Nordic Ecolabelling of

Cosmetic products

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Nordic Ecolabelling

Content

090 Cosmetic products, version 2.6, 5 July 2013

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 Swan. 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 a Nordic Ecolabelled cosmetic product?

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

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

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

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

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

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

Why choose the Nordic Ecolabel?

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

Which cosmetic products may carry the Nordic Ecolabel?

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

How to apply

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

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

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

Icons in the text

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

✉ Enclose

🔑 Requirement checked on site

Application

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

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

Sales in other Nordic countries

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

- Application form for registration or original Nordic Ecolabel application*.
- Copy of licence.

- Copy of the label in the applicable local language.
- Documentation demonstrating that particular national legislation is fulfilled in the country of application (e.g. recycling systems or recommended fluorine content in toothpaste).
- Any marketing material for the country of registration.
- The supplier/distributor in the country of registration, when other than the licensee.

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

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

On-site inspection

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

Costs

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

Enquiries

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

What are the requirements of the Nordic Ecolabel?

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

1 Environmental and health requirements

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

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

1.1 General requirements (applicable to all products)

Are the requirements met?

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

R1 Declaration of content — **Yes** ☐ **No** ☐

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

✉ Exact formulation specifying the constituent substances' chemical name, trade name, DID (Detergents Ingredients Database) number (if any), INCI (International Nomenclature of Cosmetic Ingredients) name, CAS number (if any), quantity in the product including and excluding water, as well as the function performed by the constituent substance in question. If an ingredient contains several substances, data for each constituent substance shall be presented. If information about the composition of ingredient is confidential, this information can be sent directly to the ecolabelling body. — **Appendix no.** _____

✉ Safety data sheet for each ingredient in compliance with applicable legislation in the country of application, e.g. Annex II of REACH (Council Regulation 1907/2006/EEC). — **Appendix no.** _____

Constituent substances

The following requirements apply to all constituent substances and for their known degradation products.

R2 Classification of constituent substances

Yes ☐ No ☐

Constituent substances classified according to Table 1 are prohibited.

Table 1 Classification of constituent substances

Classification	Hazard symbols and risk phrases according to 67/548/EEC[1]	Hazard category and statement according to 1272/2008/EEC[2]
Sensitizing*	Xn with R42 or Xi with R43	Resp. sens. 1 with H334 or Skin sens. 1 with H317
Carcinogenic	Carc with R40, R45 and/or R49	Carc 1A/1B/2 with H350, H350i and/or H351
Mutagenic	Mut with R46 and/or R68	Mut 1B/2 with H340 and/or H341
Reproductive toxic	Repr with R60, R61, R62, R63 and/or R64	Repr 1A/1B/2 with H360F, H360D, H361f, H361d, H360FD, H361fd, H360Fd, H360Df, Lact. H362

**See the separate requirements on perfumes and enzymes (R15 and R21).*

[1] Council Directive 67/548/EEC is applicable until 1 December 2010 and during the transition period 2010-2015.

[2] Regulation 1272/2008/EEC is applicable from 1 December 2010.

☒ Safety data sheet for each ingredient in compliance with applicable legislation in the country of application, e.g. Annex II of REACH (Council Regulation 1907/2006/EEC). Appendix no. _____

☒ Appendix 3 and 4 or equivalent declarations duly completed and signed. Appendix no. _____

R3 Environmentally hazardous substances

Yes ☐ No ☐

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

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

$100 \cdot c_{R50/53} + 10 \cdot c_{R51/53} + c_{R52/53} \leq 2.5\%$

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

BHT is considered to be classified under R50/53/H410

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

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

** In accordance to the DID-list. If the substance in not on the DID-list documentation must be according to test method No. 301 A-F or No. 310 in OECD guidelines for testing of chemicals or other equivalent test methods.*

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

☒ Declaration of surfactants that are exempted from the requirement (quantity, classification, degradability). Appendix no. _____

☒ A declaration of potential dangers posed to the environment (acute toxicity, biodegradability and/or bioaccumulative potential), in the form of either a product safety data sheet (1907/2006/EC/2001/58/EC) or other equivalent documentation. Appendix no. _____

☒ Declaration of the quantity (in per cent by weight) of R50/53, R51/53 and R52/53 or H410, H411 and H412. If data regarding the potential environmental hazards posed by a substance (biodegradability, toxicity and bioaccumulation) has not been assessed, the substance is treated according to a worst case scenario (R50/53/H410). Appendix no. _____

R4 **SCCS opinions** Yes ☐ No ☐

The recommendations of the EU's Scientific Committee on Consumer Safety (known as "SCCS Opinions") are to be followed at all times. In those cases in which these recommendations are not in agreement with the requirements set out in this document, the more restrictive requirement is to apply.

