

## Nordic Swan Ecolabelling of **Cosmetic products**



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# Content

<b>What is Nordic Swan Ecolabelled Cosmetics?</b>	<b>4</b>
<b>Why choose the Nordic Swan Ecolabel?</b>	<b>4</b>
<b>What can carry the Nordic Swan Ecolabel?</b>	<b>5</b>
<b>How to apply</b>	<b>6</b>
1 <b>General requirements</b>	<b>7</b>
2 <b>Biodegradability and aquatic toxicity</b>	<b>14</b>
3 <b>Specific requirements relating to certain product types</b>	<b>17</b>
4 <b>Packaging requirements</b>	<b>19</b>
5 <b>Consumer information requirements</b>	<b>21</b>
6 <b>Performance/quality requirements</b>	<b>22</b>
7 <b>Quality and regulatory requirements</b>	<b>23</b>
<b>Regulations for the Nordic Ecolabelling of products</b>	<b>25</b>
<b>Follow-up inspections</b>	<b>25</b>
<b>How long is a licence valid?</b>	<b>25</b>

Appendix 1 Declaration from the manufacturer of the cosmetic product

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, O24

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

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

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# Addresses

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

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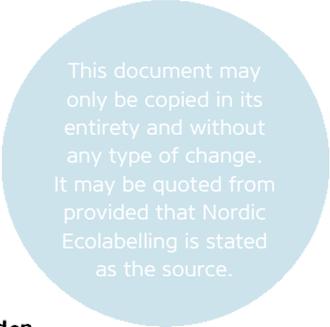
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## What is Nordic Swan Ecolabelled Cosmetics?

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 colourants, 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 sensiblizing
  - No fragrances in baby/children's products
  - No ingredients on the EU's list of potential endocrine disruptors
  - No parabens
- Strict requirements on degradability 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.

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

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

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

ℙ      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  $\geq 1000$  ppm ( $\geq 0.1000$  w-%  $\geq 1000$  mg/kg) are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.

Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines.

## 01 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 O9.

SCCS Opinions can be read at

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)

- Appendix 1 and 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 (se definition above) in the product must not be classified as shown in Table 1:

**Table 1 Classification of ingoing substances**

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

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

\*\*The following substances are exempt:

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

☒ 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.

## **05 Prohibited substances**

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

- D4 (octamethylcyclotetrasiloxane, CAS no 556-67-2)
- D5 (decamethylcyclopentasiloxane, CAS no 541-02-6)
- D6 (dodecamethylcyclohexasiloxane CAS no 540-97-6)
- BHT (butylated hydroxytoluene, CAS no128-37-0)  
*An exception is made for BHT in perfumes in the amount of ≤100 ppm provided that the amount in the cosmetic products does not exceed 1 ppm*
- BHA (butylated hydroxyanisole, CAS no 25013-16-5)
- Borates and perborates
- Perfluorinated and polyfluorinated substances
- 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](http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf) See 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) TiO<sub>2</sub> approved in SCCS opinion SCCS/1516/13. I.e. TiO<sub>2</sub> must not be photocatalytic, coating must be stable and TiO<sub>2</sub> 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 < 5 mm and are not biodegradable under OECD 301 A-F.*

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

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

Recipe.

Appendix 1 and 2 or equivalent declaration completed and signed.

## 06 Surfactants

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

The following are exempt from the requirement on anaerobic degradability:

- Emulsifiers
- Surfactants in toothpaste

Toothpaste must not contain sodium lauryl sulphate (SLS).

Reference to the DID list dated 2007, 2014, 2016 or later versions. For substances not on the DID list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented.

DID list: "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.

### 07 IFRA

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

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

- Appendix 1 or equivalent declaration completed and signed.

### 08 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.

### 09 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 2 other fragrance substances that may be included to a maximum 100 ppm for rinse-off and 10 ppm for leave-on.**

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

- 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

### 010 Bioaccumulation

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

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

- Specification of an experimentally determined BCF value (bioconcentration factor) or logKow value (logarithmic octanol-water partition coefficient), see description in Appendix 9.
- Alternatively, an E-number (allocated number in conjunction with approval of foodstuffs). Appendices 1 and 2 can be used.

### 011 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 colourants for decorative cosmetics and hair dye in concentrations above 10 ppm (0.0010%).

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

## Other Ingoing substances

### 012 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.

### 013 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.

### 014 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/EC<sub>x</sub> > 0.1 mg/l or EC/LC50 > 10.0 mg/l

- ☒ Appendix 1 and 2 or equivalent declaration completed and signed.
- ☒ State one of the following: BCF value/logKow value or lowest available NOEC/EC<sub>x</sub>/EC/LC50 value.

### 015 Polymeres

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/powder.

