Nordic Ecolabelling for

# Disposable bags, tubes and accessories for health care

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Nordic Ecolabelling

# Content




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# Contact info

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


**Denmark**
Ecolabelling Denmark
info@ecolabel.dk
www.svanemaerket.dk

**Finland**
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joutsen@ecolabel.fi
https://joutsenmerkki.fi/

**Sweden**
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# What is a Nordic Swan Ecolabelled disposable product for health care?

A Nordic Swan Ecolabelled disposable product for health care fulfils strict chemical requirements. The products do not contain PVC or harmful plasticisers. For many disposable health care products there are safe and economically viable alternatives to PVC and phthalates. EU legislation in the area is extensive and imposes strict requirements as to the safety of the products.

A Nordic Swan Ecolabelled disposable product for health care:

- Is a PVC- and phthalate free product
- Fulfils strict chemical requirements
- Fulfils EU legislation to ensure high product safety

# Why choose the Nordic Swan Ecolabel?

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

# What can carry the Nordic Swan Ecolabel?

Disposable products that can be labelled must be single-use products included under the Regulation (EU) 2017/745 on medical devices with subsequent amendments and adaptations and/or EU Medicinal Products Directive (2001/83/EC) as applicable. It is emphasized that Nordic Ecolabelling do not put any requirements to the medicinal product, but it is important that the medicinal product is according to the regulations and relevant directives.

The disposable product must be an alternative to products of softened PVC on the market. Products that can be labelled are:

- intravenous (IV) infusion treatment
- blood bags
- peritoneal dialysis (PD) treatment

- treatment of urinary retention and incontinence
- ostomy pouches and accessories for treatment following ileostomy, colostomy, or ureterostomy surgery

Other relevant disposable health care products, that are not mentioned above, may be included in the product group if they are an alternative to products made of softened PVC and if they are governed by the aforementioned regulation and directive. Nordic Ecolabelling will decide which new products may be included in the product group.

Some disposable products for medical use that are not included in these criteria can be labelled under the criteria for sanitary products, for example plasters, compresses, mattress covers/protectors, draw sheets, surgical gowns, patient gowns/patient covers, surgical masks and caps.

Disposable medical gloves cannot be labelled.

# How to apply

### Application and costs

For information about the application process and fees for this product group, please refer to the respective national web site. For contactinformation see first in this document.

### What is required?

The application must consist of an application form/web form and documentation showing that the requirements are fulfilled.

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

🔑 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.

### Licence validity

The Nordic Swan Ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be prolonged or adjusted, in which case the licence is automatically prolonged, 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 contactinformation first in this document. 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

### O1 Description of the product and production process

The applicant must provide the following information about the product and the production process:

- Trade name of the product
- Function of the product
- That the product is included in the Regulation (EU) 2017/745 and/or Directive 2001/83/EC.
- Information about the different components and their function (like bag for solutions, tubes, connectors etc.) and what materials* the different components are made of.
- A flowchart showing the production of the product, including information on what components are bought from external manufacturers and what processes are done externally and internally.

** Materials can be different plastics like polyethylene (PE), polyethylene terephthalate (PET), polyamide (PA) as well as other kind of materials like silicone.*

✉ Description in accordance with the requirement and flowchart that shows the production of the product (from the components to finalized product). Appendix 1 (applicant's declaration) and appendix 2 (for the manufacturer of the ecolabelled product) can be used.

# 2 Environmental and health requirements

This chapter covers both requirements to the materials in the product, and to chemicals added to the plastic material or used in or on the different components and product, like adhesives.

## 2.1 Materials

### O2 Halogenated plastics

Halogenated plastics such as PVC are not allowed in the product or packaging.

Packaging refers to any inner and outer packaging of the ecolabelled product, including transport packaging.

✉ Duly completed and signed appendix 2 by the manufacturer of the ecolabelled product. Equivalent documentation can be approved.

### O3 Latex

Latex (natural rubber) is not allowed in the product.

✉ Duly completed and signed appendix 2 by the manufacturer of the ecolabelled product. Equivalent documentation can be approved.