SCCS recommendation, SCCS/1459/11 on Fragrance Allergens, is exempted from this requirement. However HICC, chloroatranol and atranol are prohibited in the product. The exception is valid until 30 June 2014.

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

✉ Appendix 3 or equivalent declaration duly completed and signed. Appendix no. _____

✉ Appendix 5 or equivalent declaration duly completed and signed. Appendix no. _____

R5 **Prohibited substances** Yes ☐ No ☐

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

- D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) and D5 (decamethylcyclopentasiloxane, CAS 541-02-6)
- Borates and perborates
- Nitromusk and polycyclic musks
- EDTA (Ethylenediaminetetraacetic acid) and its salts (see however the exemption for solid soap under R22).
- Triclosan
- Parabens (4-Hydroxybenzoic acid and its salts and esters)
- Substances considered potential endocrine disrupters in accordance with European Union reports on endocrine disrupters (see Appendix 2 for a definition).

  The European Union reports on potential endocrine disrupters can be read in full at http://ec.europa.eu/environment/endocrine/index_en.htm
- Substances that have been evaluated in the EU to be PBT (Persistent, bioaccumulable and toxic) or vPvB (very persistent and very bioaccumulable) (see http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt)

✉ Recipe. Appendix no. _____

✉ Appendix 3 and 4 or equivalent declarations duly completed and signed. Appendix no. _____

Nanomaterials/particles

R6 **Nanomaterials/particles** Yes ☐ No ☐

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

✉ Recipe. Appendix no. _____

✉ Appendix 3 and 4 or equivalent declarations duly completed and signed. Appendix no. _____

Biodegradability and aquatic toxicity

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

R7 **Surfactants** Yes ☐ No ☐

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

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

✉ Reference to the DID list, approved version from January 2007 or later. If the substance is not listed on the DID list, the parameters shall be calculated in accordance with the guidelines in section B of the DID list, and the associated documentation shall be submitted. Appendix no. _____

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

✉ Toothpaste: Appendix 3 or equivalent declaration duly completed and signed. Appendix no. _____

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).

R8 **aNBO (Aerobic Non-Biodegradable Organics) and anNBO (Anaerobic Non-Biodegradable Organics)** Yes ☐ No ☐

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

Table 2 Threshold values for aNBO and anNBO

Type of product	aNBO (mg/g AI)	anNBO (mg/g AI*)
Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant	15	15
Solid soap	5	5

	anNBO (mg/dose**)	anNBO (mg/dose**)
Liquid soap	2,5	2,5
Liquid hand soap for industry***	6	6

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

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

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

✉ Calculation of the quantity (mg) of aNBO and anNBO per gram AI per dose. Appendix no. _____

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

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

R9 Critical dilution volume (CDV)

Yes ☐ No ☐

The product's critical dilution volume (CDV) must not exceed the limit values in Table 3 for $CDV_{chronic}$ for the product type in question.

The requirement applies to products that, according to their instructions for use, are rinsed off with water immediately after use. Regarding liquid soap and hand soap for industry it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in R8.

Table 3 Threshold values for CDV

Type of product	**$CDV_{chronic}$ (l/g AI*)**
Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant	13 000
Solid soap	3 000

	$CDV_{chronic}$ (l/dose)**
Liquid soap	3 000
Liquid hand soap for industry***	8 000

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

**Active ingredient(s) (AI)*

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

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

✉ Calculation of $CDV_{chronic}$ for the product. (A spreadsheet for this calculation is available from Nordic Ecolabelling). Appendix no. _____

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

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

B) Other cosmetic products

R10 Biodegradability and aquatic toxicity Yes ☐ No ☐

At least 95% by weight of the total content of organic constituent substances (with exceptions for UV filters in sunscreen and fibre material in wet wipes) must be (see, however, separate requirement R7 in respect of detersive surfactants):

- readily biodegradable (OECD 301 A-F), and/or
- lowest recorded aquatic toxicity EC/LC_{50} > 10 mg/l and not be bioavailable (molar weight > 700 g/mole), and/or
- lowest recorded aquatic toxicity EC/LC_{50} > 10 mg/l and not be bioaccumulable ($logK_{ow}$ < 4 or BCF < 500), and/or
- lowest recorded aquatic toxicity EC/LC_{50} > 10 mg/l and be inherently biodegradable (OECD 302 A-C).

