Nordic Ecolabelling of

Cosmetic products

Version 3.0 • date - date
Proposal for hearing

Nordic Ecolabelling

Content

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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.

Addresses

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

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What is Nordic Ecolabelled Cosmetics?

All cosmetic products covered by the EU Cosmetics Regulation 1223/2009 as well as Rinse-off products for use on animals can be Nordic Ecolabelled.

Ecolabelled cosmetics means

- Strict requirements on chemicals (harmful to health and the environment), including
    - No parabens
    - No MI (an allergenic preservative)
    - No fragrances in baby/children's products
    - No ingredients on the EU's list of potential endocrine disruptors
- Strict requirements on degradability and bioaccumulation, including
    - No microplastics
- Strict requirements on the amount and type of packaging

Why choose the Nordic Ecolabel?

- Licenceholder may use the Nordic Ecolabel trademark for marketing. The Nordic Ecolabel is a very well-known and well-reputed trademark in the Nordic region.
- The Nordic Ecolabel is a simple way of communicating environmental work and commitment to customers.
- The Nordic 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 Ecolabelling can be seen as providing a business with guidance on the work of environmental improvements.
- The Nordic Ecolabel not only covers environmental issues but also quality require¬ments, since the environment and quality often go hand in hand. This means that a Nordic Ecolabel licence can also be seen as a mark of quality.

What can carry the Nordic 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 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 Ecolabelled.

Rinse-off products for use on animals can be Nordic Ecolabelled although these are not covered by the Cosmetics Regulation.

Products covered by the Biocides Regulation 528/2012 cannot be Nordic 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 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 productgroup, please refer to the respective national web site. For addresses see page 2.

What is required?

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

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

✉ Enclose

🔑 The requirement checked on site.

All information submitted to Nordic Ecolabelling is treated confidentially. Suppliers can send documentation directly to Nordic 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 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 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 laber in all the applicable languages
- Documentation demonstrating compliance with national regulations, legislation and trade agreements take-back systems for packaging.

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

Ingoing substances are defined, if not otherwise mentioned, as all substances in the product – including additives (e.g. preservatives or stabilisers) in the raw materials/ingredients, but not residuals from production, incl. production of raw materials).

Residuals from production, incl. production of raw materials are defined as residuals, pollutants and contaminants derived from the production of the raw materials, which are present in the final rinse off product in amounts less than 100 ppm (0,0100 w-%, 100 mg/kg), and in final leave-on products in amounts less than 0.001% (10 ppm), but not substances added to the raw materials or product intentionally and with a purpose – regardless of amount.

Residuals in the raw materials above 0,1 % (1000 ppm) are regarded as ingoing substances. Known substances realised form the raw materials are also regarded as ingoing substances.

O1 Formulation/recipe and description of product

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

- Description of the product
- A complete recipe for the product. The recipe must 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 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)

O2 SCCS

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

SCCS recommendation, SCCS/1459/11 on fragrance allergens, is exempted from this requirement. HICC, chloroatranol and atranol are not, however, permitted in the product, see O10.

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

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

O3 Renewable raw materials

At least 50% by weight of all raw materials for ingoing surfactants (irrespective of function), emulsifiers and emollients in the product must be renewable.

Raw materials from oil palms (palm oil, palm kernel oil and their derivatives) in tensides and emollients:

- raw materials must be Roundtable on Sustainable Palm Oil (RSPO) certified
- the producer/supplier must be traceability certified under RSPO's Supply Chain Certification Standard
- the traceability of the raw material must be guaranteed via mass balance as a minimum
- the certified raw materials must be deducted from the producer's/supplier's Chain of Custody account for the Nordic Ecolabelled product.

☒ The producer of surfactants (irrespective of function), emulsifiers and emollients must declare which renewable raw materials are included and their amounts, appendix 2 can be used.

☒ Valid RSPO CoC certificate.

☒ The producer of surfactants (irrespective of function), emulsifiers and emollients or the producer of the Nordic Ecolabelled product must show by means of a balance calculation and/or invoices that the proportion of certified surfactants/emulsifiers/emollients corresponds to the amount of certified palm oil raw materials. Alternatively, a declaration from the producer of surfactants (irrespective of function), emulsifiers and emollients that all purchased palm oil raw materials are certified.

