Microplastics Consumer Affairs Statement
August 2016

Thank you for your inquiry.

We would like to reassure you that at Colgate, we are committed to safety. All of the ingredients and materials we use in our products are safe for people and the environment. They meet our strict safety standards, in addition to all applicable government regulations everywhere they are sold around the world. Our commitment is to the highest standards of product safety for our consumers.

In the past, Colgate used microbeads in a limited number of oral care and personal care products to enhance aesthetics and aid in cleaning. However, some groups raised concerns regarding the potential contribution of microbeads to pollution of the world’s oceans. Recognizing that consumers have questions, as of 2013 we are no longer using microbeads.

More recently, consumer questions have extended beyond microbeads to some polymer-based materials, many of which dissolve in water and biodegrade. Colgate continues to monitor the science and evaluate our use of polymer-based ingredients to ensure continued improvements in the environmental profile of our products.
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090 Cosmetic products, version 2.12, 27 April 2016

This document is a translation of an original in Swedish. In case of dispute, the original document should be taken as authoritative.
What is a Nordic Ecolabelled cosmetic product?

Nordic Ecolabelled cosmetic products are among the least environmentally hazardous products within their category and they fulfil both environmental and health related requirements.

Requirements are set on chemical classification and environmental characteristics, on the use of fragrances and colouring agents, on packaging and on product performance.

Products enter the waste water system following their use, either directly, such as soaps, shampoo and toothpaste, or indirectly through washing, such as lotions, creams, hair styling products and make-up. Properties such as biodegradability, bioaccumulation and toxicity to aquatic organisms are therefore highly relevant to all ingredients. Regarding shampoo and soap, this applies in particular to surfactants which are the most important substances in the products from the point of view of quantities and function.

Cosmetic products come into direct contact with the body. They should therefore contain as few irritating, sensitising or in any other way harmful ingredients and impurities as possible. The health requirements focus on allergies and other possible serious effects. This is achieved by imposing requirements on the properties of individual substances and the limitation of specific substances.

Nordic Ecolabelling of cosmetic products guarantees, among other things, that:

- Minimal amounts of environmentally hazardous substances are contained in the products.
- Strict requirements are set in regard to the permissible levels of biodegradability, toxicity and bioaccumulative potential of a product’s constituent substances.
- Products aimed at children are perfume free.
- Use of packaging materials is reduced.

Why choose the Nordic Ecolabel?

- Products may carry the Nordic Ecolabelling trademark for marketing purposes. The Nordic Ecolabel is a very well-known and well-reputed trademark in the Nordic region.
- Nordic Ecolabelling is a simple and cost-effective way of communicating environmental concerns and commitment to purchasers and consumers.
- Environmental issues are complex. It can take a long time and extensive resources to gain an understanding of a specific area. Nordic Ecolabelling facilitates this process.
- The Nordic Ecolabel not only covers environmental issues but also quality requirements, since environmental and quality concerns often go hand in hand. This means that a Nordic Ecolabel licence can also be seen as a mark of quality.
Which cosmetic products may carry the Nordic Ecolabel?

All cosmetic products that are encompassed by Council Directive 76/768/EEC on cosmetics with subsequent amendments and adaptations (see Article 1), and Cosmetics Regulation 1223/2009/EG for example skin care products, hair care products, decorative cosmetics, perfumes and sanitary products, can be Nordic Ecolabelled. Rinse-off products for animals, which are not covered by the cosmetics directive, are eligible for Nordic Ecolabelling. Products within the remit of the Biocidal Products Directive (Directive 98/8/EC) can not be Nordic Ecolabelled.

How to apply

The applicant shall refer to the “Regulations for the Nordic Ecolabelling of products” and the ecolabelling requirements in this document.

Each requirement is marked with the letter R (requirement) and a number.

To be awarded the Nordic Ecolabel, all general requirements and applicable product-specific requirements in this document must be fulfilled.

Icons in the text

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

☑ Enclose

.docs Requirement checked on site

Application

Applications shall be made to Nordic Ecolabelling in the country in which the cosmetic product is to be sold or in which the applicant keeps its base of operations, see the address list on page 2. Applications consist in an application form and documentation of compliance (specified in the requirements).

Further information and assistance may be available. Visit the Web site of the relevant national ecolabelling body for more information.

Sales in other Nordic countries

Registering a licence in another Nordic country allows the Nordic Ecolabel to be used in a larger market. The following must be submitted to Nordic Ecolabelling:

- Application form for registration or original Nordic Ecolabel application*.
- Copy of licence.
• Copy of the label in the applicable local language.

• Documentation demonstrating that particular national legislation is fulfilled in the country of application (e.g. recycling systems or recommended fluorine content in toothpaste).

• Any marketing material for the country of registration.

• The supplier/distributor in the country of registration, when other than the licensee.

*If the applicant states during the initial application that they intend to register the product in other Nordic countries, it is not necessary to submit additional material (see above) at registration. In such cases, Nordic Ecolabelling collates and forwards the documentation to the country or countries in question.

Registration is free of charge but an annual fee shall be paid in accordance with the national regulations.

On-site inspection

During the application process, Nordic Ecolabelling normally performs an on-site inspection to ensure adherence to the requirements. For this inspection, data used for calculations, original copies of submitted certificates, lists of ingredients, test records, purchase statistics, and similar documents that support the application must be available for examination.

Costs

An application fee is charged to companies applying for a licence. There is an additional annual fee based on the turnover of the Nordic Ecolabelled cosmetic product.

Enquiries

Please contact Nordic Ecolabelling if you have any queries or require further information. See page 2 for addresses.

What are the requirements of the Nordic Ecolabel?

To be awarded a Nordic Ecolabel licence, all general requirements and applicable product-specific requirements in this document must be fulfilled.
Environmental and health requirements

The requirements in this section apply to all constituent substances unless specified otherwise.

The term constituent substance refers to all substances in the product, including additives in the ingredients (such as preservatives and stabilisers), with the exception of impurities from primary production. Impurity refers to residues from primary production which may be found in rinse-off that are at concentrations below 0.01% (100 ppm) and in leave-on products at concentrations below 0.001% (10 ppm), provided the impurity has not been actively added and/or added for a particular purpose. Impurities of over 1.0% concentration in the raw material/ingredient are, however, regarded as constituent substances. Substances known to be degradation products of the constituent substances are also themselves considered to be constituent substances.

1.1 General requirements (applicable to all products)

All requirements laid out in section 1.1 must be met except for requirements R8-10, where differentiated requirements in regard of products rinsed in water (R8-9) versus other cosmetic products (R10) are set.

R1 Declaration of content

The exact formulation for the product shall be submitted to Nordic Ecolabelling.

- Exact formulation specifying the constituent substances’ chemical name, trade name, DID (Detergents Ingredients Database) number (if any), INCI (International Nomenclature of Cosmetic Ingredients) name, CAS number (if any), quantity in the product including and excluding water, as well as the function performed by the constituent substance in question. If an ingredient contains several substances, data for each constituent substance shall be presented. If information about the composition of ingredient is confidential, this information can be sent directly to the ecolabelling body.

- Safety data sheet for each ingredient in compliance with applicable legislation in the country of application, e.g. Annex II of REACH (Council Regulation 1907/2006/EEC).
Constituentsubstances
The following requirements apply to all constituent substances and for their known degradation products.

R2 Classification of constituent substances
Constituent substances classified according to Table 1 are prohibited.

Table 1 Classification of constituent substances

<table>
<thead>
<tr>
<th>Classification</th>
<th>Hazard symbols and risk phrases according to 67/548/EEC</th>
<th>Hazard category and statement according to 1272/2008/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitizing*</td>
<td>Xn with R42 or Xi with R43</td>
<td>Resp. sens. 1 with H334 or Skin sens. 1 with H317</td>
</tr>
<tr>
<td>Carcinogenic</td>
<td>Carc with R40, R45 and/or R49</td>
<td>Carc 1A/1B/2 with H350, H350i and/or H351</td>
</tr>
<tr>
<td>Mutagenic</td>
<td>Mut with R46 and/or R68</td>
<td>Mut 1B/2 with H340 and/or H341</td>
</tr>
<tr>
<td>Reproductive</td>
<td>Repr with R60, R61, R62, R63 and/or R64</td>
<td>Repr 1A/1B/2 with H360f, H360d, H361f, H361d, H360fD, H361fd, H360Fd, H360df, Lot. H362</td>
</tr>
<tr>
<td>toxic</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*See the separate requirements on perfumes and enzymes (R15 and R21).
2 Regulation 1272/2008/EEC is applicable from 1 December 2010.

Appendix no. ___

R3 Environmentally hazardous substances
The following limits apply to substances that are classified as environmentally hazardous according to Regulation 1272/2008/EEC (as of 1 December 2010) or Council Directive 67/548/EEC (until 1 December 2010 and during the transition period 2010-2015).

\[
100c_{480}+10c_{481}+c_{482} \leq 2.5% \\
100c_{533}+10c_{535}+c_{539} \leq 2.5%
\]

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

BHT is considered to be classified under R50/53/H410
Zinc oxide paste/ointment/cream marketed for use in the treatment of eczema may, however, contain compounds of Zinc (classified under R50/53/H410) in concentrations up to 25%, and in these cases may be exempted from the requirement.

Surfactants classified with H411 or H412 are exempted from the requirement, provided that they are readily degradable* and anaerobically degradable**.

* In accordance to the DID-list. If the substance in not on the DID-list documentation must be according to test method No. 301 A-F or No. 310 in OECD guidelines for testing of chemicals or other equivalent test methods.
** In accordance to the DID-list. If the substance in not on the DID-list documentation must be according to ISO 11734, ECETOC No. 28 (June 1988) or other equivalent test methods, where a minimum of 60% degradability under anaerobic conditions is achieved.

Appendix no. ___

Appendix no. ___

Declaration of surfactants that are exempted from the requirement (quantity, classification, degradability).

Appendix no. ___

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 (1907/2006/EC/2001/58/EC) or other equivalent documentation.

Appendix no. ___

Declaration of the quantity (in per cent by weight) of R50/53, R51/53 and R52/53 or H410, H411 and H412. If data regarding the potential environmental hazards posed by a substance (biodegradability, toxicity and bioaccumulation) has not been assessed, the substance is treated according to a worst case scenario (R50/53/H410).
R4  **SCCS opinions**

The recommendations of the EU's Scientific Committee on Consumer Safety (known as "SCCS Opinions") are to be followed at all times. In those cases in which these recommendations are not in agreement with the requirements set out in this document, the more restrictive requirement is to apply. SCCS recommendation, SCCS/1459/11 on Fragrance Allergens, is exempted from this requirement. However HICC, chloroatranol and atranol are prohibited in the product. The exception is valid until 30 June 2016.

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

Appendix 3 or equivalent declaration duly completed and signed.  
Appendix no. ____  
Appendix no. ____

R5  **Prohibited substances**

The following substances are prohibited from use in the product and ingredients:

- D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) and D5 (decamethylcyclopentasiloxane, CAS 541-02-6)
- Borates and perborates
- Nitromusk and polycyclic musks
- EDTA (Ethylene diaminetetraacetic acid) and its salts (see however the exemption for solid soap under R22).
- Triclosan
- Parabens (4-Hydroxybenzoic acid and its salts and esters)
- Substances considered potential endocrine disrupters in accordance with European Union reports on endocrine disrupters (see Appendix 2 for a definition).
- Substances that have been evaluated in the EU to be PBT (Persistent, bioaccumulable and toxic) or vPvB (very persistent and very bioaccumulable) (see http://esis.jrc.ec.europa.eu/index.php?PGM=pbt)
- Microplastics*

*Micropastics are defined as undissolvable plastic particles of less than 1 mm size and not biodegradable according to OEC 301 A-F.

Note the national legislations concerning PFOA in the Nordic countries. In Norway PFOA is regulated in "Forskrift om begrensning i bruk av helse- og miljøfarlige kjemikalier og andre produkter (produktforskriften)", §2- 32.

Recipe.  
Appendix no. ____  
Appendix no. ____

R6  **Nanomaterials/particles**

Nanomaterials/particles (insoluble or biopersistent and intentionally manufactured materials with one or more external structure in size 1-100 nm) are prohibited. Excepted from this requirement is hydrated silica used as abrasives in toothpaste. If documentation is published by the SCCS demonstrating that the use of specific nanomaterials/particles in sunscreen products does not give rise to concerns in respect of health, then such specific nanomaterials/particles additionally may be approved for use as sun filter in sunscreen products. This means that a UV-filter can only be used when it is listed in Annex VI of Cosmetics Regulation 223/2009/EG.

Recipe.  
Appendix no. ____  
Appendix no. ____

Recipe.  
Appendix no. ____  
Appendix no. ____

Nordic Ecolabelling of Cosmetic products 2.12 8 (25)
Biodegradability and aquatic toxicity

All products are required to fulfil R7. All products rinsed off with water immediately after use (e.g. shampoo, conditioner, shower gel, solid and liquid soap, cleanser, exfoliant, bath gel/foam, hand soap for industry and cleansing gel) (A) must fulfil the requirements R8 and R9. Other cosmetic products (B) are required to fulfil R10.

**R7**  
**Surfactants**  
All surfactants must be readily aerobically and anaerobically biodegradable, regardless of their function. However, emulsifiers and softeners are exempted from the requirement for anaerobically biodegradable.

Regarding toothpaste, all deterrent surfactants must be readily aerobically biodegradable. Toothpaste must not contain Sodium lauryl sulphate (SLS).

Reference to the DID list, approved version from January 2007 or later. If the substance is not listed on the DID list, the parameters shall be calculated in accordance with the guidelines in section B of the DID list, and the associated documentation shall be submitted.

**DID list: “Detergent Ingredient Database” list. See Appendix 2 for further information.**

Reference to the DID list, approved version from January 2007 or later. If the substance is not listed on the DID list, the parameters shall be calculated in accordance with the guidelines in section B of the DID list, and the associated documentation shall be submitted.

**Appendix no. ____**

**R8**  
**anNBO (Aerobic Non-Biodegradable Organics) and anNBO (Anaerobic Non-Biodegradable Organics)**  
Organic substances (see separate requirement R7 regarding surfactants) that are not readily biodegradable according to Appendix 2, must not be present in the product in excess of the limits indicated in Table 2. The requirement applies to products that, according to their instructions for use, are rinsed off with water immediately after use. For liquid soap and hand soap for industry it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in R9.

**Table 2 Threshold values for anNBO and anNBO**

<table>
<thead>
<tr>
<th>Type of product</th>
<th>anNBO (mg/g Al)</th>
<th>anNBO (mg/g Al*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid soap, hand soap for industry, shampoo,</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>shower gel, conditioner, bath foam, cleanser,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>exfoliant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid soap</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Liquid soap</td>
<td>2,5</td>
<td>2,5</td>
</tr>
<tr>
<td>Liquid hand soap for industry***</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

**Active ingredients** (Al) refers to the dry weight of all organic substances in the product. Abrasives in handwash and exfoliants are not included.

**One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designed for the product (0.5g minimum). If the product is not sold with a particular dispenser, a standardised dose of 0.75 g for foam soap, 1.5 g for other liquid soap and 4 g for hand soap for industry is used.**

**The product must be clearly labelled that it is intended for cleaning severely soiled hands in the context of industry or similar.**
Calculation of the quantity (mg) of aNBO and anNBO per gram AI per dose.