✉ Calculation as above as well as reference to DID list. For substances not listed on the DID list a specification is required of biodegradability/toxicity/potential for bioaccumulation/bioavailability according to Appendix 2. (The lowest available EC/LC50 value must be used). Appendix no. _____

Dye

R11 Bioaccumulation Yes ☐ No ☐

Organic colouring agents must not be bioaccumulating according to Appendix 2, item 4 (BCF<500/$logK_{ow}$<4). Alternatively, the colouring agent must be approved for use in food stuffs.

✉ Specification of empirically determined BCF value (bioconcentration factor) or $logK_{ow}$ value (logarithmic octanol-water partition coefficients), see description in Appendix 2. Alternatively, an E-number (number designated on approval of foodstuff status) may be supplied. Appendix 3 and 4 can be used. Appendix no. _____

R12 Metals Yes ☐ No ☐

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

✉ Appendix 4 or equivalent declaration duly completed and signed and/or specifications/analysis results for the dye. Appendix no. _____

✉ Specification of E-number and/or declaration from the supplier of the colouring agent conforming that the colouring agent meets the criteria for purity according to the European Commission's Directive 2008/128/EC. Appendix no. _____

Fragrances

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

R13 IFRA Yes ☐ No ☐

Fragrances must be used in accordance with the IFRA guidelines.

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

✉ Appendix 3 or equivalent declaration duly completed and signed. Appendix no. _____

R14 **Infant, baby and child products** Yes ☐ No ☐

Fragrances/aromatic substances/fragrance substances in plant extract must not be added to infant, baby and/or child products.

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

☒ Appendix 3 and 4 or equivalent declarations duly completed and signed. Appendix no. _____

☒ Recipe. Appendix no. _____

☒ Sample of a label. Appendix no. _____

R15 **Quantity of fragrance** Yes ☐ No ☐

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

☒ Appendix 5 or equivalent declaration duly completed and signed. Specification of the fragrance(s). Appendix no. _____

☒ Recipe. Appendix no. _____

Preservatives

These requirements apply to antibacterial, disinfecting and microbial substances.

R16 **Use of preservatives** Yes ☐ No ☐

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

☒ Appendix 3 and 4 or equivalent declarations duly completed and signed. Appendix no. _____

R17 **Bioaccumulation** Yes ☐ No ☐

Preservatives must not be bioaccumulating as specified by Appendix 2, item 4 ($BCF<500/\log K_{ow}<4$).

☒ Specification of BCF or $\log K_{ow}$ value. See description in Appendix 2. Appendix 3 and 4 may be used. Appendix no. _____

UV-filter

R18 **Function of the UV-filter** Yes ☐ No ☐

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

☒ Appendix 3 and 4 or equivalent declarations duly completed and signed. Appendix no. _____

R19 Environmental characteristics of the UV-filter

Yes ☐ No ☐

All organic UV-filters contained in the product:

- must not be bioaccumulating as specified by Appendix 2, item 4 (BCF<500/logK_{ow}<4), or
- must have a lowest recorded level of toxicity of EC/LC_{50} > 10.0 mg/l.

✉ Specify one of the following values:

Appendix no. _____

BCF value/logK_{ow} value/lowest EC/LC_{50} value (The lowest available EC/LC_{50} value must be used).

Polymers

R20 Content of monomers

Yes ☐ No ☐

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

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

Appendix no. _____

Enzymes

R21 Classification of enzymes

Yes ☐ No ☐

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

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

Appendix no. _____

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

Appendix no. _____

[1]Respirator with P3 dust filter protects against most types of harmful dust. These filters can protect only against solid particles or against both solid particles and liquid aerosols. The filter also protects against radioactive dust, bacteria and virus (Ref: Branchearbejdsmiljørådets håndbog for sikkerhedsgruppen bygge og anlæg, 2008).

1.2 Specific requirements relating to certain product types

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

Solid soap

R22 Content of EDTA and phosphonates in solid soap — Yes ☐ No ☐

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 AI.

✉ Calculation of the quantity (mg) of EDTA and phosphonates per gram of AI. — Appendix no. _____

Lip products, toothpaste and oral hygiene products

R23 Flavourings, colouring agents and preservatives — Yes ☐ No ☐

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

✉ Specification of E number and/or declaration from supplier of flavouring stating that the flavouring is approved for use in foodstuffs according to 88/388/EC (EU, 1988). — Appendix no. _____

Hair dyes

R24 Hair dyes — Yes ☐ No ☐

Use of lawsone (CAS no. 83-72-7) is prohibited.