O4 Classification of ingoing substances

Substances in the product must not be classified as shown in Table 1:

Table 1 Classification of ingoing substances

CLP Regulation 1272/2008:		
Hazard class	**Hazard class and category**	**Hazard phrase**
Carcinogenicity	Risk, Carc. 1A or 1B Warning, Carc. 2	H350 H351
May cause genetic defects	Risk, Muta. 1A or 1B Warning, Muta. 2	H340 H341
Toxic for reproduction	Risk, Repr. 1A or 1B Warning, Repr. 2 -	H360 H361 H362
Respiratory or skin sensitising*	Risk, Resp. Sens. 1 Warning, Skin Sens. 1	H334 H317

*The following substances are exempt:

- Enzymes (including stabilisers and preservatives in the enzyme raw material) can be included if they are liquid form or as granulate capsules, see requirement O12 for enzymes.
- Fragrance can be included in the final product, see requirements O8-10 on fragrances.

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

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

O5 Prohibited substances

The following substances must not be present in the product or appear as impurities.

- D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) D5 (decamethylcyclopentasiloxane, CAS 541-02-6) and D6 (dodecamethylcyclohexasiloxane CAS 540-97-6)
- BHT
- 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-Hydroxibenzoic acid and its salts and esters).
- Phthalates
- Substances considered to be (potential) endocrine disruptors in accordance with the European Union's reports concerning endocrine disruptors (see Appendix 8 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

- 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 hydrated silica, which is used as an abrasive in toothpaste.

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

***Microplastics are here defined as insoluble plastic particles that are are 1 µm - 5 mm and are not biodegradable under OECD 301 A-F.*

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

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

✉ Recipe.

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

O6 Surfactants

All surfactants, irrespective of their function must be readily aerobically degradable and anaerobically degradable in line with the testing methods in Appendix 8.

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 2014 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 8 for a more detailed description.

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

Fragrances and aromatic additives

Requirements 07-9 also apply to aromas and fragrances in plant extracts.

O7 IFRA

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

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

✉ Appendix 1 or equivalent declaration completed and signed.

O8 Products for infants, babies and children

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

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

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

Note that the 26 fragrance substances that are subject to declaration are covered by this requirement.

☒ Appendix 1 or equivalent declaration completed and signed.

☒ Recipe

☒ Label

O9 Amount of fragrance

A fragrance substance/flavouring/fragrance substance in plant extract which is judged to be sensitising with the hazard statement H317 and/or H334, or covered by the fragrance substances subject to declaration may be included at a maximum of 0.001% (10 ppm) in leave-on products (see section 2 Biodegradability and aquatic toxicity for definition) and a maximum of 0.01% (100 ppm) in rinse-off products.

The fragrance substances in table 2 may be included in products with a maximum of 100 ppm (0.010%) for rinse-off products and a maximum of 10 ppm (0.0010%) for leave-on products per substance:

Table 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

O10 Bioaccumulation

Organic colorants must not be bioaccumulating in line with the testing methods in Appendix 8 BCF<500/logKow<4).

Alternatively the colour must be approved for use in food.

✉ Specification of an experimentally determined BCF value (bioconcentration factor) or logKow value (logarithmic octanol-water partition coefficient), see description in Appendix 8.

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

O11 Metals in colorants for decorative cosmetics and hair dyes

None of barium, lead, mercury, cadmium, six inhalant chromium 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 documentationof 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.

O12 Enzymes

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

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

Enzymes must not be added to spray products.

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

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

O13 Preservatives

- The use of preservatives for purposes other than preservation of the product itself is prohibited.
- Preservatives must not be bioaccumulating as specified by Appendix 8 (BCF<500/logKow<4).
- Phenoxyethanol (CAS 122-99-6) may be present to a maximum limit of 0.4% in baby products (children <3) and cannot be used in products intended for the nappy area (e.g. wet wipes for babies or products inteded for diaper rash).

These requirements also apply to antibacterial disinfecting and microbial substances.

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

✉ Specification of BCF value or logKow value, see description in Appendix 8. Appendices 1 and 2 can be used.

O14 UV filter

UV filters may only be added to leave-on products and only to protect the user – not the product. Products with UV statements must comply with O34 Performance, UVA and UVB

All organic UV filters contained in the product:

- must not be bioaccumulating as specified by Appendix 8 (BCF<500/logKow<4).

  or

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

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

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

O15 Polymeres

For all polymers, the total content of residual monomers classified as one or more of the following may be a maximum of 100 ppm/dry substance per classification per polymer, measured on newly produced polymer dispersion.