Reference to the DID list, approved version from January 2007 or later. If the substance is not listed on the DID list, the parameters shall be calculated in accordance with the guidelines in section B of the DID list, and the associated documentation shall be submitted.

DID list: "Detergent Ingredient Database" list. See Appendix 2 for further information.

**Critical dilution volume (CDV)**

The product's critical dilution volume (CDV) must not exceed the limit values in Table 3 for CDV\text{\textsubscript{th}}\text{\textsubscript{ran}} for the product type in question.

The requirement applies to products that, according to their instructions for use, are rinsed off with water immediately after use. Regarding liquid soap and hand soap for industry it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in RB.

<table>
<thead>
<tr>
<th>Type of product</th>
<th>CDV\text{\textsubscript{th}}\text{\textsubscript{ran}} (l/g AI\textsuperscript{*})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant</td>
<td>13 000</td>
</tr>
<tr>
<td>Solid soap</td>
<td>3 000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Liquid soap</th>
<th>CDV\text{\textsubscript{th}}\text{\textsubscript{ran}} (l/dose\textsuperscript{**})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid soap</td>
<td>3 000</td>
</tr>
<tr>
<td>Liquid hand soap for industry\textsuperscript{***}</td>
<td>8 000</td>
</tr>
</tbody>
</table>

The calculation of CDV is based on information provided regarding the toxicity and biodegradability of the individual substances in an aquatic environment. CDV is expressed as litre/gram of AI or litre/dose, and is calculated for all substances in the product using the formula given in Appendix 8.

\textsuperscript{*}Active ingredient(s) (AI)

\textsuperscript{**}One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designated for the product (0.5g minimum). If the product is not sold with a particular dispenser, a standardised dose of 0.75 g for foam soap, 1.5 g for other liquid soap and 4 g for hand soap for industry is used

\textsuperscript{***}The product must be clearly labelled that it is intended for cleaning severely soiled hands in the context of industry or similar.

Calculation of CDV\text{\textsubscript{dynic}} for the product. (A spreadsheet for this calculation is available from Nordic Ecolabelling).

Reference to the DID list, approved version from January 2007 or later. If the substance is not listed on the DID list, the parameters shall be calculated in accordance with the guidelines in section B of the DID list, and the associated documentation shall be submitted.

DID list: "Detergent Ingredient Database" list. See Appendix 2 for further information.
B) Other cosmetic products

**R10 Biodegradability and aquatic toxicity**
At least 95% by weight of the total content of organic constituent substances (with exceptions for UV filters in sunscreen and fibre material in wet wipes) must be (see, however, separate requirement R7 in respect of detergents surfactants):
- readily biodegradable (OECD 301 A-F), and/or
- lowest recorded aquatic toxicity EC/LC50 > 10 mg/l and not be bioavailable (molar weight > 700 g/mole), and/or
- lowest recorded aquatic toxicity EC/LC50 > 10 mg/l and not be bioaccumulable (logKow < 4 or BCF < 500), and/or
- lowest recorded aquatic toxicity EC/LC50 > 10 mg/l and be inherently biodegradable (OECD 302 A-C).

❖ Calculation as above as well as reference to DID list. For substances not listed on the DID list a specification is required of biodegradability/toxicity/potential for bioaccumulation/bioavailability according to Appendix 2. (The lowest available EC/LC50 value must be used).

**Dye**

**R11 Bioaccumulation**
Organic colouring agents must not be bioaccumulating according to Appendix 2, item 4 (BCF<500/logKow<4). Alternatively, the colouring agent must be approved for use in foodstuffs.

❖ Specification of empirically determined BCF value (bioconcentration factor) or logKow value (logarithmic octanol-water partition coefficients), see description in Appendix 2. Alternatively, an E-number (number designated on approval of foodstuff status) may be supplied. Appendix 3 and 4 can be used.

**R12 Metals**
Barium, lead, mercury, cadmium, bismuth and hexavalent chromium must not be present in colouring agents in concentrations above 10 ppm (0.001 %). Colouring agents that are approved for use in foodstuffs according to the European Commission's Directive 2008/128/EC can be used without additional documentation.

❖ Appendix 4 or equivalent declaration duly completed and signed and/or specifications/analysis results for the dye.

❖ Specification of E-number and/or declaration from the supplier of the colouring agent conforming that the colouring agent meets the criteria for purity according to the European Commission's Directive 2008/128/EC.

**Fragrances**
Requirements 14-15 apply also to aromatic substances and fragrances in plant extract.

**R13 IFRA**
Fragrances must be used in accordance with the IFRA guidelines.
The IFRA (International Fragrance Association) guidelines can be read at www.ifraorg.org/

❖ Appendix 3 or equivalent declaration duly completed and signed.
R14 Infant, baby and child products
Fragrances/fragrance substances/aromatic substances/fragrance substances in plant extract must not be added to infant, baby and/or child products.

*Infant, baby and/or child products refers to products that are marketed as designed for infants, babies and/or children (<12 years old) or have any of these words on the label/packaging.*

Note that the 26 fragrance substances subject to declaration are included in this requirement.

☐ Appendix 3 and 4 or equivalent declarations duly completed and signed.
☐ Recipe.
☐ Sample of a label.

R15 Quantity of fragrance
A fragrance/aromatic substance/fragrance substance in plant extract that is classified as sensitising with risk phrase R43 (H317) and/or R42 (H334), or is one of the 26 fragrances subject to declaration, must not be present in quantities greater than 0.001% (10 ppm) in leave-on products or 0.01% (100 ppm) in rinse-off products.

☐ Appendix 5 or equivalent declaration duly completed and signed.
☐ Specification of the fragrance(s).
☐ Recipe.

Preservatives
These requirements apply to antibacterial, disinfecting and microbial substances.

R16 Use of preservatives
The use of preservatives for purposes other than preservation of the product itself is prohibited.

☐ Appendix 3 and 4 or equivalent declarations duly completed and signed.

R17 Bioaccumulation
Preservatives must not be bioaccumulating as specified by Appendix 2, item 4 (BCF<500/ logK<4).

☐ Specification of BCF or logK value. See description in Appendix 2. Appendix 3 and 4 may be used.

UV-filter

R18 Function of the UV-filter
UV-filters must only be added to leave-on products and only to protect the user - not the product. Products for which claims in regard to UV protection functionality are made must fulfil requirement R38, Performance, UVA and UVB protection.

☐ Appendix 3 and 4 or equivalent declarations duly completed and signed.
### R19 Environmental characteristics of the UV-filter

All organic UV-filters contained in the product:

- must not be bioaccumulating as specified by Appendix 2, item 4 (BCF<500/logK<4), or
- must have a lowest recorded level of toxicity of EC/LC₅₀ > 10.0 mg/l.

Specify one of the following values:

<table>
<thead>
<tr>
<th>BCF value</th>
<th>logK&lt;sub&gt;ow&lt;/sub&gt; value</th>
<th>lowest EC/LC₅₀ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(The lowest available EC/LC₅₀ value must be used).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Polymers

### R20 Content of monomers

Polymers must contain less than 100 ppm of monomers, measured on the newly produced polymer dispersion, if the monomer is classified as CMR (Carcinogenic, Mutagenic, toxic for Reproduction), see R2 for R-phrases/-hazard statements, sensitising with R42 and/or R43 (H334, H317), environmentally hazardous with R50/53 or R51/53 (H410/H411) or as a potential endocrine disrupter (see Appendix 2 for definition).

Specify of residual monomers in the polymer that are classified as stated in the requirement. Declaration from the polymer producer that the requirement is fulfilled, e.g. through specifications and/or analysis results.

### Enzymes

### R21 Classification of enzymes

- Enzymes must be encapsulated as granulates or liquids. Powdered enzymes can be used provided that:
  - The final product is a dust-free product (excludes powdered or dust products and similar)
  - Manual handling of powdered enzymes shall be carried out in a special, shielded area (for example weighing room or fume cupboard with ventilation)
  - Special work instructions shall be available concerning use of personal protective equipment and concerning collection and removal of any spillage of powdered enzymes that may occur
  - Everyone that handles enzymes shall use protective clothing, gloves, mask with dust filter (minimum P3<sup>1</sup> dust filter) and protective glasses
- Enzyme preparations may be added even when containing substances classified as sensitising with R42 (H334) and/or R43 (H317).
- Use of enzymes in spray products is prohibited.

Specify from the enzyme producer or information on safety data sheet/product specification concerning the shape of the enzyme. Special for powdered enzymes: documentation regarding handling of powdered enzymes in production as it is specified in the requirement.

Specify from the producer of spray products that enzymes have not been added. Appendix 3 may be used.

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<sup>1</sup> Respirator with P3 dust filter protects against most types of hazardous dust. These filters can protect only against solid particles or against both solid particles and liquid aerosols. The filter also protects against radioactive dust, bacteria and virus (Ref: Branche weighdannelsens håndbog for sikkerhedsgenomen bygge og anlæg, 2008).
1.2 Specific requirements relating to certain product types

The following requirements apply only to the product types stated. It should be noted that each and every requirement in section 1.1 must be fulfilled (see, however, the exemptions laid out in the differentiated requirements in regard to rinse off products versus other cosmetic products, R6-R10).

Solid soap

R22 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.
The total added quantity of EDTA, EDTA salts and phosphonates must not exceed 0.6 mg/g Al.
☐ Calculation of the quantity (mg) of EDTA and phosphonates per gram of Al.

Lip products, toothpaste and oral hygiene products

R23 Flavourings, colouring agents and preservatives
Flavourings, colouring agents and preservatives used in these products must be approved for use in foodstuffs.
☐ Specification of E number and/or declaration from supplier of flavouring stating that the flavouring is approved for use in foodstuffs according to 88/388/EC (EU, 1988).

Hair dyes

R24 Hair dyes
Use of lawsone (CAS no. 83-72-7) is prohibited.
Hair dyes considered to be sensitising/allergenic by the SCCS may not be included in the product, even if they are not classified as such with R43 (H317) and/or R42 (H334)
☐ Appendix 3 or equivalent declaration duly completed and signed.
Sanitary products, wet wipes

R25 Materials
The materials used in wet wipes must meet at least one of the requirements below for the relevant type of fibre (other fibre types may not be used):

Viscose, non-woven, polymers (PE, PP, PET):
Requirements regarding the relevant material in Section 2 of Nordic Ecolabelling’s criteria for sanitary products, version 5.0 or later. N.B. The requirement applies also to viscose/non-woven materials based on bamboo fibres.

Paper/cellulose:
Materials must be licensed to carry the Nordic Ecolabel according to, or otherwise fulfil the requirements in the criteria for Nordic Ecolabelling of tissue paper (version 4.0 or later), or have been awarded the European Ecolabel for tissue paper according to the criteria adopted in 2009 (2009/568/EC) or later.

Textile fibres (e.g. cotton, linen, jute, hemp, bamboo):
Textile fibres used in the manufacture of Nordic Ecolabelled wet wipes must be licensed according to, or otherwise fulfil the requirements in the criteria for Nordic Ecolabelling of textile products (version 3.0 or later), or the EU Ecolabel for textile products according to the criteria adopted in July 2009 (2009/567/EC) or later.

Paper: A copy of the Nordic Ecolabel licence; or documentation as required according to the criteria for tissue paper (version 4.0 or later); or a contract in respect of the EU Ecolabel from a competent body.

Textile fibres: A copy of the Nordic Ecolabel licence; or documentation as required according to the criteria for textiles (version 3.0 or later); or a contract in respect of EU ecolabelling from a competent body; or documentation as required according to the criteria for the EU Ecolabel for textile products as adopted in July 2009 (2009/567/EC) or later.

Alternatives for viscose, non-woven, polymers (PE, PP, PET): Documentation as specified in the criteria for sanitary products (version 5.0 or later) or a copy of the Nordic Ecolabel licence with information regarding approved materials for Nordic Ecolabelled hygiene products.

Rinse-off products for animals

R26 Fragrances and colouring agents in rinse-off products for animals
Fragrances and colouring agents may not be included in rinse-off products intended for use on animals.

Products must comply with cosmetics regulations (76/768/EEG, with subsequent amendments and adaptations (see Article 1) and 1223/2009/EG) in regard to their constituent substances and declaration thereof.

Appendix 3 or equivalent declaration duly completed and signed.

Sample of a label.
2 Packaging

All requirements apply only to primary packaging, including labels and information sheets, but not including printer's ink. The term primary packaging refers to packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase, e.g. toothpaste tubes and their box packaging or the plastic packaging holding together 2 bottles of shampoo (2-pack shampoo); i.e. packaging materials used in displays or in goods transportation are not included.

R27 Quantity of packaging

The packaging must fulfill the terms of the following calculation. See further information and example calculations in Appendix 8. A maximum of two layers of packaging is permitted. (A spreadsheet for this calculation is available from Nordic Ecolabelling.)

\[
\sum \left( mf_i \cdot \frac{Weight_{\text{material i}}}{2} \cdot \frac{(2 - rf_i)}{2} \right) - \frac{Weight_{\text{pump}}}{2} \leq 13 \cdot \ln(Vol_{\text{product}} + 1) + 0.035 \times Vol_{\text{product}} + 4
\]

\( mf_i \) = material factors for various types of material are assigned to the following four groups:
- \( mf_{\text{plas}} = 0.2 \)
- \( mf_{\text{paper/cotton}} = 0.6 \)
- \( mf_{\text{plastic barware}} = 1.1 \)
- \( mf_{\text{other material}} = 1.0 \)

\( Weight_{\text{material}} \) = weight of the packaging unit (incl. label and info sheet) in grams.

\( rf_i \) = fraction of material recycled following consumer use.

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

\( t \) = reuse factor

\( n \) = natural logarithm

\( Vol_{\text{product}} \) = volume of the product in ml

For decorative cosmetics products the following applies:

\[
\frac{\sum (W_{\text{packaging, i}} + W_{\text{non-recycled, i}})}{2 \times W_{\text{product total}}} \leq 0.80
\]

\( W_{\text{packaging, i}} \) = weight of the packaging unit i

\( W_{\text{non-recycled, i}} \) = weight of non-recycled material in the packaging unit i (if it is no recycled material in the packaging \( W_{\text{non-recycled}} = W_{\text{packaging}} \))

\( W_{\text{product total}} \) = weight of final product (packaging plus content)

Note: Mascara, eyeliner, eye primer, eyebrow liner, eye shadow, powder/rouge, concealer, primer, shine, nail polish, lipstick, lip pencil, lip gloss and similar products are considered decorative cosmetic products.

Description of the packaging

Appendix no.

Weight of the primary packaging and product, and calculation as specified above. (A spreadsheet for the calculation is available from Nordic Ecolabelling.)

Appendix no.
R28 Type of packaging
It must be possible to separate all materials in the packaging (paper, cardboard, plastic*, metal, glass) for sorting. Parts comprising mixed materials that cannot be separated are prohibited, with the exception of pump parts.

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

*Plastic laminate is acceptable.

Specify the materials, including description of all components (cap, pump, lid, etc.)

Appendix no. ___

R29 Plastic packaging
Plastic packaging (including labels) containing PVC or plastic based on other types of halogenated materials must not be used.

