjunction with cosmetics because “cold water shampoo” would not be relevant as a product from a consumer point of view.

Waste phase

Reducing problematic substances such as microplastics and non-degradable and/or endocrine disrupting preservatives is important for the waste phase too, and from the above it is clear that potential exists.

Requirements on e.g. information on correct waste management, are both relevant and have potential as they give the consumer opportunities to handle the waste correctly and so reduce its environmental impact.

There are packaging solutions that are easier to empty. The requirement on the emptying level therefore has the potential to reduce the amount of waste and at the same time the environmental impact in all phases of the life cycle.

Steerability

Steerability is assessed based on the scope to set requirements concerning the relevant environmental parameters with potential for improvement.

There is steerability in Nordic Swan Ecolabelled cosmetics in that many consumers demand cosmetic products that constitute a good choice in terms of health and the environment. There is growing awareness of environmental aspects among the general public, which increases demand for Nordic Swan Ecolabelled cosmetics. Those consumers who are expected to be most interested in Nordic Swan Ecolabelling are those that have an extra focus on the products they use not being damaging to health or the parents of children or infants. The latter group are particularly aware of the contents of the products they use. A growing number of consumers choose natural cosmetics for health and environmental reasons.[18] However, there are no guarantees that natural cosmetics are free from classified allergens, for example. Therefore, these consumers might also be interested in Nordic Swan Ecolabelled cosmetics if these took health issues into account.

Raw materials

Promoting renewable raw materials in Nordic Swan Ecolabelled cosmetics requires that the production of renewable raw materials, and the production of vegetable oil in particular, is sustainable. RSPO[19] is one of the initiatives that seeks to promote the production of sustainably grown palm oil.

Steerability of requirements on the origin of raw materials should be OK regarding palm oil. Major actors in the market, manufacturers of cosmetics and raw materials producers alike, have stated that they will switch to certified palm oil in 2015 and 2016.[20]

Other problematic vegetable raw materials such as soya and sugar cane also have certification systems.[21] These are used to a lesser extent than RSPO in cosmetics. These

[18] (Organic Monitoring, 2011)
[19] (RSPO, http://www.rspo.org/, ei pvm)
[20] e.g. (P&G, ei pvm), (Unilever, ei pvm), (Henkel, ei pvm)
[21] (Bonsucro, ei pvm), (RTRS, ei pvm)

certification systems have the same problem as the RSPO standard (more information under chapter "Other labels").

Although standards have their deficiencies, Nordic Swan Ecolabelling considers that for the product groups where there are no alternatives and palm oil/soy derivatives are used in large quantities, they are a good start.

There is no such system for fossil raw materials and their origin is not steerable.

There is EU legislation on animal fats: These are covered by EU Regulation 1774/2002 of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption, which ensures traceability to the point of origin of waste and residues.

Packaging

Packaging can partly be steered towards reduced use of packaging and also towards packaging material that places less of a burden on the environment than others. This can also be verified by certificates and calculations of packaging material.

Manufacture of ingoing substances and cosmetics

It is difficult to set steerability requirements on the manufacturing process of cosmetics, such as on energy use. One reason for this is that the factories often manufacture both Nordic Swan Ecolabelled and non-Nordic Swan Ecolabelled products on the same production line.

Quality procedures can, however, safeguard good quality. Requirements on pollutants ensure purer input substances.

Use phase/waste phase

When it comes to the use of cosmetic products, it is difficult to steer how the consumer will finally use their product, but demanding clear user instructions and dosing systems (for the products where this works) increases the chances of less over-use and similar. If a large amount of product remains in the packaging when it is thrown away, this results in great product wastage. If a large amount of the product remains in the packaging when it is thrown away, this results in a large amount of waste, which affects all phases of the life cycle. The choice of packaging affects the emptying level to a certain extent and some types of packaging empty better than others – screw tops and similar solutions can further help emptying. The producers thus have steerability over the emptying of packaging to a certain extent.

Consumer interest in cosmetics is predominantly about their contents. In some consumer categories, Nordic Swan Ecolabelled products are very important, such as, for example, families who buy children’s and baby products. When it comes to input substances for these products, Nordic Swan Ecolabelling can steer towards products whose contents place less of a burden on the environment by applying requirements that limit/exclude substances due to their characteristics. Licensing Nordic Swan Ecolabelled products has resulted in changes to the products’ raw materials.

The producers of Nordic Swan Ecolabelled cosmetics also have steerability over the raw materials they use in their products and the materials used in the packaging, i.e. they can influence the contents and thus the use and waste phases in their products to a large extent.

When it comes to the business to business market, environmental aspects are often involved in procurement in various ways. Nordic Swan Ecolabelled hotels and restaurants are examples of businesses that often demand Nordic Swan Ecolabelled soap.

Nordic Ecolabelling's distinctive environmental requirements

It is important that the Nordic Swan Ecoalbel is up to date with the world of cosmetics and remains a safe choice that stands for stringent environmental and health requirements and that this is clearly communicated via the consumer platforms currently available. Therefore, a joint Nordic summary of the ecolabeling's distinctive environmental requirements has been produced. Nordic Swan Ecolabelled cosmetic products:

- Meet strict requirements on health properties of chemicals. The requirements must be fulfilled by among other things perfumes and aromas, colorants, UV-filters and preservatives.
- Contains no perfume if intended for babies and children.
- Meet strict requirements on environmental properties of chemicals. The requirements cover degradability, bioaccumulation and toxicity towards aquatic organisms.
- Meet strict requirements on the amount and type of packaging.

Version and validity of the criteria

Nordic Swan Ecolabelling's criteria for cosmetic products were originally introduced as two separate criteria documents for soap and shampoo, version 1, adopted 1996, (cosmetic products that are rinsed off, "rinse-off"), and cosmetic products version 1, adopted 2004, (which covers all other cosmetic products other than those which are rinsed off).

The criteria for shampoo and soap were revised twice. Table 1 in Appendix 1 contains a history of the criteria documents.

In 2008 Nordic Swan Ecolabelling decided to merge the criteria documents into a combined document containing the criteria for Nordic Swan Ecolabelling of cosmetic products, covering both "rinse-off" and "leave-on" products. The obvious reason for this is that the products consist of similar substances with similar uses and functions, whether or not the products are intended to be rinsed off or left on the skin. In addition, all products are covered by the same legislation (Council Regulation 1223/2009 on Cosmetic Products). The criteria document was called cosmetic products and it was version 2.

Table 2 in Appendix 1 contains a history of the cosmetics criteria.

The Nordic Market

Industry and producers

In all the Nordic countries, there are global cosmetics manufacturers, such as Unilever, L'Oréal, Biotherm, Clarins and Clinique, but there are also smaller national companies, including some natural cosmetics.

Sales of cosmetic products are high throughout the Nordic countries, amounting to a total of over EUR 4 800 million, based on the following:

- Finland EUR 940 million (€171/person according to TY[22], 2014, multiplied by a population of 5.5 million)
  Norway NOK 9 790 million (based on information from KLF[23] on net sales from 2012)
- Denmark DKK 7 792 million (based on information from SPT[24] for 2012)
- Sweden SEK 15 330 million (based on information from KTF[25] from 2012)

There are many companies manufacturing cosmetics in the Nordic countries, such as Cederroth, NOPA Nordic, Allison, Persano, DermaPharm, Lumene, Lilleborg, Kiilto, Teampac, Aco, etc. The companies vary from small, to medium-sized or large. There are both private-label products and those that are sold under their own product name in all Nordic countries.

Retailers

Cosmetic consumer products are mainly sold in supermarkets and in specialist shops. Some are also sold at pharmacies, hairdressers salons and through direct selling. The distribution between the different sales channels varies in the different countries.

Some cosmetics are also sold via the internet and in various tax-free outlets (ferries, airports, etc.) These sales points are harder to monitor.

When it comes to Nordic Swan Ecolabelled cosmetic products for consumers, they are mainly found in supermarkets and pharmacies. Sometimes these include a number of products bearing the store's own name, e.g. Coop (Änglamark), Matas, Rema, Pirkka, Tusinfryd and many products for various pharmacy chains.

Products sold to commercial customers, business to business, mainly sold by direct sales and public procurement, where the environment plays an important role for many.

On the business to business side many of the products sold globally are Nordic Swan Ecolabelled, such as soaps Tork, Katrin, Rentokil and Sterisol.

The market

The view of Nordic Swan Ecolabelled products is positive in the Nordic countries. A Finnish dissertation[26] in 2012 found the following regarding the purchases we make “When using cosmetics the women in the survey appreciated **the price, the quality and the products which are tested to be good in the use**. In cosmetics the women appreciated also the products which are recommended by friends, suitable for allergic skin, against animal testing and **eco-friendly cosmetics**. Ingredients of cosmetics caused slightly a caution in the women in the survey and they wanted to be more accurate what products they use in the future...”

In Denmark in particular, consumers are health-conscious and focus on ecolabelled products as they are judged to be better products from a health point of view. Many equate eco-labelling with cosmetic products that are better for health. The media often highlight the ability to avoid the most problematic substances by choosing ecolabelled cosmetics. This is particularly true for products for babies and children.

[22] (TY, 2014)
[23] (Kosmetikkleverandørenesforening, 2012)
[24] (SPT, u.d.)
[25] (KTF, Kemtekniska Leverantörsförbundet, u.d.)
[26] (Jokela, 2012)

The trends in society in which people are increasingly visible on social media, where wellness and fitness plays a major role, means that interest in cosmetic products is increasing. There is increasing interest in the substances included in or excluded from products.

In the last few years, changes have also taken place on the issue of cosmetics and gender. There are now products for men, such as skin creams, hair dye, etc. which did not exist to as large an extent a number of years ago.

During the evaluation in 2014, several manufacturers cosmetics were contacted by e-mail and asked to answer some questions. Several of the manufacturers stated that they believe that demand for renewable raw materials will increase and similarly they believe that organic ingredients are a growing trend. Some already use Ecocert, Cosmos or RSPO-certified raw materials. One manufacturer states that they require an analysis certificate under GMP (Good Manufacturing Practice) for their raw materials.

Other issues that emerge from the e-mail survey was that work is in progress within the industry to produce more environmentally friendly packaging and that one company is working to produce airless packaging.

Nordic Swan Ecolabelling licences

The number of Nordic Swan Ecolabelling licences has increased in recent years. The market share, however, remains quite small. There are products in all the Nordic countries. Baby products, primarily baby wipes, and Nordic Swan Ecolabelled B2B soaps are product types where a larger proportion is Nordic Swan Ecolabelled than in other categories. Similarly, there is a larger proportion of ecolabelled products in the fragrance-free category then in the fragranced category.

In April 2016 there were 149 licences for cosmetics in the Nordic market, covering 2609 products. These are distributed as shown in Table 1 below.

Table 1. Number of licences in respective Nordic country (April 2016)

	No. of licences	No. of products
Denmark	**90**	**2166**
Finland	**3**	**44**
Norway	**10**	**34**
Sweden	**46**	**365**
Iceland	**0**	**0**

Other labels

Statutory requirements

<u>Regulation 1223/2009/EC on Cosmetic Products</u>

The Cosmetics Regulation 1223/2009 replaced the Cosmetics Directive on 11 July 2013.[27]

The Cosmetics Regulation is European law and is directly applicable within the Community and must therefore be complied with. One completely fundamental requirement for

[27] (EU, 2009)

cosmetic products is that they shall be safe for human health when used under normal or reasonably foreseeable conditions. The requirement on safety, however, is a general requirement and does not prevent cosmetic products containing substances that may be harmful to people with a particular sensitivity (allergy) or substances that are risk classified as hazardous to health.

The Regulation sets out a long list of substances that are prohibited in cosmetics products or that may only be included in limited amounts or for limited purposes. A large number of substances are prohibited under Annex II, limited under Annex III and approved under Annexes IV to VI. CMR substances are prohibited as previously, but there is now an opportunity for exemptions under CMR categories 1A, 1B and 2 (under the CLP Regulation). As before, CMR category 2 must be risk assessed and approved by the Scientific Committee for Consumer Safety. Similarly, to this requirement, CMR categories 1A and 1B must be approved for foodstuffs, where no suitable alternative substances exist and where the substance has a particular use in the product category.

Nanomaterials are covered separately in Article 16, which requires that nanomaterials are notified and their safety evaluated; however not when used as a colourant, UV-filter or preservative. In the Cosmetics Regulation nanomaterials have a separate definition, and it is this that the producers must comply with when stating on the packaging whether the product contains nanomaterials.

One new element compared with the previous cosmetics directive is the introduction of rules on product claims (Article 20). Standardised claims have been developed, in which what the claim covers is well-defined. Claims must be verifiable.

Ecolabelling type 1

EU Ecolabel

The EU Ecolabel has criteria for rinse-off cosmetics.[28]

The criteria exclude certain ingredients and classifications of ingredients, and have similar CDV, aNBO and anNBO calculations to the Nordic Swan Ecolabel. The criteria also include requirements on packaging and the emptying level.

The EU Ecolabel also includes requirements on sustainable procurement of palm oil, palm kernel oil and their derivatives.

According to the EU Ecolabel[29] there are in june 2016 15 licenses with 151 products currently labelled under the new criteria for rinse-off cosmetics.

Good Environmental Choice (Bra Miljöval)

The Swedish Society for Nature Conservation, the organisation that manages the Swedish ecolabel Good Environmental Choice, has an open criteria document for chemical products. Approval for all types of cosmetic products can be given through this document.[30]

[28] (EU Ecolabel, 2014)
[29] (EU Ecolabel, ei pvm)
[30] (Bra Miljöval, 2014)

The criteria exclude certain ingredients and classifications of ingredients. There are particular requirements on surfactants, complex reagents and solvents, preservatives, thickeners, whiteners, acids, colorants, perfumes, biological substances, enzymes, fillers, rubbing alcohol and other substances. The criteria also include requirements on water content and packaging, and general requirements governing the companies that manufacture these products. There are also a number of product-specific requirements. In soaps, for example, only vegetable fatty acids may be used.

According to the Good Environmental Choice website, there are 16 cosmetic products with the Good Environmental Choice label and all are rinse-off products, the majority soaps.[31]

Good Environmental Choice Australia (GECA)

GECA has criteria for "Personal care" products, which include soap, shampoo, oral hygiene products, skin care, decorative cosmetics and deodorants.[32]

The criteria include requirements on effectiveness, palm oil, VOCs, phosphorus, degradability, claims, toxic and ecotoxic ingoing substances, packaging and minimising waste.

Other private labelling

Natural/organic cosmetics

There are different standards for natural cosmetics. Some of these are national and some international. They differ from each other somewhat, but what they all have in common is that the raw materials must be of natural (vegetable, animal) origin. Most of these require that the raw materials are 95% or 100% (with some exceptions) of natural and/or organic origin. There are limitations/positive lists for the remaining raw materials and particular chemical and physical processes are usually permitted. The processes that are normally not permitted are ethoxylation, propoxylation, sulphonation, gene technology and radiation.

There are few or no requirements on the extraction of raw materials. Organic raw materials must be certified, GMO is prohibited and some standards have requirements that the raw materials must not come from species threatened with extinction, for example.

The systems are not regulated by the Council Regulation on organic production (834/2007/EEC).

The most important standards are:

- NaTrue[33]
- COSMOS[34] (Developed by the Soil Association, BDIH, Cosmebio, Ecocert and ICEA)
- Ecocert[35]
- BDIH[36]

[31] (Bra miljöval, ei pvm)
[32] (GECA, 2014)
[33] (NaTrue, 2014)
[34] (Cosmos, 2013)
[35] (Ecocert, 2012)
[36] (BDIH)

The fundamental starting point with natural/organic cosmetics is different from that of Nordic Swan Ecolabelling. In natural cosmetics (almost all) raw materials must be from vegetable or animal sources. Nordic Swan Ecolabelling also accept synthetic materials but has requirements stating that raw materials, irrespective of their origin, must be degradable and must not be ecotoxic or bioaccumulating. Classifications and groups of substances that are harmful to health or the environment are also prohibited or limited under Nordic Swan Ecolabelling. Regarding raw materials, the Nordic Swan Ecolabel has an information requirement and a policy requirement that purchasing of sustainable raw materials is to increase.

Asthma and Allergy Association

The Asthma and Allergy Associations in the Nordic countries also label cosmetic products. Sunscreens, haircare products, skin care products, soaps, wet wipes and deodorant as well as make-up, for example, can be labelled by the Asthma and Allergy Association in the Nordic countries. The requirements are not available to the public in all Nordic countries and products are assessed on a case-by-case basis by allergy experts, but some fundamental principles are similar and public. Perfumes and allergens, for example are not permitted.[37] The requirements may differ in the different Nordic countries.

For example, soaps, haircare, skin care and sun protection products, as well as make up are allergy labelled in the Nordic countries.[38]

AllergyCertified

AllergyCertified was launched in 2014 as a competitor to the Nordic Asthma and Allergy Association labelling systems[39]. AllergyCertified is a global label. The products awarded the label have been checked and undergone an allergy risk assessment. The individual requirements for awarding the label are not publicly available but fragrances and allergens are not permitted.

As this is a new label, at the current time there are only very few cosmetic products approved under AllergyCertified.

Green Public Procurement (GPP)

Products, primarily such as soap, are included under the public procurement criteria of the Swedish Competition Authority [40]in the category chemical products. There are requirements for cosmetics similar to the Nordic Swan Ecolabelling requirements on cosmetics.[41] Motiva's procurement advice in Finland also contains general instructions on sustainable procurement for chemical products and cleaning services.[42] The requirements are a selection from the Nordic Swan Ecolabelling criteria for chemicals. These also include soap. In Denmark there are no specific procurement criteria for cosmetics or other chemical

[37] (Allergia- ja astmaliitto, ei pvm), (Astma- och Allergiförbundet), (NAAF, 2013), (Astma allergi Danmark)
[38] (Astma- och allergiförbundet, ei pvm) (Allergia- ja astmaliitto, ei pvm) (NAAF, 2014)
(Astma allergi Danmark, ei pvm)
[39] (Certified Allergy & Asthma Consultants, ei pvm)
[40] (Konkurensverket, ei pvm)
[41] (Upphandlingsmyndigheten)
[42] (Motivas upphandlingsrådgivning, 2014)

products. In Norway DIFI (the Agency for Public Management and eGovernment)[43] has no procurement criteria for cosmetic products.

There are no specific requirements for public procurement of cosmetics in the EU.[44] However, through the directive, in the future it will be possible to demand ecolabelled products in public procurement in the EU.

Industry labels

The European industry organisation Cosmetics Europe does not have an industry label covering environmental issues.[45] However, they state that they are in favour of sustainable development. The global system ICCA responsible care[46] is a global initiative in which companies constantly work on health, safety and the environment and communicate this to other stakeholders.

Environment product declarations (EDP)

The EDP system is a global programme for environmental product declarations based on ISO 14025 and EN 15804. There are Product Category Rules (PCR) for cosmetics and the first EDPs for rinse-off cosmetics[47] and leave-on cosmetics[48] have been published.

Raw materials labelling and traceability systems

Palm oil

	Deforestation	Peatland	HCS	HCV	FPIC	Traceability
RSPO	Allowed Subject to HCV &Legal requirements	Allowed Subject to HCV &Legal requirements Avoid planting on peat >3m	Encourages avoidance of HCS (incl. Peat)	Required, HCVs cannot be converted	Required	Separate standard
ISPO	Permitted Subject to Legal requirements	Allowed where >70 % of the concession is < 3m deep	Not explicit	Not explicit	Not explicit	In future
MSPO	Permitted Subject to Legal requirements		Not explicit	Not explicit	Not explicit	
ISCC	Strictly prohibited	Strictly prohibited	No HCS land can be converted	Required	Not Explicit	Separate standard

[43] (Direktoratet for forvaltning og IKT , ei pvm)
[44] (European Comission, 2015)
[45] (Cosmetics Europe, ei pvm)
[46] (ICCA, ei pvm)
[47] (UNIFARCO S.p.a., 2016)
[48] (UNIFARCO S.p.a., 2016)

Figure 1 Different certification schemes for palm oil [49] (HCS: High carbon Stock, HCV: High Conservation Value, FPIC: Free Prior and Informed Consent)

A new standard, RSPO next[50], has been published and it is hich is regarded by organizations such as WWF to be a step forward. [51]

Bonsucro (previously the Better Sugar Initiative)[52] is a collaborative project between a number of actors, including sugar cane producers, investors, retailers and NGOs. It is also supported by environmental organisations, such as WWF. The first standard was adopted in 2010. The production standard contains rules on the environment, social development and economical and good business practice.

Round Table on Responsible Soy Association (RTRS)[53] is an initiative from stakeholders throughout the soya production and distribution chain. It is also supported by environmental organisations, such as WWF. The first RTRS standard was adopted in 2010 and the first RTRS soya was produced in 2011. The RTRS standard contains, for example, requirements on improved production methods in agriculture, working conditions, reduced use of plant protection products, respect for local societies and protection of areas with high biodiversity. RTRS has been criticised because it is technology neutral, i.e. it allows both GMO and GMO-free soya and it does not ban dangerous plant protection products. Under RTRS it is not permitted to certify land which changed land use after May 2009.

Nordic Swan Ecolabelling's views on raw materials labelling and traceability systems

Nordic Swan Ecolabelling's raw materials group has examined the standards in relation to the requirements we set for individual parameter labels and come to the following conclusion:

At the current time, these two systems do not fully meet Nordic Swan Ecolabelling's requirements for sustainability labels.

The RSPO standard:

It is unclear whether this extends further than legislation (seeks to satisfy particularly the international conventions), there were absolute requirement but with opportunities for exceptions, and the standard provides too poor protection for important biological areas. There were no concrete requirements on setting aside protected areas (i.e. it appears to be more on the same level as environmental management). Clear-felling is permitted, secondary forest is not protected. It is permitted to establish plantations on peat bogs, which are an important carbon sink.

The RTRS standard:

The generic standard is general, with individual clearer requirements, e.g. 4.4 Expansion of soy cultivation, which states in subordinate points that after 2009 soya plantations must not be expanded in native habitat. However, it also introduces an opportunity for exceptions here: "After May 2009 expansion for soy cultivation has not taken place on land cleared of native habitat except under the following conditions …" and "In areas that are not native

[49] (Jervan, 2014)
[50] (RSPO, 2016)
[51] (WWF, 2016)
[52] (Bonsucro, ei pvm)
[53] (RTRS, ei pvm)

forest, expansion into native habitat only occurs according to one of the following two options: ...".

It refers only to local and national legislation and rules, not to international conventions. Requirements are set that all legislation/rules must be complied with (1.1 There is awareness of, and compliance with, all applicable local and national legislation) and that the owner of the land must be made clear (1.2 Legal use rights to the land are clearly defined and demonstrable.)

Apart from this, there are no specific requirements that protect protected areas, etc.

As the production of these plant raw materials currently has major environmental consequences, Nordic Swan Ecolabelling takes these two raw materials very seriously and wishes to introduce as stringent requirements as possible within the framework of the respective product group.

In the product groups where there are alternative raw materials and steerability to exclude these without the consequence of a "Burden Shift", Nordic Swan Ecolabelling wishes to exclude the use of palm oil and soya oil. (This is the case with candles).

In product groups where there are no alternatives and no steerability for Nordic Swan Ecolabelling to avoid these raw materials, Nordic Swan Ecolabelling wishes to set as stringent requirements as possible. This is to ensure that the most environmentally friendly alternative is used in Nordic Swan Ecolabelling's products. In these cases, Nordic Swan Ecolabelling judges that RSPO and RTRS, with their associated traceability systems, the best tools in the market and will therefore require these. (This is the case with Hygiene products, for example).

Both RSPO and RTRS are systems that point in a positive direction and Nordic eco-labelling wishes to keep an eye on this development, in order to potentially accept and use these in all criteria in the future.

3 About the criteria development/revision

Purpose of the criteria revision

The main aim of the revision has been to submit a proposal for revised criteria for cosmetic products with more stringent environmental and health requirements compared with the existing version. The focus of the revision has been on:

- packaging requirements
- pack requirements and dosability
- updating in line with the DID list 2014
- requirements on (renewable) raw materials
- the new sensitising fragrances and evaluating prohibiting them
- requirements on functionality and claims
- new SCCS opinions

Other requirements have been reviewed and some have been slightly adjusted.

About this criteria revision

The project has been run as a Nordic project. At the start of the project all countries produced national documentation on criteria, industry information and other national information. During the course of the project, manufacturers, industry associations and other stakeholders in the various countries have been contacted in order to tap into the knowledge, experience and interests of the industry.

Project participants:

Project Manager	Terhi Uusitalo (FI)
Project Consultant:	Trine Pedersen (DK)
Product specialist NO:	Ingvild Kvien
Product specialist SV:	Ulf Eriksson
Product specialist FI:	Heidi Vaarala
Product specialist DK:	Michael Christensen
Internal expert	Lina Harström
Internal expert (nano)	Ingvild Kvien
Internal expert (raw materials)	Terhi Uusitalo and the Raw Materials Group
Product Development Manager	Karen Dahl Jensen (DK)

4 Justification of the requirements

4.1 General requirements

The definition of ingoing substances is included to explain what is meant by ingoing substances and impurities. The definition has been changed compared with the previous version of the criteria and following consultation. The level for pollutants in raw ingredients has been tightened up compared with version 2 while other levels remain the same, and it has been attempted to make the definition easier to understand.

Definition:

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 exempt from the requirements.

Ingoing substances and impurities are defined below, unless stated otherwise in the requirements

Ingoing substances: all substances in the Nordic Swan Ecolabelled 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 raw material/ingredient and/or in the in the Nordic Swan Ecolabelled product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg) in the Nordic Swan Ecolabelled rinse off product and less than 10 ppm (0,0010 w-%, 10,0 mg/kg) in the Nordic Swan Ecolabelled leave on product.

Impurities in the raw materials ≥ 1000 ppm (≥ 0.1000 w-% ≥ 1000 mg/kg)are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled 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.

Note that sex products are considered as leace on products in the requirements where there is a differentiation in the required limits.

O1 Formulation/recipe and description of product

The applicant must give detailed information on the cosmetic product 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 ingrediens:
  - 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
  - Function
  - A safety data sheet for each ingredient
  - If an ingredient consists of several substances, data for all ingoing substances is to be stated in the recipe.

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

✉ Complete recipe in line with the requirement, Nordic Swan Ecolabelling's calculation sheet can be used. If information about the composition of ingredient is confidential, this information can be sent directly to the ecolabelling body

✉ 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 licence application must be accompanied by a complete description of all the products covered by the licence. This information is required in order to check compliance with the following requirements. Another reason for this requirement is to provide additional and more detailed knowledge about the individual product types. This will enable more relevant and detailed requirements in future criteria documents but also ensure that the requirements can be adapted to new knowledge in the area. The requirement has been modified slightly compared with the previous version of the criteria and a description of the product has been added.

O2 SCCS

Recommendations from the EU's Scientific Committee on Consumer Safety, SCCS Opinions, must be complied with where there is an unambiguous conclusion from SCCS. In cases where there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies.

SCCS recommendation, SCCS/1459/11 on fragrance allergens, is exempted from this requirement. HICC, chloroatranol and atranol are not, however, permitted in the product, see O9.