- Acute tox 1-3 with H300, H310, H330, H301, H311, H331,
- CMR with H350, H351, H340, H341, H360, H361,
- sensitising with H334, H317
- environmentally hazardous with H410, H411
- potential endocrine disruptors (see Appendix 8 for a definition).

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

O16 Aluminium

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

✉ Formulation and calculation of the amount (%) of aluminium (Al).

2 Biodegradability and aquatic toxicity

O17 Environmentally hazardous substances

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

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

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

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

Surfactants 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 8.

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

☒ A calculation of the quantity (percentage by weight) of H410, H411 and H412 in line with the requirement above. If data on the potential dangers posed to the environment by the product (degradability, acute toxicity, and/or bioaccumulation) is not available, 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, toothpaste, bath foam and scrubs, cleansing products/gels, hair treatments and peels). If a product carries instructions on the packaging stating "...and/or rinse the product from the skin", the product is subject to requirements O18-O19. If, according to the instructions, the user is to rinse the skin after first having used cotton wool, the product is subject to requirement O20 but not requiremnts O18-O19.

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

Organic substances that are not readily biodegradable according to Appendix 8, 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.

Table 3 Threshold values for aNBO och anNBO

Type of product	**aNBO (mg/g AC*) DID2007/2014**	**anNBO (mg/g AC*) DID2007/2014**
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**	**aNBO (mg/dose**) DID2007/2014**
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.*

***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.

☒ Reference to the DID list dated 2007, 2014 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.

O19 Critical dilution volume (CDV)

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

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

Table 4 Threshold values for CDV

Type of product	CDVchronic (l/g AC*) DID2014	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
Foam soap	1 000

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

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

**Active content (AC)*

**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 Ecolabelling).

Reference to the DID list dated 2007, 2014 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 8 for a more detailed description.

B) Other cosmetic products

O20 Biodegradability and aquatic toxicity

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

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

- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or
- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol)

Exempt are

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

Note that surfactants must be degradable under O6.

✉ Calculation as above as well as reference to DID list 2014. For substances not listed on the DID list a specification is required of biodegradability/toxicity/potential for bioaccumulation/bioavailability according to Appendix 8. The lowest available NOEC/EC_x/EC/LC50 value must be used. If chronic values are available, they must be used instead of acute ones.

3 Specific requirements relating to certain product types

Solid soap

O21 Content of EDTA and phosphonates in solid soap

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

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

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

Lip products, toothpaste and oral hygiene products

O22 Flavourings, colours and preservatives

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

✉ Specification of E-number. For flavourings, specification of FL-number.

Hair dyes

O23 Hair dyes

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

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

✉ Appendix 1 or equivalent declaration completed and signed.

Wet wipes

O24 Material

Material in wet wipes must meet at least one of the following requirements for the relevant fibre type (other fibre types cannot be used):

Viscose, non-woven, polymers (PE, PP, PET):
Materials must meet the requirements in Nordic Ecolabelling's criteria for Hygiene products version 6.0 or later, or the EU Ecolabel's criteria for absorbent hygiene products 2014/765/EU of 24 October 2014 or later, see Appendix 5.

NB! The requirement also covers viscose based on bamboo fibre.

Additional requirements for materials that meet the criteria of the EU Ecolabel:

Adhesive materials, inks and dyes, fragrances, lotions and silicone as specified in Criterion 6: Other materials and components must not be included in the material.

Textile material made from viscose, cotton and other natural fibres:
Textile fibres used in Nordic Ecolabelled wet wipes must be licensed under or meet the requirements in Nordic Ecolabelling's criteria for Textiles, hides, skins and leather version 4.2 or later, or the EU Ecolabel for Textile products 2014/350/EC of 5 July 2009 or later, see Appendix 5.

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 Ecolabelling or a contract for the EU Ecolabel* showing the material.

* including additional requirements stated above

Alternative documentation under, see Appendix 5.

- Nordic Ecolabelling's criteria for hygiene products version 6.0 or later

- EU Ecolabel for absorbent hygiene products 2014/763/EU of 24 October 2014 or later and additional requirements described above

- Nordic Ecolabelling's criteria for textiles version 4.2 or later

- EU Ecolabel for textile products 2014/350/EU of 5 June 2014 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.

Rinse-off products for animals

O25 Fragrances and colouring agents in rinse-off products for animals

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

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

✉ Label

✉ Appendix 1 or equivalent declaration completed and signed.

4 Packaging requirements

O26 Amount of packaging

- More than one layer of packaging is only permitted where more than 1 product/unit are sold together. More than two layers of packaging are not permitted.