Primary packaging made from plastic should be marked according to the terms of the European Commission’s decision of the 28th January 1997, 97/129/EC (EU, 1997), ISO 11469:2000, DIN 6120, part 2 or equivalent.

Caps and pumps as well as packaging for decorative cosmetic products are exempt from the requirement on marking.

Appendix 6 or equivalent declaration duly completed and signed.

Appendix no. ___

R30 Metal packaging
Metal packaging may only be used for spray bottles/aerosols for hair styling products and shaving foams.

The use of small parts made of metal, e.g. part of a hand pump or sealing foil, is permitted.

Metal parts may be used in packaging for decorative cosmetic products if the amount of metal does not exceed 15% of the total packaging weight.

Metal parts in decorative cosmetics may be used in the packaging if the total weight of all metal parts in each separate product unit is less or equivalent to 15 grams. Mirror is not allowed as part of the packaging.

Packaging sample/product sample/images of the packaging/inspection visit.

Appendix no. ___

R31 Paper, cardboard and board packaging
Packaging paper, cardboard or board must not be bleached with chlorine.

Appendix 6 or equivalent declaration duly completed and signed.

Appendix no. ___

R32 Dispensing device
The packaging shall be designed to facilitate optimal dosage, e.g. through a correctly sized mouthpiece or a pump that supplies a suitably sized dose.

Regarding liquid soap, no pump or dispenser supplied or sold with the product shall dispense more than 2 g of soap per full depression.

In respect of hand soap for use in industry (for these products it should be clearly stated that the product is intended for washing severely soiled hands in the context of industry, or similar), no pump or dispenser supplied or sold together with the product is permitted to dispense more than 5 g of product per full depression.

Description of dispensing device and weighing results of liquid/industrial soap per full depression.

Appendix no. ___
3 Consumer information requirements

R33 Declaration of contents
A declaration of contents in accordance with the terms of Council Directive 76/768/EEC on cosmetics and/or Regulation 1223/2009/EC on cosmetics must be found in the packaging.
Label or packaging sample.

R34 Information text
The following products must bear the following or an equivalent information text on the label: “Do not discard cotton wool or paper carrying this product in the lavatory or drain. Dispose of in a dustbin.” Pictograms may be accepted:
• Cleaning products, e.g. cleansing lotions and eye make-up remover.
• Nail polish removers
• Wet wipes

The following products must bear the following or an equivalent information text on the label: “Do not discard out-of-date/unwanted product in the lavatory, drain or dustbin. Please leave at a collection point for hazardous waste:
• Nail polish
• Nail polish removers

Contact Nordic Ecolabelling for information texts applicable for the country in question.
Label or packaging sample.

R35 Information text – Sunscreen
The recommended dosage of sunscreen must be stated and the sunscreen must bear the following or an equivalent information text on the label:
• “The most effective protection against the sun’s rays is achieved by staying in the shade or wearing clothes.”
• “It is important to apply the recommended dose; otherwise you will not achieve the expected level of protection.”
• “Re-apply frequently to maintain protection, especially after perspiring, swimming or towelling.”

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

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 and 10: Low protection
• Sun protection factor 15, 20 and 25: Medium protection
• Sun protection factor 30 and 50: High protection
• Sun protection factor 50+: Very high protection
Label or packaging sample.
R36 **Product claims**

If the product is said to contain organic ingredients, the percentage of certified organic ingredients, in percent by weight, must be clearly stated. The system of certification must be indicated.

This is information may be provided in the form of, for example, the following text: "Content of organically certified ingredients in the product: x %" or with parentheses in the INCI list.

The precise content may be indicated, or, alternatively, the intervals in Table 4 may be used.

These claims for the product may only be made if proper documentation of the organic status of the ingredients can be supplied.

Table 4

<table>
<thead>
<tr>
<th>Actual content (%)</th>
<th>Interval that may be used (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.1</td>
<td>&lt;0.1</td>
</tr>
<tr>
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<tr>
<td>50-75</td>
<td>&lt;75</td>
</tr>
<tr>
<td>75-100</td>
<td>&gt;75</td>
</tr>
</tbody>
</table>

Label and certificates for the organic ingredients.

Appendix no. ____
4 Performance/quality requirements

R37 Performance/quality
The performance and quality of the product must be satisfactory. This can be demonstrated by sending in documentation according to appendix 8. Tests must at a minimum test the characteristics with which the product is marketed, see appendix 8 for information regarding what the test report needs to contain to be adequate documentation of the performance/quality. If there is a recognised test method (see for example R38 for sunscreen products), this shall be used. For other products, a test could be the manufacturer's internal quality test, a consumer test with test group of 10 or more independent individuals, or a comparative test relating to a similar product, e.g. a triangle test.

The Colipa (Cosmetics Europe) guidelines on Efficacy Evaluation of Cosmetic Products can be observed. For other test reports the information in appendix 8 needs to be included.

☐ Description of the documentation according to appendix 8. If a consumer test is used a copy of completed and signed test reports is to be supplied. This report shall include a description of the test group, the number of participants and a summary of test results.

☐ Appendix 3 or equivalent declaration duly completed and signed.

Special requirements in respect of sunscreen

R38 Performance, UVA and UVB protection
Satisfactory UVA and UVB protection shall be documented in accordance with Commission Recommendation of 22 September 2006.

☐ Description of the test and test results.

Special requirements in respect of toothpaste

R39 Performance, fluoride
Toothpaste shall contain fluoride in accordance with national recommendations for fluoride content. If the toothpaste is fluoride free or contains less than the recommended level, evidence must be presented that the efficacy of the toothpaste is equal to that of a fluoride toothpaste. This may be documented by scientific publications, recommendations by experts (dentists) and in-vivo testing.

☐ Recipe or copy of pertinent publications, recommendations and test results, as detailed above.
5 **Quality and regulatory requirements**

To ensure that Nordic Ecolabelling requirements are fulfilled, the following procedures must be implemented.

If the cosmetics manufacturer's environmental management system is certified to ISO 14001 or EMAS, where the following procedures are applied, it is sufficient if an auditor from an accredited body certifies that the requirements are implemented.

R40 **Laws and regulations**
The licensee must ensure that applicable laws and regulations in force are observed at facilities at which the Nordic Ecolabelled product is manufactured. For example, safety, work environment, environmental legislation, plant-specific conditions and concessions.

No documentation is required, but Nordic Ecolabelling may revoke the licence if the requirement is not fulfilled.

R41 **Licence administrators**
The company shall appoint an individual responsible for ensuring the fulfillment of Nordic Ecolabell requirements, and a contact person for communications with Nordic Ecolabelling.

A chart of the company's organisational structure detailing who is responsible for the above.

R42 **Documentation**
The licensee must be able to present a copy of the application and factual and calculation data supporting the documents submitted on application (including test reports, documents from suppliers and suchlike).

Checked on site.

R43 **Product quality**
The licensee must guarantee that the quality in the production of the Nordic Ecolabelled cosmetic product is maintained throughout the validity period of the licence.

Procedures for collating and, where necessary, dealing with claims and complaints regarding the quality of the Nordic Ecolabelled cosmetic product.

R44 **Planned changes**
Written notice must be given to Nordic Ecolabelling of planned changes in products and markets that have a bearing on fulfilment of Nordic Ecolabell requirements.

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

R45 **Unplanned nonconformities**
Unplanned nonconformities that have a bearing on fulfilment of the ecolabelling requirements must be reported to Nordic Ecolabelling in writing and journalled.

Procedures detailing how unplanned nonconformities are handled.

R46 **Traceability**
The licensee must have a traceability system for the production of the Nordic Ecolabelled cosmetic product.

Description of procedures for the fulfilment of the requirement.
6 Take-back system and marketing

R47 Take-back system
Relevant national regulations, legislation and/or agreements within the sector regarding the recycling systems for products and packaging shall be met in the Nordic countries in which the Nordic Ecolabelled cosmetic product is marketed. In Finland this may be documented with proof of membership of PYR (Environmental Register of Packaging), in Sweden through REPA, and in Norway documentation must be provided by Grønt Punkt. No equivalent organisation currently exists in Denmark.

A declaration from the applicant in respect of adherence to existing recycling/take-back agreements, or other documentation demonstrating fulfilment of the requirement, may also be required. See Appendix 2.

R48 Marketing
The requirement is removed as decided by the Board of Directors 17 November 2014.

Marketing

The Nordic Ecolabel is a very well-known and well-reputed trademark in the Nordic region. A Nordic Ecolabelled cosmetic product may be marketed using the Nordic Ecolabel so long as the associated licence is valid.

The label must be positioned so that there is no doubt as to what the label refers and so that it is clear that it is the cosmetic product that is ecolabelled.

More information on marketing can be found in "Regulations for the Nordic Ecolabelling of products" of 22 June 2011 or later version.

Design of the Nordic Ecolabel

Design of the Nordic Ecolabel:

![Design of the Nordic Ecolabel]

Each licence has a unique eight-digit licence number that must be displayed along with the label.

More information on the design of the label can be found in "Regulations for the Nordic Ecolabelling of products" of 22 June 2011 or later version.
Follow-up inspections

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

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

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

How long is a licence valid?

Nordic Ecolabelling adopted the criteria for cosmetic products on 12 October 2010. These criteria remain valid until 31 December 2014.

At the Secretariat Managers’ meeting on 16 February 2011 Nordic Ecolabelling decided to change the requirements R6 Nanomaterials/-particles and R21 Classification of enzymes. The new version is 2.1.

At the Secretariat Managers’ meeting on 13 September 2011 Nordic Ecolabelling decided on a change in requirement R7 Surfactants. The new version is called 2.2.

The Nordic Ecolabelling Board on 15 December 2011 decided on changes on R25, R26, R27, R28, R29 and R30. The change in R25 was a re-phrasing of the documentation requirements making them more readable. The change in R26 was to allow all rinse-off products for animals to be included in the product group. The changes in R27-R30 were adjustments to make it possible for decorative cosmetic products to apply for an Ecolabel. Furthermore some corrections were made to appendix 3 and 4. The new version is 2.3.

At the secretariat managers’ meeting on 10 May 2012 Nordic Ecolabelling decided to change the requirements R12 Metals and R27 Quantity of packaging. The change of R12 means that it is not required any additional documentation for colouring agents that meets the criteria for purity in food stuffs. The change of R27 meets the use of recycled materials in packaging materials to decorative cosmetics the same way is other products. The new version is 2.4.

On 12 December 2012 the Nordic Ecolabelling Board adopted a change in R3. The new version is 2.5.

At the secretariat managers’ meeting on 8 February 2013 Nordic Ecolabelling decided to change the requirement R4 SCCS Opinions. The change of R4 means that SCCS Opinion is exempted the requirement with exception of certain specific substances. The new version is 2.6.

At the secretariat managers’ meeting on 25 September 2013, Nordic Ecolabelling decided to change requirement R37 regarding the performance test to make it possible to document tests without following the Colipa guidelines (Cosmetics Europe). To ensure that reports not following Cosmetics Europe’s guidelines are of good quality a new appendix has been added to give information regarding reports (appendix 8). The criteria was also prolonged with 18 months and the new version is called 2.7 and is valid until 30 June 2016.
The Nordic Ecolabelling board decided on 11 December 2013, that microplastics should be added to the list prohibited substances in the products in requirement 5 (R5). The new version is called 2.8.

At the secretariat managers' meeting on 19 February 2014 Nordic Ecolabelling decided to change R14 to make it clearer that no fragrance substances can be added to infant, baby and child products. At the same time appendix 8 was updated with information on how the producer can verify claims such as "mild". The new version is called 2.9.

Nordic Ecolabelling's Criteria Group decided on 14 April 2015 to prolong the criteria with 12 months. On 17 November 2014 the Board of Directors decided to remove requirement R48 Marketing. The new version is called 2.10 and is valid until 30 June 2017.

An editorial change was made on 4 June 2015 in R6 Nanomaterials/-particles.

Nordic Ecolabelling's Criteria Group decided per capsulam on 9 September 2015 to change R3 so that the exemption for surfactants applies for all product types. The new version is called 2.11.

Nordic Ecolabelling's Criteria Group decided on 16 April 2016 to prolong the criteria with 12 months until 30 June 2018. The new version is called 2.12.

An ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be extended or adjusted, in which case the licence is automatically extended and the licensee informed.

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

If a list or document to which these criteria refer (SCCS opinions under R4 and R24 and endocrine disrupters under R5) are changed during the validity period of a licence, a standard transition period of three months is allowed from the publication of the new list/document in which to make the changes/reformulation necessary for the product to meet the modified requirements. Nordic Ecolabelling may decide to adjust the length of this transition period, and will in such a case inform licensees and applicants. It should be noted that the licence holder is always responsible for ensuring that the product is in compliance with the terms of the requirements.

**New criteria**

The following areas will, among others, be evaluated in future criteria:

- Possibility to set obligatory requirements in respect of sustainability and sourcing of raw materials from renewable sources — certified raw materials and certified organic raw materials

- Limits on degradable substances and CDV, as well as a separating of the requirements in respect of degradability and toxicity.

- Packaging/Metal packaging requirements.
References


EU (1976): Cosmetics Directive, 76/768/EEG with amendments


European Commission list of substances that are evaluated as PBT or vPvB: http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbl


OECD Guideline for testing chemicals 301 A-F Ready biodegradability

OECD Guideline for testing chemicals 302 A-C Inherent biodegradability

Appendix 1 Marketing of Nordic Ecolabelled cosmetic products

The appendix is removed as decided by the Board of Directors 17 November 2014.
Appendix 2 Test methods and documentation of environmental characteristics

1 Requirements on the analysis laboratory

The analysis laboratory used shall fulfil the general requirements of standard EN ISO 17025 or have official GLP (Good Laboratory Practice) status.

The applicant’s own analysis laboratory/test procedure may be approved for analysis and testing if:

- the analyses and tests are monitored by the authorities, or if
- the manufacturer has a quality management system encompassing sampling and analysis and has been certified to ISO 9001 or ISO 9002, or
- the manufacturer can demonstrate that there is agreement between initial analysis/testing, performed as a parallel analysis/test by an accredited laboratory, and the manufacturer’s own laboratory and that the manufacturer takes samples in accordance with a predetermined sampling programme.

2 Ecotoxicological test methods

International test methods (OECD Guidelines for the Testing of Chemicals, ISBN 92641222144) or similar methods must be used. If equivalent methods are used, these must be evaluated by an independent body to ensure that the test results are equivalent. The test methods to be used are specified below. The methods can be found at:

http://puck.sourceoecd.org/vl=31948566/cl=20/nw=1/rpsv/periodical/p15_about.htm?nlisn=1607310x

3 Acute/chronic aquatic toxicity

Use test methods 201, 202 and 203* in the OECD Guidelines for the Testing of Chemicals (ISBN 92641222144), or equivalent method to test aquatic acute toxicity.

Test methods 210*, 211, 215*, 229* from the OECD guidelines for testing of chemicals, or other equivalent testing methods, are used to test chronic aquatic toxicity.