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

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

### 016 Aluminum

Aluminum (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 aluminum (Al).
- Appendix 1 and 2 or equivalent declaration completed and signed.

## 2 Biodegradability and aquatic toxicity

### 017 Environmentally hazardous substances

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

$$100 \cdot c_{H410} + 10 \cdot c_{H411} + c_{H412} \leq 2.5\%$$

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

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

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

- A declaration of potential dangers posed to the environment (acute/chronic toxicity, biodegradability and/or bioaccumulative potential), in the form of either a product safety data sheet (e.g. Annex II to REACH 1907/2006/EC) or other documentation.
- A calculation of the quantity (percentage by weight) of H410, H411 and H412 in line with the requirement above. If data on the potential dangers posed to the environment by the product (degradability, acute toxicity, and/or bioaccumulation) is not available (see e.g. MSDS section 12), the substance is assessed according to a worst case scenario (H410).
- Declaration of surfactants that are to be exempted from the requirement (quantity, classification, degradability) and declaration of zinc compounds that are to be exempt from the requirement (quantity, label with marketing claims).

#### **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-O19. If, according to the instructions, the user is to rinse the skin after first having used cotton wool, the product is subject to requirement O20 but not requirements O18-O19.

### 018 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  $\leq 1.0$  w-% will not be included in calculations.

**Table 3 Threshold values for aNBO och anNBO**

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

Type of product	aNBO (mg/dose**) DID2007/2014/2016 or later versions	anNBO (mg/dose**) DID2007/2014/2016 or later versions
Foam soap	2.5	2.5

\* "Active content" (AC) refers to the amount (weight) of all organic substances in the product excluding the water content of the ingredients. Abrasives in handwash and exfoliants are not included, however, see O5 for microplastics.

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

Note that surfactants must be degradable under 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.

## 019 Critical dilution volume (CDV)

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

For foam soap it is permitted to choose between applying the limits per AC (active 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  $\leq 1.0$  w-% will not be included in calculations.

**Table 4 Threshold values for CDV**

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

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

The calculation of CDV is based on information provided regarding the toxicity and biodegradability of the individual substances in an aquatic environment and must be obtained from the DID list dated 2016, 2014 or 2007. 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 O5 for microplastics*

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

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

Reference to the DID list dated 2007, 2014, 2016 or later versions. For substances not on the DID list 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

### 020 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  $\text{NOEC}/\text{EC}_x > 0.1 \text{ mg/l}$  or  $\text{EC}/\text{LC50} > 10.0 \text{ mg/l}$  and not be bioaccumulable ( $\log K_{ow} < 4$  or  $\text{BCF} < 500$ ), and/or
- lowest aquatic toxicity  $\text{NOEC}/\text{EC}_x > 0.1 \text{ mg/l}$  or  $\text{EC}/\text{LC50} > 10.0 \text{ mg/l}$  and be potentially biodegradable (OECD 302 A-C) and/or
- lowest aquatic toxicity  $\text{NOEC}/\text{EC}_x > 0.1 \text{ mg/l}$  or  $\text{EC}/\text{LC50} > 10.0 \text{ mg/l}$  and not be bioavailable (molar weight  $> 700 \text{ g/mol}$ )

*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  $\leq 1.0 \text{ w-\%}$  will not be included in calculations.*

*Note that surfactants must be degradable under O6.*

☒ Calculation as above as well as reference to DID list 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  $\text{NOEC}/\text{EC}_x/\text{EC}/\text{LC50}$  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

##### 021 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

##### 022 Flavourings, colours and preservatives

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

- Specification of E-number. For flavourings, specification of FL-number.
- Appendix 1 and 2 or equivalent declaration completed and signed.

#### Hair dyes

##### 023 Hair dyes

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

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

- Appendix 1 or equivalent declaration completed and signed.

#### Wet wipes

##### 024 Material

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

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

Other material/fibre types may not be used.

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

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

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

**Process water:**

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



**All materials:**

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

\* including additional requirements stated in Appendix 5

Alternative documentation under, see Appendix 5.

- Nordic Swan Ecolabelling's criteria for sanitary products version 6.0 or later
- EU Ecolabel for absorbent hygiene products 2014/763/EU of 24 October 2014 or later and additional requirements described above
- Nordic Swan Ecolabelling's criteria for textiles version 4.2 or later
- EU Ecolabel for textile products 2014/350/EU of 5 June 2014 or later
- Nordic Swan Ecolabelling of Tissue version 5 or later
- EU Ecolabel for tissue (2009/568/EC of 9 July 2009 or later)



**Process water:**

Signed declaration 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

### 025 Animal care products

- Fragrances and colouring agents may not be included in animal care products intended for use on animals.
- Products must comply with the EU's Cosmetics Regulation 223/2009/EC regarding ingoing substances and declaration of ingoing substances.
- Products can not be classified as environmentally hazardous with H400, H410, H411, H412, or H413.