SCCS Opinions can be read at http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm

☒ Appendix 1 or equivalent declaration completed and signed.

Background to requirement O2

The EU's Scientific Committee on Consumer Safety (SCCS) has published a large number of opinions, including a large number of 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. If there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies. The requirement has been clarified in version 3 such that it is only once SCCS has reached an unambiguous conclusion that this must be complied with.

In June 2012 the EU's Scientific Committee (SCCS) issued an opinion on fragrance allergens, which recommends that a total of 127 fragrance allergens must be declared on cosmetic products, if they are included in amounts over 100ppm. These 127 substances include the 26 that are already subject to declaration under the Cosmetics Regulation and which may not be used in amounts subject to declaration in Nordic Swan Ecolabelled products (Requirement 10). In addition to this, the opinion also recommended that three named fragrances (HICC, chloroatranol and atranol) should not be included in cosmetic products due to their very high potential for sensitisation.

Notwithstanding the requirement that opinions from SCCS must always be complied with, Nordic Swan Ecolabelling has judged that it is not yet appropriate to introduce such an amendment. This assessment is based on an analysis of the situation in the market in combination with the fact that the Commission has not yet given signals on whether and to what extent the recommendation from SCCS is to be implemented in legislation. So far, there is a lack of analysis methods for many of these fragrance substances, but work is in progress to develop new analysis methods. 7 of these new fragrance substances with the highest allergy risk are limited, however, in these criteria in the same way as other sensitising fragrances (O10).

In the light of this, an exception is made for SCCS opinion 1457/11 on Fragrance Allergens. However, the recommendation that HICC, chloroatranol and atranol are not permitted in the products has been implemented.

O3 Renewable raw materials

1. The cosmetic producer must document that they are working to increase their purchasing of renewable and sustainable raw materials.

2. For each organic raw material/ingredient in the Nordic Swan Ecolabelled cosmetic product, the following data is collected:

   a) Proportion of renewable raw materials in the raw material/ingredient on an annual basis

   b) What does the raw material consist of (e.g. palm oil, coconut oil, rapeseed oil, beeswax)? State the name of the supplier.

c) Does the renewable raw material have any sustainability certification? If yes, state which, and what level of traceability (No traceability, Identity preserved, Segregated, Mass balance, Book&Claim)?

☒ 1. Policy or equivalent documentation of the producer's work for renewable and sustainable raw materials.

2. Appendix 2 from the raw materials supplier.

Background to requirement O3

Cosmetic products use ingoing substances from both renewable and non-renewable organic raw materials. In addition, there are minerals as parts of organic raw materials, and e.g. in pigments. There are limited amounts of non-renewable organic raw materials because they tend to be extracted from fossil oil which is non-renewable. Renewable raw materials mean both vegetable raw materials and animal raw materials such as beeswax or gelatine.

The renewable base materials used in cosmetics are normally various oils and fats that are further derived to e.g. surfactants, emulsifiers and emollients. By far the most common raw material is from oil palms: palm oil, palm kernel oil and their derivatives. Nordic Swan Ecolabelling judges that destruction of rain forest as a consequence of increased demand for renewable oils and fats and unsustainable agriculture can be combatted with the help of certified sustainable plantations. The most used certification system is RSPO, whose standard for sustainable palm oil production is judged by Nordic Swan Ecolabelling to meet satisfactory environmental requirements in such products where palm oil cannot be replaced by other valid alternatives. Sustainability standards are also set for other potentially problematic vegetable raw materials such as soy or sugar. These raw materials are not used in cosmetic products to an equivalent extent. Coconut is used a great deal but there are no sustainability standards yet. Animal fat is used in small amounts and use is restricted by EU legislation (1774/2002).

EU Ecolabel[54], Good Environmental Choice[55] and Australia's Good Environmental Choice[56] set ambitious requirements on the proportion of sustainable palm oil and palm kernel oil derivatives in cosmetic products.

Nordic Swan Ecolabelling carried out a survey of manufacturers of Nordic Swan Ecolabelled cosmetics and raw materials suppliers on the opportunity of setting requirements on raw materials. The majority (>95%) of the respondents considered that sustainable raw materials are and will continue to be important in cosmetics. The majority also considered that sustainable renewable alternatives for important raw materials already exist. According to several producers there is currently a satisfactory range of certified palm oil raw materials. For example, BASF stated at the Sustainable Cosmetics Summit in 2015[57] that they are very close to attaining their goal[58] of all palm kernel oil they buy coming from RSPO certified production.

The consultation responses also supported this: The majority considered that setting requirements is the correct method but that our proposed requirements were too ambitious. An additional mini consultation document was sent to the licence holders who

[54] (EU Ecolabel, 2014)
[55] (Bra Miljöval, 2014)
[56] (Good Environmental Choice Australia, 2014)
[57] (BASF, 2015)
[58] (BASF, 2014)

had answered the question during consultation and to selected raw materials suppliers and the response to a less ambitious requirement was positive.

Although there is high RPS for the raw materials requirement, we have chosen not to set an absolute requirement regarding these. We have instead chosen to require that all producers focus on their raw material choices with a requirement to work to increase sustainable raw materials in production and to list all the raw materials and whether these consist of renewable sources and whether they are certified under any certification system. The justification for this is to get cosmetics producers to focus more on the origin of the raw materials and certification schemes, and to sharpen their focus on renewable raw materials when choosing and purchasing raw materials day to day. Cosmetics producers must register the origin of each individual raw material, its certification scheme and amount at recipe level. The knowledge gained by Nordic Swan Ecolabelling from this registration will in the long term make it possible to set specific requirements on the content of renewable raw materials in Nordic Swan Ecolabelled cosmetics. At the same time, the cosmetics producers will gain an overview of all their Nordic Swan Ecolabelled recipes, so that they can quickly see how much needs to be changed, where necessary, once specific requirements for renewable materials are set. Once the cosmetics producers have a greater focus on the origin of raw materials and their certification schemes, they will already be considering alternative renewable raw materials to their traditional/common raw materials. Chemicals suppliers will thus have to offer more renewable, certified raw materials. It is therefore expected that the proportion of renewable raw materials in Nordic Swan Ecolabelled cosmetics will gradually increase across the lifetime of the criteria.

The text of the requirements states that the cosmetics producer is to work to increase their purchasing of renewable and sustainable raw ingredients. However, if a producer is already at a high level regarding the use of renewable and sustainable raw materials, the producer does not need to have high ambitions to improve further.

4.2 Requirements on ingoing substances

O4 Classification of ingoing substances

Ingoing substances (se definition above) in the product must not be classified as shown in Table 1:

Table 1 Classification of ingoing substances

CLP Regulation 1272/2008:		
Hazard class	Hazard Class and Category Code	Hazard statement
Carcinogenic*	Carc. 1A or 1B Carc. 2	H350 H351
Mutagenic*	Muta. 1A or 1B Muta. 2	H340 H341
Toxic for reproduction*	Repr. 1A or 1B Repr. 2 -	H360 H361 H362
Respiratory or skin sensitisation**	Resp. Sens. 1 Skin Sens. 1	H334 H317

* The classifications concern all classification variants. For example, H350 also covers classification H350i.

**The following substances are exempt:

- Enzymes (including stabilisers and preservatives in the enzyme raw material) can be included if they are liquid form or as granulate capsules, see requirement O12 for enzymes.
- Fragrance can be included in the final product, see requirements O7-9 on fragrances.
- Tocopherol och tocopherol acetat (DID nr. 2609)
- Amidoamin: max. 0,3% as an impurity in Cocamidopropyl Betaine (CARB)

☒ 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).

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

Background to requirement O4

There is no requirement that cosmetic products must be classified. For this reason, requirements are set for ingoing substances. The Cosmetics Regulation[59] permits the use of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) in category 1, 2, and 3 if the EU's Scientific Committee (SCCS) has assessed the substances and drawn the conclusion that they are safe to use in cosmetic products. Nordic Swan Ecolabelling applies the precautionary principle and prohibits all CMR substances to increase reassurance and safety for the user. This will also exclude potentially mutagenic and/or toxic for reproduction effects in the environment.

Examples of ingoing substances used in cosmetics today but excluded by this requirement:

- Siloxane D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) which is used, for example, as an emollient or solvent, is prohibited in Nordic Swan Ecolabelled cosmetics due to its classification as Repr. 2; H361f.
- Because Nordic Swan Ecolabelling's definition of ingoing substances counts release products as ingoing substances, preservatives which give off formaldehyde, such as sodium hydroxymethylglycinate and 2-Bromo-2-nitropropane-1,3-diol and azo dyes that release arylamine are excluded.
- BHA ((butylated hydroxyanisole, CAS 25013-16-5) is classified carc[60] and is therefore excluded.

The Cosmetics Regulation allows several sensitising substances in cosmetic products. However, allergies are a growing problem[61]. For this reason, Nordic Swan Ecolabelling has chosen to exclude substances classified as sensitising from Nordic Swan Ecolabelled cosmetics (with two exceptions). This excludes certain preservatives (e.g. methylisothiazolinone (MI) and glutaral) which are commonly used in cosmetic products, and common substances in hair dye, e.g. p-phenylenediamine (CAS 106-50-3). Fragrances are partly exempt from this requirement, because the working group has drawn the conclusion that demand for fragrance-free cosmetics is limited and the range of fragrances that do no contain allergens is limited. Thus, if perfumes or fragrances that contain allergens were to be completely prohibited, this would have a negative effect on the brand's market coverage, which would be disproportionately high compared with the potential environmental impacts of small amounts of fragrances. Substances in enzyme preparations are exempt from this requirement because all enzymes are classified as respiratory sensitisers (H334) and some stabilisers, etc. may be classified as skin sensitisers (H317).

[59] (EU, 2009)
[60] (ECHA, ei pvm)
[61] e.g. (Svedman, ym., 2012), (Videncenter for allergi, ei pvm)

Enzymes are used in toothpaste, for example. Enzymes in cosmetics, however, 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”. On the other hand, we have drawn up relevant requirements for good practice when using enzymes in Nordic Swan Ecolabelled products (see O12). Similar exemptions for preservatives have been evaluated. However, Nordic Swan Ecolabelling considers that it is possible to manufacture functional products with a sufficiently good shelf-life without sensitising preservatives. Allergies to preservatives, particularly MI (CAS 2682-20-4) have risen in recent years[62] and Nordic Swan Ecolabelling does not want to contribute towards unnecessary exposure. SCCS finds that also for leave-on products (including wet wipes) there is no safe concentration for MI med in terms of sensitising/allergies.[63]

Tocopherol and tocopherol acetate (DID no. 2609) are often used as antioxidants in leave-on products. At the moment opinion is divided as to whether or not tocopherol is to be classified with H317. Nordic Swan 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 (DID no. 2609) are judged not to be allergens, although certain raw materials suppliers classify them with H317.

The requirement was adjusted in March 2020 to allow sensitizing amidoamin as an impurity in Cocamidopropyl Betaine as it cannot be avoided. According to Asthma Allergy Denmark this should not pose a risk.[64]

O5 Prohibited substances

The following substances must not be present in the product or raw material.

- D4 (octamethylcyclotetrasiloxane, CAS no 556-67-2)
- D5 (decamethylcyclopentasiloxane, CAS no 541-02-6)
- D6 (dodecamethylcyclohexasiloxane CAS no 540-97-6)
- BHT (butylated hydroxytoluene, CAS no 128-37-0)

An exception is made for BHT in perfumes in the amount of ≤100 ppm provided that the amount in the cosmetic products does not exceed 1 ppm

- BHA (butylated hydroxyanisole, CAS no 25013-16-5)
- Borates and perborates
- Perfluorinated and polyfluorinated substances (PFC)
- Nitro musks and polycyclic musk compounds
- EDTA (Ethylenediaminetetraacetic acid) and its salts (see however exception for solid soap O21).
- Triclosan
- Hypochlorite, chloramine and sodium chlorite
- Benzalkonium chloride
- Parabens (4-Hydroxibenzoic acid and its salts and esters).
- Phthalates
- Kojic acid (CAS no 501-30-4)

[62] (Svedman, ym., 2012), (SCCS, 2013)
[63] (SCCS, 2013)
[64] Personal comminication with Asthma Allergy Denmark, February 2020

- Octocrylene (CAS no 6197-30-4)
- Triclorcarban (CAS no 101-20-2)
- Benzyl salicylate (CAS no 118-58-1): Exception until 1 December 2021
- Genistein (phytoestrogen, CAS no 446-72-0)
- Daidzein (phytoestrogen, CAS no 486-66-8)
- Benzophenone-4 (CAS no 4065-45-6)
- Benzophenone-5 (CAS no 6628-37-1)
- Salicylic acid (CAS no 69-72-7, och salter: 824-35-1 / 18917-89-0 / 59866-70-5 / 54-21-7 / 578-36-9 / 2174-16-5)
- Butylphenyl methylpropional/BMHCA/lilial (CAS no 80-54-6)
- Triphenyl phosphate (CAS no 115-86-6)
- Ethyl-hexyl salicylate (CAS no 118-60-5): Exception for sunscreen until 1 September 2022
- Substances considered to be (potential) endocrine disruptors in accordance with the European Union's reports concerning endocrine disruptors (see Appendix 9 for definition).

  The EU's report on potential endocrine duruptors can be read in their entirety at http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf Se Appendix L
- Substances that have been judged in the EU to be PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated but which meet these criteria.
- Substances on the Candidate List (SVHC)*.
- Microplastics**
- Halogenated and/or aromatic solvents***
- Nanomaterials/particles as defined in the Cosmetics Regulation****

  An exception is made to this requirement for

  a) Synthetic amorphous silica, which is used as an abrasive in toothpaste.

  b) TiO2 approved in SCCS opinion SCCS/1516/13. I.e. TiO2 must not be photocatalytic, coating must be stable and TiO2 may not be included in spray products

  c) TBPT as UV-filter as approved in SCCS opinion SCCS/1429/11, i.e. not in spray products.

  d) MBBT som UV-filter i godkänt i SCCS opinion SCCS/1546/15, i.e. not in spray products.

** The Candidate List can be found on the ECHA website at: http://echa.europa.eu/candidate-list-table*

*** Microplastics are here defined as insoluble plastic particles that are < 5 mm and are not biodegradable under OECD 301 A-F.*

**** 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*

***** Insoluble or biopersistent and deliberately manufactured material with one or more external dimensions or an internal structure in the region of 1-100 nm*

☒ Recipe.

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

Background to requirement O5

There are several problematic substances which cannot be excluded from our general requirements due to the product chemistry of the ingoing substances. For this reason Nordic Swan Ecolabelling has drawn up a list of substances that must not be included in the product, see the definition under general requirements. The aim is only to list the problematic substances which are not excluded due to other requirements and which are relevant to the product group. The requirement has changed compared with the previous criteria document: the substance group of perfluorinated compounds and pthalates has been added to the list. This requirement is to a certain extent a "double entry" for certain substances: a substance can be, for example, both PBT and on the Candidate List.

This requirement has a significant impact on the difference between Nordic Swan Ecolabelled products and other products on the market because it excludes, e.g. D4 and D5, parabens, triclosan and EDTA, which are currently generally used in cosmetics.

Silicones and siloxanes (D4, D5 and D6)

Siloxanes and silicones (including polysiloxanes, which are also called silicones, but in purely chemical terms are not genuine silicones) are used to a considerable extent in cosmetic products, e.g. as softeners, solvents, anti-static agents, moisturisers, anti-foaming agents and to control viscosity in hair care products and anti-perspirants, in creams/liquids, liquid soaps and gels and decorative cosmetics. Siloxanes used in cosmetic products are structurally diverse; cyclical, linear, polymers, can bind to longer and shorter carbon chains, etc. The search term siloxane produces 300 hits in the EU's CosIng database on ingredients in cosmetics. The term "-methicone" is often used for siloxane compounds, particularly in cosmetics.

Some of the siloxanes used in cosmetics are found in the environment and in plants and animals although in low concentrations. This indicates that the compounds are bioaccumulative. Siloxanes are first and foremost found close to densely populated areas.[65] Low-molecular, volatile siloxanes (e.g. D4, D5 and HMDS) evaporate when they are used and can be spread over large distances in the air. Non-volatile siloxanes (higher molecular weight) which are also used in cosmetic products mainly reach the sea in treatment works, where they are accumulating in the sludge because they are slowly degradable and have high bioaccumulation potential. Cyclic siloxanes have the greatest degree of spread in the environment, particularly D4 (octamethyl cyclotetrasiloxane, CAS 556-67-2) and D5 (decamethyl cyclopentasiloxane, CAS-no. 541-02-6). D4 is classified Aquatic Chronic 3 with H413 and Repr. 2 with H361f. D5 is structurally related to D4 and is on the Norwegian authorities' list of prioritised hazardous substances[66]. D5 is also under evaluation as a PBT substance but no conclusion has yet been reached. D4, D5 and the linear siloxane, HMDS (hexadimethyl siloxane, CAS 107-46-0) is categorised as an HPVC chemical (high production volume chemical) in the EU. HMDS does not, however, seem to be used in cosmetic products according to CosIng.[67]

An SCCS opinion states that D5 is not safe to use in skin cream, hair styling products or products that cause exposure via the airways.[68]

[65] (TemaNord, 2005) (Miljøstyrelsen, 2005)
[66] (Miljøstatus , 2014)
[67] (CosIng, ei pvm)
[68] (SCCS, 2015)

D6 was also studied. It is bioaccumulative with BCF = 39874 / logKow = 9.06 and is not biodegradable (4.47% in 28 days).[69] In a Swedish study D4, D5, D6 and HMDS were found in the breastmilk of 11 out of 39 women[70] and D4 in trials carried out on rats has a certain tendency to affect hormone production in female rats.[71] There is no ecotoxicological data but it is expected that D6 has some characteristics that correspond to D4 and D5. For example, it is expected that D6 will affect the liver on repeated exposure[72].

For the majority of siloxanes there is only limited data on their toxicity, degradability and bioaccumulation potential. Available data indicates that siloxanes are toxic to aquatic organisms and slowly biodegradable.[73] Because there are many silicones and siloxanes in the market which are suspected to be particularly harmful, we therefore only exclude D4 and D5. For D4 this is a double requirement because it was already prohibited under the requirement to classify ingoing substances (O5), but it is logical to mention it here together with D5. The other silicones and siloxanes must meet relevant environmental requirements in the criteria and if no data on degradability or toxicity is available, they are judged under a "worst case" like all other substances without sufficient data. The requirement is the same as in version 2.

BHT and BHA

BHT (CAS 128-37-0) is classified by some[74] as muta., carc. and repr. and BHA (CAS 25013-16-5) as carc[75] and they are thereby excluded via the hazard classification, but in order to be clear, both also remain on the list of substances that may not be included (BHA was added following consultation).

However, perfumes contain small amounts of BHT as antioxidants, which ensure the stability of the perfume mixture that can affect the stability of the entire product. Therefore, an exception was given in July 2017 that the perfume mixture may contain up to 100 ppm BHT if the content of the product does not exceed 1 ppm.

Borates and perborates

Borates and perborates are used in cosmetics, e.g. as oxidisers and buffers in oral hygiene products and as whiteners. A number of these substances and boric acid are classified as toxic for reproduction and are limited or prohibited in cosmetic products The requirement on classification of ingoing substances prohibits the use of these classified borates and perborates in Nordic Swan Ecolabelled cosmetic products. However, we know that e.g. magnesium ascorbylborate[76] (a magnesium salt from the reaction product of boric acid and ascorbic acid) is not classified as toxic for reproduction and is not limited in cosmetics under the Cosmetics Regulation, but there is no guarantee that it does not break down into boric acid, which is toxic for reproduction.[77] The prohibition on the use of all borates and

[69] (ECHA, 2015)
[70] (Miljøstyrelsen, 2014)
[71] (Miljøstyrelsen, 2014)
[72] (Environment Canada, Health Canada, 2008) (Miljøstyrelsen, 2014)

[73] (TemaNord, 2005)
[74] (ECHA, ei pvm)
[75] (ECHA, ei pvm)
[76] (CosIng, ei pvm)
[77] (SCCS, 2013)

perborates in Nordic Swan Ecolabelled products is therefore justified by Nordic Swan Ecolabelling's precautionary principle. The requirement is the same as in version 2.

Perfluorinated and polyfluorinated compounds (PFC)

Perfluorinated compounds are used in cosmetics, such as hair and skin conditioners and as solvents.[78]

The OECD has published a repport[79] listing a number of known problematic PFAS substances (Perfluorinated and polyfluorinated alkylated substances). The list shows a number of relevant substances, which are excluded by a ban on the use of PFCs. Note however, that Nordic Swan Ecolabelling's term PFC is broader than the OECD's PFAS.

Per and polyfluorinated compounds (PFCs) constitute a group of substances that have harmful properties. Certain per and polyfluorinated compounds can be broken down into the very stable PFOS (perfluorooctane sulfonate) and PFOA (perfluorooctanoic acid) and similar substances. These substances are found throughout the globe, from large oceans to the Arctic. PFOS have also been found in birds and fish and in their eggs. The substances are extremely persistent and are easily absorbed by the body.[80] The substances in this group impact on the biological processes of the body and are suspected to be endocrine disruptors, carcinogenic and have a negative impact on the human immune system.[81] PFOA, APFO (ammonium perfluorooctanoate) and some hydrofluoric acids are on the Candidate List in the light of the fact that they are toxic for reproduction and PBT, see the section later in this chapter.

There are new research results showing that shorter chains (2-6 carbon atoms) have been discovered in nature.[82] It is therefore difficult to defend and communicate the fact that Nordic Swan Ecolabelled products are able to contain perfluorinated compounds at all. For this reason a more general ban than purely on PFOS or fluorine surfactants is relevant for cosmetics The requirement is new.

Nitro musks and polycyclic musk compounds

Nitro musks and polycyclic musk compounds are suspected to be or are classified as carcinogenic. [83] In addition, nitro musks and polycyclic musk compounds may be bioaccumulating and potentially have long-term effects on the aquatic environment.[84] Nitro musk compounds may also have reproductive and endochrinological effects. Surveys show that they are often found in waste water[85] and in a Spanish study[86] several nitro musk and polycyclic musk compounds were found in the treated waste water and galaxolide and musk ketone in river water. In communication with suppliers of fragrances[87] it has emerged that many companies across Europe continue to use polycyclic musks in consumer products. E.g. nitro musk musk ketone can be used in cosmetics with certain restrictions.[88] The use of nitro

[78] (Kemikalieinspektionen, 2015)
[79] (OECD, 2007)
[80] (Borg, 2013)
[81] e.g. (Philippe Grandjean, 2013), (Arlene Blum, 2015)
[82] (Perkola, 2014)
[83] (ECHA, ei pvm), (ECHA, ei pvm)
[84] (TemaNord, 2004)
[85] (Carballa, ym., 2004)
[86] (Fernández C., 2010)
[87] (Leccia, 2009)
[88] (CosIng, ei pvm)

musks is clearly extremely limited, but manufacturers outside Europe still produce substances such as musk ambrette that are prohibited under IFRA. Excluding nitro and polycyclic musks is therefore still considered to be relevant as a preventive measure.

The requirement is the same as in version 2.

EDTA

EDTA is a powerful complexing agent which can bind metal ions and is therefore also suspected to be able to mobilise heavy metals in the aquatic environment. However, industry has questioned this latter property, mainly in areas such as the majority of Nordic waters (CEFIC, 2009).[89] EDTA is not readily biodegradable and the EU's risk assessment[90] shows that conditions in municipal treatment works are such that EDTA is not broken down or is only broken down to a limited extent. Alternatives that are degradable and thus better from an environmental viewpoint are now available and can replace EDTA. The use of EDTA is therefore excluded, with the exception of solid soaps (see **O21**) in which EDTA is considered necessary. The requirement is the same as in version 2.

Triclosan

Triclosan is an antibacterial disinfectant used in many different products, such as toothpaste and deodorants. There is a certain amount of concern that the use of antibacterial and disinfecting substances such as triclosan can play a role in increasing bacterial resistance to antibiotics.[91] Triclosan is bioaccumulating but a BCF value below 500 has been documented in some sources. It is classified as environmentally hazardous with H400[92], and is on the Norwegian Prioriteringslistan[93] (a Norwegian list of substances that cause environmental and health problems and the use of which should be reduced). Triclosan has been found in a number of different places, e.g. in waste water and water from treatment plants,[94] which indicates that the use of triclosan leads to exposure in the environment.

SCCS finds[95] that "Thus, the continued use of triclosan as a preservative at the current concentration limit of maximum 0.3% in all cosmetic products is not safe for the consumer because of the magnitude of the aggregate exposure.". It is therefore relevant to ban this disinfectant in Nordic Swan Ecolabelled products. The requirement is the same as in version 2.

Hypochlorite, chloramine and sodium chlorite

Calcium and sodium hypochlorites, chloramine and sodium chlorite can be used in cosmetics as oxidising and antimicrobial substances.[96]

Inorganic chlorine compounds such as sodium hypochlorite may be or lead to the formation of toxic, bioaccumulative substances that are hard to break downThe requirement is new.

[89] (European Chemical Industry Council (Cefic))
[90] (European Chemicals Bureau, 2004)
[91] (Miljøstyrelsen, ei pvm)
[92] (ECHA, 2015)
[93] (Miljøstatus , 2014)
[94] (TemaNord, 2007)
[95] (SCCS, 2011)
[96] (Cosing, ei pvm), (CosIng, ei pvm), (CosIng, ei pvm), (CosIng, ei pvm)

Benzalkonium chloride

Benzalkonium chloride can be used in cosmetics to perform several different functions, e.g. as a preservative, surfactant and deodorant.[97]

Unlike many of the other quaternary ammonium compounds, it is readily degradable, but it is undesirable in Nordic Swan Ecolabelled cosmetics due to its toxicity and risk of creating resistance, as benzalkonium chloride, like other quaternary ammonium compounds, is linked to bacterial resistance to antibiotics and can lead to certain types of allergies.[98]

The requirement is new, and in line with other chemical criterial.

Parabens

Parabens (4-Hydroxibenzoic acid and its salts and esters) have been found to be (potential) endocrine disruptors in different studies and may also have endocrine disrupting effects in nature.[99] Ethyl, methyl, propyl, and butylparaben are all categorised as potential endocrine disruptors (Cat 1) under the EU's strategy for endocrine disruptors. In a Spanish study, butyl, ethyl and benzylparaben were found in treated waste water.[100] However, SCCS has stated that methyl and ethylparabens and propyl and butylparabens in rinse-off products are safe to use in the concentrations permitted by the Cosmetics Regulation.[101] Isopropyl and its salts, isobutyl and its salts, benzyl, pentyl, and phenylparaben are prohibited by the Cosmetics Regulation.[102] All parabens and their salts are not prohibited, however, or on the list of potential endocrine disruptors, such as sodium and calcium paraben. These parabens are structurally related to the above and can thereby be expected to have equivalent effects. In the light of the precautionary principle, the use of all parabens is thus excluded in Nordic Swan Ecolabelled cosmetics as they were in version 2.