Exceptions: For spray and pump products with an "airless" system that reduces waste, double packaging (container + bag inside) is permitted. For aerosol products for hairstyling and shaving foam/gel, which do not use gas, double packaging is permitted (metal container + bag with valve).

- The packaging must meet the following calculation. See more information and calculation examples in Appendix 4. A spreadsheet for this calculation is available from Nordic Ecolabelling.

$$\frac{\sum\left(\mathrm{mf_i}\cdot Weight_{\mathrm{material\,i}}\cdot\frac{(2-\mathrm{rf_i})}{2}\right)-\frac{Weight_{\mathrm{pump}}}{2}}{\mathrm{t}}\leq 8\cdot\ln\left(\mathrm{Vol_{product}}+1\right)+0.004\times\mathrm{Vol_{product}}+4$$

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

mf_{glass} = 0.2

$mf_{paper/cardboard}$ = 0.6

$mf_{laminate}$ = 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

Volproduct = volume of the product in ml

The following are exempt:

- For decorative cosmetics the following apply:

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

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

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

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

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

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

✉ Description of the packaging.

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

O27 Type of packaging

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

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

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

O28 Emballagematerial - Metall

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 8 or equivalent certification completed and signed.

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

O29 Doserbarhet/ Doseringsanordning och tömningsgrad

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

The emptying level must be 90% and 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

5 Consumer information requirements

O30 Organic claims

If it is stated on the product that the product is/contains organic ingredients, EU Regulation 889/2008 on organic production must be complied with.

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”

✉ Label

✉ Certificate of organic ingoing ingredients

O31 Information text – Sunscreen

The recommended dosage of sunscreen must be stated and the sunscreen must bear the following or an equivalent information text on the label (according to 2006/647/EC, EU, 2006)

- “The most effective protection against the sun’s rays is achieved by staying in the shade or wearing clothes.”

- "It is important to apply the recommended dose; otherwise you will not achieve the expected level of protection."
- "Re-apply frequently to maintain protection, especially after perspiring, swimming or towelling."

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

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

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

✉ Label or packaging sample.

O32 Information text - specific products

The following products:

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

must bear the following or an equivalent information text on the label: "Do not discard 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 Ecolabelling for information texts applicable for the country in question.

✉ Label or packaging sample.

6 Performance/quality requirements

O33 Performance/quality and marketing claims

The performance/quality of the product must be satisfactory. This can be demonstrated by sending in documentation according to Appendix 8. Tests must at a minimum test the characteristics with which the product is marketed, in terms of performance/quality. 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, K38 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 as 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.
- The product's properties/marketing claim can also be documented via the properties of the raw materials (with the exception of mild/gentle, etc.) see Appendix 7.

✉ Description of the documentation in line with Appendix 7.

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

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

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

If the properties of the raw materials are used for marketing claims, raw materials documentation must be enclosed.

Special requirements for sunscreen products

O34 Performance, UVA and UVB

For sunscreen products it must be documented that Commission Recommendation of 22 September 2006, 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

O35 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 in-vivo testing.

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

7 Quality and regulatory requirements

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

O36 Responsible person and organisation

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

✉ Organisational chart showing who is responsible for the above.

O37 Documentation

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

🔑 Checked on site as necessary.

O38 Quality of Cosmetic product

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

✉ Procedures for archiving claims and, where necessary, dealing with claims and complaints regarding the quality of the Nordic Ecolabelled cosmetic products.

🔑 The claims archive is checked on site.

O39 Planned changes

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

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

O40 Unplanned nonconformities

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

✉ Procedures detailing how unplanned nonconformities are handled.

O41 Traceability

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

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

O42 Take-back system

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

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

O43 Legislation and regulations

The licensee shall ensure compliance with all applicable local laws and provisions at all production facilities for the Nordic 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.

Marketing

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

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

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

Design of the Nordic Ecolabel

Design of the Nordic Ecolabel:

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

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

Follow-up inspections

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

The licence may be revoked if it is evident that 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 Ecolabelling may charge the analysis costs to the licensee.

How long is a licence valid?

Nordic Ecolabelling adopted the criteria for cosmetic products on DAY MONTH YEAR. The criteria are valid until DAY MONTH YEAR.

Appendix 1 Declaration from the manufacturer of the cosmetic product

To be used in conjunction with an application for a licence for the Nordic 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 Ecolabelling.

Product name: _____

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

_____

Ingoing substances are defined, if not otherwise mentioned, as all substances in the chemical product – including additives (e.g. preservatives or stabilisers) in the raw materials/ingredients, but not residuals from the production, incl. the production of raw materials.