Hair dyes considered to be sensitising/allergenic by the SCCS may not be included in the product, even if they are not classified as such with R43 (H317) and/or R42 (H334)

✉ Appendix 3 or equivalent declaration duly completed and signed. — Appendix no. _____

Sanitary products, wet wipes

R25 **Materials** Yes ☐ No ☐

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

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

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

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

✉ **Paper**: A copy of the Nordic Ecolabel licence; or documentation as required according to the criteria for tissue paper (version 4.0 or later); or a contract in respect of the EU Ecolabel from a competent body. **Appendix no. _____**

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

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

Rinse-off products for animals

R26 **Fragrances and colouring agents in rinse-off products for animals** Yes ☐ No ☐

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

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

✉ Appendix 3 or equivalent declaration duly completed and signed. **Appendix no. _____**

✉ Sample of a label. **Appendix no. _____**

2 Packaging

Are the requirements met?

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

R27 Quantity of packaging

Yes ☐ No ☐

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

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

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

$mf_{glass} = 0.2$

$mf_{paper/cardboard} = 0.6$

$mf_{plastic\ laminate} = 1.1$

$mf_{other\ materials} = 1.0$

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

rf_i = fraction of material recycled following consumer use.

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

t = reuse factor

n = natural logarithm

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

For decorative cosmetics products the following applies:

$$\frac{\Sigma(W_{packaging,i}+W_{non\text{-}recycled,i})}{2^* W_{product,total}} \leq 0{,}80$$

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

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

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

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

☒ Description of the packaging — Appendix no. _____

☒ Weight of the primary packaging and product, and calculation as specified above. (A spreadsheet for the calculation is available from Nordic Ecolabelling.) — Appendix no. _____

R28 Type of packaging

Yes ☐ No ☐

It must be possible to separate all materials in the packaging (paper, cardboard, plastic*, metal, glass) for sorting. Parts comprising mixed materials that cannot be separated are prohibited, with the exception of pump parts.

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

**Plastic laminate is acceptable.*

✉ Specification of materials, including description of all components (cap, pump, lid, etc.) — Appendix no. _____

R29 Plastic packaging

Yes ☐ No ☐

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

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

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

✉ Appendix 6 or equivalent declaration duly completed and signed. — Appendix no. _____

✉ 🔑 Adherence with the marking requirement will be checked through packaging samples/product samples/images of the packaging/inspection visits. — Appendix no. _____

R30 Metal packaging

Yes ☐ No ☐

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

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

Metal part may be used in packaging for decorative cosmetic products if the amount of metal does not exceed 15% of the total packaging weight. Mirror is not allowed as part of the packaging.

✉ 🔑 Packaging sample/product sample/images of the packaging/inspection visit. — Appendix no. _____

R31 Paper, cardboard and board packaging

Yes ☐ No ☐

Packaging paper, cardboard or board must not be bleached with chlorine.

✉ Appendix 6 or equivalent declaration duly completed and signed. — Appendix no. _____

R32 Dispensing device

Yes ☐ No ☐

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

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

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

✉ Description of dispensing device and weighing results of liquid/industrial soap per full depression. — Appendix no. _____

3 Consumer information requirements

Are the requirements met?

R33 Declaration of contents

Yes ☐ No ☐

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

✉ Label or packaging sample. Appendix no. _____

R34 Information text

Yes ☐ No ☐

The following products must bear the following or an equivalent information text on the label: "Do not discard cotton wool or paper carrying this product in the lavatory or drain. Dispose of in a dustbin." Pictograms may be accepted:

- Cleaning products, e.g. cleansing lotions and eye make-up remover.
- Nail polish removers
- Wet wipes

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

- Nail polish
- Nail polish removers

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

✉ Label or packaging sample. Appendix no. _____

R35 Information test – Sunscreen

Yes ☐ No ☐

The recommended dosage of sunscreen must be stated and the sunscreen must bear the following or an equivalent information text on the label:

- "The most effective protection against the sun's rays is achieved by staying in the shade or wearing clothes."
- "It is important to apply the recommended dose; otherwise you will not achieve the expected level of protection."
- "Re-apply frequently to maintain protection, especially after perspiring, swimming or towelling."