* The European Commission has prohibited animal testing for ingredients in cosmetic products as of March 2009. However, for the purposes of determining aquatic toxicity the prohibition extends only to fish, invertebrates are not covered by this ban on animal testing. Accordingly, OECD test guidelines 203 (acute toxicity – fish), 210, 215 and 229 (chronic toxicity – fish) may no longer be used to document acute or chronic toxicity. Results of acute/chronic toxicity tests on fish that were performed prior to March 2009 may continue to be used.
4 Bioaccumulation

A substance is considered bioaccumulating if tested for bioaccumulation on fish according to method OECD 305 AE and its highest measured bioconcentration factor (BCF)* is ≥ 500. If no BCF value has been determined, a substance is considered bioaccumulating if its log\(K_{ow}\) value is ≥ 4.0 according to method 107, 117 or 123 in the OECD Guidelines for the Testing of Chemicals (ISBN 92641222144) or equivalent method, unless proven otherwise.

If the maximum measured BCF is < 500, the substance is not considered bioaccumulating even if its log\(K_{ow}\) value is ≥ 4.0. However, a substance is considered bioaccumulating with a log\(K_{ow}\) value at < 4.0 if the maximum measured BCF is ≥ 500.

OECD test method 107 cannot be used for surface-active substances that are both fat and water soluble. Based on current knowledge, for such substances it must be shown to a high degree of certainty that the substance itself and its decomposition products do not pose a long-term hazard to aquatic organisms.

Computer models (such as BIOWIN) are permitted but if the results of an approximation are close to the set limit values or if Nordic Ecolabelling holds contradictory information, more reliable information is required.

* The European Commission has prohibited animal testing for ingredients in cosmetic products as of March 2009. Accordingly, OECD test guideline 305 (bioconcentration factor) may no longer be used to document bioaccumulation. Results acquired prior to March 2009 may continue to be used.

5 Aerobic biodegradability

Test methods 301 (A to F) or 310 in the OECD Guidelines for the Testing of Chemicals (ISBN 92641222144) should be used to test aerobic biodegradability. Other scientifically accepted test methods may also be used. The test results of such equivalent methods must be evaluated by an independent body.

6 Anaerobic degradability

Anaerobic degradability is tested with the aid of ISO 11734, OECD 311, ECOTOC No. 28 (June 1988) or equivalent test methods. For a substance to be considered to biodegrade anaerobically, a mineralisation of >60% under anaerobic conditions after 56 days is required (ECETOC no. 28, June 1988), 60 days (ISO 11734) and 60 days (OECD 311).

Substances, other than surfactants, that are not found on the DID list may be exempted from the requirement on anaerobic biodegradability if the substance is not toxic for aquatic organisms (E/LC50 > 10 mg/l), and is readily aerobically degradable and simultaneously:

- displays low absorption properties (A < 25%), or
- displays high desorption properties (D > 25%), or
- is not bioaccumulative.

Test method 106 in the OECD Guidelines or ISO CD 18749 “Water quality – Adsorption of substances on activated sludge” is used to establish adsorption/desorption values. For bioaccumulation see item 4 above.
7 Inherent biodegradability

Test method 302 (A to C) or 310 in the OECD Guidelines for the Testing of Chemicals (ISBN 92641222144) should be used to test inherent biodegradability. For a constituent substance to be considered inherently biodegradable a mineralisation of >70% after 28 days is required (>70% BOD/DOC/COD reduction).

Other scientifically accepted test methods may also be used. The test results of such equivalent methods must be evaluated by an independent body.

8 Potential for endocrine disruption

A potential endocrine disrupter is 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 Ecolabelling includes all substances that the European Commission considers potential endocrine disrupters (classes 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 case the European Commission lists are amended, the latest updated reports shall apply. The latest reports are available to be viewed at http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf and the Access database, in which all evaluated substances are listed, is available for download at http://ec.europa.eu/environment/chemicals/endocrine/strategy/index_en.htm.

9 DID list

The DID list is common to the European ecolabel and Nordic Ecolabelling. The list has been established in collaboration with stakeholders from consumer organisations, environmental bodies and industry. The list contains information on the toxicity and degradability of substances that may be used in chemical/technical products. The DID list does not show which substances can be used in ecolabelled products.

The DID list cannot be used to document the toxicity of individual substances for classification purposes. For this purpose, MSDS, pertinent literature and information from the primary producer shall be used.

The DID list is available from the ecolabelling body or via the relevant rational Nordic Ecolabelling website (see page 2 for addresses). The list is also available at the website for EU ecolabelling http://ec.europa.eu/environment/chemicals/ecolabelled_products/categories/did_list_en.htm

If the substance is not listed on the DID list, the method defined in section B of the DID list is to be used. http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/pdf/did_list/didlist_part_b_en.pdf

Valid to these criteria is the DID list dated January 2007 or later.
Appendix 3 Declaration from the cosmetic product producer

For use in applications for the Nordic Ecolabel licence for cosmetic products

Product name: 

Type of product: 

The term constituent substance refers to all substances in the product, including additives in the ingredients (such as preservatives and stabilisers) but does not include impurities from primary production. Impurity refers to residues from primary production which may be found in rinse-off products at concentrations below 0.01% (100 ppm) and in leave-on products at concentrations below 0.001% (10 ppm), provided the impurity has not been actively added and/or added for a particular purpose. Impurities of over 1.0% concentration in the primary product are, however, regarded as constituent substances. Substances known to be degradation products of the constituent substances are also themselves considered to be constituent substances.

Does the product contain substances that are classified as carcinogenic, mutagenic, harmful for reproduction, allergenic as R42 and/or R43 (H334 and/or H317)?

Does the product contain D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) or D5 (decamethylcyclopentasiloxane, CAS 541-02-6)?

Does the product contain borates or perborates?

Does the product contain nitromusk or polycyclic musk compounds?

Does the product contain triclosan?

Does the product contain ethylene diamine tetraacetate (EDTA) and its salts?

Does the product contain parabens (4-Hydroxybenzoic acid) and their salts and esters?

Does the product contain potential endocrine disrupters as specified by the European Commission reports on endocrine disrupters (see Appendix 2 for definitions and http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf)?

Does the product contain substances that have been evaluated in the EU to be PBT (Persistent, bioaccumulable and toxic) or vPvB (very persistent and very bioaccumulable)?

Does the product contain microplastics (Microplastics are defined as undissolvable plastic particles of less than 1 mm size and not biodegradable according to OEC 301 A-F)?

Does the product contain nanomaterials/particles (except hydrated silica in toothpaste)?

Does the product contain colouring agents?

If yes, specify the E number, BCF or logKow value: 

Does the product contain fragrances (including aromatic substances and fragrance substances in plant extract)?

If yes, does the fragrance contain substances that are classified as sensitising with risk phrases R43 (H317) and/or R42 (H334), or that are included among fragrances subject to declaration?

If yes, have fragrances been added in accordance with the IFRA guidelines?

If yes, is the product intended for infants, babies and/or children?

Does the product contain preservatives?

If yes, has the preservative been added solely to protect the product?

If yes, specify BCF or logKow value: 

Does the product contain UV-filters?

If yes, has the UV-filter been added solely to protect the user?
Spray products: Have enzymes been added to the product?  
Toothpaste: Does the product contain SLS?  
Hair dyes: Does the product contain lawsone (CAS no. 83-72-7)?  
Hair dyes: Does the product contain hair dyes considered by the SCCS to be sensitising/allergenic? (even if they are not classified as such with R43 (H317) and/or R42 (H334))  
Products for animals: Does the product contain colouring agents and/or fragrances?

If yes to any of the above, please explain why and state concentration: ________________

Are SCCS opinions observed?  
Sunscreen: Is labelling of the SPF factor in accordance with Commission Recommendation of 22 September 2006?  
Have Colipa guidelines (Cosmetics Europe) for Efficacy Evaluation of Cosmetic Products been followed?  
Is the product in compliance with relevant national regulations, legislation and/or agreements within the sector regarding the recycling and take-back systems for products and packaging in Nordic countries in which the Nordic Ecolabelled cosmetic product is marketed?

Finland (e.g. PYR)
Sweden (REPA)
Norway (Grønt Funkt)

This declaration is based on best knowledge at the time of application, based on the test and/or declarations from the manufacturer of raw materials. With reservations for developments and new scientific findings. If such new knowledge should be made available, the undersigned is required to submit an updated declaration to Nordic Ecolabelling.

We confirm that the cosmetic product is in compliance with EU directives and regulations in respect of cosmetics. A safety assessment of the product signed by a qualified safety assessor exists.

Date: ___________________________ Company name: ___________________________

Signature (person responsible) ___________________________

Name in block capitals ___________________________ E-mail and phone number ___________________________
Appendix 4 Declaration from the producer of raw material

For use in applications for the Nordic Ecolabel licence for cosmetic products

Ingredient name: ________________________________

Function of ingredient: __________________________

The term constituent substance refers to all substances in the product, including additives in the ingredients (such as preservatives and stabilisers) but does not include impurities from primary production. Impurity refers to residues from primary production which may be found in rinse-off products at concentrations below 0.01% (100 ppm) and in leave-on products at concentrations below 0.001% (10 ppm), provided the impurity has not been actively added and/or added for a particular purpose. Impurities of over 1.0% concentration in the primary product are, however, regarded as constituent substances. Substances known to be degradation products of the constituent substances are also themselves considered to be constituent substances.

It must be stated in this declaration whether any of the substances below are part of the raw material, regardless of whether they are pollutants or not, and regardless of amount.

This declaration is based on best knowledge at the time of application. With reservations for developments and new scientific findings. If such new knowledge should be made available, the undersigned is required to submit an updated declaration to Nordic Ecolabelling.

Does the ingredient contain substances classified as carcinogenic, mutagenic, harmful for reproduction, allergenic as R42 and/or R43 (H334 and/or H317)?

(Declaration regarding allergenic substances in fragrances is included later and should not be regarded here).

Does the ingredient contain substances classified harmful to the environment as R50/53, R51/53 and/or R52/53 (H410, H411, H412)?

Does the ingredient contain D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) or D5 (decamethylcyclopentasiloxane, CAS 541-02-6)?

Does the ingredient contain BHT?

Does the ingredient contain triclosan?

Does the ingredient contain EDTA (Ethylenediaminetetraacetic acid)?

Does the ingredient contain borates or perborates?

Does the ingredient contain nitromusk or polycyclic musk compounds?

Does the ingredient contain potential endocrine disrupters as specified by the European Commission reports on endocrine disrupters (see Appendix 2 for definitions and http://ec.europa.eu/environment/endocrine/index_en.htm)?

Does the ingredient contain parabens?

Does the ingredient contain substances that have been evaluated in the EU to be PBT (Persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative)?

Does the ingredient contain microplastics (microplastics are defined as undissolvable plastic particles of less than 1mm size and not biodegradable according to OEC 301 A-F)?

Does the ingredient contain nanoparticles (except hydrated silica in toothpaste)?

Does the ingredient contain colouring agents?

If yes, specify the E number, BCF or logKow value: ________________________________

For colouring agents: Does the colouring agent contain barium, lead, mercury, cadmium, bismuth or hexavalent chromium?
Does the ingredient contain fragrance substances (including aromatic substances and fragrance substances in plant extract) that are classified as sensitising with risk phrases R43 (H317) and/or R42 (H334), or that are included among fragrances subject to declaration?

If yes, Appendix 5 must also be completed.

Does the ingredient contain preservatives?

If yes, specify BCF or logKow value: ____________________________

Does the ingredient contain UV-filters?

If yes to any of the above, please explain why and state concentration: ____________________________

Date: ____________________________ Company name: ____________________________

Signature (person responsible)

Name in block capitals: ____________________________ E-mail and phone number: ____________________________
Appendix 5 Declaration from the producer of fragrances, aromatic substances and plant extracts regarding ingredients in fragrance blends/aromatic substances/plant extract

Fragrance/aromatic substance/plant extract name: ______________________

Does the fragrance blend/aromatic substance/plant extract contain substances classified as sensitising with R42 and/or R43 (H334 and/or H317)?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Does the fragrance blend/aromatic substance/plant extract contain any of the fragrance substances subject to declaration?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Does the fragrance blend/aromatic substance/plant extract contain HICC, chloroatranol or atranol?

If yes, state the substance and quantity in percentage by weight or attach a summary or an analysis certificate that indicates that the product contains fragrances for which there is a duty of declaration and/or substances classified as sensitising with R42 and/or R43 (H334 and/or H317).

Date: ______________________

Company name: ______________________

Signature (person responsible): ______________________

Name in block capitals: ______________________

E-mail and phone number: ______________________

Nordic Ecolabelling of Cosmetic products - 2
Appendix 6  Declaration from the packaging producer

Plastic packaging
Is the plastic packaging labelled according to the Commission Decision of the 28th January 1997, ISO 11469:2000 or DIN 6120, part B?  
Yes □ No □
Are chlorinated plastics present in packaging or labels?  
Yes □ No □
Is the plastic packaging containing recycled material?  
Yes □ No □
If yes, specify the amount of recycled material in percent: ________________

Paper, cardboard and board packaging
Is packaging paper, cardboard or board bleached with chlorine gas?  
Yes □ No □
Is the paper/cardboard/board containing recycled material?  
Yes □ No □
If yes, specify the amount of recycled material in percent: ________________

______________________________  ________________________________
Date:                          Company name:

____________________________________________________________________
Signature (person responsible)

______________________________  ________________________________
Name in block capitals         E-mail and phone number
Appendix 7 Calculations

1 CDV

\[
CDV(\text{chronic}) = \sum (DF_i \times \text{quantity (mg) of substance } i \text{ per } g \text{ AI/TF}_i \text{ (chronic)})
\]

\[
DF_i = \text{degradation factor for substance } i, \text{ as specified by the DID list}
\]

\[
TF_i = \text{chronic toxicity factor for substance } i, \text{ as specified by the DID list}
\]

The calculation of CDV shall be performed for the highest specified in-use solution (g/l solution).

DF and TF shall where possible be taken from the DID list dated January 2007 or later. If TF<sub>chronic</sub> is unavailable TF<sub>acute</sub> may be used. If an ingredient is not found on the DID list, the factors shall be set as follows:

DF (see also Part B of the DID list):

- 0.05 for organic substances that are readily biodegradable according to Appendix 2.
- 0.15 for organic substances that are readily biodegradable according to Appendix 2 but for which the 10-day window is not met (excluding surfactants).
- 0.5 for organic substances that are inherently biodegradable according to Appendix 2.
- 1.0 for persistent organic substances.

TF is thus determined in the following manner (see also Part B of the DID list):

\[
TF = \frac{\text{toxicity}}{SF_i}
\]

Where the level of toxicity is set at the lowest established long-term NOEC value (no observed effects concentration) or the lowest established acute EC/LC₅₀ value. If no long-term NOEC value is available the acute value and higher safety factor (SF) are to be used. The safety factor (SF) is established according to the following:

SF<sub>chronic</sub> (see Part B of the DID list for further details):

- 10 Substance with three long-term NOEC from at least three species representing three trophic levels.
- 50 Substance with two long-term NOEC from at least two species representing two trophic levels.
- 100 Substances with one long-term NOEC (fish or crustaceans).
- 1 000 Substances with acute toxicity data for each of three trophic levels.
- 5 000 Substances with acute toxicity data for two trophic levels.
- 10 000 Substances with acute toxicity data for only one trophic level.
2 Quantity of packaging

The calculation for the quantity of packaging compares the quantity of packaging material with the content using the following formula:

\[
\sum \left( mf_i \cdot Weight_{material} \cdot \frac{(2 - rf_i)}{2} \right) \cdot \frac{Weight_{pump}}{2} \leq 13 \cdot ln(Vol_{product} + 1) + 0.035 \cdot Vol_{product} + 4
\]

where

mf = material factors for various types of material are assigned to the following four groups:

- mf_glass = 0.2
- mf_paper/cardboard = 0.6
- mf_plastic/latex = 1.1
- mf_other materials = 1.0

Weight_{material} = weight of the packaging unit (incl. label and info sheet) in grams.

rf = fraction of material recycled following consumer use.