Phthalates

Phthalates are used in cosmetics in different functions, such as film formation, masking and solvents.[103]

Many phthalates have negative effects on health and the environment. Some phthalates are inscribed on the EU's priority list of substances that should be investigated more closely for endocrine disruption – and some have already been identified as endocrine disruptors.[104] Some phthalates can be found on the EU's Candidate List[105] and some on the Danish "Listen over Uønskede Stoffer" (List of undesirable substances).[106] Some phthalates are prohibited in cosmetics but some can be used.[107]

As a precaution, Nordic Swan Ecolabelling has chosen to exclude phthalates as a group, since this group includes many different phthalates with various different characteristics. Nordic

[97] (CosIng, ei pvm)
[98] (Even Heir, 2001)
[99] (European comission, 2015)
[100] (Fernández C., 2010)
[101] (SCCS, 2010)
[102] (European comission, 2014)
[103] (CosIng, ei pvm)
[104] (European comission, 2015)
[105] (ECHA, 2015)
[106] (Miljøstyrelsen, 2009)
[107] (SCCS, 2007)

Swan Ecolabelling is aware that this entails that several of these phthalates are excluded by both the CMR requirement and the requirement concerning Candidate List substances, but still considers it important to highlight phthalates in this requirement. New requirement.

Suspected endocrine disruptors

On 1 December 2020, Nordic Ecolabelling decided to expand the list of prohibited substances in the Nordic Ecolabelled cosmetics with the following 12 substances:

- Kojic acid (CAS no 501-30-4)
- Octocrylene (CAS no 6197-30-4)
- Triclorcarban (CAS no 101-20-2)
- Benzyl salicylate (CAS no 118-58-1): Exception until 1 December 2021
- Genistein (phytoestrogen, CAS no 446-72-0)
- Daidzein (phytoestrogen, CAS no 486-66-8)
- Benzophenone-4 (CAS no 4065-45-6)
- Benzophenone-5 (CAS no 6628-37-1)
- Salicylic acid (CAS no 69-72-7, och salter: 824-35-1 / 18917-89-0 / 59866-70-5 / 54-21-7 / 578-36-9 / 2174-16-5)
- Butylphenyl methylpropional/BMHCA/lilial (CAS no 80-54-6)
- Triphenyl phosphate (CAS no 115-86-6)
- Ethyl-hexyl salicylate (CAS no 118-60-5): Exception for sunscreen until 1 September 2022

Suspected endocrine disruptors (Eds) is an important issue for many consumers.

In the current criteria we refer to an old list from 2007 with potential Eds because there has not been a newer list to refer to. In addition we prohibit specific individual substances.

A number of suspected endocrine disruptors / Eds have now been designated for further investigation of SCCS for use in cosmetic products ("Call for data on ingredients with potential endocrine-disrupting properties used in cosmetic products", Published on: 16/05/2019). Nordic Ecolabelling wants to exclude these suspicious substances already in Nordic Ecolabelled cosmetics - together with the UV filter ethylhexyl salicylate, which is examined for endocrine disrupting properties in accordance with the REACH regulation. These substances are expected to be excluded when the new EU Ecolabel criteria for cosmetic products are to be adopted (vote expected in April 2021).

Most of the new Eds are already excluded from the Nordic Ecolabel's criteria for cosmetic products. 12 new substances have been added. For two of these substances an appropriate transition period is needed so that licensees have time to subsitute these substances. These are the following two substances:

- Benzyl salicylate (CAS no 118-58-1): Exception until 1 December 2021

- Ethyl-hexyl salicylate (CAS no 118-60-5): Exception for sunscreen until 1 September 2022

Endocrine disruptors

The Cosmetics Regulation does not limit the use of substances seen as (potential) endocrine disruptors, other than with a general statement that a product must not damage human

health under normal or reasonably predictable conditions. The EU's strategy for endocrine disruptors[108] defines an endocrine disruptor as an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. Nordic Swan Ecolabelling consequently prohibits the use of substances that are considered to be (potential) endocrine disruptors (categories 1, 2 and 3b: "Category 1 - evidence of endocrine disrupting activity in at least one species using intact animals"; "Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption"; "Category 3b - no data available") in the EU, according to the EU's report on endocrine disruptors[109] or other studies.[110] An Access database listing all the evaluated substances can be downloaded at http://ec.europa.eu/environment/chemicals/endocrine/strategy/index_en.htm. These lists are also used to assist the European Commission in completing its work of creating a definition for endocrine disruptors so that they can start to be regulated through REACH.

The importance of excluding category 3b substances can be discussed because there is insufficient scientific evidence for endocrine disruption. However, because these products have a higher exposure compared with other chemical product groups, e.g. because they are applied directly to the skin and the majority is spread down to the environment without being first metabolised in the body, we have proposed applying the precautionary principle and prohibiting these substances in category 3b. Once more information has been gathered, substances in category 3b can be moved to category 3a "no evidence of endocrine disrupting activity" and can then be used in Nordic Swan Ecolabelled cosmetic products.

If such new information comes out, the Nordic Swan Ecolabel may, after assessing the quality of the information, allow a category 3b substance even if the category is not officially changed.

The requirement is the same as in version 2.

While the revision work was in progress in summer 2016, draft EU criteria were published on endocrine disruptors.[111] These were directly criticised by several NGOs and MEPs.[112] The Nordic Swan Ecolabel is monitoring developments and once the final criteria are accepted, the Nordic Swan Ecolabel will assess whether they can be used in these criteria for cosmetic products.

PBT and vPvB

PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) organic substances are defined in Annex XIII to REACH (Directive 1907/2006/EC). Cosmetic products are not covered by the REACH legislation but many ingredients used in cosmetics are, however, used in other areas which are covered by REACH. Although the PBT and vPvB criteria are not included in the Cosmetics Regulation, such substances are considered to be undesirable in Nordic Swan Ecolabelled products.

[108] (European comission, 2015)
[109] (DG Environment, 2000)
[110] (DHI water and environment, 2007) (DG Environment, 2002), (European Comission / DG ENV / WRc-NSF, 2002)
[111] http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm
[112] E.g. BEUC 16 June 2016: http://www.beuc.eu/publications/beuc-x-2016-063_endocrine_disruptors_criteria.pdf, Chemtrust 15 June 2016: http://www.chemtrust.org.uk/commission-edc-criteria-humanharm/, Sirpa Pietikäinen 15.6.2016: http://www.sirpapietikainen.net/2016/06/pietikainen-puutteita-komission-esityksessa-hormonihairitsijoista/

Only a few of the ingoing substances in cosmetics would meet the criteria for PBT or vPvB, mainly silicones/siloxanes. Siloxanes D4 and D5 have been excluded however, due to their inherent properties as described earlier in this document, irrespective of whether they are PBT or vPvB.

Over time it is expected that more substances will be assessed under the PBT and vPvB criteria and added to the Candidate List, i.e. the list of SVHC substances. Generally excluding PBT/vPvB substances guarantees that all substances that meet the PBT or vPvB criteria will also be excluded from Nordic Swan Ecolabelled cosmetics as more data is produced. The majority of PBT/vPvB substances are automatically excluded from Nordic Swan Ecolabelled cosmetics due to restrictions on environmentally harmful substances (see requirement O17). However, it may be the case that vPvB substances in particular are not restricted by requirement O17, despite their continuing to be considered undesirable in the environment.

The requirement is the same as in version 2.

Substances of Very High Concern (SVHC)

SVHC are defined in Article 57 of REACH[113] as substances meeting the criteria for classification as CMR category 1A or 1B, PBT and vPvB substances, substances with endocrine disrupting properties and substances which give rise to an equivalent level of concern and for which there is scientific evidence of probably serious effects to human health or the environment.

Cosmetic products are not covered by the REACH legislation, but many ingredients used in cosmetics are, however, used in other areas which are covered by REACH. Although the SVHC criteria are not included in the Cosmetics Regulation, such substances are considered to be undesirable in Nordic Swan Ecolabelled products.[114]

New requirement, in line with other chemical criteria.

Microplastics

Microplastics are small plastic particles less than 5 mm.[115] They may appear in some cosmetic products to produce an exfoliant (scrubbing) effect, such as toothpaste, soaps, shower gels and body scrubs. When microplastics are rinsed own the drain, they often pass through treatment works due to their very small size and are not filtered out (ECHA, 2015)[116],[117]. The particles then continue on to lakes and seas where they are eaten by mussels, fish and other animals, causing injury. Some microplastics are then gradually broken down to even smaller particles by sunlight. They can also absorb harmful substances.[118]

[113] (EU, 2006)
[114] (ECHA, 2015)
[115] (Miljøstyrelsen, 2015)
[116] (Stockholms universitets Östersjöcentrum, 2015)
[117] (DR DK, 2013)
[118] (Mtv3, 2015)

The microplastics found in cosmetics include the following plastics[119]:

- Polyethylene (PE)
- PMMA
- Nylon - 12
- PET
- Polyethylene terephthalate (PET)
- Polystyrene (PS)

There are biodegradable alternatives to microplastics such as PLA (=Polylactic acid), Mater-bi[120], crushed apricot kernels, salts and sugar. It is therefore judged to be possible to exclude microplastics without making it impossible to ecolabel products such as toothpaste, soaps, etc. Plastics that can be broken down and can demonstrate this under tests such as OECD 301 A-F are exempt from the requirement, because it is non-degradable plastics which are undesirable in ecolabelled products.

Cosmetics Europé recommends that their members stop using microplastics by 2020[121], but as long as microplastics may be used, a ban is considered to be relevant and have potential.

Microplastics were also prohibited in version 2, but the definition has been changed slightly with regard to the size and is now in line with the definition used elsewhere (< 5 mm.[122]).

Halogenated and/or aromatic solvents

Several halogenated or aromatic solvents are banned from use in cosmetics according to CosIng, but some are not prohibited[123]. Some of these substances are classed CMR and are also therefore prohibited in Nordic Swan Ecolabelled cosmetics.

Halogenated and aromatic organic compounds include many substances harmful to the environment and to health, which are very toxic to aquatic organisms, carcinogenic or otherwise harmful to health. The halogenated organic compounds are normally hard to degrade in the environment, which increases the risk of harmful effects from these substances. Liquid organic solvents can cause increased ground ozone content, which can damage vegetation, among other things.

For many of the substances in the group, the requirement is a double requirement, but due to the precautionary principle we choose to prohibit all halogenated and/or aromatic solvents. The requirement is new.

Nanomaterials/particles

Nanomaterials/particles are defined in the Cosmetics Regulation as an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. Note that emulsions and liposomes are not covered by the definition of nanomaterials in the Cosmetics Regulation and are thus not covered by the requirement.

[119] (Noordzee, 2013)
[120] (Novamont, ei pvm)
[121] (Cosmetics Europe, 2015)
[122] (Danish Environmental Protection Agency, 2015)
[123] (CosIng, ei pvm)

On the page of the Cosmetics Regulation entitled "Preamble to Annexes II to VI", item 3, it is worth noting that this states that the substances listed in Annexes III to VI do not cover nanomaterials, except where specifically mentioned. Annexes IV, V and VI list colorants, preservatives and UV filters, respectively.

Nordic Swan Ecolabelling views this as indicating that compounds which are not specifically labelled with the nano form can no longer be included in their nano form following the introduction of the Cosmetics Regulation in 2009. The prohibition applies until the nano form is specifically stated. At the same time Nordic Swan Ecolabelling assumes that nanomaterials continue to be included in cosmetics products on the market, for example it is assumed that carbon black and silica are extensively used.

Silica

According to SCCS' opinion, silica is extensively used in cosmetic products.[124]

Silica as an abrasive in nano form can be used in Nordic Swan Ecolabelled toothpaste for the following reasons:

- almost all toothpaste on the market contains hydrated silica, which is in nano form (Hydrated silica is a nano-structured material built up from nanoparticles/"nano objects" which form an aggregate of SiO2 which is larger than 100 nm (and contains fairly few particles under 100 nm). However, hydrated silica meets the Cosmetics Regulation's definition of nanomaterial due to the material's internal structures, which are < 100 nm and in terms of the particles' surface layer (confirmed by the Danish Environmental Protection Agency).)
- this abrasive has been used for the past 30–50 years without any evidence of harmful effects being demonstrated.[125] The advantage of hydrated silica is firstly that it is transparent and so can be used in both gel toothpastes and white and coloured toothpastes, and secondly that it is compatible with fluoride.
- the use of hydrated silica was evaluated as safe by the expert panel in Cosmetic Ingredient Reviews (CIR) 2009[126]. SCCS concluded in 2015, however, that the data they had received was not sufficient to be able to conclude whether the ingredients are safe for use in cosmetic products. [127]

In the proposed requirement, silica can be included in Nordic Swan Ecolabelled cosmetic products only in toothpaste. Please note that according to O2 SCCS opinions must be complied with and according to SCCS[128] Synthetic amourphous silica (SAS) meets the Cosmetics regulation definition for nanomaterials.

Carbon black

Carbon black is now counted as a nanomaterial. According to the SCCS opinion[129] the addition of carbon black to cosmetics varies between 0.001% and 10%, with 0.001% (= 10

[124] (SCCS, 2015)
[125] (SCCS, 2015)
[126] (Cosmetic Ingredient Review Expert Panel, 2009)
[127] (SCCS, 2015)
[128] SCCS 2019, SCCS (Scientific Committee on Consumer Safety), Opinion on solubility of Synthetic Amorphous Silica (SAS), 20-21 June 2019, SCCS/1606/2019. Corrigendum of 6 December 2019 https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_228.pdf
[129] (SCCS, 2013)

ppm) in skincare products, 5% in nail varnish and 10% for other kinds of eye make-up. In the proposed requirement, carbon black and other nanomaterials cannot be included in Nordic Swan Ecolabelled cosmetic products.

Nano UV filters

Nordic Swan Ecolabelling is concerned about the environmental consequences of extended use of nanomaterials. The OECD's Working Party on Manufactured Nanomaterials (WPMN) has started publishing new data on nanomaterials[130], but so far has only published that for titanium dioxide and zinc oxide[131].

In 2004 the Danish Environmental Protection Agency published a report which investigated 9 different nanomaterials and their fate and behaviour in the environment. [132] In conclusion, it was found that for surface-treated or functionalised nanomaterials, their environmental fate and behaviour cannot solely be predicted based on the properties of the nanomaterial's core Instead an individual evaluation is necessary, taking into account the coating, surface modifications and the existence of stabilising agents. The report concluded that a number of defects were found in the current knowledge of transformation processes for nanomaterials which prevent a valid qualitative and quantitative assessment of their fate and behaviour in environmental matrices.

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.[133] [134]

There are also individual studies which have examined the environmental consequences of nanomaterials in sunscreen. A recently published Spanish study of sunscreen containing nano titanium dioxide as a UV filter from 2014[135] showed that photoexcitation of inorganic UV filters (TiO_2 and ZnO nanoparticles) produces a considerable amount of hydrogen peroxide (H_2O_2) when subjected to solar radiation. H_2O_2 is a strongly oxidising substance which generates high levels of stress in marine plant plankton. The authors concluded that TiO_2 nanoparticles are largely the reason for the major increase in H_2O_2 levels in the sea in the summer, with potentially dangerous consequences for aquatic organisms.

According to SCCS opinion SCCS/1516/13 from 2016 nano TiO_2 which contains more than 10 % photocatalytic nano TiO_2 particles may not be used as a UV filter, and thereby the risk of a major increase in H_2O_2 in water because of these forms of UV filter is not great.

Information about the environmental impact of nano TiO_2 is sparse. However, alternative organic UV filters tend not to be readily biodegradable, and there is no data on their anaerobic biodegradability. We therefore choose to approve the use of TiO2 as a solar filter as long as SCCS opinion SCCS/1516/13 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.

[130] (SafeNano, 2015)
[131] (OECD, ei pvm)
[132] (Hartmann;Skjolding;Foss Hansen;Kjølholt;& Gottschalck, 2014)
[133] (Miljøstyrelsen, 2015)
[134] (Miljøstyrelsen, 2015)
[135] (David Sánchez-Quiles, 2014)

The Nordic Swan Ecolabel ensures that the most problematic UV filters on the market are not used: We prohibit the most ecotoxic UV filters (LC50 <10 mg/l, NOEC <0.1 mg/l) and suspected endocrine disruptive UV filters are banned.

On December 17, 2019, it was decided to also exclude two organic UV filters (TBPT and MBBT) from the nano requirement. SCCS has estimated that these are safe for humans, but believe that they should not be used in spray products. [136] All UV filters have questionable environmental profile and since these can be used in smaller quantities than the traditional UV filters, they are considered acceptable alternatives.

The requirement has been made more stringent since the previous version of the criteria and it has been moved to the list of prohibited substances. An exception for nano TiO_2 was introduced following consultation.

O6 Surfactants

All surfactants, irrespective of their function must be readily aerobically degradable and anaerobically degradable in line with the testing methods in Appendix 9.

The following are exempt from the requirement on anaerobic degradability:

- Emulsifiers
- Surfactants in toothpaste

Toothpaste must not contain sodium lauryl sulphate (SLS).

☒ Reference to the DID list dated 2007, 2014, 2016 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.

☒ DID list: "Detergent ingredient Database" list, see Appendix 9 for a more detailed description.

☒ For toothpaste: Appendix 1 or equivalent declaration completed and signed.

Background to requirement O6

A surfactant is a substance that is a surface active agent, and by definition this also makes emulsifiers surfactants as their purpose is to make two different phases mixable. Emollients are a more mixed group of substances but some of these also have surface active properties and are thus considered surfactants.

Surfactants are found in high volumes in liquid soap, shampoo and conditioner. Surfactants are often toxic to aquatic organisms.

Unlike laundry and cleaning products, which are covered by the Detergent Regulation[137], 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. The requirement has been introduced to ensure that the use of substances in such high volumes does not place a burden on the

[136] SCCS (Scientific Committee on Consumer Safety), Opinion on 2,2'methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol), SCCS/1546/15, 25 March 2015 https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_168.pdf SCCS (Scientific Committee on Consumer Safety), Opinion on 1,3,5triazine, 2,4,6-tris[1,1'-biphenyl]-4-yl-, 20 September 2011 https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_070.pdf
[137] (EU, 2004)

aquatic environment, irrespective of whether aerobic or anaerobic conditions prevail. The surfactant content is also regulated by requirements on critical dilution volume (CDV).

Special requirements for toothpaste: Some organisations are critical of the use of sodium lauryl sulphate (SLS) in toothpaste. SLS seems to be able to contribute to slower healing of recurrent oral aphthous ulcers (RAU). A Norwegian study[138] found a statistically significant reduction in the number of mouth ulcers when they changed to an SLS-free toothpaste. The study assumes that the denaturing effect of SLS on the oral mucin layer causes an increased incidence of recurring mouth ulcers. Another study[139] showed that SLS led to greater permeability of water, which increases the risk of irritants penetrating mucous membranes more easily. Triclosan and zinc hinder the effect, according to the study, but the first cannot be included in Nordic Swan Ecolabelled products and the second is strictly limited because it is classed as environmentally harmful. There is also a third study[140], that concludes that SLS and SLS with PG cause notably more erythematous reactions in the mouth than SLS together with Triclosan and zinc. It can therefore be concluded that SLS increases problems with mucous membranes and aphthous ulcers and that the requirement is therefore relevant from a health perspective. In general, sodium lauryl sulphate is added to toothpastes to generate more foam and is the most common foaming (and cleaning) agent in toothpastes. The Nordic Swan Ecolabel does not permit the substance in toothpastes also because it has been noted that alternatives are less irritating to the skin. It is possible to manufacture toothpaste without SLS by, for example, using sodium-C14-C16 oleofin sulphonate, sodium lauryl sarcosinate, cocamidopropyl betaine or Stearath 30, all of which are less irritating to the skin. For this reason, SLS is not permitted in Nordic Swan Ecolabelled toothpaste.

Toothpaste is exempt from the requirement on anaerobic degradability of surfactants. The requirement on anaerobic degradability of surfactants has been a major obstacle to Nordic Swan Ecolabelling of toothpaste. The exception for surfactants in toothpaste benefits the market share of toothpaste without triclosan or SLS.

Surfactants are also used in cosmetics as an emulsifier, and here information on anaerobic degradability is sparse. This means there is a lack of potential and steerablity and surfactants with the function of emulsifiers are exempt from the requirement. Emulsifiers are defined in CosIng as follows: "Promotes the formation of intimate mixtures of non-miscible liquids by altering the interfacial tension". After consultation, softeners were once more included in the exemption as we received comments that many emollients also have the functions “surfactant” and “emulsifying” in CosIng.

Quaternary ammonium compounds are cationic surfactants which are often used in conditioner but can also be used as biocides. Even when they are used as preservatives, they must fulfil the requirements on degradability of surfactants. In this case they must fulfil both the requirement on surfactants and the requirement on preservatives (O13). They must also be approved as preservatives in the Cosmetics Regulation.

Nordic Swan Ecolabelling is often asked about the use of SLS and SLES in cosmetic products. At the moment SLS is allowed in Nordic Swan Ecolabelled products other than toothpaste but it is not normally used any longer in soaps, skin or haircare products on the Nordic market. SLES (sodium laureth sulphate) is a very common cleansing surfactant in liquid soaps, shampoos and foam bath products but not in toothpaste. SLES has been controversial

[138] (Herlofson BB, 1994)
[139] (Healey;Cruchley ;Thornhill;& Williams , 2000)
[140] (Skaare;Rölla;& Barkvoll, 1997)

because there have been problems with pollution from the substance 1,4-dioxane, which is harmful to health, but the content is kept under strict control and the EU proposes that at the moment this is kept below 0.001%.141 The substance is therefore currently permitted in Nordic Swan Ecolabelled products, but SCCS opinion mentioned applies for 1,4-dioxan according to O2. SLES is considered to be slightly more gentle than SLS for use on skin and hair. Most common surfactant cleansing agents may have an irritating effect on skin and eyes and are often effective grease and dirt solvents that also affect the skin's natural protective barrier. For this reason, body products containing grease solvents should be used with moderation. Warm water goes a long way.

The content of the requirement has not changed compared with the previous versions of the criteria. In our view there is a difference between Nordic Swan Ecolabelled and other products because non-degradable surfactants under anaerobic conditions are used in the market.

Fragrances and aromatic additives

The requirement on fragrances has been updated in relation to Nordic Swan Ecolabelling's Fragrance Policy 2012, which was updated in 2015. It is the job of Nordic Swan Ecolabelling to ensure that only the fragrances which are least harmful to health and the environment are added to products. 8 fragrances with the greatest risk of sensitisation under the SCCS report (SCCS/1459/11)[142] and the Danish Environmental Protection Agency report Environmental project No. 1840, 2016[143] are new and added to the list of fragrances that are restricted in cosmetic products, see also O9. In conjunction with this revision, Nordic Swan Ecolabelling has been in dialogue with several fragrance producers and IFRA. If consumers wish to minimise the use of sensitising substances and thus further reduce the risk of allergies, non-perfumed Nordic Swan Ecolabelled products can be chosen.

In order to clarify the criteria and avoid interpretations, it has in December 2018 been specified how toothpaste is treated in requirements O7−O9 and O18−O20.

Requirements 07-9 also apply to aromas and fragrances in plant extracts. Note that toothpaste is considered to be rinse off product in requirements O7−O9.

O7 IFRA

Fragrances must be added in line with the IFRA's guidelines.

The IFRA's (International Fragrance Association) guidelines can be read at www.ifraorg.org/

☒ Appendix 1 or equivalent declaration completed and signed.

Background to requirement O7

IFRA stands for the "International Fragrance Association" and represents the fragrance industry. The association conducts safety assessments of individual fragrances and blends has public standards/guidelines for the use of fragrances. The requirement for compliance with IFRA's guidelines[144] 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

141 (SCCS, 2015)
142 http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf
143 (Miljøstyrelsen, 2016)
144 (IFRA, ei pvm)

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 O8 and O9 on regulation of fragrances.

O8 Products for infants, babies and children

Fragrances/perfumes/flavourings/fragrance substances in plant extracts may not be added to infant, baby or children's products.

Exceptions: Flavourings are allowed in children's toothpaste, see O22. O9 must be met.

Infant, baby and/or children's products are considered to be products that are marketed for or have words such as baby and/or children (<12) on the label.

☒ Appendix 1 or equivalent declaration completed and signed.

☒ Recipe

☒ Label

Background to requirement O8

The requirement covers product specially marketed for babies or children, e.g. with the words "bebis", "baby", "barn", "kids" or "child". Children up to the age of 12 are considered to be children in this context. The main argument is that children are more sensitive than adults and tend to have fewer opportunities to choose a product themselves. This requirement will distinguish between Nordic Swan Ecolabelled and other products. Products marketed as family products or geared towards teenagers do not need to meet this requirement. The requirement exists to attempt to reduce the risk of infants, babies and/or children developing allergies to fragrances.

All the requirements also apply to flavourings which contain equivalent substances as fragrances and fragrances in plant extracts. Many different plant-based ingredients are used in cosmetic products. These can contain allergens such as fragrances subject to declaration. Sensitising fragrances in plant extracts are handled in the same way as fragrances. Otherwise plant extracts containing sensitising substances cannot be used. All plant extracts must be assessed on a case by case basis with the help of specifications on the content. If an extract contains substances that have the function 'perfuming' in CosIng[145] (The European Commission's database with information on cosmetic ingredients) the extract must not be accepted in a children's product.

There are grounds to assess flavourings in the same way and ban them in children's products[146]. No Nordic Swan Ecolabelled toothpaste is currently available for children without a flavour/aroma. This means that consumers are not actually able to make a good choice in health and environment terms when choosing toothpaste for their children. The consumer can either choose to use Nordic Swan Ecolabelled adult toothpaste for children but adult toothpaste often contains more fluoride than is recommended for children's toothpaste, see O36. This is therefore not a good alternative to non-Nordic Swan Ecolabelled children's toothpaste in health terms. As Nordic Swan Ecolabelling sets a requirement that aromas in toothpaste must be approved for food products, see O23, it is ensured that the only flavourings that are used in children's toothpaste are those that are approved in terms

[145] (European comission, ei pvm)
[146] (Farage;Bjerke;Mahony;Blackburn;& Gerberick, 2003)

of health. An exception is therefore made for toothpaste for children, such that aromas approved for food are added.

O9 Amount of fragrance

- A fragrance substance/flavouring/fragrance substance in plant extract which is judged to be sensitising with the hazard statement H317 and/or H334, or covered by the fragrance substances subject to declaration 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. see section 2 Biodegradability and aquatic toxicity for definition of rinse of and leave on)
- The fragrance substances in table 2 may be included in products with a maximum of 100 ppm (0.010%) for rinse-off products and a maximum of 10 ppm (0.0010%) for leave-on products per substance:

  Table 2 other fragrance substances that may be included to a maximum 100 ppm for rinse-off and 10 ppm for leave-on.

INCI name (or, if none exists, perfuming name according to CosIng)	**CAS number**
Cananga Odorata and Ylang-ylang oil	83863-30-3; 8006-81-3
Eugenia Caryophyllus Leaf / Flower oil	8000-34-8
Jasminum Grandiflorum / Officinale	84776-64-7; 90045-94-6; 8022-96-6
Myroxylon Pereirae	8007-00-9;
Santalum Album	84787-70-2; 8006-87-9
Turpentine oil	8006-64-2; 9005-90-7; 8052-14-0
Verbena absolute	8024-12-02
Cinnamomum cassia leaf oil/Cinnamomum zeylanicum, ext.	8007-80-5/84649-98-9

- HICC, chloroatranol and atranol are not permitted in the product.