Residuals from production and from production of raw materials are defined as residuals, pollutants and contaminants derived from the production of the raw materials, which are present in the final product in amounts less than 100 ppm (0.0100% by weight, 100 mg/kg), but not substances added to the raw materials or product intentionally and with a purpose – regardless of amount.

Residuals in the raw materials above 0,1 % (1000 ppm) are regarded as ingoing substances. Known substances released from ingoing substances are also regarded as ingoing substances.

	Yes	No
O2: Have SCCS Opinions been followed?	☐	☐
O4: Does the product contain substances classified with any of the hazard phrases below?	☐	☐

Carc. 1A or 1B H350

Carc. 2 H351

Muta. 1A or 1B H340

Muta. 2 H341

Repr. 1A or 1B H360

Repr 2 H361

H362

	Yes	No
Acute Tox 1-3 H300, H301, H310, H311, H330, H331		
STOT SE 1 H370		
STOT SE 2 H371		
STOT RE 1 H372		
STOT RE 2 H373		
Resp. Sens. 1 H334		
Skin Sens. 1 H317		
O5: Does the product contains any of the following substances?	☐	☐
D4 (octamethylcyclotetrasiloxane, CAS 556-67-2), D5 (decamethylcyclopentasiloxane, CAS 541-02-6) and D6 (dodecamethylcyclohexasiloxane CAS 540-97-6)		
BHT		
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-Hydroxibenzoic acid and its salts and esters).		
Phthalates		
Substances considered to be (potential) endocrine disruptors in accordance with the European Union's reports concerning endocrine disruptors (see Appendix 8 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		
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)		
Mikroplastics		
Halogenated and/or aromatic solvents		
Nanomaterials/particles as defined in the Cosmetics Regulation		
O6 Does the product contain SLS?	☐	☐
O7 Have fragrances been added in line with IFRA guidelines?	☐	☐
O8 Does the product contain fragrances/fragrance substances/aromas/fragrace substances in plant extracts and is it intended for infants, babies and/or children?	☐	☐

	Yes	No
O10: Does the product contain colours?	☐	☐
If yes, state log Kow/BCF or E-number:_____		
O12: Does the product contain enzymes?	☐	☐
If yes, is the product a spray product?	☐	☐
O13: Does the product contain preservatives?	☐	☐
If yes, state log Kow/BCF:_____		
Does the baby product contain phenoxyethanol (CAS 122-99-6)?		
If yes, state amount and area of use:____ _____		
O14: Does the product contain UV filters?	☐	☐
If yes, state log Kow/BCF or lowest available NOEC/EC_x/EC/LC50:_____ _____		
O15: Does the product contain polymers?	☐	☐
If yes, send in specifications on residual monomers		
O16: Does the leave-on product contain aluminium?	☐	☐
If yes, state amount:_____		
O17: Does the product contain substances classified as environmentally hazardous with H410, H411 and H412	☐	☐
If yes, state the amount (% by weight) per classification: _____ _____		
O23: Does the product contain toothpaste or oral hygiene product flavourings, colours and preservatives?	**Yes**	**No**
If yes, state E-number or FL number:_____		
O24: Does the hair dye contain Lawsone (CAS no. 83-72-7)?	**Yes**	**No**
O26: Does the rinse-off animal care product contain fragrances or colours?	**Yes**	**No**

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

_____

_____

_____

_____

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

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

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 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 Ecolabelling.

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

Function of the raw material/ingredient:_____

_____

Ingoing substances are defined, if not otherwise mentioned, as all substances in the chemical product – including additives (e.g. preservatives or stabilisers) in the raw materials/ingredients, but not residuals from the production, incl. the production of raw materials.

Residuals from production and from production of raw materials are defined as residuals, pollutants and contaminants derived from the production of the raw materials, which are present in the final product in amounts less than 100 ppm (0.0100% by weight, 100 mg/kg), but not substances added to the raw materials or product intentionally and with a purpose – regardless of amount.

Residuals in the raw materials above 0,1 % (1000 ppm) are regarded as ingoing substances. Known substances released from ingoing substances are also regarded as ingoing substances.

	Yes	No
O3: Surfactants (irrespective of function), emulsifiers and emollients:Do they contain renewable raw materials?	☐	☐

If yes, state which and amount (% by weight): _____
_____

If palm oil is used, attach RSPO CoC certificate

O4: Does the raw material/ingredient contain substances classified with any of the hazard phrases below?