For example, if 50% of the plastic in the packaging is sourced from post-consumer reclaimed material, rf_{plastic} is 0.5. rf is always between 0 (0% post-consumer reclaimed material) and 1 (100% post-consumer reclaimed material).

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

\( t \) = reuse factor

ln = natural logarithm

Vol_{product} = volume of the product in ml

Packaging material is considered postconsumer recycled if the raw materials are recovered following use by consumers. If the raw material is industrial waste from the material producers own production or distribution chain, the material is not considered postconsumer recycled.

The reuse factor specifies how many times the packaging is reused. If the packaging is reused as packaging, the reuse factor is set at 2. A higher figure may be used if documented evidence in support of this claim is supplied. If the packaging is reused as material, the reuse factor is 1.

Example calculation for a 200 ml product with a pump (10 g, plastic packaging weighs 80 g in total and contains no recycling materials):

\[
\sum \left( mf_i \cdot Weight_{material} \cdot \frac{(2 - rf_i)}{2} \right) \cdot \frac{Weight_{pump}}{2} \leq 13 \cdot ln(Vol_{product} + 1) + 0.035 \cdot Vol_{product} + 4
\]

\[
\sum 1.0 \cdot 80g \cdot \frac{(2 - 0)}{2} \cdot \frac{10g}{2} \leq 13 \cdot ln(200 + 1) + 0.035 \cdot 200 + 4
\]

\[
80g - 5g \leq 68.94 + 7 + 4
\]

75 \leq 80, fulfills requirement
Table 5  Examples of products wrapped in plastic packaging without pump and 0% recycled material that fulfil the requirement

<table>
<thead>
<tr>
<th>Volume of product (ml)</th>
<th>Weight of packaging (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>35</td>
</tr>
<tr>
<td>50</td>
<td>56</td>
</tr>
<tr>
<td>100</td>
<td>67</td>
</tr>
<tr>
<td>150</td>
<td>74</td>
</tr>
<tr>
<td>250</td>
<td>84</td>
</tr>
<tr>
<td>500</td>
<td>102</td>
</tr>
<tr>
<td>1000</td>
<td>128</td>
</tr>
</tbody>
</table>
Appendix 8 Minimum requirements for the content in test reports as documentation of performance/quality

The product group covers a lot of different products and it is therefore not possible to, in detail, write 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, see below what information that is required for each test.

Test reports following the Colipa guidelines "Guideline for Efficacy Evaluation of Cosmetic Products" (Cosmetics Europe) are always considered to fulfil the requirement on what information that is needed in a report.

For existing products, that have been on the market for a long time period, are considered already consumer tested by the consumers that have bought the product. Sales numbers can then be used as documentation for the primary function, see below under part 3 "Sales numbers".

1. Consumer test

Information required in the test report

- When was the test performed?
- Who performed the test?
- Who ordered the test?
- Which products were tested?
- How were the testpersons chosen?
- How many testpersons participated in the test?
- What parameters/properties were tested? Why were they chosen?
  - Primary function
  - Secondary function
  - Claim
- Test results
- Conclusions of the test

Note that the test shall be a consumer test with at least 10 independent testpersons. The testpersons shall be satisfied with the product performance/quality for each test parameter/property. It is therefore important to describe why each testing parameter has been chosen for the test. Some properties (for example scent) may have been included in the test by other reasons than performance.

The test needs to have a conclusion where it is made clear what the results were for each tested parameter/property.

Claims saying that the product is mild/gentle and similar can also be documented if the product fulfills the following three requirements:

- does not contain fragrance
- contains < 10% surfactants labelled with R41
- have a pH-value between 4 and 8
2. Laboratory test

Information required in the test 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?
  - Primary function
  - Secondary function
  - Claim
- Test results
- Conclusions of the test

Note that the test needs to have a conclusion where it is made clear how the results for each tested parameter/property document the performance/property.

3. Sales numbers

Information required in the test report

For existing products, that have been on the market for a long time period, are considered already consumer tested by the consumers that have bought the product. Sales numbers can then be used as documentation for the primary function if the product has been on the market without changes in the recipe according to the product that is about to get a Nordic Ecolabelling license.

- What time period is covered by sales of the product?
- Are the sales numbers in volume, number of products or in price?
- Conclusions of the data

Note that the sales must at least have been ongoing for 2 years. The sales must be increasing or stable to be used as documentation for the primary performance.

Sales numbers can only be used as documentation of the primary function and not as documentation of different claims.

A conclusion is required for the sales numbers. It has to be clear on how the sales numbers document the primary performance/quality. If there are fluctuations in the sales numbers they need to be satisfactory explained.
Nordic Swan Ecolabelling of

Cosmetic products

Version 3.0 • 08 November 2016 • 31 December 2021
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4 Packaging requirements 19
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Appendix 2 Declaration from the manufacturer of the raw material / ingredient
Appendix 3 Declaration from the manufacturer/supplier of packaging
Appendix 4 Calculations
Appendix 5 Documentation for material to wet wipes, O25
Appendix 6 Declaration on the use of sensitising substances in the process water for material in wet wipes
Appendix 7 Performance/quality
Appendix 8 Claim Mild/gentle
Appendix 9 Analysis laboratories and test methods

090 Cosmetic products, version 3.0, 08 November 2016

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:

**Denmark**
Ecolabelling Denmark  
Fonden Dansk Standard  
Portland Towers  
Göteborg Plads 1  
DK-2150 Nordhavn  
Tel: +45 72 300 450  
Fax: +45 72 300 451  
info@ecolabel.dk  
www.ecolabel.dk

**Iceland**
Ecolabelling Iceland  
Umhverfisstofnun  
Suðurlandsbraut 24  
IS-108 Reykjavik  
Tel: +354 591 20 00  
Fax: +354 591 20 20  
svanurinn@ust.is  
www.svanurinn.is

**Finland**
Ecolabelling Finland  
Box 489  
FI-00101 Helsingfors  
Tel: +358 9 61 22 50 00  
joutsen@ecolabel.fi  
www.ecolabel.fi

**Norway**
Ecolabelling Norway  
Henrik Ibsens gate 20  
NO-0255 Oslo  
Tel: +47 24 14 46 00  
info@svanemerket.no  
www.svanemerket.no

**Sweden**
Ecolabelling Sweden  
Box 38114  
SE-100 64 Stockholm  
Tel: +46 8 55 55 24 00  
svanen@ecolabel.se  
www.ecolabel.se
What is Nordic Swan Ecolabelled Cosmetics?

All cosmetic products covered by the EU Cosmetics Regulation 1223/2009, wet wipes as well as animal care products can be Nordic Swan Ecolabelled.

Nordic Swan Ecolabelled cosmetic products are some of the products that have the lowest impact on their environment in their category and they meet both environmental and health requirements. Requirements are set on the classification and environmental properties of the chemicals used, of the use of fragrances and colorants, on packaging and on the effectiveness of the products.

The products go down the drain after use, either directly such as soap, shampoo and toothpaste, or indirectly by washing bodies, hair or clothes, such as lotions, creams, hairstyling products and make-up. Properties such as biodegradability, bioaccumulability and aquatic toxicity are therefore essential for all ingredients.

Cosmetic products come into direct contact with the body. Therefore, the Nordic Swan Ecolabel also sets strict requirements on the substances with potentially effects that are harmful to health.

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 in all phases of the life cycle of the product. 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.

Ecolabelled cosmetics means, among other things,

- Strict requirements on chemicals (harmful to health and the environment), including
  - No MI or other preservatives classified as sensibilizising
  - No fragrances in baby/children's products
  - No ingredients on the EU's list of potential endocrine disruptors
  - No parabens
- Strict requirements on biodegradability and bioaccumulation, including
  - No microplastics
- Strict requirements on the amount and type of packaging

Why choose the Nordic Swan Ecolabel?

- Licenceholder may use the Nordic Swan Ecolabel trademark for marketing. The Nordic Swan Ecolabel is a very well-known and well-reputed trademark in the Nordic region.
- The Nordic Swan Ecolabel is a simple way of communicating environmental work and commitment to customers.
• The Nordic Swan Ecolabel clarifies the most important environmental impacts and thus shows how a company can cut emissions, resource consumption and waste management.
• Environmentally suitable operations prepare the producer for future environmental legislation.
• Nordic Swan Ecolabelling can be seen as providing a business with guidance on the work of environmental improvements.
• The Nordic Swan Ecolabel not only covers environmental issues but also quality requirements, since the environment and quality often go hand in hand. This means that a Nordic Swan Ecolabel licence can also be seen as a mark of quality.

What can carry the Nordic Swan Ecolabel?

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. Washing up liquid with added skin protection, perfumed toilet paper or tissues with lotion, for example, do not meet the above criteria and are not included in the definition.

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

Animal care products can be Nordic Swan Ecolabelled although these are not covered by the Cosmetics 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.
How to apply

Application and costs
For information about the application process and fees for this product group, please refer to the respective national web site. For addresses see page 3.

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

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

- Enclose
- The requirement checked on site.

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

License validity
The ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be extended or adjusted, in which case the licence is automatically extended and the licensee informed.

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

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

Queries
Please contact Nordic Swan Ecolabelling if you have any queries or require further information. See page 3 for addresses. Further information and assistance (such as calculation sheets or electronic application help) may be available. Visit the relevant national website for further information.
1 General requirements

In order to get a Nordic licence granted, the following documentation must be submitted:

- Copy of the label in all the applicable languages
- Documentation demonstrating compliance with national regulations, legislation and trade agreements take-back systems for packaging.

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 exceeding concentrations of 0.10 % 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.

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 ingoing substance:
  - Trade name
  - Chemical name
  - INCI name (International Nomenclature of Cosmetic Ingredients)
  - Amount (both with and without solvents, e.g. water)
- CAS no. and/or EC number
- DID number for substances that can be placed in the DID list
- 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)

**02 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 O19.

SCCS Opinions can be read at

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

**03 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.

**04 Classification of ingoing substances**

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

Cosmetic products 8 (25)
Table 1 Classification of ingoing substances

<table>
<thead>
<tr>
<th>CLP Regulation 1272/2008:</th>
<th>Hazard class</th>
<th>Hazard Class and Category Code</th>
<th>Hazard statement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Carcinogenic*</td>
<td>Carc. 1A or 1B, Carc. 2</td>
<td>H350 H351</td>
</tr>
<tr>
<td></td>
<td>Mutagenic*</td>
<td>Muta. 1A or 1B, Muta. 2</td>
<td>H340 H341</td>
</tr>
<tr>
<td></td>
<td>Toxic for reproduction*</td>
<td>Reor. 1A or 1B, Reor. 2</td>
<td>H360 H361 H362</td>
</tr>
<tr>
<td></td>
<td>Respiratory or skin sensitisation**</td>
<td>Resp. Sens. 1, Skin Sens. 1</td>
<td>H334 H317</td>
</tr>
</tbody>
</table>

* 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 O8-10 on fragrances.
- Tocopherol och tocopherol acetat (DID nr. 2609)

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.

O5 Prohibited substances

The following substances must not be present in the product or raw material
- D4 (octamethylcyclotetrasiloxane, CAS 556-67-2)
- D5 (decamethylcyclopentasiloxane, CAS 541-02-6)
- D6 (dodecamethylcyclohexasiloxane CAS 540-97-6)
- BHT (butylated hydroxytoluene, cas 128-37-0)
- BHA (butylated hydroxyanisole, cas 25013-16-5)
- Borates and perborates
- Perfluorinated and polyfluorinated substances
- 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-Hydroxybenzoic acid and its salts and esters).
- Phthalates
- 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 reports on potential endocrine disruptors 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) hydrated 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

* 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 are < 5 mm and are not biodegradable under OECD 301 A-F.

***Solvents are defined under 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

recip

Appendix 1 and 2 or equivalent declaration completed and signed.

Q6

Surfactants

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

The following are exempt from the requirement on anaerobic biodegradability:

• Emulsifiers

• Surfactants in toothpaste

Toothpaste must not contain sodium lauryl sulphate (SLS).

Refer to the DID list dated 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: “Detergents Ingredients Database” list, see Appendix 9 for a more detailed description.

For toothpaste: Appendix 1 or equivalent declaration completed and signed.
Fragrances and aromatic additives
Requirements 07-9 also apply to aromas and fragrances in plant extracts.

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.ifra.org/
Appendix 1 or equivalent declaration completed and signed.

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

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 (see section 2 Biodegradability and aquatic toxicity for definition) and a maximum of 0.01% (100 ppm) in rinse-off products.
- 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>
<thead>
<tr>
<th>INCI name (or, if none exists, perfuming name according to Cosing)</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cananga Odorata and Ylang-ylang oil</td>
<td>83863-30-3; 8006-81-3</td>
</tr>
<tr>
<td>Eugenia Caryophyllus Leaf / Flower oil</td>
<td>8000-34-8</td>
</tr>
<tr>
<td>Jasminum Grandiflorum / Officinale</td>
<td>84775-64-7; 90045-94-6; 8022-96-6</td>
</tr>
<tr>
<td>Myroxylon Pereirae</td>
<td>8007-00-9</td>
</tr>
<tr>
<td>Santalum Album</td>
<td>84787-70-2; 8006-87-9</td>
</tr>
<tr>
<td>Turpentine oil</td>
<td>8006-64-2; 9005-90-7; 8052-14-0</td>
</tr>
<tr>
<td>Verbena absolute</td>
<td>8024-12-02</td>
</tr>
</tbody>
</table>
- HICC, chloroatranol and atranol are not permitted in the product.
Appendix 1 and 2 or equivalent certification completed and signed plus fragrance specifications.

Recipe

Colorants

O10 Bioaccumulation
Organic colorants must not be bioaccumulating in line with the testing methods in Appendix 9 BCF<500/logKow<4).
Alternatively, the colorants 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.

O11 Metals in colorants for decorative cosmetics and hair dyes
None of barium, lead, mercury, cadmium, six inhalant chromium, nickel or bismuth may be found in colorants for decorative cosmetics and hair dye in concentrations above 10 ppm (0.0010%).
Colorants that are approved for use in foodstuffs in accordance with Commission Directive 2008/128/EC may be used without further documentation of the metals listed above.

Appendix 2 or equivalent declaration completed and signed and/or specifications/analysis results of the colorants.

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

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.

**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.

**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 toxicity with NOEC/EC50 > 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/EC50/EC/LC50 value.

**O15 Polymers**

For all 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.

- 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 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.

**O16 Aluminium**

Aluminium (as Al) may only be included in leave on products to a maximum level of 0.6%)*

*The threshold values are to be assessed if required once the SCCS opinion on aluminium is published and amended accordingly.
Formulation and calculation of the amount (%) of aluminium (Al).
Appendix 1 and 2 or equivalent declaration completed and signed.