☒ Appendix 1 and 2 or equivalent certification completed and signed plus fragrance specifications.

☒ Recipe.

Background to requirement O9

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

The Cosmetics Regulation currently lists 26 fragrance compounds that must be declared on the packaging when the concentration exceeds > 0.0100%/100 ppm (“rinse-off” products) or 0.0010%/10 ppm (“leave-on” products). Because Nordic Swan Ecolabelling does not see a reason to distinguish between the fragrances that are subject to declaration and other fragrances with an official classification of H317 (May cause sensitisation by skin contact) or H334 (May cause allergy or asthma symptoms or breathing difficulties if inhaled) the requirement is now set out for all these substances. This is because allergies (and allergies to

fragrances in particular) constitute a growing problem and there is every reason to minimise the risk of increasing the number of hypersensitive consumers.

In June 2012 a new opinion was issued by the EU's Scientific Committee, SCCS, stating that 127 substances should be declared on products instead of the current 26.[147] In this report, SCCS recommends that all the fragrance substances that they have found evidence for being potential allergens must be declared by name on the cosmetics product. Among the 127 fragrance substances, 26 are already restricted under the Cosmetics Regulation, and in total 20 are classified as health hazards with H317. SCCS refrains from recommending decided maximum limits for the content of all the fragrance substances in cosmetic products, particularly due to a lack of underlying data. However, SCCS states that the general limit of 100 ppm is tolerated by the majority of consumers and wishes to guard against the development of new allergy sufferers both within generally tolerant and sensitive people.

SCCS also recommends that three substances Chloroatranol, Atranol2 and Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) are not included in cosmetic products. Chloratranol and Atranol occur in Oak moss (Evernia Prunastri) and Tree moss (Evernia Furfuracea) extract. These three substances are also included under requirement O2 SCCS Opinions. These three fragrances are expected to be incorporated into the Cosmetics Regulation with a ban on their use. Until this happens, the substances are excluded in the Nordic Swan Ecolabel's criteria. Nordic Swan Ecolabelling has conducted a dialogue with IFRA and fragrance producers and checked the status of IDEA (International Dialogue for the Evaluation of Allergens)[148] concerning the 127 allergenic fragrances. SCCS and IDEA are working to develop methods for quantifying more substances of these 127. This work has not been completed and the earliest date in which there is expected to be a declaration requirement in European legislation is 2019. In the light of this, Nordic Swan Ecolabelling has chosen to tighten up the requirement on fragrances by adding a requirement to restrict the 7 substances (see table 2), with the greatest risk of sensitisation in the SCCS report (SCCS/1459/11)[149]. Most of these 7 substances do not have a harmonised classification under ECHA's summary of classification[150], but many are classified by some under H317. Bans on more fragrances will gradually be introduced in line with SCCS' recommendations but this will be done at a pace that ties in with testing methods and opportunities to document that the fragrances are not found in the fragrance blend.

The Danish Environmental Protection Agency has investigated 42 sensitising fragrances to assess whether these fragrances are potent enough to meet the criteria for classification as substances causing hypersensitivity in category 1A of the CLP Regulation.[151] The report concludes that 11 fragrances should be classified in subcategory 1A (causes hypersensitivity). These are the following substances: Citral CAS no. 5392-40-5, Cinnamaldehyde CAS no. 104-55-2, Cinnamyl alcohol CAS no. 104-54-1, Coumarin CAS no. 91-64-5, Eugenol CAS no. 97-53-0, Farnesol CAS no. 4602-84-0, Geraniol CAS no. 106-24-1, 7-Hydroxycitronellal CAS no. 107-75-5, Methyl oct-2-ynoate CAS no. 111-12-6, Evernia prunastri, ext. (Oakmoss extract) CAS no. 90028-68-5 and Cinnamomum cassia leaf oil/Cinnamomum zeylanicum, ext. CAS no. 8007-80-5/CAS no. 84649-98-9. The 10 first substances are among the 26 fragrances that must be declared and are already regulated by the Nordic Swan Ecolabel's requirements. Cinnamomum cassia leaf oil/Cinnamomum zeylanicum, ext. CAS no. 8007-80-5/CAS no.

[147] (SCCS, 2013)
[148] (IDEA, ei pvm)
[149] (SCCS, 2013)
[150] (ECHA, ei pvm)
[151] (Miljøstyrelsen, 2016)

84649-98-9 is new and is added to the list of fragrances that must not be included in cosmetic products under 100 ppm for rinse-off and 10 ppm for leave-on.

The fragrance producers can then avoid these substances when mixing fragrances, if it is not possible to quantify these substances. Nordic Swan Ecolabelling sees this as the first step towards more stringent requirements to restrict fragrance allergens.

Table 2 The 7 substances with the greatest risk of sensitisation under the SCCS report (SCCS/1459/11)[152] and Danish Environmental Protection Agency's report Environmental project No. 1840, 2016[153].

INCI name (or, if none exists, perfuming name according to CosIng)	**CAS number**
Cananga Odorata and Ylang-ylang oil	83863-30-3; 8006-81-3
Eugenia Caryophyllus Leaf / Flower oil	8000-34-8
Jasminum Grandiflorum / Officinale	84776-64-7; 90045-94-6; 8022-96-6
Myroxylon Pereirae	8007-00-9;
Santalum Album	84787-70-2; 8006-87-9
Turpentine oil	8006-64-2; 9005-90-7; 8052-14-0
Verbena absolute	8024-12-02
Cinnamomum cassia leaf oil/Cinnamomum zeylanicum, ext.	8007-80-5/84649-98-9

According to the Videnscenter for Allergi (the Danish centre for research into allergies) there is in principle no limit for when an allergy causes problems[154]. It would not be realistic, considering the prevailing situation in the market, to prohibit the use of fragrances in the products. So far, the demand for fragrance-free cosmetics is low and if fragrances were to be prohibited entirely, this would probably 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 O17 Environmentally hazardous substances. Consumers can choose between fragranced and fragrance-free products because the existence of fragrance must always be declared on the packaging. In purely general terms, there is demand for both fragranced and fragrance-free products both as consumer products and B2B products, something which is clear among current Nordic Swan Ecolabelled products and the market in general.

In addition, the possible consequences of a total ban on fragrances may lead to a general problem of how to define a fragrance. It is possible that fragrances would simply be replaced by different vegetable oils, which would hardly be a step forwards because information on the environmental impacts or allergies related to these substances is usually limited. We 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. On the other hand, plant extracts or other ingredients with sensitising substances are only used for perfuming the product.

[152] http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf
[153] (Miljøstyrelsen, 2016)
[154] (Duus, 2009)

Fragrances which have two functions, e.g. benzylalcohol, which can both have a function as a scent and as a preservative, must continue to comply with our requirements for fragrance substances subject to declaration, whether or not it is stated by the producer that the purpose of its use is other than fragrance. If the purpose is stated to be other than fragrance, the substance must also comply with the requirements we make for the function in question.

All fragrance substances subject to declaration are considered to be fragrances 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 considered to be “leave-on” in relation to the content of sensitising fragrance substances. Toothpaste is counted as rinse-off.

Colorants

The Cosmetics Regulation[155] defines colorants as substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants; A colourant covers salts and substrate pigments and when a colourant is expressed as a specific salt its other salts and substrate pigments are also covered.

The content of colorants in cosmetics varies considerably depending on the type of cosmetic and runs from hundredths in soaps etc., up to at least 15% in lipsticks.[156]

All cosmetic products and all colorants irrespective of function are covered by the requirement.

O10 Bioaccumulation

Organic colorants must not be bioaccumulating in line with the testing methods in Appendix 9 BCF<500/logKow<4).

Alternatively, the colour must be approved for use in food.

☒ Specification of an experimentally determined BCF value (bioconcentration factor) or logKow value (logarithmic octanol-water partition coefficient), see description in Appendix 9.

☒ Alternatively, an E-number (allocated number in conjunction with approval of foodstuffs). Appendices 1 and 2 can be used.

Background to requirement O10

A study carried out by Nordic Swan Ecolabelling in 2003 of 48 colorants approved for use in cosmetics (equivalent to 30% of the approved colours) showed that several of these had bioaccumulation potential and were toxic or very toxic to aquatic organisms. Relevant environmental requirements can and should therefore be introduced for these colorants. The study showed that colorants approved for use in food do not constitute a major environmental problem. Where colours are approved for use in food, their safety is evaluated by the European Food Safety Authority (EFSA). The evaluation also discusses absorption, distribution, metabolism and excretion (ADME) in line with various animal tests. The EFSA has no official guidelines on when colours can be approved and evaluates them on

[155] (EU, 2009)
[156] (Naughton, 2003)

a case by case basis. They can also state ADI (Acceptable Daily Intake) values for approved colours. The background to the ADI values is an ADME evaluation, plus toxicity data such as gene toxicity or sensitisation. Nordic Swan Ecolabelling relies on the EFSA's evaluation that it is likely that highly bioaccumulating colours will not be approved for use in food. Therefore, and on the basis of our own study described above where logKow or BCF values were lacking, we also accept E-numbers as documentation of low bioaccumulation potential.

The requirement excludes about ten colorants with logKow values up to 17, which are approved under the Cosmetics Regulation.[157] In addition, the requirement on environmentally hazardous substances also excludes the use of more toxic colorants.

The BCF and LogKow values are used as indicators for bioaccumulation in line with the definitions in the CLP Regulation.[158]

The requirement only covers organic colorants as bioaccumulation cannot be used for organic compounds. Inorganic colorants such as titanium dioxide can therefore be used in Nordic Swan Ecolabelled cosmetics without special requirements when these are approved for use in cosmetics and meet our classification and toxicity requirements.

O11 Metals in colorants for decorative cosmetics and hair dyes

Following metals from colourants may be found in decorative cosmetics and hair dye at a maximum following concentration in the product

Cadmium 1 ppm

Chromium 10 ppm

Cobolt 10 ppm

Lead 1 ppm

Mercury 1 ppm

Nickel 10 ppm

Bismuth Oxychloride can not be added to decorative cosmetics.

Colours that are approved for use in foodstuffs in accordance with Commission Directive 2008/128/EC may be used without further documentationof the metals listed above.

☒ Appendix 2 or equivalent declaration completed and signed and specifications/analysis results of the colour and calculation of the amount of metals in the Nordic Ecolabelled product. Alternative test report showing that the quantities in the Nordic Ecolabelled product meet the requirement.

☒ Specification of E-number and/or a declaration from a supplier confirming that the colour complies with the purity criteria for colours for use in foodstuffs in accordance with Commission Directive 2008/128/EC.

Background to requirement O11

The purpose of setting requirements on heavy metals in colours is to protect the consumer from unnecessary exposure to heavy metals when using cosmetic products.

A particular limit has been set for a number of relevant heavy metals in colorants. Lead, for example, has been found in lipstick in concentrations of up to 0.65 ppm [159] and in 2015

[157] (EU, 2009)
[158] (EU, 2008)
[159] (Safe Cosmetics, ei pvm)

cadmium was found in a lipstick in the EU[160]. Because lipstick is in fact consumed, to a certain extent[161] and lead is stored in the body over time, this can lead to significant exposure levels combined with lead from other sources. Because 39% of the lipstick tested in the American study does not contain any measurable amounts of lead, it is possible for cosmetics to be manufactured without dubious metals in their colorants.

Nickel, which is highly sensitising, was added after the consultation in line with comments received. It is banned under the Cosmetics Regulation (like lead) but residues may be found in colorants. According to the Karoliniska Institute's Institute for Environmental Medicine, it is known that mascara often contains nickel, which causes problems for those with a nickel allergy.

Bismuth is used in make-up in the form of bismuth chloride oxide (BiClO) as a colour with the aim of providing a shimmering surface. Gunnar Guzikovski from the Swedish Medical Products Agency also stated that the Agency had received an increasing number of questions about bismuth in recent years and that this may be due to increased use of what is known as mineral make-up in which bismuth chloride oxide is often a ingoing substance.[162] According to the ECHA's summary of classification, approximately 20% of notifiers classify bismuth chloride oxide as an irritant to skin and eyes (H315 and H319). Internet searches show that certain make-up producers have chosen to market make-up products as bismuth-free.

A limit of 10 ppm (0.0010%) of lead, barium, mercury, cadmium, bismuth or hexavalent chromium in colourants and other raw materials is judged to be acceptable, according to information from the colorant industry. The addition of less than 0.10%, or raw materials that contain less than 10 ppm of these metals, will result in products with less than 1 ppm of these metals (detection limit for lead in the study). According to a study, it is recommended that the residues of nickel, chrome and cobalt are kept below 1 ppm in ordinary consumer products to avoid allergies.[163] The limit of 10 ppm is therefore considered relevant.

Commission Directive 2008/128/EC[164] laying down specific purity criteria concerning colours for use in foodstuffs can also be used because the colourants used in food have been safety evaluated on the basis of an exposure scenario in which they are "closer" to the body than cosmetic products. This directive lists all the colours approved for use in food and sets threshold values for the content of heavy metals, among other things. Where heavy metals are specifically mentioned, the threshold values are lower or equal to the limit set in O12. While not all metals from O12 are included, for the majority of colours the Directive contains a collective criterion covering "other heavy metals" where the limit is above that of the requirement in O12, however. 40 ppm is, however, still considered to be a very low limit. Colours that are approved for use in foodstuffs (under Directive 2008/128/EC) do not need further documentation on their metal content.

The requirement has been changed so that it only concerns colorants in decorative cosmetics and hair dye. For other products the requirement is not considered to be relevant: soap and other cosmetic products contain very small amounts of colours (normally <1%). Documentation is weighty and there are risks in decorative cosmetics that are based on colorants, where impurities are also included in products at very high amounts.

[160] (European comission - Rapex, 2015)
[161] (Kuluttaja, 1996)
[162] (Läkemedelsvärket, 2009)
[163] (Basketter, ym., 2003)
[164] (EU, 2008)

In March 2020 it was decided to adjust the requirement so that the limit values apply for the Swan Ecolabelled product and not the pigments.

Other Ingoing substances

O12 Enzymes

Enzymes must be capsulated granulates or in liquid form. Enzymes in powder form may be used, however, provided that:

- The finished product is a product that does not give off dust (excludes products in powder form and similar)
- Manual handling of powder enzymes must take place in a separate, screened off area (e.g. weighing room or a ventilated fume cupboard)
- Special work instructions must be available regarding the use of protective equipment when manually handling enzymes and regarding the collection and disposal of any spilled enzyme powder.
- Everyone who handles enzymes must wear protective clothing, gloves, a mask with dust filter (minimum: P31 dust filter) and protective goggles

Enzymes must not be added to spray products.

✉ Declaration from the enzyme manufacturer or information on a safety data sheet/product data sheet regarding the form of the enzyme. For enzyme powders in particular: Documentation regarding the handling of powder enzymes in production as stated in the requirement.

✉ Declaration from the manufacturer of spray products that enzymes have not been added, Appendix 1 can be used.

Background to requirement O12

It may be necessary to add stabilisers and preservatives to liquid enzyme ingredients to prevent the enzymes breaking down and so losing their activity. This applies, for example, to proteases, where a protease inhibitor is added. Preservatives in enzyme ingredients will solely be aimed at preserving the ingredient, not the finished products. Such preservatives are excluded from the requirement which excludes sensitising substances in the finished product, as the amount of preservatives in the finished product is very low and the preservative performs an important function in an important ingredient.

The requirement made of enzymes concerns the protection of health and safety in the production of cosmetic products in that enzymes must be liquid or a granulate that does not produce dust. This is to prevent workers manufacturing cosmetics from being exposed to the potential effect of enzymes sensitising the airways.

Enzyme preparations must not be found in spray products. This is intended to protect consumers from breathing in spray containing enzymes. Soap with a pump Tvål med en pump räknas inte som en spray, men spraysolkräm är sprayprodukter.

In other cosmetic products, substances in enzyme preparations may be classified H334 and H317, see O4 Classification of ingoing substances. They 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”.

The requirement has been changed so as not to permit enzymes in powder form.

O13 Preservatives

These requirements also apply to antibacterial disinfecting and microbial substances.

- The use of preservatives for purposes other than preservation of the product itself is prohibited.
- Preservatives must not be bioaccumulating as specified by Appendix 9 (BCF<500/logKow<4).

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

☒ Specification of BCF value or logKow value, see description in Appendix 9. Appendices 1 and 2 can be used.

Background to requirement O13

All antibacterial, disinfecting and antimicrobial substances must comply with the requirements that cover preservatives. This is to ensure that the substances are not added to products unless they comply with the requirements that apply for preservatives.

Preservatives may only be used with the aim of preserving the product to avoid products that are said to be biocides. Household use of biocides is not considered to be beneficial and can increase bacterial resistance.

The requirement that preservatives must not be bioaccumulating reduces the serious environmental impact associated with bioaccumulative substances.

Oral hygiene products may contain substances that produce an “antibacterial” effect. These substances must comply with the requirements for preservatives.

Different dandruff shampoos may contain different substances specifically designed to have an antimicrobial effect against fungus (fungicides). Some of these substances are associated with a risk of environmental damage. As we have seen that in consumer products it is possible to create sufficient antidandruff effect by combining non-fungicidal substances, we wish to promote these. Therefore, we make no exceptions for antimicrobial substances in dandruff shampoo. The most effective products have indications against seborrhoea and are sold as non-prescription drugs, which our requirements do not cover.

These requirements have been merged but are otherwise unchanged since version 2.

Following the consultation, we removed the requirement for limiting phenoxyethanol (CAS 122-99-6) in products for children. In the proposal for consultation phenoxyethanol was limited in baby products and banned in products intended for the nappy area and this was motivated by the precautionary principle following the French study in which this was recommended by Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM).[165] Following consultation, however, an SCCS opinion[166] has been published on the matter (hearing proposal for May 31) which considers that it is safe to use phenoxyethanol in children’s products in the concentration approved by the Cosmetics Regulation. This is confirmed by a study from the Danish Environmental Protection Agency.[167] In addition the choice of preservative is limited by many other requirements: preservatives that are sensitising, endocrine disruptors or release formaldehyde are banned (O5 and O6).

[165] (ANSM, 2012)
[166] (SCCS, 2016)
[167] (Miljøstyrelsen, 2015)

O14 UV filter

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 bioaccumulating as specified by Appendix 9 (BCF<500/logKow<4).

or

- must have a lowest measured toxicity NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

☒ State one of the following: BCF value/logKow value or lowest available NOEC/EC_x/EC/LC50 value.

Background to requirement O14

UV filters can be divided into two types of filter: physical organic filters such as titanium dioxide and chemical organic filters such as benzophenone-3.

UV filters can be problematic from an environmental and health point of view (see e.g. O7 on nanoparticles and O6 on endocrine disruptors).

UV filters provide protection against the sun and thus reduce the risk of skin cancer, so there are also advantages to using sun protection products with UV filters.

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).[168] In addition, UV filters used to protect the user are the only filter covered by Annex VI to the Cosmetics Regulation and are approved there. Requirements on the function of the UV filter (O35) will ensure that Nordic Swan Ecolabelled products only contain approved UV filters and only to protect the user (skin/hair).

The number of available UV filters allowed in cosmetic products is limited by the Cosmetics Regulation and a number of our general requirements (e.g. the requirement on potential endocrine disruptors) restrict this number further.

With the aim of restricting the available UV filters in Nordic Swan Ecolabelled products even more and only accepting those which have a better environmental performance in general, we have reached the conclusion that the UV filters must not be bioaccumulative or toxic to aquatic organisms. Note that O17 further limits the amount of substances that are harmful to the aquatic environment. We realise that the requirement on stability for organic UV filters in the product and on application is not necessarily compatible with rapid or even potential degradability of the substances. An NOEC/EC_x/EC/LC50 value is sufficient but the lowest available value must be used. If Nordic Swan Ecolabelling has access to a lower value than that on e.g. a safety data sheet, this is to be used instead.

The above requirement excludes UV filters such as 4-methylbenzylidene camphor (4-MBC, LogKow = 5.92; molar weight = 254 g/mol; LC50 = 0.13 mg/l) which has been found in lakes in Switzerland.[169]

[168] (Öko-Test 2009a), (Öko-Test 2009b), (Forbrugerrådet Tænk Kemi, 2015)
[169] (Balmer A, 2010)

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 (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 logKow is >3.

NB! Nano UV filters, with exemption to nano TiO_2, are banned under O7 Nanoparticles.

The requirements are the same as in version 2, an opportunity to use data on chronic ecotoxicity has been added.

O15 Polymeres

For all synthetic polymers the following requirements apply to residual monomers: Residual monomers classified as below may only be included at a maximum of 100 ppm/dry substance per classification per monomer, measured on newly produced polymer dispersion/poeder.

- Acute tox 1-3 with H300, H310, H330, H301, H311, H331,
- CMR with H350, H351, H340, H341, H360, H361,
- sensitising with H334, H317
- environmentally hazardous with H410, H411
- potential endocrine disruptors (see Appendix 9 for a definition).

☒ When stating the residual monomers in the polymer that are classified according to the requirement above, Appendix 1 and 2 can be used, as can a declaration from the polymer producer stating that the requirement is met, e.g. accompanied by specifications and/or analysis results.

Background to requirement O15

Synthetic polymers can exist in large quantities in certain types of product.

Monomers in the polymer can involve a health burden, for example due to their characteristics that are harmful to health such as being allergenic or carcinogenic. This burden is considered to be so high, partly because monomers are often very reactive substances, that it is relevant to set a separate requirement limiting the total content of residual monomers in the polymer.

Polymers must have a low monomer content (less than 100 ppm per classification per polymer) if the monomer is classified as acutely toxic category 1-3 (H300, H310, H330, H301, H311, H331), carcinogenic (H350, H351), mutagenic (H340, H341), toxic for reproduction (H360, H361), sensitising (H334, H317) or environmentally harmful under H410/H411 or is considered to be an endocrine disruptor. This requirement limits the content of monomers that pose a risk to health or the environment. Other monomers that we know often occur in cosmetics are not limited because they do not pose any environmental or health problems. Acute toxicity was added to the list in version 2 such that the requirement is identical to other chemical criteria.

Non-synthetic polymers (vegetable), such as polysaccharides do not contain monomer residues but they may instead contain residues from extraction – typically organic solvents. These are not covered by the requirements. However, if it starts to become evident that solvent residues in these are a problem, this is an issue that may need to be reviewed.

O16 Aluminium

In leave-on cosmetic products, aluminium may be present at the following maximum concentrations (corresponding to elemental % Al):

- 6.25% in non-spray antiperspirants/deodorants
- 10.60% in spray antiperspirants/deodorants
- 2.65 % in tooth paste
- 0.77 % in lipstick
- 17.5% in other leave-on cosmetic products

☒ Formulation and calculation of aluminium content (corresponding to elemental % Al).

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

Background to requirement O16

The requirement is new and has been adjusted during the period of validity of the criteria, in connection with a new SCCS opinion[170] showing in which concentrations it is safe to use aluminum in leave on products.

Various raw materials containing aluminum and are used in for example antiperspirants, makeup, skin cream, toothpaste and sunscreen in various functions such as antiperspirant, abrasive, viscosity controlling and colorant.

The aluminum compounds used may be organic (e.g. aluminum citrates) or inorganic (e.g. Al sulfates or Al silicates) as well as soluble (e.g. most inorganic salts) or insoluble (e.g. Al silicates). Among other things, molecular weight (for the organic aluminum compounds) and pH influence the solubility.

The amount of aluminum varies from <1% up to 20% in antiperspirants and up to 80% in face mask and makeup.

The SCCS opinion shows that the following concentrations are safe to use, and that "significant accumulation in the body is unlikely to result from daily use of cosmetic products" However, decorative cosmetics or other cosmetic products have not been evaluated in opinion focusing on antiperspirants, lipsticks and toothpaste.

6.25% och 10.60% i non-spray antiperspirants och spray antiperspirants (water soluble salts of aluminium) och 2,65 % i tandkräm samt 0,77 % i läppstift (både två innehåller enligt SCCS water-insoluble aluminium ingredients such as aluminium colloidal colorant 'lakes' (A 'lake' is any of a class of pigments composed of organic dyes that have been rendered insoluble by interaction with a compound of a metal, sometimes aluminium.) and insoluble minerals).

Nordic Ecolabelling chooses to follow these limits from SCCS for these 4 products.

Since SCCS has not set limit values for all leave-on products, Nordic Ecolabelling has hired an external consultant to make worst case safety calculations for make-up, since it is estimated that these have the highest content of aluminum. The safety calculations were made by the Folkehelseinstituttet, FHI, in Norway (Institute of Public Health) in accordance with the method stated in the SCCS opinion on aluminum. The calculations were made for eye-shadow, blush and facial powder. The conclusion is that the use of aluminum in these

[170] SCCS Opinion on the safety of alumnium in cosmetic products, Subsmission II, SCCS/1613/19 (3-4 marst 2020)

products can be considered safe at concentrations up to 17.5% for all three products. Nordic Ecolabelling has chosen to set the limit for safe use of aluminum to 17.5% for other leave-on cosmetics. Note that Aluminium Oxide is considered nano and can not be used.

4.3 Biodegradability and aquatic toxicity

O17 Environmentally hazardous substances

Substances classified as environmentally hazardous according to Regulation 1272/2008/EEC may be included in the product to a maximum:

$100 \cdot c\,H410 + 10 \cdot cH411 + cH412 \leq 2.5\%$

where c is the fraction of the product, measured in percentage by weight, made up of the classified substance.

Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation.

Surfactants regardless of their function classified with H411 or H412 are exempted from the requirement, on condition that they are readily degradable and anaerobically degradable in line with the test methods in Appendix 9.

☒ A declaration of potential dangers posed to the environment (acute toxicity, biodegradability and/or bioaccumulative potential), in the form of either a product safety data sheet (e.g. Annex II to REACH 1907/2006/EC) or other documentation.

☒ A calculation of the quantity (percentage by weight) of H410, H411 and H412 in line with the requirement above. If data on the potential dangers posed to the environment by the product (degradability, acute toxicity, and/or bioaccumulation) is not available (see e.g. MSDS section 12), the substance is assessed according to a worst case scenario (H410).

☒ Declaration of surfactants that are to be exempted from the requirement (quantity, classification, degradability) and declaration of zinc compounds that are to be exempt from the requirement (quantity, label with marketing claims).

Background to requirement O17

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. The majority of ingredients in cosmetic products finally end up in the aquatic environment through the wastewater system, either directly when they are used (e.g. soap, toothpaste, shampoo, hair dye) or after they have been used (rinsing in the shower) (e.g. make-up, deodorant, hair care products, fragrances). Certain products/ingredients are also released directly into the environment (both the aquatic environment and air) during use (e.g. sunscreen, hair care products, creams). Applying the precautionary principle reduces the use, spread and flow in society of substances with these properties as only some of the substances reach the aquatic environment in a harmful form and cause environmental risks.

The Cosmetics Regulation does not prohibit or limit the use of substances in cosmetic products due to their environmental properties. Nordic Swan Ecolabelling has thus identified a need to limit environmentally harmful substances by means of a “cut-off” value for these substances. The requirement is based on a weighted method: 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. The limit enables proper storage of the products and acts as a guideline for the use of fragrances including fewer and lower content of blends classified as environmentally hazardous. The limit has not

been changed because new substances have been classified as environmentally hazardous following the review of CLP, in practice the requirement may have become stricter.