### O4 Silicone

**For products made of silicone, like a tube or catheter:**

Octamethylcyclotetrasiloxane, D4, (CAS 556-67-2), decamethylcyclopentasiloxane, D5, (CAS 541-02-6) and dodecamethylcyclohexasiloxane, D6, (CAS 540-97-6) must not form part of the silicone material. The requirement does not apply to D4, D5 and D6 contained as impurities* up to a limit of 100 ppm for each substance.

**For small parts of silicone, like sealing:**

Octamethylcyclotetrasiloxane, D4, (CAS 556-67-2), decamethylcyclopentasiloxane, D5, (CAS 541-02-6) and dodecamethylcyclohexasiloxane, D6, (CAS 540-97-6) must not form part of the silicone material. The requirement does not apply to D4, D5 and D6 contained as impurities* up to a limit of 1000 ppm for each substance.

* *Impurities of D4, D5 and D6 are defined as residual products from the raw material production that can be found in the silicone material.*

✉ Duly completed and signed appendix 4, Silicone in the product or appendix 5, Silicone in small parts. Equivalent documentation can be approved.

## 2.2 Chemicals

The requirements apply to:

- Plasticisers and other additives, e.g. colourants/pigments and antioxidants, added to the plastic to give the plastic certain properties.
- Adhesive used in or on the various parts/components of the product.

The requirements apply to additives added to both soft and hard plastic, and any other material that might be a part of the product, like rubber and silicone.

O5 concerns the classification of the chemical product and not the classification of ingoing substances in the chemical product. Chemical product refers to for instance adhesives, softeners, colourants/pigments, antioxidants or other additives. The requirements O6 and O7 and accompanying appendices apply to all ingoing substances in the chemical product, but not impurities unless stated otherwise in the requirements. Ingoing substances and impurities are defined below:

***Ingoing substances:*** *All substances in the chemical product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine) are also regarded as ingoing substances.*

***Impurities:*** *Residuals, pollutants, contaminants etc. from production, including production of raw materials that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg).*

The requirements do not apply to residual monomers in the plastic material from the production process of the plastic. However, for D4, D5 and D6 as residual products from the production of silicone there is a separate requirement, see O4.

There are no requirements for chemicals used for maintenance of machines or in the production processes (such as lubricants, cleaning chemicals etc.).

There are no requirements for chemicals used on the packaging, for instance adhesives and printing inks used on a cardboard box for packaging of the final product for transportation.

Information can be sent directly to Nordic Ecolabelling. Nordic Ecolabelling will provide confidentiality agreements if requested.

## O5 Chemical products, classification

The requirement applies to:

- Plasticisers and other additives e.g. colourants/pigments and antioxidants added to the plastic material.
- Adhesives used in or on the various parts/components of the product.

The plasticisers, other additives and adhesives cannot be classified according to table 1.

**Table 1. Classification**

| Classification under CLP Regulation (EC) No 1272/2008 | | |
|---|---|---|
| **Hazard class** | **Category** | **Hazard code** |
| Hazardous to the aquatic environment*,*** | Aquatic Acute 1<br>Aquatic Chronic 1<br>Aquatic Chronic 2<br>Aquatic Chronic 3<br>Aquatic Chronic 4 | H400<br>H410<br>H411<br>H412<br>H413 |
| Carcinogenic | Carc. 1A or 1B<br>Carc. 2 | H350<br>H351 |
| Germ cell mutagenicity | Muta. 1A or 1B<br>Muta. 2 | H340<br>H341 |
| Reproductive toxicity**** | Repr. 1A or 1B<br>Repr. 2<br>Lact. | H360<br>H361<br>H362 |
| Acute toxicity | Acute Tox 1 or 2<br>Acute Tox 1 or 2<br>Acute Tox 1 or 2<br>Acute Tox 3<br>Acute Tox 3<br>Acute Tox 3 | H300<br>H310<br>H330<br>H301<br>H311<br>H331 |
| Specific target organ toxicity | STOT SE 1<br>STOT SE 2<br>STOT RE 1<br>STOT RE 2 | H370<br>H371<br>H372<br>H373 |
| Aspiration hazard | Asp. Tox. 1 | H304 |
| Allergenic**,*** | Resp. sens 1, 1A and 1B or<br>Skin sens 1, 1A and 1B | H334<br>H317 |

** There is an exemption of up to 0,1 % by weight of additives classified as hazardous for the environment. The weight calculation shall be based on the total weight of the materials in the Nordic Swan Ecolabelled product. Any*