2 Biodegradability and aquatic toxicity

O17 Environmentally hazardous substances
Substances classified as environmentally hazardous according to Regulation 1272/2008/EC may be included in the product to a maximum:
$$100cH410+10cH411+cH412 \leq 2.5\%$$
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 classified with H411 or H412 are exempted from the requirement, on condition that they are readily biodegradable and anaerobically biodegradable 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 (biodegradability, 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, biodegradability) and declaration of zinc compounds that are to be exempt from the requirement (quantity, label with marketing claims).

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).
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 O18-019. 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 requirements O18-019.

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

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

<table>
<thead>
<tr>
<th>Type of product</th>
<th>aNBO (mg/dose**)</th>
<th>anNBO (mg/dose**)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DID2007/2014/2016 or later versions</td>
<td>DID2007/2014/2016 or later versions</td>
</tr>
<tr>
<td>Foam soap</td>
<td>2.5</td>
<td>2.5</td>
</tr>
</tbody>
</table>

* "Active content" (AC) refers to the amount (weight) of all organic substances in the product excluding the water content of the ingredients. Abrasives in handwash and exfoliants are not included, however, see OS 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 biodegradable under O6.

- 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 or for which data is missing on DID-list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented. Note that the same version of the DID list must be used for all substances in the calculation.

O19 Critical dilution volume (CDV)
The product’s critical dilution volume (CDV) must not exceed the threshold values in Table 3 for CDVchronic for the product type in question.

For foam soap it is permitted to choose between applying the limits per AC (active contents) 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

<table>
<thead>
<tr>
<th>Type of product</th>
<th>CDVchronic (l/g AC*)</th>
<th>CDVchronic (l/g AC*)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DID2014 and 2016 or later versions</td>
<td>DID2007</td>
</tr>
<tr>
<td>Solid soap</td>
<td>2 000</td>
<td>3 000</td>
</tr>
<tr>
<td>Other rinse-off products</td>
<td>12 000</td>
<td>13 000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of product</th>
<th>CDVchronic (l/dose**)</th>
<th>CDVchronic (l/dose**)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DID2014 and 2016 or later versions</td>
<td>DID2007</td>
</tr>
<tr>
<td>Foam soap</td>
<td>1000</td>
<td>1000</td>
</tr>
</tbody>
</table>
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. For substances not on the DID list or for which data is missing on DID-list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented.

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, however, see 05 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 or for which data is missing on DID-list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented. Note that the same version of the DID list must be used for all substances in the calculation.

DID list: “Detergents Ingredients Database” list, see Appendix 9 for a more detailed description.

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/EC50 > 0.1 mg/l or EC50 > 10.0 mg/l and not be bioaccumulable (logKow < 4 or BCF < 500), and/or
- lowest aquatic toxicity NOEC/EC50 > 0.1 mg/l or EC50 > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or
- lowest aquatic toxicity NOEC/EC50 > 0.1 mg/l or EC50 > 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 biodegradable under 06.

Calculation as above as well as reference to DID list 2007, 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 or for which data is missing on DID-list a specification is required of biodegradability/toxicity/potential for bioaccumulation/bioavailability according to Appendix 9. The lowest available NOEC/EC50 value must be used. If chronic values are available, they must be used instead of acute ones.
3 Specific requirements relating to certain product types

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.
The total added quantity of EDTA, EDTA salts and phosphonates must not exceed 0.6 mg/g AC.
☐ Calculation of the quantity (mg) of EDTA and phosphonates per gram of AC.
☐ Appendix 1 or equivalent declaration completed and signed.

Lip products, toothpaste and oral hygiene products

O22 Flavourings, colorants and preservatives
Flavourings, colorants and preservatives used in these products must be approved for use in foodstuffs.
☐ Specification of E-number. For flavourings, specification of FL-number.
☐ Appendix 1 and 2 or equivalent declaration completed and signed.

Hair dyes

O23 Hair dyes
Lawson (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.

Wet wipes

O24 Material
Material/fibre type must meet relevant requirements* or have a licence for the relevant fibre type/material either in
- Nordic Swan Ecolabelling for Hygiene 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

Alternative documentation under, see Appendix 5.
- Nordic Swan Ecolabelling's criteria for hygiene 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 on the use of sensitising substances in the process water for material in wet wipes. Appendix 6 can be used.

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.

Products for animals

O25 Animal care products
- Fragrances and colorants 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 cannot 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).
4 Packaging requirements

O26 Amount of packaging

- More than one layer of packaging is only permitted where more than 1 product/unit are sold together 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.

\[
\sum \left( m_{f_i} \cdot V_{ikt_{\text{material}_i}} \cdot \frac{(2 - r_{f_i})}{2} \right) \cdot \frac{V_{ikt_{\text{pump}}}}{2} \leq a \cdot \ln(V_{\text{product}} + 1) + b \cdot V_{\text{product}} + c
\]

- \( m_{fi} \) = material factor for type of material divided into the following 4 groups of materials:
  - \( m_{f\text{glass}} = 0.1 \)
  - \( m_{f\text{paper/cardboard}} = 0.5 \)
  - \( m_{f\text{laminates}} = 1.1 \)
  - \( m_{f\text{other materials}} = 1.0 \)

- \( V_{\text{material}_i} \) = weight of the packaging component (including label + information sheet) in grams

- \( r_{fi} \) = the fraction of the amount of recycled material i after the consumer stage.

- \( V_{\text{pump}} \) = weight of pump (if applicable) in grams.

- \( t = \text{reuse factor, } t=1 \text{ for packaging which is not reused for the same purpose.} \)

- \( \ln = \text{natural logarithm} \)

- \( V_{\text{product}} = \text{volume of the product in ml} \)

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

<table>
<thead>
<tr>
<th>Packaging type</th>
<th>a</th>
<th>b</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump bottle incl. &quot;Airless&quot;</td>
<td>9</td>
<td>0.017</td>
<td>0</td>
</tr>
<tr>
<td>Tub</td>
<td>8.6</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Bottle</td>
<td>7</td>
<td>0.03</td>
<td>2</td>
</tr>
<tr>
<td>Can</td>
<td>15</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>&quot;Stick + roll on&quot;</td>
<td>4</td>
<td>0.4</td>
<td>2</td>
</tr>
<tr>
<td>Wet wipes</td>
<td>4</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>8</td>
<td>0.004</td>
<td>4</td>
</tr>
</tbody>
</table>
The following are exempt:

- For decorative cosmetics the following apply:

\[
\frac{\sum_i (W_{\text{packaging},i} + W_{\text{non-recycled},i})}{2 \cdot W_{\text{product, total}}} \leq 0.80
\]

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

- 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.

**O27  Type of packaging**

All parts of the 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.)

**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.

Metal parts are permitted in decorative cosmetics 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.

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

**O29  Dosability/ Dosing systems and emptying level**

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

- Bottles with a pump 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.

- 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 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.

5 Consumer information requirements

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:

- 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 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

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.

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 products, 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.

6 Performance/quality requirements

O33 Performance/quality and marketing claims

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 test reports 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.

O34 The claim mild/gentle

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

Documentation for mild/gentle, see appendix 8.

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.
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.

7  **Quality and regulatory requirements**
To ensure that Nordic Swan Ecolabel requirements are fulfilled, the following procedures must be implemented.

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.

setChecked 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.

setChecked 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.

☑ 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 journaled.

☑ 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
Relevant national regulations, legislation and/or agreements within the sector regarding the recycling systems for products and packaging shall be met in the Nordic countries in which the Nordic Swan Ecolabelled Cosmetic products are marketed.

Declaration from the applicant regarding adherence to existing recycling/take-back agreements.

These systems are PYR in Finland, Grønt Punkt in Norway and FTI in Sweden. In Denmark and Island there is no such system.

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.
Regulations for the Nordic Ecolabelling of products

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

More information on graphical guidelines, regulations and fees can be found at www.svanen.se/regulations/ or at www.nordic-ecolabel.org/regulations/

Follow-up inspections

Nordic Swan Ecolabelling may decide to check whether Cosmetic products fulfil Nordic Swan Ecolabel requirements during the licence period. This may involve a site visit, random sampling or similar test.

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

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

How long is a licence valid?

Nordic Swan Ecolabelling adopted the criteria for cosmetic products on 8 November 2016. The criteria are valid until 31 December 2021.

If a list or document to which these criteria refer (SCCS opinions under O2, O16 and O23 and endocrine disrupters under O5) are changed during the validity period of a licence, a standard transition period of three months is allowed from the publication of the new list/document in which to make the changes/reformulation necessary for the product to meet the modified requirements. Nordic Swan Ecolabelling may decide to adjust the length of this transition period, and will in such a case inform licensees and applicants. It should be noted that the licence holder is always responsible for ensuring that the product is in compliance with the terms of the requirements.
Appendix 1  Declaration from the manufacturer of the cosmetic product

To be used in conjunction with an application for a licence for the Nordic Swan Ecolabelling of cosmetic products. To complete the following declaration, you will need declarations for all raw materials (Appendix 2 or equivalent declaration).

This declaration is based on the knowledge we have at the time of the application, based on tests and/or declarations from raw material manufacturers, with reservations for new advances and new knowledge. Should such new knowledge arise, the undersigned is obliged to submit an updated declaration to Nordic Swan Ecolabelling.

Product name: ____________________________

Product’s function/product group (e.g. shampoo, soap, make up, lotion):

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 exceeding concentrations of 0.10 % 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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>O2: Have SCCS Opinions been followed?</td>
<td></td>
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<tr>
<td>O4: Does the product contain substances classified with any of the hazard phrases below?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incl. all classification variants. For example, H350 also covers classification H350i.</td>
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<tr>
<td>Carc. 1A or 1B H350</td>
<td></td>
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<tr>
<td>Carc. 2 H351</td>
<td></td>
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<tr>
<td>Muta. 1A or 1B H340</td>
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<tr>
<td>Muta. 2 H341</td>
<td></td>
<td></td>
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<tr>
<td>Repr. 1A or 1B H360</td>
<td></td>
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</tbody>
</table>

Cosmetic products
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr 2 H361</td>
<td>☐</td>
</tr>
<tr>
<td>H362 (Toxic for reproduction, effects on or via lactation. Additional category)</td>
<td>☐</td>
</tr>
<tr>
<td>Resp. Sens. 1, 1A eller 1B H334</td>
<td>☐</td>
</tr>
<tr>
<td>Skin Sens. 1, 1A eller 1B H317</td>
<td>☐</td>
</tr>
</tbody>
</table>

**O5: Does the product contains any of the following substances?**

- D4 (octamethylcyclotetrasiloxane, CAS 556-67-2)
- D5 (decamethylcyclopentasiloxane, CAS 541-02-6)
- D6 (dodecamethylcyclohexasiloxane CAS 540-97-6)
- BHT (butylated hydroxytoluene, cas 128-37-0)
- BHA (butylated hydroxyanisole, cas 25013-16-5)
- Borates and perborates
- Perfluorinated and polyfluorinated substances (PCF)
- Nitro musks and polycyclic musk compounds
- EDTA (Ethyleneediaminetetraacetic acid) and its salts (see however exception for solid soap O21)
- Triclosan
- Hypochlorite, chbramine and sodium chlorite
- Benzalkonium chloride
- Parabens (4-Hydroxibenzoic acid and its salts and esters).
- Phthalates

**Substances considered to be (potential) endocrine disruptors in accordance with the European Union’s reports concerning endocrine disruptors (see Appendix 9 for definition).**


**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), se ECHA webpage:** [http://echa.europa.eu/sv/candidate-list-table](http://echa.europa.eu/sv/candidate-list-table)

**Microplastics (< 5 mm and are not biodegradable under OECD 301 A-F)**

**Halogenated and/or aromatic solvents (Solvents are defined under Commission Directive 1999/13/EC: organic substances with a vapour pressure of at least 0.01 kPa at 20 °C)**

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

(Note: a) hydrated silica as an abrasive in toothpaste and TiO2 approved in SCCS opinion SCCS/1516/13. exempted)

If yes because of TiO2, is product spray?

**O6 Toothpaste: Does the product contain sodium lauryl sulphate (SLS)?**

**O7-09 Does the product contain fragrances/fragrance substances/aromas/fragrance substances in plant extracts?**

If yes, fill in O7-C9 below

**O7 Have fragrances been added in line with IFRA guidelines?**

**O8 Is the product intended for infants, babies and/or children**

If yes, is product a toothpaste?
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>09: Does the product contain following:</strong></td>
<td></td>
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</tr>
<tr>
<td>• Cananga Odorata and Ylang-ylang oil (CAS-nr 83863-30-3, 8006-81-3)</td>
<td></td>
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<tr>
<td>• Eugenia Caryophyllus Leaf / Flower oil (CAS-nr 8000-34-8)</td>
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<tr>
<td>• Jasminum Grandiforum / Officinale (CAS-nr 84776-64-7, 90045-94-6, 8022-96-6)</td>
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<tr>
<td>• Myroxylon Pereirae (CAS-nr 8007-00-9)</td>
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<tr>
<td>• Santalum Album (CAS-nr 84787-70-2, 8006-87-9)</td>
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<tr>
<td>• Turpentine oil (CAS-nr 8006-64-2; 9005-90-7; 8052-14-0)</td>
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<tr>
<td>• Verbena Absoluto (CAS-nr 8024-12-02)</td>
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<tr>
<td>• Cinnamomum cassia leaf oil/Cinnamomum zeylanicum, ext. (CAS-nr 8007-80-5/84649-98-9)</td>
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<tr>
<td>• HICC (Hydroxyisohexyl 3-cyclohexene carboxaldehyde)</td>
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<tr>
<td>• Chloroatranol</td>
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<td>• Atranol</td>
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<tr>
<td><strong>010: Does the product contain colorants?</strong></td>
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<tr>
<td>If yes, state log Kow/BCF or E-number: _________</td>
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<tr>
<td><strong>012: Does the product contain enzymes?</strong></td>
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<tr>
<td>If yes, is the product a spray product?</td>
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<tr>
<td><strong>013: Does the product contain preservatives?</strong></td>
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<tr>
<td>If yes, is it/they added for purpose of preservation of the product?</td>
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<tr>
<td>If yes, state name(s) and log Kow/BCF: ______________________________</td>
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<tr>
<td><strong>014: Does the product contain UV filters?</strong></td>
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<tr>
<td>If yes, state log Kow/BCF: ______________________________</td>
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<tr>
<td>or lowest available NOEC/EC10/LC50: ______________________________</td>
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<tr>
<td><strong>015: Does the product contain polymers?</strong></td>
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<tr>
<td>If yes, are residual monomers classified with one of more of the following</td>
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<tr>
<td>• Acute tox 1-3 with H300, H310, H330, H301, H311, H331,</td>
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<td>• CMR with H350, H351, H340, H341, H360, H361,</td>
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<tr>
<td>• sensitising with H334, H317</td>
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<tr>
<td>• environmentally hazardous with H410, H411</td>
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<tr>
<td>• potential endocrine disruptors.</td>
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<tr>
<td>If yes to the classifications above, send in specifications on residual monomers</td>
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<tr>
<td><strong>016: Does the leave-on product contain aluminium?</strong></td>
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<tr>
<td>If yes, state amount as Al (%): ______________________________</td>
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<tr>
<td><strong>017: Does the product contain substances classified as environmentally hazardous with H410, H411 and H412?</strong></td>
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<tr>
<td>If yes, state the amount (% by weight) per classification:</td>
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<tr>
<td>Note that an account of the hazard to environment (acute/chronic aquatic toxicity, biodegradability and/or bioaccumulation) is needed. If data is not available (e.g. SDS Section 12), the substance is assessed according to a worst case scenario (H410). Note: An exception is made for: Compounds of zinc (classified with 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 biodegradable and anaerobically biodegradable in line with the test methods in Appendix 9.</td>
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<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>-------------------------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>O21</strong>: Solid soap: Does the product contain EDTA and its salts?</td>
<td>☐</td>
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<tr>
<td>If yes, state the amount (mg/g active content):</td>
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<td><strong>O23</strong>: Toothpaste or oral hygiene product: Does the product contain</td>
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<tr>
<td>flavourings, colorants and preservatives?</td>
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<td>If yes, state E-number or FL number:</td>
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<tr>
<td><strong>O24</strong>: Hair dye: Does the product contain Lawson (CAS no. 83-72-7)?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td><strong>O26</strong>: Does the rinse-off animal care product contain fragrances or</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>colorants?</td>
<td></td>
<td></td>
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<tr>
<td><strong>O43</strong>: Take-back system</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are Relevant national regulations, legislation and/or agreements within</td>
<td></td>
<td></td>
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<tr>
<td>the sector regarding the recycling systems for products and packaging</td>
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<tr>
<td>met in the Nordic countries in which the Nordic Swan Ecolabelled</td>
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<tr>
<td>Cosmetic products are marketed?</td>
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<tr>
<td><strong>Finland (PYR)</strong></td>
<td>☐</td>
<td>☐</td>
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<tr>
<td><strong>Norway (Grønt Punkt)</strong></td>
<td>☐</td>
<td>☐</td>
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<tr>
<td><strong>Sweden (FTI)</strong></td>
<td>☐</td>
<td>☐</td>
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<tr>
<td><strong>Denmark and Iceland: no system</strong></td>
<td>☐</td>
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</tbody>
</table>