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

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

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

✉ Label or packaging sample. Appendix no. _____

R36 Product claims

Yes ☐ No ☐

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

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

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

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

Table 4

Actual content (%)	Interval that may be used (%)
< 0,1	<0,1
0.1-1	<1
1-5	<5
5-10	<10
10-15	<15
15-20	<20
20-25	<25
25-50	<50
50-75	<75
75-100	>75

✉ Label and certificates for the organic ingredients.

Appendix no. _____

4 Performance/quality requirements

Are the requirements met?

R37 Performance/quality

Yes ☐ No ☐

The performance and quality of the product must be satisfactory. This can be demonstrated through relevant testing. Testing must at a minimum test the characteristics with which the product is marketed. If there is a recognised test method (see for example R38 for sunscreen products), this shall be used. For other products, a test could be the manufacturer's internal quality test, a consumer test with test group of 10 or more independent individuals, or a comparative test relating to a similar product, e.g. a triangle test.

The Colipa (European Cosmetics Association) guidelines on Efficacy Evaluation of Cosmetic Products must be observed.

✉ Description of test, including an account of chosen testing methods and test results. If a consumer test is used a copy of completed and signed test reports is to be supplied. This report shall include a description of the test group, the number of participants and a summary of test results. Appendix no. _____

✉ Appendix 3 or equivalent declaration duly completed and signed. Appendix no. _____

Special requirements in respect of sunscreen

R38 Performance, UVA and UVB protection

Yes ☐ No ☐

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

✉ Description of the test and test results. Appendix no. _____

Special requirements in respect of toothpaste

R39 Performance, fluoride

Yes ☐ No ☐

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

✉ Recipe or copy of pertinent publications, recommendations and test results, as detailed above. Appendix no. _____

5 Quality and regulatory requirements

Are the requirements met?

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

If the cosmetics manufacturer's environmental management system is certified to ISO 14 001 or EMAS, where the following procedures are applied, it is sufficient if an auditor from an accredited body certifies that the requirements are implemented.

R40 Laws and regulations

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

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

Yes ☐ No ☐

R41 Licence administrators

The company shall appoint an individual responsible for ensuring the fulfilment of Nordic Ecolabel requirements, and a contact person for communications with Nordic Ecolabelling.

Yes ☐ No ☐

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

Appendix no. _____

R42 Documentation

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

Yes ☐ No ☐

🔎 Checked on site.

R43 Product quality

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

Yes ☐ No ☐

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

Appendix no. _____

R44 Planned changes

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

Yes ☐ No ☐

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

Appendix no. _____

R45 Unplanned nonconformities

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

Yes ☐ No ☐

✉ Procedures detailing how unplanned nonconformities are handled.

Appendix no. _____

R46 Traceability

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

Yes ☐ No ☐

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

Appendix no. _____

6 Take-back system and marketing

Are the requirements met?

R47 Take-back system Yes ☐ No ☐

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

✉ A declaration from the applicant in respect of adherence to existing recycling/take-back agreements, or other documentation demonstrating fulfilment of the requirement, may also be required. See Appendix 3. Appendix no. _____

R48 Marketing Yes ☐ No ☐

Marketing of the Nordic Ecolabelled cosmetic product shall comply with "Regulations for the Nordic Ecolabelling of products" of 22 June 2011 or later version.

✉ Appendix 1 duly completed. Appendix no. _____

Marketing

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

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

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

Design of the Nordic Ecolabel

Design of the Nordic Ecolabel:

Licence number

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

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

Follow-up inspections

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

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

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

How long is a licence valid?

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

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

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

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

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

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

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

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

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

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

New criteria

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

- Possibility to set obligatory requirements in respect of sustainability and sourcing of raw materials from renewable sources – certified raw materials and certified organic raw materials
- Limits on degradable substances and CDV, as well as a separating of the requirements in respect of degradability and toxicity.
- Packaging/Metal packaging requirements.