Carc. 1A or 1B H350

Carc. 2 H351

Muta. 1A or 1B H340

Muta. 2 H341

Repr. 1A or 1B H360

Repr 2 H361

H362

Acute Tox 1-3 H300, H301, H310, H311, H330, H331

STOT SE 1 H370

STOT SE 2 H371

STOT RE 1 H372

STOT RE 2 H373

Resp. Sens. 1 H334

Skin Sens. 1 H317

O5: Does the raw material/ingredient contains any of the following substances? ☐ ☐

D4 (octamethylcyclotetrasiloxane, CAS 556-67-2), D5 (decamethylcyclopentasiloxane, CAS 541-02-6) and D6 (dodecamethylcyclohexasiloxane CAS 540-97-6)

BHT

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-Hydroxibenzoic acid and its salts and esters).

Phthalates

Substances considered to be (potential) endocrine disruptors in accordance with the European Union's reports concerning endocrine disruptors (see Appendix 8 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

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)

Mikroplastics

Halogenated and/or aromatic solvents

Nanomaterials/particles as defined in the Cosmetics Regulation

	Yes	No
O7 Does the raw material/ingredient contain fragrances/fragrance substances/aromas/fragrace substances in plant extracts?	☐	☐
If yes, answer the following question:		
Is the perfume added and handled in line with the IFRA's guidelines?	☐	☐
Does the perfume contain fragrance substances subject to declaration?	☐	☐
Does the perfume contain fragrance substances which are judged to be sensitising with the hazard statement H317 and/or H334?	☐	☐
Does the perfume contain: • Cananga Odorata and Ylang-ylang oil (CAS-nr 83863-30-3, 8006-81-3) • Eugenia Caryophyllus Leaf / Flower oil (CAS-nr 8000-34-8) • Jasminum Grandiflorum / Officinale (CAS-nr 84776-64-7, 90045-94-6, 8022-96-6) • Myroxylon Pereirae (CAS-nr 8007-00-9) • Santalum Album (CAS-nr 84787-70-2, 8006-87-9) • Turpentine oil (CAS-nr 8006-64-2; 9005-90-7; 8052-14-0) • Verbena Absolute (CAS-nr 8024-12-02)	☐	☐
O10: Does the raw material/ingredient contain colours?	☐	☐
If yes, state log Kow/BCF or E-number:_____		
O11: Metals: Does the raw material/ingredient contain barium, lead, mercury, cadmium, six inhalant chromium or bismuth?	☐	☐
O13: Does the raw material/ingredient contain preservatives?	☐	☐
If yes, state log Kow/BCF:_____		
O14: Does the raw material/ingredient contain UV filters?	☐	☐
If yes, state log Kow/BCF or lowest available NOEC/EC_x/EC/LC50 _____		
O15: Does the raw material/ingredient contain polymers?	☐	☐
If yes, send in specifications on residual monomers		
O16: Does the raw material/ingredient contain aluminium	☐	☐
If yes, state the amount in Al: _____		
O17: Does the raw material/ingredient contain substances classified as environmentally hazardous with H410, H411 and H412	☐	☐
If yes, state the amount (% by weight) per classification: _____ _____ _____		

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

_____

_____

_____

_____

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

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

Appendix 3 Declartion from the manufacturer/supplier of packaging

To be used in conjunction with an application for a licence for the Nordic 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 Ecolabelling.

Manufacturer/supplier
Packaking type

	Ja	Nej
Plastic packaging		
Does the plastic contain postconsumer recycled material? (O27)	☐	☐
If yes, state amount of recycled material _____		
Paper, cardboard and board packaging		
Does the paper, cardboard or board contain postconsumer recycled material? (O27)	☐	☐
If yes, state amount of recycled material _____		
Metal packaging		
Does the metal contain postconsumer recycled material? (O27)	☐	☐
If yes, state amount of recycled material _____		

Manufacturer's/supplier's signature

Place and date:	Company name/stamp:
Responsible person:	Responible persons signature:

Appendix 4 Calculations

1 CDV

CDV(chronic) = Σ(DF_i x 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 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 8
0,15	for organic substances that are readily biodegradable according to Appendix 8 but for which the 10-day window is not met (excluding surfactants)
0,5	for organic substances that are inherently biodegradable according to Appendix 8
1,0	for persistent organic substances