From 1 December 2012 the CLP Regulation changed the criteria used as its basis for classification as environmentally hazardous. This means that some substances which were not previously classified as environmentally hazardous have now become so. This primarily concerns surfactants, which in the new classification are classified with H411 or H412. This is a problem, as surfactants have an important irreplaceable function in many rinse-off products and also as an emulsifier in leave-on cosmetics. There is therefore an exception for surfactants in calculating the content of environmentally hazardous substances in requirement O17.

Zinc compounds that are classified as environmentally hazardous are permitted in higher concentrations when they are used in zinc creams to heal irritated skin and nappy rash with documented effects. For such products, where we see a lack of high-quality alternatives, Nordic Swan Ecolabelling is still able to make a positive difference. In a market screening on the Internet and in some stores in 2010 we found that besides zinc, baby products for red skin can also contain, e.g.

- Essential oils and other fragrances – excluded by the ban on fragrances in products intended for children.
- Problematic preservatives – (various parabens – excluded due to suspected endocrine disruptive effects, chlorphenesin – the vast majority of producers classify it with H319 or H315 under the ECHA's classification and labelling inventory [171].)
- Balsam of Peru & TeaTree, allergy risk – excluded by classification/self-classification – allergenic.
- BHA (butylated hydroxyanisole, cas 25013-16-5) – excluded as it is on the list of potential endocrine disruptors.
- Tetrasodium EDTA – excluded by the prohibition on EDTA and its salts.

The limit for zinc compounds is the same as in version 2: 25% to ensure that it is possible to manufacture products that are highly effective without preservatives. High effectivity can lead to fewer applications, making it not necessarily a higher load per functional unit.

We have judged that M-factors are not necessary in cosmetics. M-factors are multiplication factors that are used in classifying environmentally hazardous substances in the categories acute 1 and chronic 1 to separate the extremely toxic components from the ordinary components that are classified with the categories acute and chronic 1. Without M-factors, the extremely toxic components can lead to "under classification" of the mixture. The limit for environmentally hazardous substances with H410 in cosmetic products is already set at 0.025 %, if no other environmentally hazardous substances are found in the product. In practice this means that we allow small amounts of environmentally hazardous fragrances. Fragrances are often classified with H410, H411 or H412. In our experience, the addition of M-factors makes no difference in cosmetic products in particular but makes the formula more complicated.

A) Products rinsed off with water immediately after use (e.g. shampoo, conditioner, solid and liquid soap, cleanser, exfoliant and bath foam/gel, hand soap for industry and cleansing gel).

[171] (ECHA, 2015)

These requirements concern products that according to the usage instructions on the product 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). If a product carries instructions on the packaging stating "...and/or rinse the product from the skin", the product is subject to requirements O18-O19. If, according to the instructions, the user is to rinse the skin after first having used cotton wool, the product is subject to requirement O20 but not requiremnts O18-O19. Note that toothpaste must meet requirement O20 (and not O18 and O19).

O18 aNBO (Aerobic Non-Biodegradable Organics) and anNBO (Anaerobic Non-Biodegradable Organics)

Organic substances that are not readily biodegradable according to Appendix 9, must not exceed the limits indicated in Table 3. 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 O19.

Exceptions to the definition of ingoing substances and impurities:

Impurities in raw material ≤ 1.0 w-% will not be included in calculations.

Table 3 Threshold values for aNBO och anNBO

Type of product	**aNBO (mg/g AC*)** **DID2007/2014/2016 or later versions**	**anNBO (mg/g AC*)** **DID2007/2014/2016 or later versions**
Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant	15	15
Solid soap	5	5

Type of product	**aNBO (mg/dose**)** **DID2007/2014/2016 or later versions**	**anNBO (mg/dose**)** **DID2007/2014/2016 or later versions**
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, se O5 for 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*

Note that surfactants must be degradable under O7.

☒ Calculation of the quantity (mg) of aNBO and anNBO/g AC or mg/dose.

☒ Reference to the DID list dated 2007, 2014, 2016 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. Note that the same version of the DID list must be used for all substances in the calculation.

Background to requirement O18

Restrictions on the content of organic substances that are not rapidly and anaerobically degradable reduce the total level of non-degradable organic substances to a minimum for Nordic Swan Ecolabelled rinse-off products.

The levels for these threshold values are based on Nordic Swan Ecolabelling's experiences from current licences. The documentation submitted under the licensing process has shown that this requirement is already quite strict and that it is one of the most important parameters that distinguishes Nordic Swan Ecolabelled products from other products in this category and therefore the level of the requirement is the same as in version 2.

The limit for solid soaps is more stringent than for other products because solid soap has very high levels of active content and the requirement is based on the active content of the product. In addition, the relative content of aNBO/anNBO substances in general is lower in solid soap compared with liquid products.

The requirement for soap and shampoo is stricter than for other cosmetic products because their composition differs from other cosmetics and so can fulfil more specific requirements. Liquid products that are rinsed off ("rinse-off") such as soap and shampoo generally have a lower active content compared, e.g. with liquids, creams, etc.

Foam soaps have found it difficult to meet our requirements per active ingredients (AC) despite the fact that they were 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 O19 (CDV).

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 (a foam soap from Berendsen Textile Service at 500 ml with a matching dispenser produces, for example, approximately 1 250 doses, which is equivalent to between 0.4 and 0.5 g per dose).

Version 2 of the criteria contained two alternatives for aNBO/anNBO calculations for liquid soap and liquid hand cleanser for industry. Experience shows that l/g AC is used to calculate CDV for the majority of liquid soaps and hand cleanser for industry. Liquid soap is the only type of product where aNBO/anNBO is solely calculated on the basis of dose per wash (l/dose), which is why this calculation option has been retained. The requirement has been changed such that only aNBO/anBNO for liquid soap is calculated on a dose basis.

O19 Critical dilution volume (CDV)

The product's critical dilution volume (CDV) must not exceed the threshold values in Table 4 for CDVchronic for the product type in question.

For foam soap it is permitted to choose between applying the limits per AC (active content) or per dose. The unit used shall be the same as in O18.

Exceptions to the definition of ingoing substances and impurities:

Impurities in raw material ≤ 1.0 w-% will not be included in calculations.

Table 4 Threshold values for CDV

Type of product	CDVchronic (l/g AC*) DID2014 and 2016 or later versions	CDVchronic (l/g AC*) DID2007
Solid soap	2 000	3 000
Other rinse-off products	12 000	13 000

Type of product	CDVchronic (l/dose**) DID2014 and 2016 or later versions	CDVchronic (l/dose**) DID2007
Foam soap	1000	1000

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 dated 2016, 2014 or 2007 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.

CDV is expressed as litre/g of AC or litre/dose, and is calculated for all substances in the product using the formula given in Appendix 4.

**Active content (AC)). Abrasives in handwash and exfoliants are not included, see O5 for microplastics.*

**One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designed for the product (0.5 g minimum). If the product is not sold with a particular dispenser, a standardised dose of 0.75 g for foam soap is used.*

☒ Calculation of CDVchronic for the product. (A spreadsheet for this calculation is available from Nordic Swan Ecolabelling).

Reference to the DID list dated 2007, 2014, 2016 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. Note that the same version of the DID list must be used for all substances in the calculation.

For the DID list: "Detergents Ingredients Database" list, see Appendix 9 for a more detailed description.

Background to requirement O19

This requirement covers only rinse-off products which must be rinsed off with water after use. Other types of cosmetics constitute a very varied group of products such as liquids, toothpaste, make-up, wet wipes, et. for which it is not appropriate to set common CDV values. Instead the potential content of ecotoxic and non-biodegradable substances is regulated by requirement O20 on the degradability of "other cosmetic products".

The critical dilution volume of the product (CDV) must be calculated for all ingoing substances. CDV is a theoretical value which takes into account the toxicity and aquatic degradability of each substance. The method has been developed for the EU Ecolabel. 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.

Rinse-off products are a mixed group of products and in conjunction with the revision it was assessed whether there should be separate CDV requirements for several product types, e.g. conditioner, liquid soap, shampoo, hand cleanser for industry, etc. Immediately this complicates the criteria, making it more difficult to assess which CDV value should be used in

each individual case if a product is calculated, e.g. as shampoo and as body wash. Therefore it has been decided to continue with the same two types as today: solid soap and other rinse-off products.

The threshold values have been set based on Nordic Swan Ecolabelling's experience of existing rinse-off licences. In conjunction with this revision the DID list 2014 (Detergent Ingredient Database) was introduced as an alternative to DID2007. The limit in version 3 of the criteria is set for solid soap, CDVchronic (I/g AC) ≤ 2 000, and other rinse-off products ≤ 12 000 according to DID2014. According to DID2007 the limits are: CDVchronic (I/g AC) ≤ 3 000, and other rinse-off products ≤ 13 000. The DID list was updated in 2016 and the new list is expected to be approved by the Nordic Swan Ecolabelling Board in November 2016. Updates were relatively minor and the use of the new list from 2016 is not expected to cause major changes to the CDV values of cosmetic products. The same threshold values therefore apply for the 2014 and 2016 lists.

Version 2 of the criteria contained two alternatives for CDV calculations for liquid soap and liquid hand cleanser for industry. Experience shows that l/g AC is used to calculate CDV for the majority of liquid soaps and hand cleanser for industry. Liquid soap is the only type of product where CDV is solely calculated on the basis of dose per wash (I/dose), which is why this calculation option has been retained. The requirement has been tightened up to CDVchronic (I/dose) ≤ 1 000 for liquid soap.

For liquid 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.

The water content of the product in relation to the CDV value has been studied. The water content 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. The water content of today's products would not change markedly and a limit on the water content could lead to more concentrated products, leading to irritation problems, and to handling and dosing problems when viscosity increases. In addition to mild products (often containing more water) are needed for children/infants and liquid soaps also often have a high water content.

In conjunction with processing applications for cosmetics and shampoo/soap, and the revision of these criteria documents, it has been made clear that the DID list is insufficient when it comes to handling the many vegetable oils/fats used in cosmetic products. Until now, normal practice has been to use the chemicals list's data for fatty acids in the absence of specific data for vegetable oils. However, fatty acids are judged to have higher toxicity than many vegetable oils – which is why a high content of vegetable oils, e.g. in conditioner or liquid soap can determine whether the CDV requirement can be complied with. Because degradation products are not included in the CDV calculation for all other raw materials, we accept own toxicity and degradability data for vegetable oils instead of the DID list's data for fatty acids.

B) Other cosmetic products

O20 Biodegradability and aquatic toxicity

At least 95% by weight of the total content of organic ingoing substances* must be:

- readily biodegradable (OECD 301 A-F), and/or
- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioaccumulable (logKow < 4 or BCF < 500), and/or
- lowest aquatic toxicity NOEC/EC_x > 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/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol)

Exempt are

- UV filters in sun products
- fibre material in wet wipes

** Exceptions to the definition of ingoing substances and impurities:*

Impurities in raw material ≤ 1.0 w-% will not be included in calculations.

Note that surfactants must be degradable under O6.

☒ Calculation as above as well as reference to DID list 2014, 2016 or later. Note that the same version of the DID list must be used for all substances in the calculation. For substances not listed on the DID list a specification is required of biodegradability/toxicity/potential for bioaccumulation/bioavailability according to Appendix 9. The lowest available NOEC/EC_x/EC/LC50 value must be used. If chronic values are available, they must be used instead of acute ones.

Background to requirement O20

Some products (e.g. wet wipes, some facial cleaning products and nail polish removers) are disposed most likely through house hold waste. Most cosmetic products are largely washed off the body and clothes and therefore end up to a certain extent in the aquatic environment via waste water treatment. Some are washed directly into the aquatic environment. It is therefore important to set requirements on degradability and/or toxicity/bioaccumulation potential for all ingoing substances.
We want to limit the use of substances with these characteristics also generally in the life cycle.

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

If chronic data is not available, acute values may be approved and they must, in such cases be > 10 mg/l, see requirement text.

Colours, antioxidants, preservatives, etc. must be stable in the products and perhaps not meet the requirement for rapid degradability. In addition, long carbon chains such as long chained vegetable oils or paraffin, which is often used in cosmetics, are not rapidly degradable. For this reason, a strict requirement on rapid degradability of all organic substances will be a major obstacle for Nordic Swan Ecolabelling and drastically reduce the number and type of ingredients that meet the criteria, so reducing the flexibility of manufacturers. For example, in our own market survey of seven different lipsticks, we found

that they often contain a high proportion of non-readily degradable ingredients such as binders, polymers, siloxanes and waxes. Hair care products often contain polymers and waxes that are not rapidly degradable.

Reference is now made to chronic toxicity exceeding the acute values. Otherwise the requirement remains unchanged compared with version 2. The “cut-off” limit is set on the basis of Nordic Swan Ecolabelled cosmetic products and a limited examination of the products on the market. The purpose of the requirement is to exclude the worst products on the market.

Molar weight > 700 g/has been chosen as the “cut-off” value for bioavailability. An examination of the literature[172] judged the opportunity to estimate bioaccumulation potential on the basis of 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 “cut-off” 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 LogKow value.

UV filters in sun products are exempt from the requirement because they are needed in sun products in amounts greater than 5% and they must be stable in the products so that they do not meet the criteria for rapid degradability. Because UV filters are often not potentially degradable and due to their molecular size cannot be counted as non-bioavailable substances, they do not comply with the alternative to degradability either. In O15, however, we require that UV filters must not be bioaccumulating and have a lowest toxicity of NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l. This limits the worst UV filters and they can be exempted from the requirement. Several chemical UV filters permitted in non-ecolabelled sunscreens do not comply with our requirements.

In this requirement toothpaste is counted as leave-on, although the Danish Environmental Protection Agency considers that toothpaste must be considered a rinse-off product. In other requirements toothpaste is counted as rinse-off.

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

4.4 Specific requirements relating to certain product types

This section sets requirements on certain selected product types. The requirements described in this section apply only to the specified product types but it should be emphasised that all products, even those set out in section 4.4 must comply with the requirements in all the other chapters.

Solid soap

O21 Content of EDTA and phosphonates in solid soap

Ethylene diamine tetraacetate (EDTA) and its salts (e.g. CAS no. 64-02-8) are permitted in solid soap.

[172] (Frauenhofer Institut Molekularbiologie und Anwandte Oekologie, 2007)

The total added quantity of EDTA, EDTA salts and phosphonates must not exceed 0.6 mg/g Active content (AC).

☒ Calculation of the quantity (mg) of EDTA and phosphonates per gram of AC.

☒ Appendix 1 or equivalent declaration completed and signed.

Background to requirement O21

EDTA (ethylenediaminetetraacetic acid) is permitted in limited amounts in solid soap because its use can reduce the need for preservatives. Without EDTA and phosphonates, the soap will be of poorer quality and will go off more quickly (see soap on the right in picture 1).



Picture 1 Soap containing EDTA (left) and without EDTA (right)

A limit for the accepted amount of phosphonates has been introduced as phosphonates, in the same way as EDTA, are hard to break down. The amount of phosphonates is limited by O18 (aNBO and anNBO) but is limited further here. When they are ultimately broken down into phosphorus, phosphonates also contribute towards eutrophication.

We have information that the soap producers can use as much as 0.5% of both EDTA and phosphonates and that this can be lowered to as little as 0.02% of each, for example by using high quality fatty acids,[173] see picture 2.



Picture 2 Interval of EDTA and phosphonates in solid soap

A limit value of 0.6 mg/g AC (or 0.06 % of AC) for the total EDTA content and phosphonates is strict but within reasonable limits.

The requirement has not been changed compared with the previous version of the criteria.

[173] (Frejl, 2009)

Lip products, toothpaste and oral hygiene products

O22 Flavourings, colours and preservatives

Flavourings, colours and preservatives used in these products must be approved for use in foodstuffs.

☒ Specification of E-number. For flavourings confirmation that flavoring substances meet the requirements in EU Regulation 1334/2008 and specification of FL-number for the flavoring substances for which it is required by this Regulation.

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

Background to requirement O22

Because the consumer is exposed to these products via the mouth, flavourings, colours and preservatives in the product must be approved for use in foodstuffs. According to the Finnish consumer magazine Kuluttaja, applying lipstick three times a day can lead to an intake of up to 15-20 g lipstick a year through absorption and swallowing.[174]

Flavourings do not have E-numbers (under Regulation 1333/2008 on food additives, substances should not be seen as food additives when they are used to add aroma and/or flavour) but they are now listed in Regulation 872/2012 and can be found in an on-line database: https://webgate.ec.europa.eu/foods_system/main/?event=substances.search&substances.pagination=1. For this reason, a declaration from the manufacturer stating that the flavouring is approved for foodstuffs is no longer accepted as documentation and instead the substance's unique identity number (FL-number) in the EU's list of flavourings (Annex to 872/2012) is required. Otherwise the requirement is the same as in the most recent version of the criteria. Since FL numbers are not required for all types of aromas in the regulation 872/2012 the requirement has been adjusted in June 2019 so that it is taken into account.

Hair dyes

O23 Hair dyes

Lawsone (CAS no. 83-72-7) may not be included in the product.

Hair dyes judged to be sensitising/allergenic by the SCCS may not be included in the product, even if they are not classified as such with H317 and/or H334.

☒ Appendix 1 or equivalent declaration completed and signed.

Background to requirement O23

The EU's Scientific Committee SCCS/SCCP/SCCNFP has investigated Lawsone and henna several times. Among other things, in 2001 they found that Lawsone (the colour in henna, CI 75480, CAS 83-72-7) is mutagenic in vitro and in vivo and that it is not possible to be used as a non-oxidising colour in hair dye.[175] Later SCCS/SCCP stated that they consider that the information submitted is insufficient to allow safe use of the substance as a hair dye.[176] The most recent opinion from 2013[177] finds, however, that henna containing max 1.4% Lawsone is safe to use as 100 g henna powder is mixed with 300 ml boiling water. They also call for a

[174] (Kuluttaja, 1996)
[175] (SCCNFP, 2001)
[176] (SCCP, 2005)
[177] (SCCS, 2013)

re-evaluation of the genotoxicity of Lawsone. On the precautionary principle, Nordic Swan Ecolabelling excludes the use of Lawsone (the colour in henna, CI 75480, CAS 83-72-7).

Several hair dyes are sensitising. Many, however, do not have a harmonised classification as sensitising with H317 and/or H334 even if SCCS has judged them to be sensitising/allergenic. Hydroxyethyl-3,4-methylenedioxyaniline HCl (CAS 94158-14-2) and hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl, (CAS 128729-28-2) are examples of such hair dyes. Nordic Swan Ecolabelling therefore prohibits all hair dyes judged to be sensitising/allergenic by the SCCS, even if they are not classified as such with H317 and/or H334.

It is also uncertain whether we, given the requirement above and considering what hair dyes currently look like, will be able to obtain Nordic Swan Ecolabelled hair dyes. But through product development, we hope in the future to be able to have the best hair dyes Nordic Swan Ecolabelled.

Wet wipes

O24 Material

Material/fibre type:

Material/fibre type must meet relevant requirements* or have a licence for the relevant fibre type/material either in

- Nordic Swan Ecolabelling for Sanitary products version 6.0 or later, or
- EU Ecolabel for absorbent hygiene products 2014/763/EU of 24 October 2014 or later
- Nordic Swan Ecolabelling for Textiles version 4.2 or later, or
- EU Ecolabel for textile products 2014/350/EC of 5 July 2009 or later
- Nordic Swan Ecolabelling of Tissue version 5 or later**
- EU Ecolabel for tissue (2009/568/EC).**

Other material/fibre types may not be used.

** The requirements for the relevant material/fibre type that must be met in the different criteria are listed in the table in Appendix 5.*

** For nonwoven material, the requirements for the relevant constituent material must be met, see Appendix 5.*

*** Paper material must be included in an already approved licence under Nordic Swan Ecolabelling of Tissue version 5 or later or the EU Ecolabel criteria for tissue (2009/568/EC).*

Process water:

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

✉ **All materials:**

A copy of any licence from Nordic Swan Ecolabelling or a contract for the EU Ecolabel* showing the material.

* including additional requirements stated in Appendix 5

For alternative documentation, see under and Appendix 5 in the criteria.

- Nordic Swan Ecolabelling's criteria for Sanitary products version 6.0 or later
- EU Ecolabel for Absorbent hygiene products 2014/763/EU of 24 October 2014 or later and additional requirements described above
- Nordic Swan Ecolabelling's criteria for Textiles version 4.2 or later

- EU Ecolabel for textile products 2014/350/EU of 5 June 2014 or later
- Nordic Swan Ecolabelling of Tissue version 5 or later
- EU Ecolabel for Tissue (2009/568/EC of 9 july 2009 or later

☒ **Process water:**

Signed declaration from Producent av servettmaterialet on the use of sensitising substances in the process water for material in wet wipes, Appendix 6 can be used. Non-woven approved under hygiene criteria meets this requirement, no further documentation is needed.

If sensitising substances are used, an analysis report is to be enclosed showing <0.10 ppm for each sensitising substance, see Appendix 5 for a more detailed description.

Background to requirement O24

Wet wipes can be Nordic Swan Ecolabelled even if there is only lotion in the product, which is covered by the Cosmetics Regulation. [178]

Wet wipes are products consisting of a carrier material and chemical ingredients (possibly stated as "liquid"). The carrier material is often made using non-woven technology and often consists of textile/fibre material (viscose, polyester) but can also be made from paper or other natural fibres (e.g. bamboo). Because several studies have shown that the production of these types of material/products can have a significant effect on the environment, requirements have been introduced on the carrier material.

Criteria for the Nordic Swan Ecolabel and the EU Ecolabel exist for both textiles and hygiene products where requirements have already been set for relevant types of carrier materials. Thus, we refer to these criteria documents for requirements on the carrier materials. If the material in the wet wipe can be included in several product criteria, the applicant can choose the criteria document whose requirements they wish to meet.

Through analysing wet wipes, Nordic Swan Ecolabelling has become aware that substances such as MI (methylisothiazolinone), CMI (methylchloroisothiazolinone) 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 Swan Ecolabel does not permit sensitising substances classified with H334 or H317 in cosmetic products, see requirement O5. The ecolabelling criteria for textiles, hygiene products and paper/tissue do not set requirements on process chemicals, and it cannot consequently be ruled out that the wipe material/carrier material may contain residues of sensitising substances from the process water.

The requirement has been changed such that reference is also made to version 6 of Nordic Swan Ecolabelling's Hygiene criteria.

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 such as MI, CMI and glutaraldehyde or other 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.

[178] (EU, 2013)

Proposed analysis method for MI/CMI:

The detection limit must be <0.10 ppm of the substance concerned.

The analysis must be carried out on a standard wipe, approx. 4.8 g.

Liquid chromatography - Mass spectrometry/Mass spectrometry (LC-MS/MS)

Gas chromatography/Mass spectrometry (GS/MS)

Products not covered by the Cosmetic Regulation

O25a Animal care products

Fragrances and colouring agents may not be included in animal care products intended for use on animals.

Products must comply with the EU's Cosmetics Regulation 223/2009/EC regarding ingoing substances and declaration of ingoing substances.

Products can not be classified as environmentally hazardous with H400, H410, H411. H412, or H413.

☒ Appendix 1 or equivalent declaration completed and signed.

☒ Label

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

Background to requirement O25a

Nordic Swan Ecolabelling wishes to continue to Nordic Swan Ecolabel animal care products for even though these are not covered by the Cosmetic Products Regulation. Following the consultation, we have chosen to expand the product group by adding leave-on products for animals (including sun products). There are many different products, including for horses, dogs and cats, which are not rinse-off products. 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 waste water 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[179] in the amounts listed (provided that they meet other requirements). The user's health is the justification behind the requirement.

The requirement has been changed compared with the previous version of the criteria: Leave-on products have been added. Because animal care products are covered by CLP 1272/2008, it has been made clear that products may not be classified as environmentally hazardous.

O25b Sex products

- Fragrances and colouring agents may not be included in sex products.
- Products must comply with the EU's Cosmetics Regulation 223/2009/EC regarding ingoing substances and declaration of ingoing substances.
- Products can not be classified as environmentally hazardous with H400, H410, H411, H412, or H413.
- Products must have been safety assessed according to the requirements set in EU's Cosmetics Regulation 223/2009/EC.
- The safety assessment should be done by:
  a) a person with speciality knowledge regarding safety assessments for cosmetics in a company where also cosmetic products are produced in accordance with the Cosmetics Regulation.
  b) an independent third part with speciality knowledge regarding safety assessments for cosmetics needs to do the safety assessment, for companies that do not produce cosmetics under the Cosmetics Regulation.

☒ Appendix 1 or equivalent declaration completed and signed.

☒ Label.

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

☒ Safety assessment in accordance with the Cosmetics Regulation.

☒ Information stating if the company also produces cosmetic products under the the Cosmetics Regulation.

☒ Information regarding education and background for the person who has done the safety assessment.

Background to requirement O25b

In the criteria document for cosmetics it is stated that the productgroup covers products within the Cosmetics Regulation. The Nordic Ecolabelling board decided on June 15, 2018 to extend the scope of the productgroup to also include sex products such as lube, anal cream and orgasm gels. This product segment has similar formulaes compared to other cosmetic products but are not covered by the Cosmetics Regulation. Nordic Ecolabelling has compared products on the Nordic market and has concluded that there are differences between products on the market regarding health and environmental profiles. The Nordic Ecolabelling thinks that it is possible to differentiate between the products with the cosmetics criteria and labelling the environmentally best products.

[179] (EU, 2009)

The products shall, besides the rest of the requirements, also fulfill a new requirement (O25b). This requirement excludes fragrances and colouring agents in the products since these products are used on intimate and sensitive parts of the body.

The sex products are not within the scope of the Cosmetics Regulation and the extra requirements here are therefore added. The products should be declared in the same way as products within the Cosmetics Regulation to make it clear to the consumer what the content is.

The products should be classified according to CLP. Nordic Ecolabelling does not wish to ecolabel products classified as environmentally harmful with H400, H410, H411, H412 or H413 and has therefore included this requirement here.

The products need to be saftey assessed in accordance with the Cosmetics Regulation in the same way as other cosmetic products. The safety assessment should be done by either a person within a company producing other cosmetic products under the Cosmetics Regulation. This person needs to have speciality knowledge on safety assessment for cosmetics products. Nor an independent third party can do the safety assessment for companies not producing products within the Cosmetics Regulation.

The safety assessment according to the Cosmetics Regulation should include the following ten parts: Säkerhetsvärderingen enligt kosmetikaförordningen ska innefatta följande tio punkter[180]:

- Quantitative and qualitative composition of the cosmetic product
- Physical/chemical characteristics and stability of the cosmetic product
- Microbiological quality
- Impurities, traces, information about the packaging material
- Normal and reasonably foreseeable use
- Exposure to the cosmetic product
- Exposure to the substance
- Toxicological profile of the substances
- Undesirable effects and serious undesirable effects
- Information on the cosmetic product

4.5 Packaging requirements

Packaging often accounts for a relatively large proportion of a cosmetic product. Products with several layers are common, especially luxury products. It is considered important to limit the amount of packaging materials with a general requirement setting a limit on the total amount of packaging compared with the packaging's contents.