References

DID list (2007): Detergents Ingredients Database (DID-list) Part A. List of ingredients January 2007 + Part B

Colipa (2008): Guidelines - Efficacy Evaluation of Cosmetic Products. 5 May 2008

EU (1967): Dangerous Substance Directive, 67/548/EEC and 1999/45/EEG with amendments

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

EU (1988): COUNCIL DIRECTIVE of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (88/388/EEC, http://ec.europa.eu/food/fs/sfp/addit_flavor/flav09_en.pdf)

EU (1991): COUNCIL REGULATION (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs

EU (1997): Commission Decision of 28 January 1997 ((97/129/EC) establishing the identification system for packaging materials pursuant to European Parliament and Council Directive 94/62/EC on packaging and packaging waste (Text with EEA relevance)

EU (1967): REACH Directive 1907/2006

EU (2006b): COMMISSION RECOMMENDATION of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto. (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:265:0039:0043:en:PDF)

EU (2009): REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products with adjustments and amendments (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF)

European Commission reports on endocrine disrupters: http://ec.europa.eu/environment/endocrine/index_en.htm

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

EU Ecolabel (2009) Commission Decision 9th of July 2009 establishing the ecological criteria for the award of the Community eco-label to tissue-paper products (2009/568/EC)

EU Ecolabel (2009): Commission Decision of 9 July 2009 establishing the ecological criteria for the award of the Community Ecolabel for textile products (2009/567/EC)

Nordic Ecolabelling (2006) Nordic Ecolabelling of tissue paper: Version 4. 23 March 2006.

Nordic Ecolabelling (2008) Nordic Ecolabelling of sanitary products, Version 5. 5 march 2008.

OECD Guideline for testing chemicals 301 A-F Ready biodegradability

OECD Guideline for testing chemicals 302 A-C Inherent biodegradability

SCCS Opinions: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm

Appendix 1 Marketing of Nordic Ecolabelled cosmetic products

www.nordic-ecolabel.org

We hereby certify that we are well acquainted with the regulations governing the use of the Nordic Ecolabel, as detailed in ”Regulations for the Nordic Ecolabelling of products” of 22 June 2011 or later version. We agree to follow these regulations when marketing the Nordic Ecolabelled cosmetic product.

Further, we confirm that we are familiar with the criteria document regarding the Nordic Ecolabelling of cosmetic products.

We undertake to advise those individuals within the company involved in marketing the Nordic Ecolabelled cosmetic products of the criteria for the Nordic Ecolabelling of cosmetic products and ”Regulations for the Nordic Ecolabelling of products” of 22 June 2011 or later version.

Location and date

Company

Signature, contact person

Name in block capitals

Phone

Signature, marketing manager

Name in block capitals

Phone

In case of a change in personnel, a new declaration must be submitted to Nordic Ecolabelling.

Appendix 2 Test methods and documentation of environmental characteristics

1 Requirements on the analysis laboratory

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

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

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

2 Ecotoxicological test methods

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

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

3 Acute/chronic aquatic toxicity

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

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

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

4 Bioaccumulation

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

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

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

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

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

5 Aerobic biodegradability

Test methods 301 (A to F) or 310 in the OECD Guidelines for the Testing of Chemicals (ISBN 92641222144) should be used to test aerobic biodegradability.

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

6 Anaerobic degradability

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

Substances, other than surfactants, that are not found on the DID list may be exempted from the requirement on anaerobic biodegradability if the substance is not toxic for aquatic organisms (E/LC_{50} > 10 mg/l), and is readily aerobically degradable and simultaneously:

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

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

7 Inherent biodegradability

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

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

8 Potential for endocrine disruption

A potential endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.

Nordic Ecolabelling includes all substances that the European Commission considers potential endocrine disrupters (classes 1, 2 and 3b). 'Category 1 - evidence of endocrine disrupting activity in at least one species using intact animals'; 'Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption'; 'Category 3b - no data available'). In case the European Commission lists are amended, the latest updated reports shall apply. The latest reports are available to be viewed at http://ec.europa.eu/environment/endocrine/index_en.htm and the Access database, in which all evaluated substances are listed, is available for download at http://ec.europa.eu/environment/endocrine/strategy/short_en.htm.

9 DID list

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

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

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

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

Valid to these criteria is the DID list dated January 2007 or later.