Appendix 1 or equivalent declaration completed and signed.



Label



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

## 4 Packaging requirements

### 026 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  $\geq 80\%$  recycled materials in packaging.

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

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

$mf_i$  = material factor for type of material divided into the following 4 groups of materials:

$$mf_{\text{glass}} = 0.1$$

$$mf_{\text{paper/cardboard}} = 0.5$$

$$mf_{\text{laminat}} = 1.1$$

$$mf_{\text{other materials}} = 1.0$$

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

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

$\text{Weight}_{\text{pump}}$  = 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

$\text{Vol}_{\text{product}}$  = volume of the product in ml

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

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

The following are exempt:

- For decorative cosmetics the following apply:

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

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

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

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

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

- 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.

## 027 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.)

## 028 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

## 029 Dosability/ Dosing systems and emptying level

- a) For liquid soap no pump or dispenser sold with the product may provide more than 2 g soap per full press
- b) 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.
- c) Conditioner bottles must have an emptying level\* of 90 % or have a lid that can be removed without tools.

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

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

- ☒ Description of dosing system and weighing results for liquid 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

### 030 Organic claims

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

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

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

- ☒ If the product 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.

### 031 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.

### 032 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

### 033 Performance/quality

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

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

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

- Description of the documentation in line with Appendix 7.
- If an internal quality test is used, a copy of the test description, the results and the conclusion must be enclosed.
- If a consumer test is used, a copy of the completed and signed reply forms must be sent in. In addition, a report that describes which and how many people were asked and a summary of the results must be enclosed. At least 8 out of 10 consumers must be satisfied with the product.
- If sales figures are used, documentation for at least 3 years showing stable or rising sales must be enclosed.

### 034 The claim mild/gentle

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

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

- Documentation for mild/gentle, see appendix 8.

## Special requirements for sunscreen products

### 035 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

### 036 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.

### 037 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.

### 038 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.

- ℙ Checked on site as necessary.

### 039 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.

- ℙ The claims archive is checked on site.

### 040 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.

### 041 Unplanned nonconformities

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

- ☒ Procedures detailing how unplanned nonconformities are handled.

### 042 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.

**043 Take-back system**

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

**044 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/](http://www.svanen.se/regulations/) or at [www.nordic-ecolabel.org/regulations/](http://www.nordic-ecolabel.org/regulations/)

## Follow-up inspections

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

The licence may be revoked if it is evident that 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.

Nordic Ecolabelling's Criteria Group decided per capsulam on 5 July 2017 to change the requirement O5 Prohibited substances to allow small amounts of BHT in perumes. Errors were corrected at the same time in both the Swedish and the English versions and appendix 2 was adjusted. The new version is called 3.1.

On the 9 October 2017 Nordic Ecolabelling's Criteria Group decided to remove O43 Take-back system. Furthermore Nordic Ecolabelling's Criteria Group decided on 7 February 2018 to adjust requirement O26 by adding a new packaging category for plastic packaging under pressure. At the same time clarifications were made in O34 and appendix 8. The new version is called 3.2.

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  $\geq 1000$  ppm ( $\geq 0.1000$  w-%,  $\geq 1000$  mg/kg) are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.*

*Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines.*

<b>O2: Have SCCS Opinions been followed?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O4: Does the product contain substances classified with any of the hazard phrases below?</b>		
Incl. all classification variants. For example, H350 also covers classification H350i.		
Carc. 1A or 1B H350	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Carc. 2 H351	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Muta. 1A or 1B H340	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Muta. 2 H341	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Repr. 1A or 1B H360	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Repr 2 H361	Yes <input type="checkbox"/>	No <input type="checkbox"/>
H362 (Toxic for reproduction, effects on or via lactation. Additional category)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Resp. Sens. 1, 1A eller 1B H334	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Skin Sens. 1, 1A eller 1B H317	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O5: Does the product contains any of the following substances?</b>		
D4 (oktametylcyklotetrasiloxan, CAS 556-67-2) D5 (dekametylcyklopentasiloxan, CAS 541-02-6) D6 (dodekametylcyclohexasiloxane CAS 540-97-6)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
BHT (butylated hydroxytoluene, cas 128-37-0) <i>An exception is made for BHT in perfumes in the amount of ≤100 ppm provided that the amount in the cosmetic products does not exceed 1 ppm</i> BHA (butylated hydroxyanisole, cas 25013-16-5)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Borates and perborates	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Perfluorinated and polyfluorinated substances (PCF)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Nitro musks and polycyclic musk compounds	Yes <input type="checkbox"/>	No <input type="checkbox"/>
EDTA (Ethylenediaminetetraacetic acid) and its salts (see however exception for solid soap O21)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Triclosan	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Hypochlorite, chloramine and sodium chlorite	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Benzalkonium chloride	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Parabens (4-Hydroxibenzoic acid and its salts and esters).	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Phthalates	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Substances on the Candidate List (SVHC), se ECHA webpage: <a href="http://echa.europa.eu/sv/candidate-list-table">http://echa.europa.eu/sv/candidate-list-table</a>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Mikroplastics (< 5 mm and are not biodegradable under OECD 301 A-F)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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: hydrated silica as an abrasive in toothpaste and TiO <sub>2</sub> approved in SCCS opinion SCCS/1516/13 is exempted. If yes because of TiO <sub>2</sub> , is the product a spray?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