[180] Cosmetics regulation, safety assessment, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D0674&from=EN (visited 2018-03-15)

O26 Amount of packaging

- or where the packaging layer is made from recycled* material. More than two layers of packaging are not permitted.

**Recycled materials means ≥80 % recycled materials in packaging.*

- The primary packaging must meet the following calculation. See more information and calculation examples in Appendix 4. A spreadsheet for this calculation is available from Nordic Swan Ecolabelling. The requirement applies to primary packaging, i.e. the packaging that the consumer buys.

$$\frac{\sum\left(\mathrm{mf_i}\cdot Vikt_{\text{material i}}\cdot\frac{(2-\mathrm{rf_i})}{2}\right)-\frac{Vikt_{\text{pump}}}{2}}{\mathrm{t}}\leq a\cdot\ln\left(\mathrm{Vol_{produkt}}+1\right)+b\times\mathrm{Vol_{product}}+c$$

mfi = material factor for type of material divided into the following 4 groups ofmaterials:

mf_{glass} = 0.1

$mf_{paper/cardboard}$ = 0.5

$mf_{laminate}$ = 1.1

$mf_{other\ materials}$ = 1.0

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

rfi = the fraction of the amount of recycled material i after the consumer stage.

$Weight_{pump}$ = weight of pump (if applicable) in grams.

t = reuse factor, t=1 for packaging which is not reused for the same purpose.

ln = natural logarithm

Volproduct = volume of the product in ml

a, b and c are constants that vary for different packaging types

Packaging type	**a**	**b**	**c**
Pump bottle incl. ”Airless”	9	0.017	0
Tub	8.6	0	2
Bottle	7	0.03	2
Can	15	0	1
”Stick + roll on”	4	0.4	2
Wet wipes	4	0	2
Miscellaneous	8	0.004	4
Plastic packaging under preassure	12	0	4

The following are exempt:

- For decorative cosmetics the following apply:

$$\frac{\Sigma(W_{packaging,i}+W_{not-recycled,i})}{2*W_{product,total}}\leq 0.80$$

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

$W_{non\text{-}recycled,\ i}$ = the weight of non-recycled material in packaging component i (if it is not recycled material in the packaging is $W_{non\text{-}recycled}$ = $W_{packaging}$)

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

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

- B2B packaging with a volume > 2 litres, no calculation is needed.

☒ Description of the packaging.

☒ The weight of the primary packaging and the calculation as above (A spreadsheet for this calculation is available from Nordic Swan Ecolabelling).

☒ Appendix 3 or equivalent certification completed and signed by packaging producer if recycled material is included.

Background to requirement O26

The requirement has been tightened up as the formula has been made more stringent. After consultation we amended the requirement such that two layers of packaging are now only permitted where two products are sold together or where the packaging layer is made from recycled material. 80 % post consumer recycled material counts as being made from recycled material. We have also changed the material factors, see below. This is to avoid unnecessary use of packaging.

It is difficult to compare the packaging needs of different cosmetic products. Products with a low volume, such as eye shadow, have much more packaging per product volume compared with high volume products such as most shampoos.

A formula which takes into account the volume of the product, the amount of recycled materials after the consumer stage, reusable/refillable packaging and a potential pump to make correct dosage easier was created for version 2. This has now been made considerably more stringent for version 3. After consultation we have also divided the requirement into different packaging types such that there are different limits for, e.g. tubes and pump bottles. This ensures a more stringent requirement for all types of packaging. The basis for determining the constants was data from current Nordic Swan Ecolabelled products (140 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 packaging calculation for wet wipes must be made by measuring the volume of the content (carrier material) as a block, l x b x h.

The formula works by calculating the amount of packaging on the left-hand side, taking into account recycled materials and return figures. The weight of the pump has less of an impact than the other parts of the packaging. A pump is considered to be good for correct dosing. On the right-hand side the volume is taken into account. The logarithm and different constants attempt to take into account the very high variation in cosmetic products from 5 ml lipbalmstick to 5 l B2B soap bottles. The formula is also described in more detail below.

The material factor value produces a rough “environment weight” which represents energy consumption per kg of different materials. Compared with the previous version, we have increased the energy consumption for injection moulded plastic. Here the source[181] gives consumption of between 4MJ/kg and 60MJ/kg and states that small substances typically demand higher energy consumption. Cosmetics packaging is generally relatively small in

[181]Danish Environmental Protection Agency, 2001. Håndbog i miljøvurdering af produkter (Handbook in environmental assessment of products).

relation to other injection moulded substances such as barrels, bottles, etc. For this reason, we have adjusted the assumed energy consumption from 30MJ/kg to 42MJ/kg, as we judge that this is more representative. Because metals are only allowed for special types of products, no separate material factor was developed for them. Se Appendix 3.

$\sum\left(\mathrm{mf_i} \cdot Weight_{\mathrm{material\,i}} \cdot \frac{(2 - \mathrm{rf_i})}{2} \right)$ expresses a wish to limit the total weight of the packaging and encourage the use of e.g. recycled plastic after the consumer stage and take into account the type of material used (mf_i) and the fraction of recycled material (rf_i).

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

$\frac{1}{\mathrm{t}}$ is included in the formula to encourage direct recycling 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 than products 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.

$a \times \ln\left(\mathrm{Vol_{produkt}} + 1\right)$ describes the logarithmic increase 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 constant (a) is determined iteratively for different packaging types. It has been changed compared with version 2.

$b \times \mathrm{Vol_{produkt}} + c$ is a linear function that takes into account the fact that increased product volume requires larger pacs. The constants (b and c) are determined iteratively for different packagingypes. They have been changed compared with version 2.

On February the 7th 2018 a decision was made by Nordic Ecolabelling's Criteria Group to add a new packaging category. The new category is for plastic packaging under preassure. This is mainly plastic containers of PET with preassurized liquids inside, which then are distributed on the body with a spray function. Nordic Ecolabelling has come to the conclusion that this type of packaging can not be placed under any of the existing categories and has therefore chosen to add this new category.

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 that small products (decorative cosmetics) have a relatively larger proportion of packaging even if the amount of packaging itself is very small. Nordic Swan Ecolabelling has carried out an internal survey of the type and amount of packaging used in decorative cosmetics collected from employees at Nordic Swan Ecolabelling. This survey showed that there are large differences in both the type and amount of packaging between the different product types and within the same product type. This means that it is possible to set requirements that certain

products can meet and others cannot meet. Based on the survey, the requirement was set permitting an amount of packaging in decorative cosmetics amounting to 80% of the total weight of the product.

O27 Type of packaging

All parts of the primary packaging must be able to be sorted separately (paper, cardboard, plastic, metal, glass) without using a tool. Parts comprising mixed materials that cannot be separated are prohibited, with the exception of pump parts.

This requirement does not apply to pressurised containers and packaging for decorative cosmetic products.

✉ Specification of materials, including description of all components (cap, pump, lid, etc.)

Background to requirement O27

With the requirement that all parts of the packaging must be able to be sorted separately (with the exception of plastic and plastic-paper laminates) Nordic Swan Ecolabelling wants to promote the recycling of packaging and the development of packaging that is recyclable, because this is important for a sustainable society and contribute to cirkular ekonomy. Packaging for decorative cosmetics often consists of several materials (glass, metal, plastic) which cannot be separated from each other, but here too there are alternatives. The requirement is that paper, cardboard, plastic, metal and glass must be able to be separated, even if we realise that not all municipalities in the Nordic countries collect the different materials. This means that e.g. silicone cannot be mixed with plastic packaging. Pumps and spray bottles are excluded because there are no alternatives to these.

The pigment/printing ink in/on plastic packaging can mean that the recirculated product cannot be used as recirculated clear plastic,[182] but so as not to reduce consumer demand for Nordic Swan Ecolabelled cosmetics, we have chosen not to set a requirement on pigments and printing ink, which also applies to the use of e.g. metal silver as a pigment in plastic or hot foils. Plastic laminate and plastic-paper laminate are accepted in the light of the fact that even if they cannot be material sorted as plastic, they can be a light-weight alternative to plastic bottles in certain applications. Both laminates can be used as energy waste. Laminate is a material that consists of several different layers that sit on top of each other. In plastic laminate all the layers are plastic while in plastic-paper laminate there are paper and plastic layers. In the light of the limited capacity to reuse laminate, these have a separate material factor of 1.1 which is to be used for plastic laminate. Decorative cosmetics are exempt, due to the complex nature of the packaging.

O28 Packaging material - Metal

Metal packaging may only be used in spray bottles/propellant bottles for hairstyling products and shaving foam.

Small metal parts, e.g. parts of a hand pump or sealing foil across the opening are permitted.

Decorative cosmetics: Metal parts are permitted if the amount of metal does not exceed 15% of the weight of the packaging. Metal elements are permitted in decorative cosmetics if the combined weight of all the metal parts per individual product unit is less than or equal to 15 grammes. Mirrors are not permitted as part of the packaging.

✉ Appendix 3 or equivalent certification completed and signed by packaging producer.

[182] (Plastindustrien i Danmark, 2010)

✉ For metal packaging: Packaging sample/product sample/photo of packaging. Account of the content of metal in packaging for decorative cosmetics

Background to requirement O28

Plastic

The majority of bottles used for packaging chemical products consist of polypropylene (PP) or polyethylene (PE), but certain types of packaging can theoretically consist of PVC. Auraprint, which delivers labels for Finnish chemical producers, which has a Nordic Swan Ecolabel licence, considers that the most common materials used in labels are PP, PE, PET and paper.[183] Auraprint has stopped making labels from PVC, and considers that most other producers have also stopped using PVC in labels. The risk of PVC in packaging especially for cosmetic products and PVC labels is considered to be so small that the requirement has been deleted.[184]

Paper, cardboard packaging or paper packaging

Bleaching with elemental chlorine releases a significant amount of chlorinated organic substances and dioxins in waste water. Due to this it has been banned from use in the Nordic countries since 1994. The alternative bleaching methods that replaced bleaching with elemental chlorine are TCF (totally chlorine free) and ECF (free from elemental chlorine). There is a very small risk that bleaching with elemental chlorine still takes place in other countries. For this reason, the requirement banning the use of bleaching methods using elemental chlorine when manufacturing packaging for Nordic Swan Ecolabelled cosmetics has been deleted.

Metal packaging

Metal spray bottles are usually used, e.g. for hair care products, shaving foam, etc.

Nordic Swan Ecolabelling does not wish to exclude spray bottles in situations where they are needed and so totally exclude certain product types from Nordic Swan Ecolabelling.

New metal has considerably higher CO2 emissions (up to 95% more, depending on the metal and the process) and their production requires considerably larger amounts of energy (up to 95% more, depending on the metal and the process) than secondary metals (from scrap).[185] All use of metal, however, has an effect on the net use of new metal. Metals must therefore only be used where no other alternatives are available. As we see it, these areas of use are hair care products and shaving foam (foam and gel).. 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 the opening are also permitted. Metal that has no hygienic or practical function cannot be used, e.g. metal/metal lines are not permitted as decorating packaging. Metal ink can be used when printing on labels and packaging.

[183] (Ääritalo, 2012)
[184] Examples of packaging in plastic: http://www.arcabox.it/en/pvc-pet-plastic-packaging.html# (website visited 3 December 2012)

[185] (Metal Packaging Europe, ei pvm)

The use of CFC and HCFC compounds as a propellant are limited in the Montreal Protocol on Substances that Deplete the Ozone Layer, which has been introduced in the EU through Regulation 2037/2000/EC. CFC and HCFC compounds are only permitted in certain specific functions (cosmetic packaging is not included). CFC compounds as a propellant have been replaced by hydrocarbons (e.g. N-Butane/Isobutane), dimethyl ether (DME), N2 or trans-1,3,3,3-Tetrafluoroprop-1-ene. Mixtures of propane and butane (LPG)m, Propane-butane and CO2 as well as Isobutane and DME are also used. In addition, F-gases (e.g. HFC-152a) have been used as a replacement for CFCs. The use of F-gases is also restricted in EU Regulation 842/2006/EC. Most of the fluorinated greenhouse gases identified in this regulation has a high global warming potential. Because these compounds are already banned, no requirements have been set on propellant gases.

The internal survey of decorative cosmetics carried out by Nordic Swan Ecolabelling found that the majority of packaging contained metal for various reasons. To provide an opportunity to ecolabel a wide range of products, it has been decided to permit up to 15% metal in packaging. This would make it possible to stabilise the product without too high a use of metal. Mirrors are not permitted, however, as they are considered unnecessary and contribute a lot of extra metal and weight to the packaging.

Metal elements are permitted in decorative cosmetics if the combined weight of all the metal parts per individual product unit is less than or equal to 15 grammes.

Single-pack wet wipes with paper with an aluminium layer is not counted as small metal parts and is not permitted. They lead to a large amount of waste that cannot be material recycled.

Glass

Glass is a heavy material that is restricted by requirement O26 Amount of packaging. However, no particular requirements on glass have been set.

O29 Dosing systems and emptying level

a) For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press

b) Bottles with a pump incl. dispenser bottles or bag-in-box dispenser systems 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.

c) Conditioner bottles must have an emptying level* of 90 % or have a lid that can be removed without tools.

d) Cream bottles must have an emptying level* of 90 % or have a lid that can be removed without tools.

** Emptying level must be calculated according to the formula and taking into account the emptying methods in Appendix 4.*

☒ Description of dosing system and weighing results for liquid hand soap/industrial soap per full press.

☒ Documentation of emptying level according to Appendix 4 or a picture/description of how the lid/pump can be taken apart without tools. Airless pump bottles always meet the requirement and do not need to be documented.

Background to requirement O29

Dosability

Over-dosing of the product increases its environmental impact but does not improve its efficiency. The requirement on dosability/dosing systems has been judged not to be steerable other than for liquid hand soap with a dispenser. For this reason, the requirement has been deleted in version 3. The maximum dose at 1 press for liquid hand soap is the same as in version 2. The maximum dose is related to the CDV requirement (O19).

Emptying level

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.[186]

According to the EU Ecolabel's technical report on criteria for cosmetics [187] there is however no universal truth on the matter and packaging must be adapted to different products and situations. Because there was no methodology on how the parameters such as product design and minimising the product remaining in the packaging can be defined, the EU Ecolabel developed its own system, Nordic Swan Ecolabelling has received a large amount of data on emptying levels during consultation and realised that the consultation proposal for this requirement had poor steerability due to non-standardised tests and varying test results. The requirement has, however, been identified as having very great relevance and it affects all phases of the life cycle.

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

- viscous products in pump bottles
- viscous products in tubes
- 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.

For pump bottles there are two alternatives: 1) they must have an emptying level of 90 % 2) alternatively they must have a screw top or another type of lid that is easy to remove so that the remaining parts of the product can be accessed without using tools. The purpose of alternative 2 is that water can either be added to access the rest of the product or that the opening is large enough that the bottle can be emptied properly. According to data we have received, pump products with an "Airless" system or similar system where there is a bag on 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. In December 2018 it was specified that the requirement also applies to dispenser bottles or bag-in-box dispenser systems.

Viscous products in bottles also proved to have a poor emptying level according to the data we received in consultation. These are often conditioner and skin cream. When it comes to

[186] (Institute for European Environmental Policy, 2004)
[187] (EU Ecolabel, 2013)

conditioner, users can add a little more water to get more of the product out. But in order to do this it must be possible to unscrew the lid. For this reason, the requirement is set that conditioner must have a screw top or another type of lid that is easy to remove so that the remaining parts of the product can be accessed or that the product has an emptying level of 90 %.

Skin cream and lotions in bottles must either have an emptying level of 90 % or have a screw top so that it is easier to access the rest of the packaging. Packaging that can stand on its lid contributes further towards emptying packaging properly, but no requirement is made that the packaging must be able to stand on its lid.

The data we received shows that emptying viscous products in tubes is also very difficult. The emptying level will be better for some products after the products have been stood upside down on their lid. Most tubes, however, stand on their lid and the requirement has no potential. It was unfortunately not possible to set a requirement with relevance, potential and steerability on emptying tubes. Excluding tubes is not a good alternative either because tubes have other advantages: The amount of packaging is lower and less preservatives are needed as the risk of contamination is small. If the consumer wants to access the residual quantities, it is easy to cut up a soft tube.

Other packaging types are about 10 % or less if instead of the test description in the consultation proposal test conditions can be used that correspond to consumer behaviour (such as turning it upside down for longer or using more force). Therefore, requirements on other types of products are considered to have little potential or steerability and no requirement is set.

For pump botlles, cream bottles and balsam bottles the amount of product remaining in the packaging (R), which must be less than 10% is calculated using the following formula:

R = ((m2-m3) / (m1-m3)) x 100 (%)

where:

m1= mass of primary packaging and product (g)

m2= mass of primary packaging and remainder of product in normal conditions (g)

m3= mass of empty and clean primary packaging (g)

Normal conditions are defined as:

Normal conditions of use are defined as:

- Pump bottle: Repeatedly press the mouth of the pump. If nothing has come out of the packaging after 5 presses in a row, the packaging is considered to be empty. The mouth of the pump may not be taken apart and water must not be introduced in the packaging.

- Vials/flasks: The vial is turned upside down, with the cap in the downward position and is pressed as it would usually be pressed when using the product. After the trickle is not continuous, the bottle is left in the same position for a maximum of 24 hours. The bottle can also be hit on the table which corresponds to normal

consumer behaviour. Neither the cap is dismantled, nor water is introduced inside the packaging

The packaging is approved if an average of 3 tests come in below the limit. The same test can be used for products that are similar but have different perfumes or colours. The products must be the same viscosity.

The requirement is new and it has been changed after consultation by modifying normal test conditions and stating that the requirement does not apply to all packaging types.

4.6 Consumer information requirements

The purpose of the requirements on consumer information is to further reduce the environmental impact of the product and guarantee safe use for the consumer.

O30 Organic claims

If it is stated on the product that the product is/contains organic ingredients, at least one of the following must be complied with for these raw materials:

- The EU Regulation on organic production 834/2007.
- Organically certified under NOP
- Organically certified under NPOP
- Organically certified under a system approved by IFOAM

This is stated, for example, with an asterisk following the substance on the INCI list and with the following text: "Organic under EU 889/2008/NOP/NPOP/xx"

☒ If the product or raw material is certified under Ecocert Organic, NaTrue Organic Cosmetics or COSMOS Organic, no further documentation is required for organic raw materials.

☒ Label

☒ Certificate of organic ingoing ingredients

Background to requirement O30

Cosmetics are often sold today with marketing claims on organic ingredients. For Nordic Swan Ecolabelled products, these claims must be based on facts in order to maintain the trustworthiness of the ecolabel and the labelled products. In the consultation proposal only cultivation that complies with the EU's Regulation 889/2008 on organic production, which must be documented by a certificate, is permitted. Because the EU Regulation only covers the labelling of food, following consultation other organic certification systems have been added.

If the finished cosmetic product is labelled with the following recognised standards for organic natural cosmetics Ecocert Organic, NaTrue Organic Cosmetics or COSMOS Organic, no further documentation is required for organic raw materials.

O31 Information text – Sunscreen

The labelling of sunscreen products with information text and SPF factor are to follow Commission Recommendation 2006/647/EC on the efficacy of sunscreen products and the claims made relating thereto

☒ Label or packaging sample.

Background to requirement O31

One common misconception among consumers is that sunscreen enables them to spend longer time in the sun, and that they are sufficiently protected. To increase consumer safety, they should be informed that the use of sunscreen is a good idea but that it is not the best protection against the harmful rays of the sun. In addition, many consumers do not know how much sunscreen they should use to attain the level of protection stated by the sun protection factor on the product. follow the EU's general recommendations on efficacy and labelling of sunscreen and therefore bear a compulsory text drawing the attention of consumers to these points and providing dosage information.

This means that at least the following or equivalent text must be shown on the packaging:

- ”Do not stay too long in the sun, even while using a sunscreen product”
- ”Reducing this quantity will lower the level of protection significantly”
- ”Re-apply frequently to maintain protection, especially after perspiring, swimming or towelling'.”

The labelling of a sunscreen product with its SPF factor must follow the European Commission recommendations of 22 September 2006 (EU, 2006). The product must be labelled with the following declaration:

- Sun protection factor 6 och 10: Low protection
- Sun protection factor 15, 20 och 25: Medium protection
- Sun protection factor 30 och 50: High protection
- Sun protection factor 50+: Very high protection

An exception is made for day cream/face cream and leave-on hair products with UV filters and low sun protection (SPF 6-10), where texts on dosage need not be given on the packaging while information on the SPF factor must be stated.

The requirement has been simplified after consultation and compared with version 2 and now reference is only made to EU Recommendation 2006/647/EC.

O32 Information text - specific products

The following products:

- cleaning products, e.g. cleansing lotions and eye make-up remover
- nail varnish remover
- wet wipes

must bear the following or an equivalent information text on the label: “Do not discard product, cotton wool or paper carrying this product in the lavatory or drain. Dispose of in a rubbish bin instead.” Pictograms are also accepted.

The following products:

- nail varnish
- nail varnish remover

must bear the following or an equivalent information text on the label: “Do not throw out-of-date/unwanted product in the lavatory, drain or rubbish bin. Please leave at a collection point for hazardous waste instead.”

Contact Nordic Swan Ecolabelling for information texts applicable for the country in question.

✉ Label or packaging sample.

Background to requirement O32

To reduce the effects of paper/cotton and cosmetic products in the aquatic environment and waste water treatment plants an information text is required about correct disposal of paper/cotton in the packaging. The same applies to material in wet wipes

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 be sorted as hazardous waste. For this reason an information text is required advising correct handling when the packaging contains remains of the product. The requirement has not changed compared with the previous versions of the criteria.

4.7 Performance/quality requirements

O33 Performance/quality

The performance/quality of the product must be satisfactory. This can be demonstrated by sending in documentation according to Appendix 7. Cosmetics Europe's guidelines on "Efficacy Evaluation of Cosmetic Products" can be followed. For other test reports the information in Appendix 7 needs to be included.

If there is a recognised test (see, for example, O35 for sunscreen products) this must be used. For other products a test could be:

- The applicant's internal quality test.
- A consumer test with at least 10 independent testers, 80% of whom think the product is as good or better than the reference product.
- A test where comparisons are made with an equivalent product, e.g. a triangle test.
- For existing products that have been on the market for at least 3 years, sales figures can be used as documentation of the primary function. Sales must be increasing or stable to be used as documentation for the primary performance/quality.

✉ Description of the documentation in line with Appendix 7.

✉ If an internal quality test is used, a copy of the test description, the results and the conclusion must be enclosed.

✉ If a consumer test is used, a copy of the completed and signed reply forms must be sent in. In addition, a report that describes which and how many people were asked and a summary of the results must be enclosed. At least 8 out of 10 consumers must be satisfied with the product.

✉ If sales figures are used, documentation for at least 3 years showing stable or rising sales must be enclosed.

Background to requirement O33

The performance/quality of Nordic Swan Ecolabelled products must be satisfactory. Because cosmetic products covered by the criteria document cover so wide a range of different products and there are no international standardised tests in this area (with the exception of sunscreens), Nordic Swan Ecolabelling has decided to leave the requirement as open as possible. Cosmetics Europe's (formerly Colipa's) guidelines for evaluating the performance of

cosmetic products provide advice on what should be taken into account when products are evaluated using sensory tests on people, either by consumers or in expert panels/by experts. Effectiveness can be documented via internal quality tests, user tests or laboratory tests. Guidelines are also given for laboratory tests, both for ex vivo and in vitro tests. Guidelines are also given on which information is to be included in the test procedure and in the test report. Cosmetics Europe's guidelines[188] can be followed as they meet the minimum requirements set. Appendix 7 sets out the minimum requirements made of test reports as documentation of the performance/quality of the products.

Cosmetics Europe's guidelines also state that substantiating cosmetic claims should be an integrated part of product development and design and should not be carried out after development merely to support communication of the product's performance and advantages.

Most cosmetic products state marketing claims praising the products' function and properties. In conjunction with the consultation, we were made aware of the amendment to the legislation on cosmetic products (Commission Regulation (EU) No. 655/2013 of 10 July 2013), where it is shown that claims on products must be supported by sufficient and verifiable documentation. As all Nordic Swan Ecolabelled cosmetic products must comply with the legislation, it must be expected that all Nordic Swan Ecolabelled products meet requirements on claims, and Nordic Swan Ecolabelling does not wish to check this in the future. However, this does not apply to the claim mild/gentle, which continues to be documented, see below.

Where there is no standardised test, the evaluation is often subjective, e.g. in user tests. The background to the performance requirement is that the applicant demonstrates that they have made active efforts to judge the performance of the product. If a test panel is used, at least 10 people must test the product, which should then be assessed in comparison with a reference product. (this may be a product that is normally used, or it may be a product delivered for the test). The marks from at least 80% of the testers should indicate that the product is as good as or better than the reference product. In the consultation we were criticised that 10 test persons are not enough for a user test, and 20 people were proposed instead. However, we maintain at least 10 test people, so that the burden of work is not too high for the producers, as it is difficult to get test forms returned and it is very demanding in terms of resources to carry out a user test. User tests for shampoo should at least assess capacity to clean and usability (dosage and how easy it is to spread on the hair). For skin cream, for example, tests should be carried out on how easy it is to spread on the skin and ability to moisturise the skin. A triangle test can also be used in which consumers/users test the product such that they use three products simultaneously; two of these products are identical and the third differs from the other two.

Internal quality tests can also be used as documentation of the product's quality. There must be a description of how the test was carried out and what the result showed. In conjunction with consultation we have received proposals for what the applicants' internal tests might be. For example, it may be applicants' internal loop of quality testing in conjunction with product development, i.e. employees' investigations/evaluation of the product in the laboratory, internal user tests and brand owners' (for private label products) investigation and approval of product samples. For internal quality tests a description must be submitted of how the test was carried out and the result/evaluation that shows satisfactory quality.

[188] (Cosmetics Europe, 2008)

For existing products that have been on the market for a long time, it is judged that the product has already undergone consumer testing by the consumers that have bought the product. Here sales figures can be used as documentation of the primary function. Primary function means what the product is designed for or the product's function. E.g. Shampoo - it must be expected that it washes hair clean, Conditioner – it must be expected that it makes hair soft and easy to detangle, Lotion/cream – it must be expected that it moisturises the skin, Deodorant - prevents the smell of sweat. Note that sales must have been ongoing for at least 3 years. Sales must be increasing or stable to be used as documentation for the primary performance/quality. Note that sales figures can only be used as documentation of the product's primary function.

O34 The claim mild/gentle/sensitive

If claim mild/gentle/sensitive or similar is used it should be documented in accordance with Appendix 8.

Exemption: Mild flavour/aroma in toothpaste does not have to be documented in this requirement.

✉ Documentation for mild/gentle/sensitive, see appendix 8.

Background to requirement O34

In principle, all products that are Nordic Swan Ecolabelled are gentle and mild (the word "sensitive" was added to version 3.6 for clarity), but there are differences between them. For example, there is less risk of allergy if a product is fragrance-free compared with a fragranced product, even if the Nordic Swan Ecolabel sets strict requirements on fragrances. And a product that contains surfactants classified with H318 will sting more if it comes into contact with the eye, than a product without H318 classified surfactants. A product with a pH which is close to the skin's natural pH (4.7-6.5), will be seen as mild, while a product with a considerably lower or higher pH will be seen as less mild.