*pharmaceutical inside the Nordic Swan Ecolabelled product shall not be included in the weight of the product.*

*** There is an exemption for the classification H317 for the hardener of 2-component adhesives and for dye products used in components that do not come in contact with the medicinal solution or the patient during treatment.*

**** Exemptions for the classifications "Hazardous to the aquatic environment" and H317 (Skin sens 1, 1A and 1B) only applies to UV-cured acrylates-based adhesives cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.*

***** When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, exemption is given to antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the part at maximum 0.5% and assessed as safe and not detectable in an ISO 10993 evaluation.*

Exemption applies to:

- Titanium dioxide (CAS No. 13463-67-7) classified as H351.

✉ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier. Equivalent documentation with date and signature can also be approved. After assessment by Nordic Ecolabelling, the requirement may be documented solely by a duly completed and signed appendix 3.

✉ Exemption for UV-cured acrylates-based adhesives: Description of the application system and how workers are protected from exposure.

✉ Exemption for antioxidants classified as H361 in polyisoprene parts:

- Data from licensee confirming that a replacement is required for regulatory reasons due to release of n-nitrosamine impurities from polyisoprene part(s).
- Data from supplier showing that the level of such antioxidant does not exceed 0.5% in the polyisoprene material.
- An evaluation according to ISO 10993 concluding that the use of an antioxidant (classified as above) in the polyisoprene part is safe, and that the antioxidant is not released in detectable amounts from the medicinal product and medical device.

## O6 CMR substances

The requirement applies to:

- Plasticisers and other additives, e.g. colourants/pigments and antioxidants, added to the plastic material.
- Adhesives used in or on the various parts/components of the product.

Ingoing substances (apart from impurities) in the plasticisers, other additives and adhesives must not be classified as carcinogenic (Carc.), mutagenic (Muta.) and/or toxic for reproduction (Repr.) according to CLP Regulation (EC) No 1272/2008 (see Table 2).

For definition of ingoing substances and impurities, see beginning of the section 2.2 Chemicals.

**Table 2. Classification of CMR substances**

| Classification in line with CLP Regulation (EC) No 1272/2008 | |
|---|---|
| **Hazard class and category** | **H phrases (Code)** |
| Carcinogenic<br>Carc. 1A/1B<br>Carc. 2 | <br>H350<br>H351* |
| Mutagenic<br>Muta. 1A/B<br>Muta. 2 | <br>H340<br>H341 |
| Toxic for reproduction<br>Repr. 1A/1B<br>Repr. 2 | <br>H360, H361**, ***<br>H362 |

** Exemption is given for 2-component adhesives with isocyanates (classified H351), if the workers are not exposed during the production of the product and the isocyanates are cured in the finished product. Legislation for working environment must be fulfilled.*

*** Exemption is given to photoinitiators classified as H361 in UV-cured acrylates-based adhesives if the chemical product is cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.*

**** When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, exemption is given to antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the part at maximum 0.5 % and assessed as safe and not detectable in an ISO 10993 evaluation.*

Exemptions apply to:

- Titanium dioxide (CAS No. 13463-67-7) classified as H351.
- 1,1,1-Trimethylolpropane (TMP, CAS No. 77-99-6) classified as H361.

✉ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier.
Equivalent documentation with date and signature can also be approved.

✉ Exemption for 2-component adhesives with isocyanates (classified H351), a description of how the workers are protected and how the legislation for working environment is fulfilled.

✉ Exemption for photoiniators in UV-cured acrylates-based adhesives: Description of the application system and how workers are protected from exposure.

✉ Exemption for antioxidants classified as H361 in polyisoprene parts:

- Data from licence holder confirming that a replacement is required for regulatory reasons due to release of n-nitrosamine impurities from polyisoprene part(s).
- Data from supplier showing that the level of such antioxidant does not exceed 0.5 % in the polyisoprene material.
- An evaluation according to ISO 10993 concluding that the use of an antioxidant (classified as above) in the polyisoprene part is safe, and that the antioxidant is not released in detectable amounts from the medicinal product and medical device.

## O7 Other excluded chemical substances

The requirement applies to:

- Plasticisers and other additives like colourants/pigments and antioxidants added to the plastic material.

- Adhesives used in or on the various parts/components of the product.