<b>O6 Toothpaste: Does the product contain SLS?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O7-O9 Does the product contain fragrances/fragrance substances/aromas/fragrance substances in plant extracts?</b> If yes, fill in O7-O9 below	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O7 Have fragrances been added in line with IFRA guidelines?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O8 Does the product intended for infants, babies and/or children</b> If yes, is the product a tooth paste?	Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/>
<b>O9: Does the product contain following:</b> <ul style="list-style-type: none"> <li>• Cananga Odorata and Ylang-ylang oil (CAS-nr 83863-30-3, 8006-81-3)</li> <li>• Eugenia Caryophyllus Leaf / Flower oil (CAS-nr 8000-34-8)</li> <li>• Jasminum Grandiflorum / Officinale (CAS-nr 84776-64-7, 90045-94-6, 8022-96-6)</li> <li>• Myroxylon Pereirae (CAS-nr 8007-00-9)</li> <li>• Santalum Album (CAS-nr 84787-70-2, 8006-87-9)</li> <li>• Turpentine oil (CAS-nr 8006-64-2; 9005-90-7; 8052-14-0)</li> <li>• Verbena Absolute (CAS-nr 8024-12-02)</li> <li>• Cinnamomum cassia leaf oil/Cinnamomum zeylanicum, ext. (CAS-nr 8007-80-5/84649-98-9)</li> <li>• HICC (Hydroxyisohexyl 3-cyclohexene carboxaldehyde)</li> <li>• Chloroatranol</li> <li>• Atranol2</li> </ul>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O10: Does the product contain colours?</b> If yes, state log Kow/BCF or E-number: _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O12: Does the product contain enzymes?</b> If yes, is the product a spray product?	Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/>
<b>O13: Does the product contain preservatives?</b> If yes, is it added for purpose of preservation of the product  If yes, state name and log Kow/BCF: _____	Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/>
<b>O14: Does the product contain UV filters?</b> If yes, state log Kow/BCF: _____  or lowest available NOEC/EC <sub>x</sub> /EC/LC50: _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O15: Does the product contain polymers?</b> If yes, are residual monomers classified with one of more of the following <ul style="list-style-type: none"> <li>• Acute tox 1-3 with H300, H310, H330, H301, H311, H331,</li> <li>• CMR with H350, H351, H340, H341, H360, H361,</li> <li>• sensitising with H334, H317</li> <li>•environmentally hazardous with H410, H411</li> <li>•potential endocrine disruptors.</li> </ul> If yes to the classifications above, send in specifications on residual monomers	Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/>
<b>O16: Does the leave-on product contain aluminium?</b> If yes, state the amount as Al (%) : _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O17: Does the product contain substances classified as environmentally hazardous with H410, H411 and H412?</b> If yes, state the amount (% by weight) per classification:  _____  Note that account of the hazard to environment (acute/chronic aquatic toxicity, degradability and/or bioaccumulation) is needed. If data is not available (e.g. SDS chapter 12), the substance is assessed according to a worst case scenario (H410).	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Note: An exception is made for: Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation. Surfactants regardless of their function classified with H411 or H412 are exempted from the requirement, on condition that they are readily degradable and anaerobically degradable in line with the test methods in Appendix 9.		
<b>O21: Solid soap: Does the product contain EDTA and its salts?</b> If yes, state the amount (mg/g active content): _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O23: toothpaste or oral hygiene product: Does the product contain flavourings, colours and preservatives?</b> If yes, state E-number _____ or FL number: _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O24: Hair dye: Does the product contain Lawsone (CAS no. 83-72-7)?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O26: Does the rinse-off animal care product contain fragrances or colours?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O43: Take-back system</b> Are Relevant national regulations, legislation and/or agreements within the sector regarding the recycling systems for products and packaging met in the Nordic countries in which the Nordic Swan Ecolabelled Cosmetic products are marketed.?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Finland (Rinki)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Norway (Grønt Punkt)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Sweden (FTI)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Denmark and Island: no system		

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.

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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.