This can be documented by expert assessment or by testing methods to document mildness, e.g. HET-CAM or a test for red blood cells (RBC test) (Brantom PG et al, 1997, Ronald E. Hester et al., 2006), and these tests or tests/expert assessments that give similar results should be used. Note that animal testing is not permitted. In RBC tests Nordic Swan Ecolabelling accepts non-irritant and slightly irritant and in HET-CAM non-irritating and slightly irritating. Claims of "gentle/mild/sensitive" and similar cannot be documented via a consumer test but can be shown, in addition to the above tests, by meeting the following three points:

- not containing fragrances or plant extracts
- containing < 10% surfactants classified with H318
- pH between 4 and 8.

If a perfumed product or a product containing plant extracts is claimed to be mild/gentle/sensitive, there must be a HET-CAM test or red blood cell test (RBC) to document this.

Nordic Ecolabelling has on February 7 2018 decided to make a clarification regarding mild flavours/aromas in toothpaste and that they are not to be documented according to O34. On 20 August 2019, a separate upper pH limit for mild toothpaste has also been added to better take into account the pH of the mouth.

Nordic Ecolabelling has also clarified the text in appendix 8 regarding claims on "mild" that have to be shown if the product is perfumed or contains plant extracts. Perfume substances and plant extracts are treated the same in O9 already and should be treated equally here as well.

Special requirements for sunscreen products

O35 Performance, UVA and UVB

For sunscreen products it must be documented that Commission Recommendation 2006/647/EG on the efficacy of sunscreen products and the claims made relating thereto, and Cosmetics Europe's guidelines are complied with in terms of effective protection against both UVB and UVA.

✉ Description of the test and test results.

Background to requirement O35

The performance requirement states that "available tests should be used where possible". This is relevant for sunscreen products and it is emphasised that the products are expected to meet the Commission's recommendation of 22 September 2006[189] on UVA and UVB protection, and other recommendations on labelling etc. plus the Cosmetics Europe guidelines.[190]

UVB test: To ensure reproducibility and comparability regarding the recommended minimum protection against UVB radiation, we recommend standard EN ISO 24444:2010 Cosmetics – Sun protection test methods – In vivo determination of the sun protection factor (SPF)

UVA test: To assess minimum protection against UVA radiation, we recommend standard EN ISO 24443:2012 Cosmetics – Sun protection test methods – In vitro determination of sunscreen UVA photoprotection.

The UVB/UVA ratio can be determined with ISO 24443:2012 and Water resistance with Guidelines for Evaluation of Sun Product Water Resistance, COLIPA December 2005.

Test methods have been developed since version 2 and the background text now refers to the most recent test methods. An addition has been made to the text of the requirements stating that Cosmetics Europe's (formerly Colipa's) guidelines must be used

Special requirements for toothpaste

O36 Performance, fluoride

Toothpaste must contain fluoride in line with the national recommendations on fluoride content. If the toothpaste is fluoride free or has a lower fluoride content than recommended, there must be evidence that the effect is nevertheless equivalent to the effect of a fluoride toothpaste. This is documented through scientific publications, recommendations from experts (dentists) and/or in-vivo testing.

✉ Formulation or copy of publications, recommendations and test results as above.

[189] (EU, 2006)
[190] (Cosmetics Europe, 2013)

Background to requirement O36

In recent years, toothpastes which do not contain fluoride and which are marketed as natural, environmentally friendly and/or good for the health have increased their market share. This is due to concern that a high fluoride intake causes fluorosis which is a developmental disruption in tooth enamel caused by chronic exposure to high fluoride content during tooth development, which leads to enamel with a lower mineral content and higher porosity.[191] Once teeth are fully developed, there is no risk. Fluorosis is often linked to fluoridation of water, which does not take place in the Nordic countries. The risks of chronic exposure to high amounts of fluoride at an early age are well documented.

However, it is also well documented that fluorine prevents caries[192] and in all the Nordic countries the respective dental organisations recommend using toothpaste that contains fluoride[193], although the amounts vary.

It is therefore appropriate to require that toothpaste that is not intended for infants contains an amount of fluoride in line with the national recommendations as evidence of sufficient performance. Alternatively, a level of protection equivalent to the recommended fluoride amount should be demonstrated for the same use of toothpastes without fluoride through scientific publications, approval for use by dentists and documented in-vivo testing.

4.8 Quality and regulatory requirements

Quality and regulatory requirements are general requirements that are always included in Nordic Swan Ecolabelling's product criteria. The purpose of these is to ensure that fundamental quality assurance and applicable environmental requirements from the authorities are dealt with appropriately. They also ensure compliance with Nordic Swan Ecolabelling's requirements for the product throughout the period of validity of the licence.

O37 Responsible person and organisation

The company shall appoint individuals who are responsible for ensuring the fulfilment of Nordic Swan Ecolabel requirements, for marketing and for finance, as well as a contact person for communications with Nordic Swan Ecolabelling.

✉ Organisational chart showing who is responsible for the above.

O38 Documentation

The licensee must archive the documentation that is sent in with the application, or in a similar way maintain information in the Nordic Swan Ecolabelling data system.

🔑 Checked on site as necessary.

O39 Quality of Cosmetic product

The licensee must guarantee that the quality of the Nordic Swan Ecolabelled product does not deteriorate during the validity period of the licence.

✉ The claims archive is checked on site.

O40 Planned changes

Written notice must be given to Nordic Swan Ecolabelling of planned changes in products and markets that have a bearing on Nordic Swan Ecolabel requirements.

[191] (Jenny Abanto Alvarez, 2009)
[192] e.g. (NHMRC (Australia), 2007)
[193] (Suomen hammaslääkäriliitto, ei pvm), (Sveriges Tandläkarförbund , ei pvm), (Tandlægeforeningen, ei pvm), (Den norske tannlegeforenings Tidende, ei pvm)

✉ Procedures detailing how planned changes in products and markets are handled.

O41 Unplanned nonconformities

Unplanned nonconformities that have a bearing on Nordic Swan Ecolabel requirements must be reported to Nordic Swan Ecolabelling in writing and journalled.

✉ Procedures detailing how unplanned nonconformities are handled.

O42 Traceability

The licensee must be able to trace the Nordic Swan Ecolabelled Cosmetic products in the production.

✉ Description of/procedures for the fulfilment of the requirement.

O43 Take-back system

The Nordic Ecolabelling's Criteria Group decided on the 9 October 2017 to remove this requirement.

O44 Legislation and regulations

The licensee shall ensure compliance with all applicable local laws and provisions at all production facilities for the Nordic Swan Ecolabelled product, e.g. with regard to safety, working environment, environmental legislation and site-specific terms/permits.

✉ Applications must state which supervisory authorities they are covered by, and the plant-specific conditions and environmental permits issued by the authorities.

✉ Duly signed application form.

🔑 The requirement is checked on site.

5 Changes compared to previous version

The main changes compared with the previous version are:

- Information and policy requirement on renewable raw materials
- New substances added to the list of prohibited substances
- Ban on nano UV filters with exemption to nano TiO_2
- Restriction on aluminium in leave on products
- Stricter packaging requirements
- New requirement on the residual amount of the product in the container after use
- CDV can be calculated based on the DID list from 2014 and 2016

Additional changes are listed in Table 3 below.

Table 3 Overview of changes to criteria for cosmetics version 3 compared with previous version 2.

Proposed reguirement version 3	**Requirement Version 2**	**Same require ment**	**Change**	**New requirem ent**	**Comment**
Product group definition	Product group definition		x		Clearer definition, no real changes. Tighter limit on impurities at raw material level.
O1 Description of the product and INCI list	R1		X		Description of the product added to the requirement
O2 SCCS	R4	X			
O3 Sustainable raw materials	-			X	Information and policy requirement on sustainable raw materials
O4 Classification of ingoing substances	R2	X			-
O5 New substances added to the list of prohibited substances	R5		X		New substances added to the list of prohibited substances
O6 Nano	R6		X		Nano prohibited with exception only for silica as an abrasive in toothpaste and TiO2 as sun screen filter
O7 Surfactants	R7	X			
O8 Fragrances	R13	X			-
O9 Fragrances	R14		X		Flavourings allowed in children's toothpaste
O10 Fragrances	R15		X		New fragrances that must be declared
O11 Colours	R11	X			-
O12 Metals in colours	R12		X		Requirements on metal now only apply to decorative cosmetics and hair dye. Nickel has been added.
O13 Enzymes	R21		X		The requirement has been modernised to bring it into line with other criteria and the latest information from the industry
O14 Preservatives	R16+17		X		The requirements have been merged
O15 UV filters	R18+R19		X		The requirements on UV filters have been merged and chronic toxicity values can be used

Proposed reguirement version 3	Requirement Version 2	Same require ment	Change	New requirem ent	Comment
O16 Polymers	R20		X		The requirement has been harmonised with other criteria and with CLP and new risk phrases have been added
O17 Environmentally hazardous substances			X		The level of the requirement on environmentally hazardous substances is the same. The requirement has been harmonised with CLP
O18 aNBO and anNBO (rinse-off)	R8		X		The requirement level is the same, also refers to DID 2014 and 2016, opportunity to use dose remains only for liquid soap
O19 CDV (rinse-off)	R9		X		The requirement level has been increased slightly, DID list from 2014 can be used. Opportunity to use dose remains only for liquid soap
O20 Degradability and toxicity (leave-on)	R10				The requirement level is the same but chronic values can be used in line with the CDV requirement.
O21 Solid soap	R22	X			-
O22 Lip products, toothpaste and oral hygiene products	R23		X		Opportunity to use declaration for flavourings deleted, approved flavourings now listed in EU
O23 Hair dye	R24	X			-
O24 Hygiene products, wet wipes	R25		X		The requirement has been modified with new criteria versions and it is clearer which requirements in these apply
O25 Animal care products	R26	X			Leave-on products for animals added to the requirement
O26 Amount of packaging			X		Level of requirement (packaging calculation) considerably higher. two layers of packaging are now only permitted where two products are sold together or where the packaging layer is made from recycled material.
O27 Type of packaging	R28		X		Interpretation on plastic-paper laminate included
O28 Packaging material	R29, R30, R31	X			The requirements have been merged The requirements on DIN labelling, PVC and chlorine bleaching have been removed
O29 Dosability/Dosing systems and emptying level	R32		X		Emptying level is a new requirement, dosability requirement has been deleted
O30 Organic claims	R36		X		Approved ecology certifications have been listed
O31 Information test – Sunscreen	R35	X			-
O32 Information text - specific products	R34	X			-

Proposed reguirement version 3	Requirement Version 2	Same require ment	Change	New requirem ent	Comment
O33 Performance/quality a	R37		X		It was specified that minimum 80% must be happy with the product when it comes to user test. Sales figures have been changed to 3 years and internal quality test has been clarified. Claims must not be documented with exeption to claim mild which was moved to its own requirement (O34).
O34 Claimet mild/gentle/sensitive	K37	X			O34 Requirement is the same as in version 2 but it has been moved to its own requirement.
O35 Performance, UVA and UVB	R38	X			-
O36 Performance, fluorine	R39	X			-
O37-O44 Quality and regulatory requirements	R40-R46		X		Small adjustments in line with the criteria template
-	R33		X		Requirement on declaration of contents removed
-	K48				Requirement on marketing removed

6 New Criteria

In the future criteria, the following areas will be evaluated, among others:

- The opportunity to set more stringent requirements on raw materials
- The opportunity to set packaging requirements in another way
- The use only of the most recent DID list
- The opportunity to exclude all siloxanes.

7 Referenser

Astma allergi Danmark. (u.d.). Hämtat från http://www.astma-allergi.dk/den-bla-krans/grundlaeggende-krav den 25 februari 2015

NAAF. (den 21 11 2013). *Kriterier for produktvurdering.* Hämtat från http://www.naaf.no/no/marked_og_produkt/produktguiden/Kriterier-for-produktvurdering/#Hudpleieprodukter den 25 februari 2015

NHMRC (Australia). (2007). *A systematic review of the efficacy and safety of fluoridation PART A: review of methodology and results.* Hämtat från https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/eh41_1.pdf

AAK. (den 11 december 2014). Personlig kontakt med AAK.

AkzoNobel. (u.d.). *DeMythe® LDD* . Hämtat från https://www.akzonobel.com/ic/products/dimethyl_ether/ldd_demythe/ den 2 september 2015

Allergia- ja astmaliitto. (u.d.). *Allergia- ja astmaliitto » Allergiatunnus*. Hämtat från http://www.allergia.fi/allergiatunnus/kriteerit/ den 25 februari 2015

Allergia- ja astmaliitto. (u.d.). *Ihonhoitotuotteet*. Hämtat från http://www.allergia.fi/allergiatunnus/tuotteet/ihonhoitotuotteet/ den 25 februari 2015

Annette Koehler, C. W. (2009). Comparing the Environmental Footprints of Home-Care and Personal-Hygiene Products: The Relevance of Different Life-Cycle Phases. *Environ. Sci. Technol*, 8643–8651.

Ansm. (2011). *Évaluation du risque lié à l'utilisation de l'aluminium dans les produits cosmétiques.* Hämtat från http://ansm.sante.fr/var/ansm_site/storage/original/application/ad548a50ee74cc320c788ce8d11ba373.pdf

ANSM. (2012). *Evaluation du risque lié à l'utilisation du phénoxyéthanol dans les produits cosmétiques.*

Arlene Blum, S. A. (maj 2015). The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs). *Environ Health Perspect, 123*(5). doi:10.1289/ehp

Astma allergi Danmark. (u.d.). *Produkter med Den Blå Krans*. Hämtat från http://www.astma-allergi.dk/den-bla-krans/produkter den 25 februari 2015

Astma- och Allergiförbundet. (u.d.). *Astma- och Allergiförbundets Kriterier förkemisk-tekniska produkter.* Hämtat från http://astmaoallergiforbundet.se/wp-content/uploads/2012/12/Kriterier-Kem-tekn-FS-1-2.pdf den 25 februari 2015

Astma- och allergiförbundet. (u.d.). *Rekommenderade produkter - Hygien*. Hämtat från http://astmaoallergiforbundet.se/svalanmarkt/hygien/ den 25 februari 2015

AURENA Laboratories . (u.d.). *Bag On Valve Technology*. Hämtat från http://bagonvalve.com/technology/ den 2 september 2015

Axelsson, L. (2012). *Att författa ett bakgrundsdokument.* Produktutvecklingen.

Axelsson, L. (2013). *LAx så här skriver man referenser.* Produktutvecklingen.

Axelsson, L. (den 20 maj 2013). *Svanen*. Hämtat från www.svanen.se: www.svanen.se den 20 maj 2013

Bakke, H. (2003). Solskinn kan omdanne desinfiserende triclosan til dioksiner. Bellona.

Balmer A, P. T. (den 23-27 maj 2010). Environmental concentrations of 4-MBC, an endocrine disrupting UV filter, decreased during the last ten years.

BASF. (Juni 2013). BASF Statement regarding sustainable Palm oil and Palm Kernel Oil.

BASF. (den 2014 februari 2014). BASF launches diverse range of ingredients based on certified sustainable palm (kernel) oil. *Pressmeddelande*. Hämtat från https://www.basf.com/en/company/news-and-media/news-releases/2014/02/p-14-134.html

BASF. (den 22 Oktober 2015). Addressing Impacts of Cosmetics Ingredients. *Presentation på Sustainable Cosmetics Summit i Paris*.

BDIH. (u.d.). Hämtat från http://www.kontrollierte-naturkosmetik.de/sv/riktlinjer_naturkosmetik.htm den 25 februari 2015

Bonsucro. (u.d.). *Production Standard*. Hämtat från http://bonsucro.com/site/production-standard/ den 21 september 2015

Borg, D. (2013). TISSUE DISTRIBUTION STUDIES AND RISK ASSESSMENT OF PERFLUOROALKYLATED AND POLYFLUOROALKYLATED SUBSTANCES (PFASS). INSTITUTE OF ENVIRONMENTAL MEDICINE (IMM) Karolinska Institutet, Stockholm, Sweden. Hämtat från https://openarchive.ki.se/xmlui/bitstream/handle/10616/41507/Thesis_Daniel_Borg.pdf?sequence=1

Bra Miljöval. (den 15 december 2014). *Kemiska produkter, Kriterier 2006:5.* Hämtat från http://www.naturskyddsforeningen.se/sites/default/files/dokument-media/bra-miljoval/KemiskaProdukter/kriterier_kem_20150312.pdf

Bra miljöval. (u.d.). *Hitta miljömärkta produkter och tjänster*. Hämtat från http://www.naturskyddsforeningen.se/bra-miljoval/register den 25 februari 2015

Carballa, M., Omil, F., Lema, J., Llompart, M., García-Jares, C., Rodríguez, I., . . . Ternes, T. (July 2004). Behavior of pharmaceuticals, cosmetics and hormones in a sewage treatment plant. *Water Research, 38*(12), 2918-2926.

Certified Allergy & Asthma Consultants. (u.d.). Hämtat från http://www.certifiedallergy.com/ den 14 april 2015

COMMISSION OF THE EUROPEAN COMMUNITIES. (2000). *GREEN PAPER Environmental issues of PVC.* Brussels. Hämtat från http://ec.europa.eu/environment/waste/pvc/pdf/en.pdf

CosIng. (u.d.). *Advanced Search*. Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.advanced den 23 juni 2015

CosIng. (u.d.). *Ingredient : BENZALKONIUM CHLORIDE* . Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=32129 den 23 juni 2015

CosIng. (u.d.). *Ingredient : CHLORAMINE T* . Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=55258 den 23 juni 2015

CosIng. (u.d.). *Ingredient : MAGNESIUM ASCORBYLBORATE*. Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=85162 den 8 juni 2015

Cosing. (u.d.). *Ingredient: Calcium hypochlorite*. Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=83660 den 23 juni 2015

CosIng. (u.d.). *Ingredient: MUSK KETONE* . Hämtat från CosIng: http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=35408 den 8 juni 2015

CosIng. (u.d.). *Ingredient: SODIUM CHLORITE* . Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=58885 den 23 juni 2015

CosIng. (u.d.). *Ingredient: Sodium hypochlorite*. Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details_v2&id=59174 den 23 juni 2015

CosIng. (u.d.). *Search Criteria: Version:Search Results EC Regulation (v.2) | INCI/Substance name: aromatic | Type: Ingredient | Status: Active*. Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.results den 23 juni 2015

CosIng. (u.d.). *Search Results. Search Criteria: Version: EC Regulation (v.2) | INCI/Substance name: aromatic | Status: Active*. Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.results den 23 juni 2015

Cosmetic Ingredient Review Expert Panel. (2009). *Safety Assessment of Silica and Related Cosmetic Ingredients.* Hämtat från http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR466.pdf

Cosmetics Design Europe. (den 3 december 2014). Croda announces RSPO certification for cosmetics ingredient factories in India and Brazil. *Cosmetics Design Europe*. Hämtat från http://www.cosmeticsdesign-europe.com/Market-Trends/Croda-announces-RSPO-certification-for-cosmetics-ingredient-factories-in-India-and-Brazil

Cosmetics Europe. (2008). *GUIDELINES FOR THE EVALUATION OF THE EFFICACY OF COSMETICS PRODUCTS.* Hämtat från https://www.cosmeticseurope.eu/downloads/8781.html

Cosmetics Europe. (2013). Recommendation No 25 Use of appropriate validated methods for evaluating sun product protection.

Cosmetics Europe. (u.d.). *Sustainable development*. Hämtat från https://www.cosmeticseurope.eu/responsible-industry-the-european-cosmetic-cosmetics-association/sustainable-development.html den 21 september 2015

Cosmos. (den 21 Oktober 2013). *Cosmetics organic and natural standard.* Hämtat från http://www.cosmos-standard.org/docs/COSMOS-standard-v2-21102013.pdf

David Sánchez-Quiles, A. T.-S. (den 1 augusti 2014). Sunscreens as a Source of Hydrogen Peroxide Production in Coastal Waters. *Environ. Sci. Technol, 48*(16), 9037–9042. doi:10.1021/es5020696

Den norske tannlegeforenings Tidende. (u.d.). *Helsetilsynet – retningslinjer om bruk av fluor*. Hämtat från http://www.tannlegetidende.no/i/2001/1/chap09_0101idm603584 den 9 september 2015

DG Environment. (2000). *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption.* Hämtat från http://ec.europa.eu/environment/archives/docum/pdf/bkh_main.pdf

DG Environment. (2002). *Endocrine disrupters: Study on gathering information on 435 substances with insufficient data.* Hämtat från http://ec.europa.eu/environment/chemicals/endocrine/pdf/bkh_report.pdf#page=1

DHI water and environment. (2007). *Study on enhancing the Endocrine Disrupter priority list with a focus on low production volume chemicals.* DG Environment. Hämtat från http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf

Direktoratet for forvaltning og IKT . (u.d.). Hämtat från http://www.difi.no/ 2014

DR DK. (den 30 april 2013). Plejeprodukter fyldt med plastik. Hämtat från http://www.dr.dk/DR1/kontant/2013/04/30121844.htm

Duus, J. (2009). Personlig kontakt?

ECHA. (u.d.). Hämtat från http://echa.europa.eu/sv/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/21513 den 8 juni 2015

ECHA. (den 22 may 2015). *Databasen för klassificerings- och märkningsregistret* . Hämtat från http://echa.europa.eu/sv/information-on-chemicals/cl-inventory-database den 2 juni 2015

ECHA. (den 15 juni 2015). *Kandidatförteckning över SVHC-ämnen för godkännande* . Hämtat från ECHA: http://echa.europa.eu/sv/candidate-list-table den 23 juni 2015

ECHA. (den 10 september 2015). Reach dossier om dodecamethylcyclohexasiloxane. Hämtat från http://apps.echa.europa.eu/registered/data/dossiers/DISS-9875b402-454f-

57f6-e044-00144f67d031/AGGR-f5e43ceb-e647-4392-bec6-0f8966475b48_DISS-9875b402-454f-57f6-e044-00144f67d031.html#section_1.1 den 13 november 2015

ECHA. (u.d.). *Summary of Classification and Labelling*. Hämtat från http://echa.europa.eu/sv/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/20902 den 8 juni 2015

ECHA. (u.d.). *Summary of Classification and Labelling (BHA)*. Hämtat från http://echa.europa.eu/sv/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/97532 den 11 september 2015

ECHA. (u.d.). *Summary of Classification and Labelling (BHT)*. Hämtat från http://echa.europa.eu/sv/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/24787 den 11 september 2015

Ecocert. (den 1 Juli 2012). *Ecocert Standard NATURAL AND ORGANIC COSMETICS.* Hämtat från http://www.ecocert.com/sites/default/files/u3/Ecocert-Standard.pdf

Environment Canada, Health Canada. (2008). *Screening Assessment for the Challenge Dodecamethylcyclohexasiloxane (D6).* Hämtat från http://ec.gc.ca/ese-ees/FC0D11E7-DB34-41AA-B1B3-E66EFD8813F1/batch2_540-97-6_en.pdf

Erichsen, H. (2000). *Technical data for waste incineration – background for modelling of product specific emissions in a life cycle assessment context.* Technical University of Denmark, Department of manufacturing engineering.

EU. (den 31 mars 2004). EUROPAPARLAMENTETS OCH RÅDETS FÖRORDNING (EG) nr 648/2004 om tvätt- och rengöringsmedel. Hämtat från http://eur-lex.europa.eu/legal-content/sv/TXT/PDF/?uri=CELEX:02004R0648-20120419&from=EN

EU. (den 18 december 2006). EUROPAPARLAMENTETS OCH RÅDETS FÖRORDNING (EG) nr 1907/2006 om registrering, utvärdering, godkännande och begränsning av kemikalier (Reach). Hämtat från http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:02006R1907-20140822

EU. (den 22 septemer 2006). Kommissionens rekommendation av den 22 September 2006 om solskyddsmedels effektivitet och påståenden om detta (2006/647/EG). Hämtat från http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:265:0039:0043:sv:PDF

EU. (den 22 september 2006). kommissionens rekommendation om solskyddsmedels effektivitet och påståenden om detta. Hämtat från http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:32006H0647&from=SV

EU. (den 17 may 2006). REGULATION (EC) No 842/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on certain fluorinated greenhouse gases. Hämtat från http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:32006R0842&from=EN

EU. (den 16 december 2008). EUROPAPARLAMENTETS OCH RÅDETS FÖRORDNING (EG) nr 1272/2008 om klassificering, märkning och förpackning av ämnen och blandningar.

Hämtat från http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:02008R1272-20131201&from=EN

EU. (den 22 december 2008). KOMMISSIONENS DIREKTIV 2008/128/EG om särskilda renhetskriterier för färgämnen som används i livsmedel .

EU. (den 30 vovember 2009). EUROPAPARLAMENTETS OCH RÅDETS FÖRORDNING (EG) nr 1223/2009 av den 30 november 2009 om kosmetiska produkter . Hämtat från http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:sv:PDF

EU. (November 2013). MANUAL ON THE SCOPE OF APPLICATION OF THE COSMETICS REGULATION (EC) NO 1223/2009 (ART. 2(1)(A)). *Version 1.0*. http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/manual_borderlines_ol_en.pdf. Hämtat från Borderlinemanualen till kosmetikförordningen: http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/manual_borderlines_ol_en.pdf

EU. (den 2014 december 2014). KOMMISSIONENS BESLUT av den 9 december 2014 om fastställande av ekologiska kriterier för tilldelning av EU-miljömärket till kosmetiska produkter som sköljs bort. Hämtat från http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:32014D0893&from=EN

EU Ecolabel. (2013). *Revision of EU Ecolabel Criteria for Soaps, Shampoos and Hair Conditioners - Technical report including revised draft criteria proposal for the product group of rinse-off cosmetic products.*

EU Ecolabel. (2013). *Technical report including revised draft criteria proposal for the product group of rinse off cosmetics.*

EU Ecolabel. (den 9 december 2014). KOMMISSIONENS BESLUT om fastställande av ekologiska kriterier för tilldelning av EU-miljömärket till kosmetiska produkter som sköljs bort. Hämtat från http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:32014D0893&from=EN

EU Ecolabel. (u.d.). *Ecolabel Catalogue*. Hämtat från http://ec.europa.eu/ecat/ den 11 september 2015

European Chemical Industry Council (Cefic). (u.d.). *CHELATING AGENTS - Questions and Answers - EDTA.* Hämtat från http://www.cefic.org/: http://www.cefic.org/Documents/Other/EAC_broch_EDTA_03.pdf den 23 juni 2015

European Chemicals Bureau. (2004). *Euro pean Union Risk Assessment Report edetic acid (EDTA).* Hämtat från http://echa.europa.eu/documents/10162/65615721-ab6d-4f28-b48f-73cf9d8cc529 den 23 Juni 2015

European comission - Rapex. (april 2015). Notification Reference: A12/0100/15. Hämtat från http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.notification&search_term=A12/0100/15&exclude_search_term=0&search_year=2015

European Comission / DG ENV / WRc-NSF. (2002). *Study on the scientific evaluation of 12 substances in the context of endocrine disrupter priority list of actions.*

doi:http://ec.europa.eu/environment/chemicals/endocrine/pdf/wrc_report.pdf#page=29

European comission. (den 10 april 2014). *Kommissionens förordning (EU) nr 358/2014 av den 9 april 2014 om ändring av bilagorna II och V till Europaparlamentets och rådets förordning (EG) nr 1223/2009 om kosmetiska produkter (1)*. Hämtat från http://eur-lex.europa.eu/legal-content/SV/TXT/?uri=uriserv:OJ.L_.2014.107.01.0005.01.SWE den 23 juni 2015

European comission. (den 22 april 2015). *Endocrine Disruptors*. Hämtat från http://ec.europa.eu/environment/chemicals/endocrine/ den 23 juni 2015

European Comission. (den 22 april 2015). *EU GPP criteria*. Hämtat från http://ec.europa.eu/environment/gpp/eu_gpp_criteria_en.htm

European comission. (u.d.). *CosIng*. Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/ den 3 juni 2015

European Comission. (u.d.). *CosIng*. Hämtat från http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple den 12 03 2015

Even Heir, S. L. (2001). Kan desinfeksjionsmidler bidra til bateriell antibiotikaresistens? . *Tidsskrift for Den norske Legeforening, 27*.