Appendix 3 Declaration from the cosmetic product producer

www.nordic-ecolabel.org

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

Product name: _____

Type of product: _____

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

Does the product contain substances that are classified as carcinogenic, mutagenic, harmful for reproduction, allergenic as R42 and/or R43 (H334 and/or H317)?	Yes ☐	No ☐
Does the product contain D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) or D5 (decamethylcyclopentasiloxane, CAS 541-02-6)?	Yes ☐	No ☐
Does the product contain borates or perborates?	Yes ☐	No ☐
Does the product contain nitromusk or polycyclic musk compounds?	Yes ☐	No ☐
Does the product contain triclosan?	Yes ☐	No ☐
Does the product contain ethylene diamine tetraacetate (EDTA) and its salts?	Yes ☐	No ☐
Does the product contain parabens (4-Hydroxybenzoic acid) and their salts and esters?	Yes ☐	No ☐
Does the product contain potential endocrine disrupters as specified by the European Commission reports on endocrine disrupters (see Appendix 2 for definitions and http://ec.europa.eu/environment/endocrine/index_en.htm)?	Yes ☐	No ☐
Does the product contain substances that have been evaluated in the EU to be PBT (Persistent, bioaccumulable and toxic) or vPvB (very persistent and very bioaccumulable)?	Yes ☐	No ☐
Does the product contain nanomaterials/particles (except hydrated silica in toothpaste?	Yes ☐	No ☐
Does the product contain colouring agents?	Yes ☐	No ☐
If yes, specify the E number, BCF or logKow value: _____		
Does the product contain fragrances (including aromatic substances and fragrance substances in plant extract)?	Yes ☐	No ☐
If yes, does the fragrance contain substances that are classified as sensitising with risk phrases R43 (H317) and/or R42 (H334), or that are included among fragrances subject to declaration?	Yes ☐	No ☐
If yes, have fragrances been added in accordance with the IFRA guidelines?	Yes ☐	No ☐
If yes, is the product intended for infants, babies and/or children?	Yes ☐	No ☐
Does the product contain preservatives?	Yes ☐	No ☐
If yes, has the preservative been added solely to protect the product?	Yes ☐	No ☐
If yes, specify BCF or logKow value: _____		
Does the product contain UV-filters?	Yes ☐	No ☐
If yes, has the UV-filter been added solely to protect the user?	Yes ☐	No ☐

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

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

_____

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Are SCCS opinions observed?	Yes ☐	No ☐
Sunscreen: Is labelling of the SPF factor in accordance with Commission Recommendation of 22 September 2006?	Yes ☐	No ☐
Have Colipa guidelines for Efficacy Evaluation of Cosmetic Products been followed?	Yes ☐	No ☐
Is the product in compliance with relevant national regulations, legislation and/or agreements within the sector regarding the recycling and take-back systems for products and packaging in Nordic countries in which the Nordic Ecolabelled cosmetic product is marketed?	Yes ☐	No ☐
Finland (e.g. PYR)	Yes ☐	No ☐
Sweden (REPA)	Yes ☐	No ☐
Norway (Grønt Punkt)	Yes ☐	No ☐

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

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

Date: Company name:

Signature (person responsible)

Name in block capitals E-mail and phone number

Appendix 4 Declaration from the producer of raw material

www.nordic-ecolabel.org

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

Ingredient name: _____

Function of ingredient: _____

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

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

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

Does the ingredient contain substances classified as carcinogenic, mutagenic, harmful for reproduction, allergenic as R42 and/or R43 (H334 and/or H317)? *(Declaration regarding allergenic substances in fragrances is included later and should not be regarded here).*	Yes ☐	No ☐
Does the ingredient contain substances classified harmful to the environment as R50/53, R51/53 and/or R52/53 (H410, H411, H412)?	Yes ☐	No ☐
Does the ingredient contain D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) or D5 (decamethylcyclopentasiloxane, CAS 541-02-6)?	Yes ☐	No ☐
Does the ingredient contain BHT?	Yes ☐	No ☐
Does the ingredient contain triclosan?	Yes ☐	No ☐
Does the ingredient contain EDTA (Ethylenediaminetetraacetic acid)?	Yes ☐	No ☐
Does the ingredient contain borates or perborates?	Yes ☐	No ☐
Does the ingredient contain nitromusk or polycyclic musk compounds?	Yes ☐	No ☐
Does the ingredient contain potential endocrine disrupters as specified by the European Commission reports on endocrine disrupters (see Appendix 2 for definitions and http://ec.europa.eu/environment/endocrine/index_en.htm)?	Yes ☐	No ☐
Does the ingredient contain parabens?	Yes ☐	No ☐
Does the ingredient contain substances that have been evaluated in the EU to be PBT (Persistent, bioaccumulable and toxic) or vPvB (very persistent and very bioaccumulable)?	Yes ☐	No ☐
Does the ingredient contain nanoparticles (except hydrated silica in toothpaste)?	Yes ☐	No ☐
Does the ingredient contain colouring agents?	Yes ☐	No ☐
If yes, specify the E number, BCF or logKow value: _____		
For colouring agents: Does the colouring agent contain barium, lead, mercury, cadmium, bismuth or hexavalent chromium?	Yes ☐	No ☐
Does the ingredient contain fragrance substances (including aromatic substances and fragrance substances in plant extract) that are classified as sensitising with risk phrases R43 (H317) and/or R42 (H334), or that are included among fragrances subject to declaration?	Yes ☐	No ☐
If yes, Appendix 5 must also be completed.		