Place and date	Company name/stamp
Responsible person	Signature of responsible person
Telephone	Email

## 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.

Trade name of the raw material / ingredient:

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Ingoing substances in the raw material / ingredient (chemical name, INCI name if one exists, CAS number, amount in weight-%):

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If a raw material / ingredient consists of more than one ingoing substance can specifications or technical data sheet be attached.

Function of the raw material / ingredient: \_\_\_\_\_

Other substances\* in the raw material / ingredient and amount in weight-%:

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\* Other substances mean the following in this case (Se also Nodic Ecolabellings definition of ingoing substances on page7 in the criteria document):

- Additives 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 % (Note that there might be lower limits on part 1 of this appendix))

Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines.

The information in this declaration is internally shared with certification personnel in Nordic Ecolabelling to be used in evaluation of applications of chemical technical products.

<b>Part 1 – General requirements (applies to all raw materials / ingredients)</b>		
<b>O4: Does the raw material/ingredient contain substances classified with any of the hazard statements below?</b>		
Incl. all classification variants. For example, H350 also covers classification H350i.		
Carc. 1A or 1B H350	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Carc. 2 H351	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Muta. 1A or 1B H340	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Muta. 2 H341	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Repr. 1A or 1B H360	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Repr 2 H361	Yes <input type="checkbox"/>	No <input type="checkbox"/>
H362 (Toxic for reproduction, effects on or via lactation. Additional category)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Resp. Sens. 1, 1A eller 1B H334	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Skin Sens. 1, 1A eller 1B H317	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does the raw material contain >10 ppm impurities classified with any of the above mentioned hazard statements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes to any of the questions above, state CAS no. (where possible), chemical name, CPL classification, and amount (in ppm, % by weight or mg/kg): _____		
<b>O5: Does the raw material / ingredient contains any of the following substances?</b>		
D4 (oktametylcyklotetrasiloxan, CAS 556-67-2) D5 (dekametylcyklopentasiloxan, CAS 541-02-6) D6 (dodekamethylcyclohexasiloxane CAS 540-97-6)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
BHT (butylated hydroxytoluene, cas 128-37-0) BHA (butylated hydroxyanisole, cas 25013-16-5)	Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/>
Borates and perborates	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Perfluorinated and polyfluorinated substances (PCF)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Nitro musks and polycyclic musk compounds	Yes <input type="checkbox"/>	No <input type="checkbox"/>
EDTA (Ethylenediaminetetraacetic acid) and its salts (see however exception for solid soap O21)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Triclosan	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Hypochlorite, chloramine and sodium chlorite	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Benzalkonium chloride	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Parabens (4-Hydroxybenzoic acid and its salts and esters).	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Phthalates	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Substances on the Candidate List (SVHC), se ECHA webpage: <a href="http://echa.europa.eu/sv/candidate-list-table">http://echa.europa.eu/sv/candidate-list-table</a>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Mikroplastics (< 5 mm and are not biodegradable under OECD 301 A-F)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 that an exception is made for hydrated silica, which is used as an abrasive in toothpaste and for TiO <sub>2</sub> concluded to not pose risk in SCCS opinion SCCS/1516/13.) If yes because of TiO <sub>2</sub> :  Is TiO <sub>2</sub> photocatalytic? Is the coating stable?  Please send in specifications of TiO <sub>2</sub> .	Yes <input type="checkbox"/>  Yes <input type="checkbox"/>	No <input type="checkbox"/>  No <input type="checkbox"/>
Does the raw material / ingredient contain above mentioned substances as impurities >10 ppm impurities?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes to any of the questions above, state CAS no. (where possible), chemical name, CPL classification, and amount (in ppm, % by weight or mg/kg): _____		
<b>O7 and O9 Does the raw material/ingredient contain fragrances/fragrance substances/aromas/fragrance substances in plant extracts?</b> If yes, answer the following 3 questions, if no, go to question O10.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O7 Have fragrances been added and handled in line with IFRA guidelines?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O9: 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?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Please, always send in perfume specifications.		
<b>O9: Does the raw material/ingredient contain following:</b> <ul style="list-style-type: none"> <li>• Cananga Odorata and Ylang-ylang oil (CAS-nr 83863-30-3, 8006-81-3)</li> <li>• Eugenia Caryophyllus Leaf / Flower oil (CAS-nr 8000-34-8)</li> <li>• Jasminum Grandiflorum / Officinale (CAS-nr 84776-64-7, 90045-94-6, 8022-96-6)</li> <li>• Myroxylon Pereirae (CAS-nr 8007-00-9)</li> <li>• Santalum Album (CAS-nr 84787-70-2, 8006-87-9)</li> <li>• Turpentine oil (CAS-nr 8006-64-2; 9005-90-7; 8052-14-0)</li> <li>• Verbena Absolute (CAS-nr 8024-12-02)</li> <li>• Cinnamomum cassia leaf oil/Cinnamomum zeylanicum, ext. (CAS-nr 8007-80-5/84649-98-9)</li> <li>• HICC (Hydroxyisohexyl 3-cyclohexene carboxaldehyde)</li> <li>• Chloroatranol</li> <li>• Atranol2</li> </ul>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Please, always send in perfume specifications.		
<b>O10: Does the raw material/ingredient contain colourants?</b> If yes, state log Kow/BCF or E-number: _____	Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/>
<b>O11: Colourants for decorative cosmetics and hair dyes: Does the raw material / ingredient contain barium, lead, mercury, cadmium, six inhalant chromium, nickel or bismuth in concentrations over 10 ppm?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>O13: Does the raw material / ingredient contain preservatives, incl. as impurities?</b> If yes, is it added for purpose of preservation of the raw material/ingredient If yes, state name and log Kow/BCF: _____	Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/>
<b>O14: Does the raw material/ingredient contain UV filters, incl. as impurities?</b> If yes, state log Kow/BCF: _____ or lowest available NOEC/EC <sub>x</sub> /EC/LC50: _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>