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

TF = toxicity/SF,

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

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

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

2 Amount of packaging

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

$$\frac{\sum\left(\mathrm{mf_i}\cdot \mathit{Weight}_{\text{material i}}\cdot\frac{(2-\mathrm{rf_i})}{2}\right)-\frac{\mathit{Weight}_{\text{pump}}}{2}}{\mathrm{t}} \leq 8\cdot\ln\left(\mathrm{Vol}_{\text{product}}+1\right)+0.004\times\mathrm{Vol}_{\text{product}}+4$$

where

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

mf_{glass} = 0.2

$mf_{paper/cardboard}$ = 0.6

$mf_{laminate}$ = 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

Volproduct = volume of the product in ml

For example, if 50% of the plastic in the packaging is sourced from post-consumer reclaimed material, $rf_{plastic}$ is 0.5. rfi 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 (10 g, plastic packaging weighs 80 g in total and contains no recycling materials):

$$\frac{\sum\left(\mathrm{mf_i}\cdot Vikt_{\text{material i}}\cdot\frac{(2-\mathrm{rf_i})}{2}\right)-\frac{Vikt_{\text{pump}}}{2}}{\mathrm{t}}\leq 10\cdot\ln\left(\mathrm{Vol_{produkt}}+1\right)+0.008\times\mathrm{Vol_{product}}+8$$

$$\frac{\sum\left(1{,}0\cdot 50g\cdot\frac{(2-0)}{2}\right)-\frac{10g}{2}}{1}\leq 10\cdot\ln(200+1)+0.008\times 200+8$$

$$\frac{50g-5g}{1}\leq 53{,}03+1{,}6+8$$

$$45\leq 62{,}63\Rightarrow OK$$

3 Tömningsgrad

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

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

where:

m1= mass of primary packaging and product (g)

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

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

Normal conditions are defined as:

Normal conditions of use are defined as:

- Tube: Applying pressure succesively on the body of the primary packaging until it appears to be empty. The test is considered complete when no amount of liquid will flow after five successive pressures on the body of the primary packaging in direct contact. Neither the cap is dismantled, nor water is introduced inside the packaging.
- Spray: Applying pressure succesively on the tip of the spray by pressing the spring down entirely. Wait until the spring has returned to its initial position prior to applying a new pressure. Repeat until no amount of product flows from the spray after five successive pressures. Neither the cap is dismantled, nor water is introduced inside the packaging
- Pot: The product is removed using the index and middle fingers carefully but relentlessly. Neither the cap is dismantled, nor water is introduced inside the packaging
- Vial/flask: The vial is turned upside down, with the cap in downward position. After the trickle is not continuous, the bottle is left in the same position for another two minutes. Neither the cap is dismantled, nor water is introduced inside the packaging
- If another type of packaging is used, the emptying method would be accepted by Nordic Ecolabelling

Appendix 5 Dokumentation för material till våtservetten, O25

Material in wet wipes must meet at least one of the following requirements for the relevant fibre type (other fibre types cannot be used):

Viscose, non-woven, polymers (PE, PP, PET):

1. Material must meet following requirements in Nordic Ecolabelling's criteria for Hygiene products version 6.0 or later

   All Materials
   O3 Chemical products, classification
   O4 Chemical substances, CMR
   O5 Other excluded substances

   Viscose
   O21 Viscose, bleaching
   O22 Viscose, production requirements

   Polymers (polyester (PET), polyethylene (PE), polypropylene (PP))
   O23 Polymers, halogen-based
   O24 Polymers, ingoing substances
   O25 Polyurethane
   O26 Polyamide
   O27 Energy consumption in polymer production for fossil-based polymers
   O28 Energy consumption for production of polymers from renewable raw materials
   O29 Palm oil, soybean oil and sugar beet as feedstock for the renewable polymer
   O30 Recycled plastic

   Non-woven
   034 Non-woven, general requirement
   035 Non-woven, chemicals

   or

2. Material must meet following requirements in or the EU Ecolabel's criteria for absorbent hygiene products 2014/765/EU of 24 October 2014 or later:

   NB! The requirement also covers viscose based on bamboo fibre.