EWG. (2009). Sunscreen investigation.

EWG. (u.d.). *Nanoparticles in Sunscreens*. Hämtat från http://www.ewg.org/2015sunscreen/report/nanoparticles-in-sunscreen/ den 16 juni 2015

Farage, M., Bjerke, D., Mahony, C., Blackburn, K., & Gerberick, F. (2003). Quantitative risk assessment for the induction of allergic dermatitis: uncertainty factors for mucosal exposures. *Contact Dermatis, 49*, ss. 140-147.

Fernández C., G.-D. M. (2010). Analytical setup for the occurrence of personal care products in urban effluents and surface waters of the Henares-Jarama-Tajo river system (Madrid, Spain). (s. Poster). Sevilla: SETAC Europe 20th Annual Meeting .

Forbrugerrådet Tænk . (u.d.). *Testskema: Renseservietter.* Hämtat från http://taenk.dk/test/renseservietter/testskema/51577 den 09 mars 2015

Forbrugerrådet Tænk. (u.d.). *http://taenk.dk/*. Hämtat från http://taenk.dk/ den 30 06 2014

Forbrugerrådet Tænk Kemi. (den 13 augusti 2015). *Test: Kemi i bodylotion*. Hämtat från http://kemi.taenk.dk/bliv-groennere/test-kemi-i-bodylotion den 11 september 2015

Forbrugerrådet Tænk Kemi. (den 21 augusti 2015). Test: Kemi i håndsæbe. Hämtat från http://kemi.taenk.dk/bliv-groennere/test-kemi-i-haandsaebe den 11 september 2015

Frauenhofer Institut Molekularbiologie und Anwandte Oekologie. (2007). *Literature Study: Effects of Molecular Size and Lipid Solubility on Bioaccumulation Potential.*

Frauenhofer Institut Molekularbiologie und Anwandte Oekologie. Hämtat från http://www.reach-info.de/dokumente/bcf.pdf

Frejl, J. (2009). Personal dialog. (J. Frydendal, Intervjuare) Victoria Soap AB.

GECA. (den 7 maj 2014). *GECA Standards » Personal Care Products*. Hämtat från http://www.geca.org.au/products/standards/55/ den 13 maj 2015

Good Environmental Choice Australia. (den 9 juli 2014). Environmental Performance Standard - Personal Care Products. Hämtat från http://www.geca.org.au/media/medialibrary/2014/07/Personal_Care_Products_PCPv4.1i-2013.pdf

Grønt Punkt. (den 28 november 2013). E-mailkommunikationmed Svein Erik Rødvik i Grønt Punkt Norge .

Hartmann, N. B., Skjolding, L. M., Foss Hansen, S., Kjølholt, J., & Gottschalck, F. B. (2014). *Environmental fate and behaviour of nanomaterials, New knowledge on important transformation processes.* Environmental Project No. 1594, Miljøstyrelsen.

Henkel. (u.d.). *Raw materials*. Hämtat från http://sustainabilityreport.henkel.com/product-stewardship/raw-materials/ den 19 mars 2015

Herlofson BB, B. P. (oktober 1994). Sodium lauryl sulfate and recurrent aphthous ulcers. A preliminary study. *Acta Odontol Scand, 52*(5), ss. 257-259. Hämtat från http://informahealthcare.com/doi/abs/10.3109/00016359409029036

Herron, S. (June 18 2013). *Life Cycle Impact Study of Leave-on Skin Care Products.* http://www.sustainabilityconsortium.org/wp-content/themes/sustainability/assets/pdf/whitepapers/TSC_LCIS_of_Leave_On_Skin_Products_Final.pdf: The Sustainability Consortium®.

Hjelmar. (2002). *Forbrænding af PVC: Påvirkning af massestrømmene gennem et forbrændingsanlæg.* DHI – Institut for Vand og Miljø.

ICCA. (u.d.). *Responsible Care*. Hämtat från http://www.icca-chem.org/en/Home/Responsible-care/ 2014

IDEA. (u.d.). *Welcome to IDEA*. Hämtat från http://www.ideaproject.info/ den 3 juni 2015

IFRA. (u.d.). Hämtat från http://www.ifraorg.org/ den 3 juni 2015

Institute for European Environmental Policy. (2004). *PACKAGING FOR SUSTAINABILITY: Packaging in the context of the product, supply chain and consumer needs.* An IEEP Report for INCPEN. Hämtat från http://www.ieep.eu/assets/179/packingforsustainability.pdf

Jenny Abanto Alvarez, K. M. (februari 2009). Dental fluorosis: Exposure, prevention and management. *Med Oral Patol Oral Cir Bucal*, 103-107. Hämtat från http://www.medicinaoral.com/medoralfree01/v14i2/medoralv14i2p103.pdf

Jervan, H. (den 8 oktober 2014). : Om oljepalmer og palmeoljer, Foredag på Miljømerking Norge.

Jokela. (2012). *Negation Marketing Of Cosmetics And How It Affects The Consumer's Buying Purchase, Bachelor´S Thesis* . Turku, Finland: Turku University Of Applied Sciences http://www.theseus.fi/handle/10024/53991 . Hämtat från http://www.theseus.fi/handle/10024/53991

Kemikalieinspektionen. (2015). *Förekomst och användning av högfluorerade ämnen och alternativ.* Rapport 6/15. Hämtat från http://www.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Rapport6_15.pdf

Konkurensverket. (u.d.). *Upphandling*. Hämtat från http://www.kkv.se/upphandling/ den 22 maj 2015

Kosmetikkleverandørenesforening. (2012). *Kosmetikkleverandørenes forening - KLF*. Hämtat från http://www.klf.no/ den 23 05 2014

KTF. (u.d.). *Kemtekniska Leverantörsförbundet*. Hämtat från www.ktf.se den 25 April 2014

KTF. (u.d.). *KTF/Statistik*. Hämtat från http://ktf.se/statistik/ den 08 08 2014

Kuluttaja. (1996). Huulipunat tutkittiin - Herkistäviä ja ärsyttäviä aineita löytyi paljon. *Kuluttaja*(3).

Kuluttaja. (2012). Myrkyllinen Katse. *Kuluttaja*(2), ss. 12-17.

Kuluttaja. (2014). Testi BB- ja CC-meikkivoiteet. *Kuluttaja*(7), ss. 16-21.

Leccia, J.-F. (2009).

Lindahl, H. (den 19 08 2014). *www.fremtiden.no*. Hämtat från http://www.framtiden.no/201408196534/aktuelt/forbruk/deodoranter-kan-skape-antibiotikaresistens.html den 25 08 2014

Läkemedelsvärket. (2009). Muntlig info från Gunnar Guzikovski hos Läkemedelsverket .

Metal Packaging Europe. (u.d.). *Metal Packaging Europe / Sustainability*. Hämtat från http://metalpackagingeurope.org/sustainability/towards-a-circular-economy/ den 9 september 2015

Miljøstatus . (den 4 december 2014). *Prioritetslisten*. Hämtat från Miljøstatus: http://www.miljostatus.no/Tema/Kjemikalier/Kjemikalielister/Prioritetslisten/ den 8 juni 2015

Miljøstyrelsen. (2005). *Siloxanes - Consumption, Toxicity and Alternatives.* Miljøprojekt nr. 1031. Hämtat från http://www.miljoestyrelsen.dk/udgiv/publications/2005/87-7614-756-8/pdf/87-7614-757-6.pdf

Miljøstyrelsen. (2009). *Listen over uønskede stoffer 2009.* Hämtat från http://www2.mst.dk/udgiv/publikationer/2010/978-87-92617-15-6/pdf/978-87-92617-16-3.pdf den 23 juni 2015

Miljøstyrelsen. (2014). *Siloxanes (D3, D4, D5, D6, HMDS) Evaluation of health hazards and proposal of a health-based quality criterion for ambient air, Environmental Project*

No. 1531. Hämtat från http://www2.mst.dk/Udgiv/publications/2014/01/978-87-93026-85-8.pdf

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

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

Miljøstyrelsen. (2015). *Microplastics Occurrence, effects and sources of releases to the environment in Denmark.* Environmental project No. 1793. Hämtat från http://www2.mst.dk/Udgiv/publications/2015/10/978-87-93352-80-3.pdf

Miljøstyrelsen. (u.d.). *Triclosan* . Hämtat från http://mst.dk/virksomhed-myndighed/kemikalier/fokus-paa-saerlige-stoffer/triclosan/ den 22 juni 2015

Motivas upphandlingsrådgivning. (den 19 maj 2014). *http://www.motivanhankintapalvelu.fi/files/507/Motivan_hankintaohje_Siivous_ja_teknokemiantuotteet_final.pdf.* Hämtat från http://www.motivanhankintapalvelu.fi/files/507/Motivan_hankintaohje_Siivous_ja_teknokemiantuotteet_final.pdf den 22 maj 2015

Mtv3. (den 4 juni 2015). Itämeren muoviroskat keräävät itseensä haitallisia kemikaaleja – saattavat päätyä ihmisiin. Hämtat från http://www.mtv.fi/uutiset/kotimaa/artikkeli/itameren-muoviroskat-keraavat-itseensa-haitallisia-kemikaaleja-saattavat-paatya-ihmisiin/5133192 den 8 juni 2015

NAAF. (den 6 augusti 2014). *Anbefalte produkter*. Hämtat från http://www.naaf.no/no/marked_og_produkt/produktguiden/Produktavtaler/ den 25 februari 2015

NaTrue. (den 26 juni 2014). *NATRUE Label: requirements to be met by natural and organic cosmetics.* Hämtat från http://www.natrue.org/fileadmin/natrue/downloads/Criteria_2.9/NATRUE-Label_Requirements_V2_9_EN.pdf

NaTrue. (u.d.). *Natrue the friends of Natural and Organic cosmetics*. Hämtat från http://www.natrue.org/home/ den 25 April 2014

Naughton, J. (den 3 januari 2003). Clinique's Burst of Color. *Women's Wear Daily* .

NMR. (den 19 juni 2001). Nordiska ministerrådets beslut om mål och principer för Nordisk Miljömärkning .

Noordzee. (den 18 februari 2013). Lijst gevonden “Plastic Soep”-producten. Hämtat från http://www.noordzee.nl/wp-content/uploads/2013/02/18.2.13.Rood_.pdf

Novamont. (u.d.). *What’s Mater-Bi®*. Hämtat från http://www.novamont.com/Products/default.asp?id=505 den 25 augusti 2015

OECD. (2007). *Lists of PFOS, PFAS, PFOA, PFCA, Related Compounds and Chemicals that may degrade to PFCA (as revised in 2007).* Series on Risk Management No. 21, IOMC.

OECD. (u.d.). *Testing Programme of Manufactured Nanomaterials - Dossiers and Endpoints*. Hämtat från http://www.oecd.org/chemicalsafety/nanosafety/dossiers-and-endpoints-testing-programme-manufactured-nanomaterials.htm juni 2015

Organic Monitoring. (december 2011). *Global Market for Natural & organic personal care products*. Hämtat från http://www.organicmonitor.com/700160.htm den 13 maj 2015

P&G. (u.d.). *Sustainably Sourced Renewable Materials*. Hämtat från http://www.pg.com/en_US/sustainability/environmental_sustainability/renewable_resources/renewable_resources.shtml den 19 mars 2015

Pastemballage. (u.d.).

Perkola, N. (den 12 december 2014). Fate of artificial sweeteners and perfluoroalkyl acids in aquatic environment. Hämtat från https://helda.helsinki.fi/bitstream/handle/10138/136494/fateofar.pdf?sequence=1

Philippe Grandjean, E. B.-J. (den 30 mars 2013). Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations in children. *Environmental Health, 12*(35). Hämtat från http://www.ehjournal.net/content/pdf/1476-069X-12-35.pdf

Plastics Europe. (2013). *Plastics – the Facts 2013.* Hämtat från http://www.plasticseurope.org/cust/documentrequest.aspx?DocID=59108 och http://www.plasticseurope.org/Document/plastics-the-facts-2013.aspx?FolID=2 den november 27 2013

Plastindustrien i Danmark. (august 2010). Personlig dialog med Helle Fabiansen .

Politiken. (den 14 oktober 2007). Deklarationer snyder dig. Hämtat från http://politiken.dk/tjek/dagligliv/kropspleje/article392653.ece

RSPO. (u.d.). Hämtat från http://www.rspo.org/

RSPO. (u.d.). *http://www.rspo.org/*. Hämtat från http://www.rspo.org/

RSPO. (u.d.). personlig kontakt med Inge van der Sluijs.

RTRS. (u.d.). *Types of Certification*. Hämtat från http://www.responsiblesoy.org/en/certification/tipos-de-certificacion/ den 21 september 2015

Safe Cosmetics. (u.d.). *Lead In Lipstick* . Hämtat från Campaign for safe cosmetics: http://www.safecosmetics.org/get-the-facts/regulations/us-laws/lead-in-lipstick/ den 7 september 2015

SafeNano. (den 10 juni 2015). *OECD releases new data on nanomaterials*. Hämtat från http://www.safenano.org/news/news-articles/oecd-releases-new-data-on-nanomaterials/ juni 2015

SCCNFP. (den 13 mars 2001). OPINION CONCERNING Lawsone (Colipa no C146). Hämtat från http://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out139_en.pdf

SCCP. (den 13 december 2005). Opinion on Lawsonia inermis (Henna, C169). Hämtat från http://ec.europa.eu/health/archive/ph_risk/committees/04_sccp/docs/sccp_o_034.pdf

SCCS. (2007). *Opinion on phthalates in cosmetic products.* Hämtat från http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_106.pdf den 23 juni 2015

SCCS. (den 14 december 2010). Opinion on parabens. Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf

SCCS. (den 22 Mars 2011). OPINION ON TRICLOSAN - COLIPA n° P32 ADDENDUM to the SCCP Opinion on Triclosan (SCCP/1192/08) from January 2009. Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_054.pdf den 22 juni 2015

SCCS. (den 12 december 2013). Opinion on carbon black (nano-form).

SCCS. (den 13-14 december 2013). OPINION on Fragrance allergens in cosmetic products. Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf

SCCS. (den 19 september 2013). Opinion on Lawsonia inermis (henna). Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_140.pdf

SCCS. (den 12 december 2013). OPINION ON Methylisothiazolinone (P94) – Submission II . Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_145.pdf

SCCS. (2013). *Opinion on the safety of boron compounds in cosmetic products.* SCCS Opinion. Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_146.pdf

SCCS. (2014). *Opinion on the safety of aluminium in cosmetic products.* Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_153.pdf

SCCS. (den 22 april 2014). Request for a scientific opinion for the use of Phenoxyethanol CAS n. 122-99-6 as. Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_q_093.pdf

SCCS. (den 25 mars 2015). Opinion on decamethylcyclopentasiloxane (cyclopentasiloxane, D5) in cosmetic products. Hämtat från

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_174.pdf

SCCS. (den 20 mars 2015). Opinion on Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form). Hämtat från http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_175.pdf

SCCS. (3-4 marst 2020). Opinion on the safety of alumnium in cosmetic products, Subsmission II, SCCS/1613/19 https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_235.pdf

SPT. (u.d.). *SPT*. Hämtat från www.spt.dk den 23 05 2014

Stockholms universitets Östersjöcentrum. (April 2015). Mikroplaster i hygienartiklar - ett första steg för att minska utsläppen till Östersjön. *Baltic Eye Policy Brief*. Hämtat från http://www.su.se/polopoly_fs/1.232433.1429020022!/menu/standard/file/PBmicroplastSVEwebb.pdf

Suomen hammaslääkäriliitto. (u.d.). *Fluori*. Hämtat från http://www.hammaslaakariliitto.fi/fi/suunterveys/yleistietoa-suunterveydesta/hampaiden-ja-suun-puhdistus/fluori#.VfAvvk3osSs den 9 september 2015

Svedman, C., Andersen, K., Brandao, F., Bruynzeel, D., Diepgen, T., Frosch, P., . . . Bruze, M. (2012). Follow-up of the monitored levels of preservative sensitivity in Europe. Overview of the years 2001–2008. *Contact Dermatitis, 67*(5), ss. 306-320. Hämtat från http://qap2.onlinelibrary.wiley.com/doi/10.1111/j.1600-0536.2012.02140.x/pdf

Sveriges Tandläkarförbund . (u.d.). *Frågor och svar om fluor*. Hämtat från http://www.tandlakarforbundet.se/For-allmanheten/fluor---fragor-och-svar/ den 9 september 2015

Tandlægeforeningen. (u.d.). *Gode råd til god mundhygiejne*. Hämtat från https://www.tandlaegeforeningen.dk/Pressen/aktuelle_kampagner/stoffer_oedelaegger_taenderne_forsiden/gode_tandtaad.aspx den 9 september 2015

TemaNord. (2004). *Musk Compounds in the Nordic environment.* Nordic Council of Ministers.

TemaNord. (2005). *Siloxanes in the Nordic Environment.* Miljøprojekt 1031. Hämtat från http://www.norden.org/sv/publikationer/publikationer/2005-593/at_download/publicationfile

TemaNord. (2007). *Bronopol, Recorcinol, m-Cresol and Triclosan in the Nordic Environment: 585.* Nordisk Ministerråd. Hämtat från http://nordicscreening.org/index.php?module=Pagesetter&type=file&func=get&tid=5&fid=reportfile&pid=2

Testfakta. (den 26 februari 2011). *Mascarorna håller inte måtten.* Hämtat från http://www.testfakta.se/tester/kropp-och-h%C3%A4lsa/mascarorna-h%C3%A5ller-inte-m%C3%A5tten den 9 mars 2015

Testfakta. (den 26 juni 2014). *Test: Solcremer til børn (faktor 30 og 50).* Hämtat från http://taenk.dk/test/solcremer-til-boern-faktor-30-og-50 den 09 mars 2015

Testfakta. (den 20 januari 2015). *Billig hudlotion bäst i test .* Hämtat från http://www.testfakta.se/sites/default/files/tittbild_grafik-hudlotion_1150121.pdf den 9 03 2015

TY. (2014). *Teknokemia*. Hämtat från http://www.teknokemia.fi/fin/teknokemian_yhdistys/

Unilever. (u.d.). *Sustainable Living*. Hämtat från http://www.unilever.com/sustainable-living-2014/reducing-environmental-impact/sustainable-sourcing/sustainable-palm-oil/our-targets/index.aspx den 19 mars 2015

Upphandlingsmyndigheten. (u.d.). UPPHANDLINGSMYNDIGHETENS upphandlingskriterier för Kemisk-tekniska produkter för professionell hygien, rengöring och underhåll. Hämtat från http://kriteriedatabas.upphandlingsmyndigheten.se/data/export/wizard-documents/UHM_kemisk-tekniska-produkter-for-professionell-hygien-rengoring-och-underhall_20150921_134511.pdf den 21 september 2015

Videncenter for allergi. (u.d.). Hämtat från http://www.videncenterforallergi.dk/Allergi%20i%20befolkningen-192.aspx den 3 juni 2009

Ääritalo. (2012). Personlig kommunikation mellem Terhi Uusitalo, Nordisk Miljømærkning og Juha Ääritalo, Auraprint.

Öko-Test 2009a. (u.d.). *Test Haartönungen and Test After-shave-balsam. p. 70-80. Nr. 02. February 2009.*

Öko-Test 2009b. (u.d.). *Test Shampoos. p. 86-103. Nr. 03. March 2009.*

Öko-Test. (2009c). *Test Handcremes. p. 72-77. Nr. 06. June 2009.*

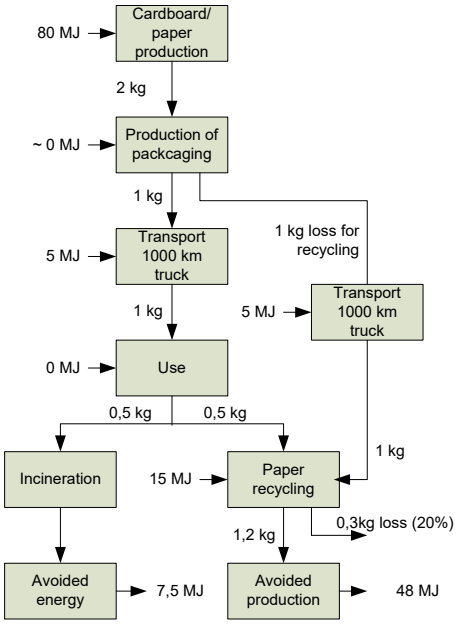
Appendix 1 History of the criteriadocuments of soaps and shampoos and cosmetics

These are available in Swedish.

Appendix 2 MEKA-Schema

These are available in Swedish.

Appendix 3 Materialfactors in packaging requirement



Cardboard/ Paper
+80 MJ
+0 MJ
+5 MJ
+5 MJ
+0 MJ
+15 MJ
- 7,5 MJ
- 48 MJ
= 49,5 MJ

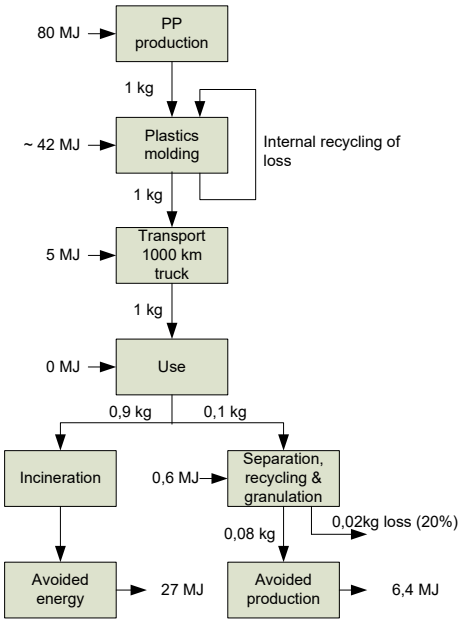
~ 0,5

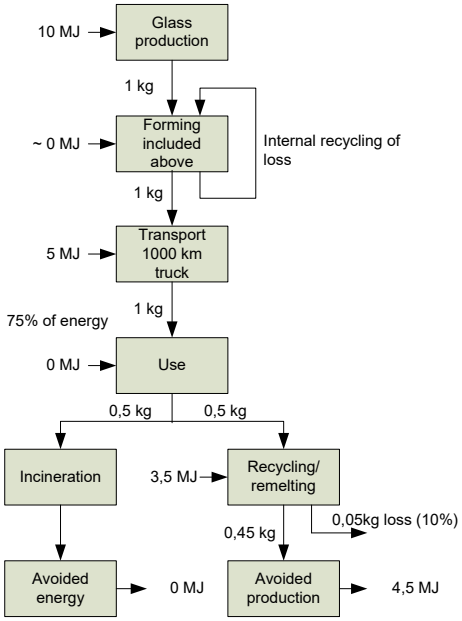
Glass:
+10 MJ
+0 MJ
+5 MJ
+0 MJ
+3,5 MJ
- 0 MJ
- 4,5 MJ
= 14,0 MJ

~ 0,1

Other (represented by PP)
+80 MJ
+42 MJ
+5 MJ
+0 MJ
+0,6 MJ
- 27 MJ
- 6,4 MJ
= 94,2 MJ

~ 1,0





All energy data from Miljøstyrelsen (2001):
Håndbog i miljøvurdering af produkter

Appendix 4 Minimum requirements for the content in test reports as documentation of performance/quality

The product group covers a large number of different products and it is therefore not possible to write a concrete requirement specifying what a test report is supposed to look like. This appendix describes the minimum information required in a test report. The test can be performed as a user test or as a laboratory test, or an internal quality test, see below for the information required for each test.

Test reports following Cosmetics Europe's guidelines "Guideline for Efficacy Evaluation of Cosmetic Products" are always considered to fulfil the requirement for a test report.

For existing products that have been on the market for a long time, it is judged that the product has already undergone consumer testing by the consumers that have bought the product. Here sales figures can be used as documentation of the primary function, see below under section 3 "Sales figures".

1. User test

Points to be described in the report

- When was the test performed?
- Who performed the test?
- Who ordered the test?
- Which products were tested?
- How were the testers chosen?
- How many testers participated in the test?
- What parameters/properties were tested? Why were they chosen?
- Test results
- Conclusions of the test

Note that the test shall be a consumer test with at least 10 independent testers. At least 80% of the testers must be satisfied with the performance/quality. This applies for each individual parameter in the test. It is therefore important to describe why each testing parameter/property has been included in the test. Some parameters/properties may have been included in the test for reasons other than performance (e.g. the scent of the product or similar).

The test needs to have a conclusion. This must clearly state how the results of the test document each individual test parameter/property.

2. Laboratory test

Points to be described in the report

- When was the test performed?
- Who performed the test?
- Who ordered the test?
- Which products were tested?
- How was the test method chosen and how can it be used to document the product's performance/quality?
- What parameters/properties were tested? Why were they chosen?
- Test results
- Conclusions of the test

Note that the test needs to have a conclusion. This must clearly state how the results of the test document each individual test parameter/property.

3. Intern qualitytest

There must be a description of how the test is conducted and what the results showed.

For example, it can be applicants' intern quality testing during product development, i.e. employee survey / assessment of the product in the laboratory, internal user testing or brand owners (for private label products) examination and approval of product samples. A description of how the test has been conducted, as well as results showing satisfactory quality must be accompanied.

4. Sales figures

Points to be described in the report

For existing products that have been on the market for a long time, it is judged that the product has already undergone consumer testing by the consumers that have bought the product. Here sales figures numbers can be used as documentation of performance, provided that the product has been on the market without changes in the recipe in relation to the product for which a Nordic Swan Ecolabelling licence has been applied.

- What time period is covered by sales of the product?
- Are the sales figures in volume, number of products or in price?
- Conclusions of the summary

Note that sales must have been ongoing for at least 3 years. Sales must be increasing or stable to be used as documentation for the primary performance/quality.

Note that sales figures can only be used as documentation of the product's primary function and not as documentation of claims.

A conclusion is required for the sales figures. It must be clear how the sales figures document the primary performance/quality. If there are fluctuations in the sales figures, they need to be satisfactorily explained.