<p><b>O15: Does the raw material/ingredient contain polymers?</b></p> <p>If yes, are residual monomers classified with one of more of the following</p> <ul style="list-style-type: none"> <li>• Acute tox 1-3 with H300, H310, H330, H301, H311, H331,</li> <li>• CMR with H350, H351, H340, H341, H360, H361,</li> <li>• sensitising with H334, H317</li> <li>•environmentally hazardous with H410, H411</li> <li>•potential endocrine disruptors.</li> </ul>	Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/>
If yes to the classifications above, send in specifications on residual monomers		
<p><b>O16: Does the leave-on raw material/ingredient contain aluminium?</b></p> <p>If yes, state the amount as Al (%): _____</p>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<p><b>O17: Does the raw material/ingredient contain substances classified as environmentally hazardous with H410, H411 and H412?</b></p> <p>Note that account of the hazard to environment (acute/chronic aquatic toxicity, degradability and/or bioaccumulation) is needed. If data is not available (e.g. SDS chapter 12), the substance is assessed according to a worst case scenario (H410)</p> <p>If yes, state the amount (% by weight) per classification:</p> <p>_____</p>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<p><b>O22: Is raw material/ingredient a flavouring, colour or preservative?</b></p> <p>If yes, state E-number _____ or FL number: _____</p>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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

**Part 2 - Only to be used if a raw material/ingredient contains renewable raw materials**

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

PLEASE ONLY ONE RENEWABLE RAW MATERIAL PER LINE

	Origin of renewable raw material in the raw material/ingredient (e.g. palm oil, coconut oil, rapeseed oil, beeswax, etc)	Amount of the renewable raw material (weight-%) in the raw material/ingredient on a yearly basis
Renewable raw material 1		
Renewable raw material 2		
Renewable raw material 3		
Renewable raw material 4		
Renewable raw material 5		
Total amount (weight-%) of renewable raw materials in the raw material/ingredient:		

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

<b>Renewable raw material 1 (e.g. palm oil or coconut oil or rapeseed oil or beeswax):</b> _____	
<b>Name of the supplier:</b>	
<b>Is the renewable raw material sustainability certified?</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>If yes, state the raw material sustainability certification system:</b>	
<b>If a raw material sustainability certification system is used, state the level of traceability (shown in a Chain of Custody certificate where applicable)</b>	
No traceability	<input type="checkbox"/>
Identity preserved	<input type="checkbox"/>
Segregated	<input type="checkbox"/>
Mass balance	<input type="checkbox"/>
Book&Claim	<input type="checkbox"/>

<b>Renewable raw material 2 (e.g. palm oil or coconut oil or rapeseed oil or beeswax):</b> _____	
<b>Name of the supplier:</b>	
<b>Is the renewable raw material sustainability certified?</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>If yes, state the raw material sustainability certification system:</b>	
<b>If a raw material sustainability certification system is used, state the level of traceability (shown in a Chain of Custody certificate where applicable)</b>	
No traceability	<input type="checkbox"/>
Identity preserved	<input type="checkbox"/>
Segregated	<input type="checkbox"/>
Mass balance	<input type="checkbox"/>
Book&Claim	<input type="checkbox"/>

<b>Renewable raw material 3 (e.g. palm oil or coconut oil or rapeseed oil or beeswax):</b> _____	
<b>Name of the supplier:</b>	
<b>Is the renewable raw material sustainability certified?</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>If yes, state the raw material sustainability certification system:</b>	
<b>If a raw material sustainability certification system is used, state the level of traceability (shown in a Chain of Custody certificate where applicable)</b>	
No traceability	<input type="checkbox"/>
Identity preserved	<input type="checkbox"/>
Segregated	<input type="checkbox"/>
Mass balance	<input type="checkbox"/>
Book&Claim	<input type="checkbox"/>