   All Materials
   Criterion 1. Product description
   Criterion 2. Fluff pulp
   Criterion 7. Excluded or limited substances or mixtures

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

Man-made cellulose fibres
Criterion 3. Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

Cotton and other natural cellulosic seed fibres
Criterion 4. Cotton and other natural cellulosic seed fibres

Plastic materials and superabsorbent polymers
Criterion 5. Plastic materials and superabsorbent polymers

Textile material made from viscose, cotton and other natural fibres:

1. Material must be licensed under Bordic Ecolabelling's criteria for Textiles, hides, skins and leather version 4.2 or later
   or

2. Material must be licensed under the EU Ecolabel for Textile products 2014/350/EC of 5 July 2009 or later
   or

3. Material must meet following requirements in Nordic Ecolabelling's criteria for Textiles, hides, skins and leather version 4.2 or later

   All textile fibres
   R24-R29 and R31-R36 General requirements for chemicals

   Cotton, other natural cellulose seed fibres (visckose)
   R3 Cotton and other natural cellulose seed fibres

   Flax, bamboo and bast fibres
   R4 Flax, bamboo and other bast fibres
   or

4. Material must meet following requirements under the EU Ecolabel for Textile products 2014/350/EC of 5 June 2014 or later:

   All textile fibres
   Criterion 13. Restricted Substance List (RSL)
   Criterion 14. Substitution of hazardous substances used in dyeing, printing and finishing

   Cotton and other natural cellulosic seed fibres
   Criterion 1. Cotton and other natural cellulosic seed fibres (including kapok)

   Flax and other bast fibres
   Criterion 2. Flax and other bast fibres (including hemp, jute and ramie)

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 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 Ecolabelling.

Producer / supplier of wet wipe material
Wet wipe material

	Yes	**No**
Are sensitising substances with H317 and/or H334 used in the process water of the wet wipe material (O29)	☐	☐
If yes, does the concentration in the carrying material/wipe exceed 0.10 ppm per sensitising substance? Enclose an analysis report.	☐	☐

Manufacturer's/supplier's signature

Place and date:	Company name/stamp:
Responsible person:	Responible persons signature:

Appendix 7 Performance/quality and marketing claims

Minimum requirements for the content in test reports as documentation of performance/quality and raw materials documentation for marketing claims

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

Note that the test shall be a consumer test with at least 10 independent 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.

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 Ecolabelling accepts non-irritant and slightly irritant and in HET-CAM non-irritating and slightly irritating. Claims of "gentle/mild" and similar can alternatively be shown by the product meeting the following three points:

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

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?
    - Primary function
    - Secondary function
    - Claim
- 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. 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 Ecolabelling licence has been applied.

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

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

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

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

4. Raw materials documentation

The following documentation can be used to document the properties of the raw materials and marketing claims:

- Data sheet/product sheet/presentations of raw materials showing who produced the material and when
- Scientific articles and reports

For the following raw materials and claims, no documentation is required as the properties of the raw materials are well-known:

Raw material/substance	**Property**
Glycerine	Moisturiser
Aloe Vera	Moisturising, anti-aging, soothing, regenerating, moisture-retaining
Tocopherol	antioxidant
Jojoba oil	moisturising
Lactic acid	moisturising (humectant)
Creatine	skincare
Collagen	haircare, skincare
Panthenol	skincare, moisturising
Allantoin	Moisturising, reduces skin irritation
Bisabolol	soothing effect
Blueberries	antioxidant
Sea buckthorn	antioxidant
Camomile	soothing effect
Caprylic/Capric triglyceride	Moisturising
Shea butter	moisturising, elasticity, UV protection, anti-inflammatory
Beeswax (Cera Alba)	Provides a protective layer
Eucalyptus	antibacterial, stimulates the immune system.
Menthol	cooling
Camphor	cooling effect, healing extremely dry or broken skin
Oils	moisturising
Wheat extract	Moisturising
Keratin	protein for skin and nails
Ethanol	cooling
Aluminium chlorhydrate	rapid penetration
Polyacrylate	Gives hair hold
Chlorhydrate	antiperspirant

Appendix 8 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

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.

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

4 Bioaccumulation

Unless otherwise proven, substances are considered to be bioaccumulating if logKow ≥ 4.0 under the OECD's guidelines 107 or 117 or equivalent. Such a substance may be tested on fish in line with the OECD's testing instructions 305 A-E.

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

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

Data models (such as BIOWIN) are accepted, but if the results of the model calculations are close to the threshold values or if Nordic 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.

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). N> 60% mineralisation corresponds to >60% ThOD/$ThCO_2$ or > 70% DOC reduction)

Substances that are not surfactants and which are not included in the DID list may be exempt from the requirements on anaerobic degradability if they are not toxic to aquatic organisms (NOEC/EC_x > 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 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. The most recent reports can be obtained from 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.

9 DID list

The DID list is a common list for the EU’s ecolabel and Nordic 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 2014 or later versions apply.