If the answer to any of the above questions is Yes, state the CAS no. (where possible), chemical name and level (in ppm, % by weight or mg/kg). Also state whether the substance is contained in the form of an impurity or an added substance.

In the event of any change to the composition of the product, a new declaration of fulfilment of the requirements is to be submitted to Nordic Swan Ecolabelling.

<table>
<thead>
<tr>
<th>Place and date:</th>
<th>Company name/stamp:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible person:</td>
<td>Signature of responsible person:</td>
</tr>
<tr>
<td>Telephone:</td>
<td>Email:</td>
</tr>
</tbody>
</table>
Appendix 2 Declaration from the manufacturer of the raw material / ingredient

To be used in conjunction with an application for a licence for the Nordic Swan Ecolabelling of cosmetic products.

This declaration is based on the knowledge we have at the time of the application, based on tests and/or declarations from raw material manufacturers, with reservations for new advances and new knowledge. Should such new knowledge arise, the undersigned is obliged to submit an updated declaration to Nordic Swan Ecolabelling.

Name of the raw material/ingredient, incl INCI-name:

Function of the raw material/ingredient:

Amount of ingoing substances in the raw material/ingredients:

- Ingoing substances
- Additives regardless of the concentration regardless of the concentration (e.g. preservatives and stabilisers)
- Substances known to be released from ingoing substances regardless of the concentrations (e.g. formaldehyde, arylamine, in situ-generated preservatives)
- Impurities in a concentration > 1,0 %

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.

<table>
<thead>
<tr>
<th>Chemical name (and INCI name if exists)</th>
<th>CAS no. and/or EC number</th>
<th>Concentration</th>
<th>Classification</th>
<th>Ingoing substance/impurity</th>
</tr>
</thead>
<tbody>
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</table>

Amount of problematic impurities covered by O4, O5 and 017 (part 1 in this appendix) in the ingredient/raw material in concentrations between 0,1000% ≤ X ≤ 1,0%:
<table>
<thead>
<tr>
<th>Chemical name (and INCI name if exists)</th>
<th>CAS no. and/or EC number</th>
<th>Concentration</th>
<th>Classification</th>
<th>Ingoing substance/impurity</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**Can the appendix be added to the Nordic Swan Ecolabel internal chemical database?**

Yes – Signed appendix needs to be sent once and can thereafter used for all applications in all Nordic countries.

No – A new signed appendix needs to be sent in by each applicant.

Yes  No

□  □
### Part 1 – General requirements (applies to all raw materials)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>04:</strong> Does the raw material/ingredient contain substances classified with any of the hazard phrases below?</td>
<td></td>
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</tr>
<tr>
<td>Incl. all classification variants. For example, H350 also covers classification H350i.</td>
<td></td>
<td></td>
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<tr>
<td>Carc. 1A or 1B H350</td>
<td></td>
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<td>Carc. 2 H351</td>
<td></td>
<td></td>
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<tr>
<td>Muta. 1A or 1B H340</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muta. 2 H341</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repr. 1A or 1B H360</td>
<td></td>
<td></td>
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<tr>
<td>Repr. 2 H361</td>
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<tr>
<td>H362 (Toxic for reproduction, effects on or via lactation. Additional category)</td>
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<tr>
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<td>Skin Sens. 1, 1A or 1B H317</td>
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<tr>
<td><strong>05:</strong> Does the raw material/ingredient contain any of the following substances?</td>
<td></td>
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</tr>
<tr>
<td>D4 (octamethylcyclotetrasiloxane, CAS 556-67-2)</td>
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<tr>
<td>D5 (decamethylcyclopentasiloxane, CAS 541-02-6)</td>
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</tr>
<tr>
<td>D6 (dodecamethylcyclohexasiloxane CAS 540-97-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BHT (butylated hydroxytoluene, cas 128-37-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BHA (butylated hydroxyanisole, cas 25013-16-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Borates and perborates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perfluorinated and polyfluorinated substances (PCF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitro musks and polycyclic musk compounds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EDTA (Ethylenediaminetetraacetic acid) and its salts (see however exception for solid soap O21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triclosan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypochlorite, chloramine and sodium chlorite</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parabens (4-Hydroxibenzoic acid and its salts and esters).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phthalates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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 reports on potential endocrine disruptors can be read in their entirety at <a href="http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf">http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf</a>, see appendix L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substances on the Candidate List (SVHC), see ECHA webpage: <a href="http://echa.europa.eu/sv/candidate-list-table">http://echa.europa.eu/sv/candidate-list-table</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mikroplastics (&lt; 5 mm and are not biodegradable under OECD 301 A-F)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halogenated and/or aromatic solvents (Solvents are defined under Commission Directive 1999/13/EC. organic substances with a vapour pressure of at least 0.01 kPa at 20 °C)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cosmetic products
<table>
<thead>
<tr>
<th>Nanomaterials/particles (Insoluble or biopersistent and deliberately manufactured material with one or more external dimensions or an internal structure in the region of 1-100 nm)</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Note: An exception is made for hydrated silica used as an abrasive in toothpaste and TiO₂ concluded to not pose risk in SCCS opinion SCCS/1516/13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Note that an exception is made for hydrated silica, which is used as an abrasive in toothpaste and for TiO₂ concluded to not pose risk in in SCCS opinion SCCS/1516/13.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes because of TiO₂:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is TiO₂ photocatalytic?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the coating stable?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Send in specifications of TiO₂.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**07-09 Does the raw material/ingredient contain fragrances/fragrance substances/aromas/fragrance substances in plant extracts?**  
If yes, answer the following questions:

**09: Does the perfume contain fragrance substances subject to declaration or fragrance substances which are judged to be sensitising with the hazard statement H317 and/or H334?**  
If yes, answer the following questions:

**09: Does the raw material/ingredient contain following:**
- Cananga Odorata and Ylang-ylang oil (CAS-nr 83863-30-3, 8006-81-3)
- Eugenia Caryophyllus Leaf / Flower oil (CAS-nr 8000-34-8)
- Jasminum Grandiforum / Officinale (CAS-nr 84776-64-7, 90045-94-6, 8022-96-6)
- Myroxylon Pereira (CAS-nr 8007-00-9)
- Santalum Album (CAS-nr 84787-70-2, 8006-87-9)
- Turpentine oil (CAS-nr 8006-64-2; 9005-90-7; 8052-14-0)
- Verbena Absolute (CAS-nr 8024-12-02)
- Cinnamomum cassia leaf oil/Cinnamomum zeylanicum, ext. (CAS-nr 8007-80-5/84649-98-9)
- HICC (Hydroxyisohexyl 3-cyclohexene carboxaldehyde)
- Chloroatranol
- Atranol2

**10: Does the raw material/ingredient contain colorants?**  
If yes, state log Kow/BCF or E-number: ____________________________________________

**11: Metals: Does the raw material/ingredient contain barium, lead, mercury, cadmium, six inhalant chromium, nickel or bismuth in concentrations over 10 ppm**  
If yes, is it/they added for purpose of preservation of the raw material/ingredient?  
If yes, state name(s) and log Kow/BCF: ____________________________________________

**13: Does the raw material/ingredient contain preservatives?**  
If yes, state log Kow/BCF: ____________________________________________

**14: Does the raw material/ingredient contain UV filters?**  
If yes, state log Kow/BCF: ____________________________________________  
or lowest available NOEC/EC/EC/LC50: ____________________________________________

**15: Does the raw material/ingredient contain polymers?**  
If yes, are residual monomers classified with one of more of the following  
- 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.  
If yes to the classifications above, send in specifications on residual monomers

---

Cosmetic products
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>O16: Does the leave-on raw material/ingredient contain aluminium?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, state the amount as Al (%):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>O17: Does the raw material/ingredient contain substances classified as environmentally hazardous with H410, H411 and H412?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, state the amount (% by weight) per classification:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note that an account of the hazard to environment (acute/chronic aquatic toxicity, biodegradability and/or bioaccumulation) is needed. If data is not available (e.g. SDS Section 12), the substance is assessed according to a worst case scenario (H410)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>O22: Is raw material/ingredient a flavouring, colorant or preservative?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, state E-number or FL number:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Part 2 - Only to be used if a raw material/ingredient contains renewable raw materials

Are renewable raw materials used in the raw material/ingredient? □ Yes □ No

If yes, list the renewable raw materials used (e.g. palm oil, coconut oil, rapeseed oil, beeswax) and the amount in % in yearly basis:

<table>
<thead>
<tr>
<th>Renewable raw material in the raw material/ingredient</th>
<th>Amount (%) in raw material/ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Total amount of renewable raw materials in raw material/ingredient</td>
<td></td>
</tr>
</tbody>
</table>

For each renewable raw material in the raw material / ingredient, the following data is to be completed

Renewable raw material 1
Raw material (e.g. palm oil, coconut oil, rapeseed oil, beeswax):

Name of the supplier:

Certification system:

If a certification system is used, state the level of traceability shown in a Chain of Custody certificate where applicable

<table>
<thead>
<tr>
<th>Traceability</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>No traceability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identity preserved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Segregated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mass balance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Book&amp;Claim</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Renewable raw material 2
Raw material (e.g. palm oil, coconut oil, rapeseed oil, beeswax):

Name of the supplier:

Certification system:

If a certification system is used, state the level of traceability shown in a Chain of Custody certificate where applicable

<table>
<thead>
<tr>
<th>Traceability</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>No traceability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identity preserved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Segregated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mass balance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Book&amp;Claim</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renewable raw material 3</td>
<td>Raw material (e.g. palm oil, coconut oil, rapeseed oil, beeswax):</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Name of the supplier:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certification system:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If a certification system is used, state the level of traceability shown in a Chain of Custody certificate where applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No traceability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identity preserved</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Segregated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mass balance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Book&amp;Claim</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renewable raw material 4</th>
<th>Raw material (e.g. palm oil, coconut oil, rapeseed oil, beeswax):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the supplier:</td>
<td></td>
</tr>
<tr>
<td>Certification system:</td>
<td></td>
</tr>
<tr>
<td>If a certification system is used, state the level of traceability shown in a Chain of Custody certificate where applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No traceability</td>
</tr>
<tr>
<td></td>
<td>Identity preserved</td>
</tr>
<tr>
<td></td>
<td>Segregated</td>
</tr>
<tr>
<td></td>
<td>Mass balance</td>
</tr>
<tr>
<td></td>
<td>Book&amp;Claim</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renewable raw material 5</th>
<th>Raw material (e.g. palm oil, coconut oil, rapeseed oil, beeswax):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the supplier:</td>
<td></td>
</tr>
<tr>
<td>Certification system:</td>
<td></td>
</tr>
<tr>
<td>If a certification system is used, state the level of traceability shown in a Chain of Custody certificate where applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No traceability</td>
</tr>
<tr>
<td></td>
<td>Identity preserved</td>
</tr>
<tr>
<td></td>
<td>Segregated</td>
</tr>
<tr>
<td></td>
<td>Mass balance</td>
</tr>
<tr>
<td></td>
<td>Book&amp;Claim</td>
</tr>
</tbody>
</table>
In the event of any change to the composition of the product, a new declaration of fulfilment of the requirements is to be submitted to Nordic Swan Ecolabelling.

<table>
<thead>
<tr>
<th>Raw material producer (if another company signs the appendix):</th>
<th>Company name/stamp:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible person:</td>
<td>Signature of responsible person:</td>
</tr>
<tr>
<td>Telephone:</td>
<td>Email:</td>
</tr>
<tr>
<td>Place and date:</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 3  Declaration from the manufacturer/supplier of packaging

To be used in conjunction with an application for a licence for the Nordic Swan Ecolabelling of cosmetic products.

This declaration is based on the knowledge we have at the time of the application, based on tests and/or declarations from raw material manufacturers, with reservations for new advances and new knowledge. Should such new knowledge arise, the undersigned is obliged to submit an updated declaration to Nordic Swan Ecolabelling.

<table>
<thead>
<tr>
<th>Manufacturer/supplier</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Packaing type</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Plastic packaging</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the plastic contain postconsumer recycled material? (O27)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If yes, state amount of recycled material</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paper, cardboard and board packaging</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the paper, cardboard or board contain postconsumer recycled material? (O27)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If yes, state amount of recycled material</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metal packaging</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the metal contain postconsumer recycled material? (O27)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If yes, state amount of recycled material</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Glass packaging</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the metal contain postconsumer recycled material? (O27)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If yes, state amount of recycled material</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Packaging manufacturer’s/supplier’s signature

<table>
<thead>
<tr>
<th>Place and date:</th>
<th>Company name/stamp:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible person:</td>
<td>Responsible persoons signature:</td>
</tr>
<tr>
<td>Telephone:</td>
<td>Email:</td>
</tr>
</tbody>
</table>

Cosmetic products
Appendix 4  Calculations

1 CDV

CDV(chronic) = ∑(DF_i x amount (mg) of ingoing substance per g AC (or dose) / TF_i (chronic))

DF_i = Degradation Factor for substance i.
TF_i = Toxicity Factor for substance i.