<b>Renewable raw material 4 (e.g. palm oil or coconut oil or rapeseed oil or beeswax):</b> _____	
<b>Name of the supplier:</b>	
<b>Is the renewable raw material sustainability certified?</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>If yes, state the raw material sustainability certification system:</b>	
<b>If a raw material sustainability certification system is used, state the level of traceability (shown in a Chain of Custody certificate where applicable)</b>	
No traceability	<input type="checkbox"/>
Identity preserved	<input type="checkbox"/>
Segregated	<input type="checkbox"/>
Mass balance	<input type="checkbox"/>
Book&Claim	<input type="checkbox"/>

<b>Renewable raw material 5 (e.g. palm oil or coconut oil or rapeseed oil or beeswax):</b> _____	
<b>Name of the supplier:</b>	
<b>Is the renewable raw material sustainability certified?</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>If yes, state the raw material sustainability certification system:</b>	
<b>If a raw material sustainability certification system is used, state the level of traceability (shown in a Chain of Custody certificate where applicable)</b>	
No traceability	<input type="checkbox"/>
Identity preserved	<input type="checkbox"/>
Segregated	<input type="checkbox"/>
Mass balance	<input type="checkbox"/>
Book&Claim	<input type="checkbox"/>

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

Place and date	
Raw material / ingredient manufacturer	Company name/stamp
Responsible person	Signature of responsible person
Telephone	E-mail

## 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.

Manufacturer/supplier
Packaging type

<b>Plastic packaging</b> Does the plastic contain postconsumer recycled material? (O267) If yes, state amount of recycled material _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Paper, cardboard and board packaging</b> Does the paper, cardboard or board contain postconsumer recycled material? (O26) If yes, state amount of recycled material _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Metal packaging</b> Does the metal contain postconsumer recycled material? (O26) If yes, state amount of recycled material _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Glass packaging</b> Does the metal contain postconsumer recycled material? (O26) If yes, state amount of recycled material _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>

### Packaging manufacturer's/supplier's signature

Place and date	Company name/stamp
Responsible person	Responsible persons signature
Telephone	E-mail

## Appendix 4 Calculations

### 1 CDV

$CDV(\text{chronic}) = \Sigma(DF_i \times \text{amount (mg) of ingoing substance per g AC (or dose) / TFi (chronic)})$

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 TFchronic is unavailable TFacute 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):

$TF = \text{toxicity}/SF,$

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:

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

10	Substance with at least three long-term NOEC or EC <sub>10</sub> from at least three species representing three trophic levels
50	Substance with two long-term NOEC or EC <sub>10</sub> from at least two species representing two trophic levels
100	Substances with one long-term NOEC or EC <sub>10</sub>
1 000	Substances with at least 3 short-term L(E)C <sub>50</sub> from from each of three trophic levels of the base-set (fish, daphnia and algae)
5 000	Substances with 2 short-term L(E)C <sub>50</sub> from species representing two trophic levels
10 000	Substances with 1 short-term L(E)C <sub>50</sub>

## 2 Amount of packaging

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

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

where

$mf_i$  = material factor for type of material divided into the following 4 groups of materials:

$mf_{glass} = 0.1$

$mf_{paper/cardboard} = 0.5$

$mf_{laminat} = 1.1$

$mf_{other\ materials} = 1.0$

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

$rf_i$  = the fraction of the amount of post consumer recycled material i.

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

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

$\ln$  = natural logarithm

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

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

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

For example, if 50% of the plastic in the packaging is sourced from post-consumer reclaimed material,  $rf_{plastic}$  is 0.5.  $rf_i$  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,  $t=1$  for packaging which is not reused for the same purpose.
- $\ln$  = 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 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):

$$\frac{\sum \left( mf_i \cdot Vikt_{\text{material } i} \cdot \frac{(2 - rf_i)}{2} \right) - \frac{Vikt_{\text{pump}}}{2}}{t} \leq 9 \cdot \ln(\text{Vol}_{\text{produkt}} + 1) + 0.017 \times \text{Vol}_{\text{produkt}} + 0$$

$$\frac{\sum \left( 1,0 \cdot 50 \text{ g} \cdot \frac{(2 - 0)}{2} \right) - \frac{10 \text{ g}}{2}}{1} \leq 9 \cdot \ln(200 + 1) + 0.017 \times 200 + 0$$

$$\frac{50 \text{ g} - 5 \text{ g}}{1} \leq 47,7 + 3,4 + 0$$

$$45 \leq 51,5 \Rightarrow OK$$

### 3 Emptying level

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

$$R = ((m2 - m3) / (m1 - m3)) \times 100 (\%)$$

where:

m1= mass of primary packaging and product (g)