Ingoing substances (apart from impurities) in the plasticisers, other additives and adhesives must not be from the list below.

For definition of ingoing substances and impurities, see beginning of the section 2.2 Chemicals.

**List of excluded substances**

- Substances on the Candidate List*

*D4, D5 and D6 in silicone polymers, see O4.*

- Substances that have been evaluated in the EU to be PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative)**
- Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects***
- Phthalates****

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

*** PBT and vPvB in accordance with the criteria in Annex XIII of REACH*

**** Substances considered being potential endocrine disruptors in category 1 or 2, see the following link: http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf, see appendix L*

***** Esters of phtalic acid (orthophthalic acid / phthalic acid /1,2-benzenedicarboxylic acid). The prohibition does not include polyethylene terephthalate (PET).*

✉ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier.
Equivalent documentation with date and signature can also be approved.

# 3 Safety requirement

## O8 Safety

Both product and parts must be safe to use and function well according to the EU Medicinal Products Directive (2001/83/EC) and/or the EU Medical Devices Regulation (2017/745) with subsequent amendments and adaptations, as applicable.

✉ Medical device: Copy of the approval/certificate from a notified body.
✉ Medicinal product: Copy of the market authorisation from the reference member state or national authority.

# 4 Quality and regulatory requirements

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

## O9 Responsible person and organisation

The company shall appoint individuals who are responsible for ensuring the fulfilment of the Nordic Ecolabelling 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.

## O10 Documentation

The licensee must archive the documentation that is sent in with the application.

🔑 Checked on site as necessary.

## O11 Quality of the disposable article

The licensee must guarantee that the quality of the Nordic Swan Ecolabelled disposable product does not deteriorate for its defined shelf-life 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 Swan Ecolabelled disposable article.

🔑 The claims archive is checked on site.

## O12 Planned changes

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

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

## O13 Unplanned nonconformities

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

✉ Procedures detailing how unplanned nonconformities are handled.

## O14 Traceability

The licensee must be able to trace the Nordic Swan Ecolabelled disposable product in the production.

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

## O15 Legislation and regulations

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

✉ Signed application form.

# Regulations for the Nordic Ecolabelling of products

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

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

The products may also be provided with following additional and explanatory text (replace "peritoneal dialysis" with correct term for other product categories):

- Disposable peritoneal dialysis product – does not contain PVC or
- The Nordic Swan Ecolabel requirements cover the packaging, bag and accessories

# Follow-up inspections

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

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

# Criteria version history

Nordic Ecolabelling adopted version 2.0 of the criteria on 09 September 2019. The criteria are valid until 31 December 2023.

On the 14 April 2020 Nordic Ecolabelling decided to adjust requirement O5. The new version is called 2.1.

On the 5 May 2021, Nordic Ecolabelling decided to adjust requirement O5. The new version is called 2.2.

On the 5 October 2021, Nordic Ecolabelling decided to adjust requirement O6 regarding an exemption for titanium dioxide and 1,1,1-Trimethylolpropane (TMP). Simultaneously, exemptions for UV-cured acrylates-based adhesives were introduced in requirements O5 and O6 according to the decision taken the 15 June. The new version is called 2.3.

Nordic Ecolabelling decided on 14 December 2021 to prolong the validity of the criteria to the 31 December 2024. The new version is called 2.4.

Nordic Ecolabelling decided on 29 November 2022 to prolong the validity of the criteria to the 31 December 2026. The new version is called 2.5.

Nordic Ecolabelling decided on 16 April 2024 to adjust requirement O6 regarding an exemption for antioxidants classified as toxic to reproduction cat 2 (H361) in polyisoprene parts on the conditions described in the requirement. The new version is called 2.6.

Nordic Ecolabelling decided on 15 October 2024 to adjust requirement O5 regarding an exemption for antioxidants classified as toxic to reproduction cat 2 (H361) in polyisoprene parts on the conditions described in the requirement. The new version is called 2.7.

Nordic Ecolabelling decided on 1 April 2025 to adjust requirement O5 regarding an exemption for titanium dioxide (CAS No. 13463-67-7) classified as H351. The new version is called 2.8.

# New criteria

- Look at the possibility to set requirements to harmful residual monomers in plastic material.
- Investigate status for recycling of PVC waste from the medical industry. Requirements for packaging, for instance certified fibres in cardboard.