Does the ingredient contain preservatives? Yes ☐ No ☐

If yes, specify BCF or logKow value: _____

Does the ingredient contain UV-filters? Yes ☐ No ☐

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

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Date: Company name:

Signature (person responsible)

Name in block capitals E-mail and phone number

Appendix 5 Declaration from the producer of fragrances, aromatic substances and plant extracts regarding ingredients in fragrance blends/aromatic substances/ plant extract

www.nordic-ecolabel.org

Fragrance/aromatic substance/plant extract name: _____

_____

Does the fragrance blend/aromatic substance/plant extract contain substances classified as sensitising with R42 and/or R43 (H334 and/or H317)? Yes ☐ No ☐

Does the fragrance blend/aromatic substance/plant extract contain any of the fragrance substances subject to declaration? Yes ☐ No ☐

Does the fragrance blend/aromatic substance/plant extract contain HICC, chloroatranol or atranol? Yes ☐ No ☐

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

_____

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_____

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_____

Date: Company name:

Signature (person responsible)

Name in block capitals E-mail and phone number

Appendix 6 Declaration from the packaging producer

www.nordic-ecolabel.org

Plastic packaging

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

If yes, specify the amount of recycled material in percent: _____

Paper, cardboard and board packaging

Is packaging paper, cardboard or board bleached with chlorine gas?	Yes ☐	No ☐
Is the paper/cardboard/board containing recycled material?	Yes ☐	No ☐

If yes, specify the amount of recycled material in percent: _____

Date: Company name:

Signature (person responsible)

Name in block capitals E-mail and phone number

Appendix 7 Calculations

1 CDV

CDV(chronic) = Σ(DFi x quantity (mg) of substance i per g AI/TFi (chronic))

DFi = degradation factor for substance i, as specified by the DID list

TFi = chronic toxicity factor for substance i, as specified by the DID list

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

DF and TF shall where possible be taken from the DID list dated January 2007 or later. If 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 2.

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

0.5 for organic substances that are inherently biodegradable according to Appendix 2.

1.0 for persistent organic substances.

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

TF = 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/LC_{50} value. If no long-term NOEC value is available the acute value and higher safety factor (SF) are to be used. The safety factor (SF) is established according to the following:

$SF_{chronic}$ (see Part B of the DID list for further details):

10 Substance with three long-term NOEC from at least three species representing three trophic levels.

50 Substance with two long-term NOEC from at least two species representing two trophic levels.

100 Substances with one long-term NOEC (fish or crustaceans).

1 000 Substances with acute toxicity data for each of three trophic levels.

5 000 Substances with acute toxicity data for two trophic levels.

10 000 Substances with acute toxicity data for only one trophic level.

2 Quantity of packaging

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

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

Where

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

$mf_{glass} = 0.2$

$mf_{paper/cardboard} = 0.6$

$mf_{plastic\ laminate} = 1.1$

$mf_{other\ materials} = 1.0$

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

rf_i = fraction of material recycled following consumer use.

For example, if 50% of the plastic in the packaging is sourced from post-consumer reclaimed material, $rf_{plastic}$ is 0.5. rf_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

ln = natural logarithm

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

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

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

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

$$\frac{\sum\left(mf_i \cdot Weight_{material\ i} \cdot \frac{(2-rf_i)}{2}\right) - \frac{Weight_{pump}}{2}}{t} \leq 13 \cdot ln\left(Vol_{product} + 1\right) + 0.035 \times Vo$$

$$\frac{\sum\left(1.0 \cdot 80g \cdot \frac{(2-0)}{2}\right) - \frac{10g}{2}}{1} \leq 13 \cdot ln\left(200 + 1\right) + 0.035 \times 200 + 4$$

$$\frac{80g - 5g}{1} \leq 68.94 + 7 + 4$$

$75 \leq 80$, *fulfills requirement*

Table 5 Examples of products wrapped in plastic packaging without pump and 0% recycled material that fulfil the requirement

Volume of product (ml)	Weight of packaging (g)
10	35
50	56
100	67
150	74
250	84
500	102
1000	128