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

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

Normal conditions are defined as:

Normal conditions of use are defined as:

- Pump bottle: Repeatedly press the mouth of the pump. If nothing has come out of the packaging after 5 presses in a row, the packaging is considered to be empty. The mouth of the pump may not be taken apart and water must not be introduced in the packaging.
- Vials/flasks: The vial is turned upside down, with the cap in the downward position and is pressed as it would usually be pressed when using the product. After the trickle is not continuous, the bottle is left in the same position for a maximum of 24 hours. The bottle can also be hit on the table

which corresponds to normal consumer behaviour. Neither the cap is dismantled, nor water is introduced inside the packaging

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

## Appendix 5 Documentation for material to wet wipes, O24

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.

Material/fiber type	Requirements that need to be met in the Nordic Swan Ecolabellingcriteria for Sanitaryproducts version 6.0	Requirements that need to be met in the EU Ecolabel criteria for absorbent hygiene products 2014/763/EU	Requirements that need to be met in the Nordic Swan Ecolabelling criteria for Textiles version 4.2	Requirements that need to be met in the EU Ecolabel criteria for textile products 2014/350/EC
Regenerated cellulose	O3-O5 O24 and O25	Criterion 1,2 and 3 Criterion 7*	O12-O16 O24-O29 O31-O36	Criterion 9 Criterion 13 and 14
PE	O3-O5 O27	Criterion 1 Criterion 5 Criterion 7*	-	-
PET	O3-O5 O27	Criterion 1 Criterion 5 Criterion 7*	-	-
PP	O3-O5 O27	Criterion 1 Criterion 5 Criterion 7*	-	-
Cotton and other natural cellulosic seed fibres	-	-	O3 O24-O29 O31-O36	Criterion 1 Criteria 13 and 14
Flax, bamboo and bast fibres	-	-	O4 O24-O29 O31-O36	Criterion 2 Criterion 13 and 14
Non-woven**	O34 O35	Criterion 1, 2, 3, 4, and 5 Criterion 7*	-	-

\* 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 (GS/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.

Producer / supplier of wet wipe material
Wet wipe material

Are sensitising substances with H317 and/or H334 used in the process water of the wet wipe material (O29)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, does the concentration in the carrying material/wipe exceed 0.10 ppm per sensitising substance? Enclose an analysis report.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If no, which preservative is used in the process water?		

### Manufacturer's/supplier's signature

Place and date	Company name/stamp
Responsible person	Responsible persons signature
Telephone	E-mail

## 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 3 years. Sales must be increasing or stable to be used as documentation for the primary performance/quality.

Note that sales figures can only be used as documentation of the product's primary function and not as documentation of claims.

A conclusion is required for the sales figures. It must be clear how the sales figures document the primary performance/quality. If there are fluctuations in the sales figures, they need to be satisfactorily explained.

## **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 or fragrances in plant extract
- containing < 10% surfactants classified with H318
- pH between 4 and 8.

If a perfumed product or a product with fragrances in plant extracts 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 fulfil 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.sourceoecd.org/vl=31948566/cl=20/nw=1/rpsv/periodical/p15\\_about.htm?jnlissn=1607310x](http://puck.sourceoecd.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  $\log K_{ow} \geq 4.0$  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)  $\geq 500$  the substance is considered to be bioaccumulative, and if the BCF  $< 500$  the substance is considered not to be bioaccumulative. If there is a measured BCF value, it is always the highest measured BCF that is used in assessing a substance's bioaccumulative potential.

OECD'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 BIOWIN) 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 degradability**

For aerobic degradability 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 degradability**

For anaerobic degradability ISO 11734, OECD 311, ECOTOC no. 28 (June 1988) or equivalent test methods are used.

For a substance to be seen as an aerobically degradable, the requirement is a minimum 60% degradability under anaerobic conditions for 56 days (ECETOC no. 28, June 1988), 60 days (ISO 11734) and 60 days (OECD 311). (> 60% mineralisation corresponds to >60% ThOD/ThCO<sub>2</sub> 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 degradability if they are not toxic to aquatic organisms (NOEC/EC<sub>x</sub> > 0.1 mg/l or E/LC50 > 10 mg/l), and are easily aerobically degradable 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".

## 7. Potential degradability

For potential (inherent) degradability 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 degradable, 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.

The most recent reports can be obtained from

[http://ec.europa.eu/environment/chemicals/endocrine/pdf/final\\_report\\_2007.pdf](http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf) and an Access database in which all evaluated substances listed can be downloaded at

[http://ec.europa.eu/environment/chemicals/endocrine/strategy/index\\_en.htm](http://ec.europa.eu/environment/chemicals/endocrine/strategy/index_en.htm).

## 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 degradability 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.