# Appendix 1 Applicant's declaration

*For the requirements O1 and O8*

Trade name of the product(s): _____

Type of product:

Blood bag ☐

Intravenous (IV) infusion treatment ☐

Peritoneal dialysis treatment ☐

Treatment of urinary retention and incontinence ☐

Ostomy pouches and accessories for treatment following ileostomy, colostomy or ureterostomy surgery ☐

**Description of the product**

| Parts of the product | Function | Weight of part (g)* | Manufacturer (if external) | Legislation** |
|---|---|---|---|---|
| | | | | ☐ Medicinal product<br>☐ Medical device |
| | | | | ☐ Medicinal product<br>☐ Medical device |
| | | | | ☐ Medicinal product<br>☐ Medical device |
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| | | | | ☐ Medicinal product<br>☐ Medical device |
| | | | | ☐ Medicinal product<br>☐ Medical device |

* *Approximate weight in grams.*

** *The implementation of the EU Medicinal Products Directive (2001/83/EC) and the Regulation (EU) on Medical Devices (2017/745), with subsequent amendments and adaptations.*

### O8 Safety

Are the product and/or parts according to the EU Medicinal Products Directive (2001/83/EC) and/or the EU Medical Devices Regulation (2017/745) with subsequent amendments and adaptations. ☐ Yes ☐ No

Please attach:

- Medical device: Copy of the approval/certificate from a notified body.
- Medicinal product: Copy of the market authorisation from the reference member state or national authority.

### Signature

| | |
|---|---|
| Date and place: | Name of the company: |
| Responsible person: | Signature of responsible person: |

# Appendix 2 Description of the product and production process

*For the requirements O1, O2 and O3*

To be completed by the manufacturer of the ecolabelled product

Name of the product(s): _____

## 1. Production process

Please attach a flowchart showing the production of the product, including information on what components are bought from external manufacturers and what processes are done externally and internally.

## 2. Materials in the product

### O1 Materials in the product

Please fill in the table below:

| Parts of the product | Material* |
|---|---|
| | |
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* *Indicated as for instance PP, PE, PET, silicone and so on*

### O2 Halogenated plastics

Does the product or packaging* contain halogenated plastic? ☐ Yes ☐ No

State the material in the packaging:_____

**Packaging refers to any inner and outer packaging of the ecolabelled product.*

### O3 Latex

Does the product contain latex (natural rubber)? ☐ Yes ☐ No

## 3. Chemicals

### Additives

Are any additives* added to the plastic raw material** during the manufacturing process? ☐ Yes ☐ No

**Additives refer to for instance plasticisers, pigments and antioxidants.*

***Please note that this applies to both soft and hard plastic, and any other material that might be a part of the product, like rubber and silicone.*

If yes, please state the additives in the table below:

**Additives in the plastic**

| Parts | Name of plastic raw material | Additives (chemical name and or CAS No.) | Function |
|---|---|---|---|
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For documentation of the chemical requirements to additives, please use appendix 3.

### Adhesives

Is adhesive used in or on the various parts/components of the product? ☐ Yes ☐ No

If yes, state the name of the adhesive(s) in the table below:

| |
|---|
| |
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| |
| |

For documentation of the chemical requirements to adhesives, please use appendix 3.

### Signature

| | |
|---|---|
| Date and place: | Name of the producer of the disposable product for health care: |
| Responsible person: | Signature of responsible person: |

# Appendix 3 Plasticisers, other additives and adhesives

*For requirements O5, O6 and O7*

Filled out by:

Manufacturer of the ecolabelled product: ☐

Material supplier: ☐

Chemical supplier: ☐

Name of the chemical and purpose of use:

_____

The requirements (O6 and O7) apply to all ingoing substances in the chemical product (plasticisers, other additives and adhesives), but not impurities unless stated otherwise in the requirements. Ingoing substances and impurities are defined below:

**Ingoing substances:** All substances in the chemical product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine) are also regarded as ingoing substances.