DF and TF shall where possible be taken from the DID list dated 2007, 2014, 2016 or later. If TF_chronic is unavailable TF_acute may be used. If an ingredient is not found on the DID list, the factors shall be set as follows:

DF (see also Part B of the DID list):

| 0,05 | for organic substances, that are readily biodegradable according to appendix 9 |
| 0,15 | for organic substances that are readily biodegradable according to Appendix 9 but for which the 10-day window is not met (excluding surfactants) |
| 0,5  | for organic substances that are inherently biodegradable according to Appendix 9 |
| 1,0  | for persistent organic substances |

TF is thus determined in the following manner (see also Part B of the DID list):

TF = toxicity/SF,

Where the level of toxicity is set at the lowest established long-term NOEC value (no observed effects concentration) or the lowest established acute EC/LC50 value. If no long-term NOEC value is available the acute value and higher safety factor (SF) are to be used. The safety factor (SF) is established according to the following:

SF_chronic (see Part B of the DID list for further details):

| 10 | Substance with at least three long-term NOEC or EC10 from at least three species representing three trophic levels |
| 50 | Substance with two long-term NOEC or EC10 from at least two species representing two trophic levels |
| 100| Substances with one long-term NOEC or EC10 |
| 1 000| Substances with at least 3 short-term L(E)C50 from from each of three trophic levels of the base-set (fish, daphnia and algae) |
| 5 000| Substances with 2 short-term L(E)C50 from species representing two trophic levels |
| 10 000| Substances with 1 short-term L(E)C50 |
2 Amount of packaging

The amount of packaging compares the amount of packaging material with the content using the following formula:

\[
\sum \left( mf_i \cdot \frac{V_{lt, material i} \cdot (2 - rf_i)}{2} - \frac{V_{lt, pump}}{t} \right) \leq a \cdot \ln(V_{l, product} + 1) + b \times V_{l, product} + c
\]

where

- \( mf_i \) = material factor for type of material divided into the following 4 groups of materials:
  - \( mf_{\text{glass}} = 0.1 \)
  - \( mf_{\text{paper/cardboard}} = 0.5 \)
  - \( mf_{\text{laminate}} = 1.1 \)
  - \( mf_{\text{other materials}} = 1.0 \)

- \( \text{Weight}_{\text{material i}} \) = weight of the packaging component (including label + information sheet) in grams
- \( rf_i \) = the fraction of the amount of post consumer recycled material i.
- \( \text{Weight}_{\text{pump}} \) = 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
- \( V_{l, product} \) = volume of the product in ml

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

<table>
<thead>
<tr>
<th>Packaging type</th>
<th>a</th>
<th>b</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump bottle incl. &quot;Airless&quot;</td>
<td>9</td>
<td>0.017</td>
<td>0</td>
</tr>
<tr>
<td>Tub</td>
<td>8.6</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Bottle</td>
<td>7</td>
<td>0.03</td>
<td>2</td>
</tr>
<tr>
<td>Can</td>
<td>15</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>&quot;Stick + roll on&quot;</td>
<td>4</td>
<td>0.4</td>
<td>2</td>
</tr>
<tr>
<td>Wet wipes</td>
<td>4</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>8</td>
<td>0.004</td>
<td>4</td>
</tr>
</tbody>
</table>

For example, if 50% of the plastic in the packaging is sourced from post-consumer reclaimed material, \( rf_{\text{plastic}} \) is 0.5. \( rf_i \) is always between 0 (0% post-consumer reclaimed material) and 1 (100% post-consumer reclaimed material).

- \( \text{Weight}_{\text{pump}} \) = 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
- \( V_{l, product} \) = volume of the product in ml

Packaging material is considered postconsumer recycled if the raw materials are recovered following use by consumers. If the raw material is industrial waste from Cosmetic products.
the material producer's own production or distribution chain, the material is not considered postconsumer recycled.

The reuse factor specifies how many times the packaging is reused. If the packaging is reused as packaging, the reuse factor is set at 2. A higher figure may be used if a higher reuse factor than 2 can be documented. If the packaging is reused as material, the reuse factor is 1.

Example calculation for a 200 ml product with a pump (pump 10 g, plastic packaging weighs 50 g in total and contains no recycling materials):

\[
\sum \left( m_i \cdot V_{ikt_{material}} \cdot \left( \frac{2 - r_i}{2} \right) - \frac{V_{ikt_{pump}}}{2} \right) \leq 9 \cdot \ln \left( \frac{Vol_{product}}{Vol_{product} + 1} \right) + 0.017 \times Vol_{product} + 0
\]

\[
\sum \left( 10 \cdot 0.50 \cdot \left( \frac{2 - 0}{2} \right) - \frac{10.0}{2} \right) \leq 9 \cdot \ln \left( 200 + 1 \right) + 0.017 \times 200 + 0
\]

\[
\frac{50.0 - 5.0}{1} \leq 47.7 + 3.4 + 0
\]

45 \leq 51.5 \Rightarrow OK

3 Emptying level

The amount of product remaining in the packaging (R), which must be less than 10% is calculated using the following formula:

\[
R = \frac{(m_2 - m_3)}{(m_1 - m_3)} \times 100 \%
\]

where:

- \( m_1 \) = mass of primary packaging and product (g)
- \( m_2 \) = mass of primary packaging and remainder of product in normal conditions (g)
- \( m_3 \) = 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 colorants. The products must be the same viscosity.
Appendix 5  Documentation for material to wet wipes, O25

Material in wet wipes must meet at least one of the following requirements for the relevant fibre type (other fibre types cannot be used). Paper materials should be included in any already approved the license according to Nordic Swan labeling of Tissue paper version 5 or later or the EU Ecolabel criteria for tissue paper (2009/568 / EC). If a material / product is licensed according to one of the criteria mentioned below, the requirement can be documented by providing a valid license number.

<table>
<thead>
<tr>
<th>Material/fiber type</th>
<th>Requirements that need to be met in the Nordic Swan Ecolabelling criteria for Hygiene products version 6.0</th>
<th>Requirements that need to be met in the EU Ecolabel criteria for absorbent hygiene products 2014/763/EU</th>
<th>Requirements that need to be met in the Nordic Swan Ecolabelling criteria for Textiles version 4.2</th>
<th>Requirements that need to be met in the EU Ecolabel criteria for textile products 2014/350/EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regenerated cellulose</td>
<td>O3-05, O24 and O25</td>
<td>Criterion 1, 2, and 3 Criterion 7*</td>
<td>O12-016, O24-029, O31-036</td>
<td>Criterion 9 Criterion 13 and 14</td>
</tr>
<tr>
<td>PE</td>
<td>O3-05, O27</td>
<td>Criterion 1 Criterion 5 Criterion 7*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PET</td>
<td>O3-05, O27</td>
<td>Criterion 1 Criterion 5 Criterion 7*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PP</td>
<td>O3-05, O27</td>
<td>Criterion 1 Criterion 5 Criterion 7*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cotton and other natural cellulosic seed fibres</td>
<td>-</td>
<td>-</td>
<td>O3, O24-029, O31-036</td>
<td>Criterion 1 Criterion 13 and 14</td>
</tr>
<tr>
<td>Flax, bamboo and bast fibres</td>
<td>-</td>
<td>-</td>
<td>O4, O24-029, O31-036</td>
<td>Criterion 2 Criterion 13 and 14</td>
</tr>
<tr>
<td>Non-woven**</td>
<td>O34, O35</td>
<td>Criterion 1, 2, 3, 4, and 5 Criterion 7*</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*Note: Adhesive materials, inks and dyes, fragrances, lotions and silicone as specified in criterion 6 may not be included in the material.

** For nonwoven it is specified in requirements O34 and O35 which other requirements of the Nordic Ecolabel hygiene criteria version 6 must be met.

Proposal for analysis method of MI / CM in the process of wet wipe material:

- The detection limit must be <0.10 ppm per substance
- The analysis should be conducted on a standard Napkin, ca. 4.8 g
- Liquid chromatography-mass spectrometry / mass spectrometry (LC-MS/MS)
- Gas chromatography / mass spectrometry (GC/MS)
**Appendix 6 Declaration on the use of sensitising substances in the process water for material in wet wipes**

To be used in conjunction with an application for a licence for the Nordic Swan Ecolabelling of cosmetic products.

This declaration is based on the knowledge we have at the time of the application, based on tests and/or declarations from raw material manufacturers, with reservations for new advances and new knowledge. Should such new knowledge arise, the undersigned is obliged to submit an updated declaration to Nordic Swan Ecolabelling.

<table>
<thead>
<tr>
<th>Producer / supplier of wet wipe material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wet wipe material</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Are sensitising substances with H317 and/or H334 used in the process water of the wet wipe material (O29)</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, does the concentration in the carrying material/wipe exceed 0.10 ppm per sensitising substance? Enclose an analysis report.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If no, which preservative is used in the process water?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Manufacturer's/supplier's signature**

<table>
<thead>
<tr>
<th>Place and date:</th>
<th>Company name/stamp:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible person:</td>
<td>Responsible persons signature:</td>
</tr>
<tr>
<td>Telephone:</td>
<td>Email:</td>
</tr>
</tbody>
</table>
Appendix 7 Performance/quality

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, 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 quality test

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 primary 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 2 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.
Appendix 8  Claim Mild/gentle

Claims saying that the product is mild/gentle and similar can also be demonstrated by means of a user test. The claim 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" and similar can alternatively be shown by the product meeting the following three points:

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

If a perfumed product uses claims as mild / gentle, there shall be a HET-CAM test or red blood cells test (RBC) test, documenting it.
Appendix 9  Analysis laboratories and test methods

1 Requirement for analysis laboratory
The analysis laboratory shall fulfill the general requirements of standard EN ISO 17025 or have official GLP status.

The applicant's own analysis laboratory/test procedure may be approved for analysis and testing if:

- the authorities monitor the sampling and analysis process, or if
- the manufacturer has a quality management system encompassing sampling and analysis and has been certified to ISO 9001 or ISO 9001, or if
- the manufacturer can demonstrate agreement between a first-time test conducted at the manufacturer's own laboratory and testing carried out in parallel at an independent test institute, and that the manufacturer takes samples according to a set sampling plan.

2 Exotoxological test methods
International test methods (OECD Guidelines for Testing of Chemicals, ISBN 92-64-1222144) or equivalent methods must be used for documentation. If equivalent methods are used, these must be assessed by an independent body to ensure that the results are also equivalent. The relevant test methods that must be used are stated below. The methods can be found at: http://puck.sourceforge.org/vl=31948566/cl=20/nw=1/rpsv/periodical/p15_about.htm?jnlissn=1607310x

3 Aquatic toxicity
For acute aquatic toxicity test methods nos. 201, 202 and 203 in the OECD Guideline for the Testing of Chemicals (ISBN 92-64-1222144) or equivalent test methods are used.

For chronic aquatic toxicity test methods nos. 210*, 211, 215 and 229* in the OECD Guideline for the Testing of Chemicals (ISBN 92-64-1222144) or equivalent test methods are used. OECD 201 can be used as chronic test if chronic endpoints are chosen.

*The Commission prohibited animal testing of ingredients for cosmetic products from March 2009 onwards. To determine aquatic toxicity, however, the prohibition only concerns testing with fish (does not include invertebrates). As such, OECD test guideline no. 203 (acute toxicity – fish), 210, 215 and 229 (chronic toxicity – fish) cannot be used to document acute/chronic toxicity in the future. The results of acute/chronic toxicity testing using fish produced before March 2009 may still be used, however.

4 Bioaccumulation
Unless otherwise proven, substances are considered to be bioaccumulating if logKow ≥ 4.0 under the OECD's guidelines 107 or 117 or equivalent. Such a substance may be tested on fish in line with the OECD's testing instructions 305 A-E.
If the substance has a biological concentration factor (BCF) ≥ 500 the substance is considered to be bioaccumulative, and if the BCF < 500 the substance is considered not to be bioaccumulative. If there is a measured BCF value, it is always the highest measured BCF that is used in assessing a substance’s bioaccumulative potential.

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

Data models (such as BLOWIN) are accepted, but if the results of the model calculations are close to the threshold values or if Nordic Swan Ecolabelling has contradictory data, more certain information may be required.

*The Commission prohibited animal testing of ingredients for cosmetic products from March 2009 onwards. As such, OECD test guideline no. 305 (bioconcentration factors), cannot be used to document bioaccumulation in the future. Results produced before March 2009 may still be used, however.

5 Aerobic biodegradability
For aerobic biodegradability test method no. 301 (A to F) of the OECD Guidelines or equivalent test methods are used.

Other scientifically accepted test methods may also be used. The test results of such equivalent methods must be evaluated by an independent body.

6 Anaerobic biodegradability
For anaerobic biodegradability ISO 11734, OECD 311, ECOTOX no. 28 (June 1988) or equivalent test methods are used.

For a substance to be seen as an aerobically biodegradable, the requirement is a minimum 60% biodegradability under anaerobic conditions for 56 days (ECETOX no. 28, June 1988), 60 days (ISO 11734) and 60 days (OECD 311). (> 60% mineralisation corresponds to >60% ThOD/ThCO₂ or > 70% DOC reduction).

Substances that are not surfactants and which are not included in the DID or for which data is missing on DID-list list may be exempt from the requirements on anaerobic biodegradability if they are not toxic to aquatic organisms (NOEC/EC₅₀ > 0.1 mg/l or E/LC₅₀ > 10 mg/l), and are easily aerobically biodegradable and at the same time either:

- have low adsorption (A < 25 %) or
- have high desorption (D > 25 %) or
- not be bioaccumulating

Testing for adsorption/desorption can be carried out under OECD guidelines 106 or under ISO CD 18749 “Water quality - Adsorption of substances on activated sludge - Batch test using specific analytical methods”.

Cosmetic products
7 Potential biodegradability

For potential (inherent) biodegradability test method no. 302 (A-C) in the OECD Guidelines for the Testing of Chemicals (ISBN 92-64-1222144) or equivalent test methods are used. For an included substance to be considered to be potentially biodegradable, it must attain at least 70% mineralisation in the test (> 70 % BOD/DOC/COD reduction) after 28 days.

8 (Potential) endocrine disruptors

A (potential) endocrine disruptor is an exogenous substance or mixture of substances that changes the function(s) of the hormonal system and thus causes serious health effects in an unaffected organism, its offspring or populations.

Nordic Swan Ecolabelling counts all substances that in the EU 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"). Where changes are made to the EU's list, it is the latest updated reports that apply. As more information is collected, substances of category 3b can be moved to category 3a; 'No evidence of endocrine disrupting activity' and can then be used in Swan labeled cosmetic products. If such new information comes out can Nordic Swan Ecolabel allow such substance after an assessment of the quality of information even if the category is not officially changed.


9 DID list

The DID list is a common list for the EU's ecolabel and Nordic Swan Ecolabelling. The list is then drawn up in collaboration with stakeholders from consumer and environmental organisations and industry, and contains information on toxicity and biodegradability of a number of substances that might use products in the chemical/technical field. The substances on the DID list are not an expression of the substances that are contained in ecolabelled products.

The DID list cannot be used to document the toxicity of the individual substances in connection with the classification rules. Here, information from safety data sheets, literature or the raw materials producer must be used.

The DID list can be obtained from the ecolabelling organisation or the website of the respective country.

If a substance is not included on the DID list, the method in part B of the DID list must be used:

For these criteria, the DID list dated 2007, 2014, 2016 or later versions apply.