**Impurities:** Residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg).

O5 Chemical product - classification

Is the plasticiser, additive or adhesive classified according to the table below?

| **Classification under CLP Regulation (EC) No 1272/2008** | | | |
|---|---|---|---|
| **Hazard class** | **Category** | **Hazard code** | |
| Hazardous to the aquatic environment* | Aquatic Acute 1<br>Aquatic Chronic 1<br>Aquatic Chronic 2<br>Aquatic Chronic 3<br>Aquatic Chronic 4 | H400<br>H410<br>H411<br>H412<br>H413 | ☐ Yes ☐ No |
| Carcinogenic | Carc. 1A or 1B<br>Carc. 2 | H350<br>H351 | ☐ Yes ☐ No |
| Germ cell mutagenicity | Muta. 1A or 1B<br>Muta. 2 | H340<br>H341 | ☐ Yes ☐ No |
| Reproductive toxicity**** | Repr. 1A or 1B<br>Repr. 2<br>Lact. | H360<br>H361<br>H362 | ☐ Yes ☐ No |
| Acute toxicity | Acute Tox 1 or 2<br>Acute Tox 1 or 2<br>Acute Tox 1 or 2<br>Acute Tox 3<br>Acute Tox 3<br>Acute Tox 3 | H300<br>H310<br>H330<br>H301<br>H311<br>H331 | ☐ Yes ☐ No |

| | | | |
|---|---|---|---|
| Specific target organ toxicity | STOT SE 1<br>STOT SE 2<br>STOT RE 1<br>STOT RE 2 | H370<br>H371<br>H372<br>H373 | ☐ Yes ☐ No |
| Aspiration hazard | Asp. Tox. 1 | H304 | ☐ Yes ☐ No |
| Allergenic**, *** | Resp. sens 1, 1A and 1B or<br>Skin sens 1, 1A and 1B | H334<br>H317 | ☐ Yes ☐ No |

** There is an exemption of up to 0,1 % by weight of additives classified as hazardous for the environment. The weight calculation shall be based on the total weight of the materials in the Nordic Swan Ecolabelled product. Any pharmaceutical inside the Nordic Swan Ecolabelled product shall not be included in the weight of the product. Please add a calculation showing that the requirement is fulfilled.*

*** There is an exemption for the classification H317 for the hardener of 2-component adhesives and for dye products used in components that do not come in contact with the medicinal solution or the patient during treatment.*

**** Exemptions for the classifications "Hazardous to the aquatic environment" and H317 (Skin sens 1, 1A and 1B) only applies to UV-cured acrylates-based adhesives cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.*

***** When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, exemption is given to antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the part at maximum 0.5 % and assessed as safe and not detectable in an ISO 10993 evaluation.*

Please state the name of the hardener:_____

## O6 Chemical substances - CMR

Are ingoing substances (apart from impurities) in the plasticiser, additive or adhesive classified as carcinogenic (Carc.), mutagenic (Muta.) and/or toxic for reproduction (Repr.) according to CLP Regulation (EC) No 1272/2008 (see table below):

**Classification of CMR substances**

| **Classification in line with CLP Regulation (EC) No 1272/2008** | | |
|---|---|---|
| **Hazard class and category** | **H phrases (Code)** | |
| Carcinogenic<br>Carc. 1A/1B<br>Carc. 2 | H350<br>H351* | ☐ Yes ☐ No<br>☐ Yes ☐ No |
| Mutagenic<br>Muta. 1A/B<br>Muta. 2 | H340<br>H341 | ☐ Yes ☐ No<br>☐ Yes ☐ No |
| Toxic for reproduction<br>Repr. 1A/1B<br>Repr. 2 | H360, H361**, ***<br>H362 | ☐ Yes ☐ No<br>☐ Yes ☐ No |

** Exemption is given for 2-component adhesives with isocyanates (classified H351, if the workers are not exposed during the production of the product) and the isocyanates are cured in the finished product. Legislation for working environment must be fulfilled.*

*** Exemption is given to photoinitiators classified as H361 in UV-cured acrylates-based adhesives if the chemical product is cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.*

**** When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, exemption is given to antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the part at maximum 0.5 % and assessed as safe and not detectable in an ISO 10993 evaluation.*

Exemptions apply to:

- Titanium dioxide (CAS No. 13463-67-7) classified as H351.
- 1,1,1-Trimethylolpropane (TMP, CAS No. 77-99-6) classified as H361.

### O7 Chemical substances – other excluded substances

Are ingoing substances (apart from impurities) in the plasticiser, additive and adhesive from the list below:

Substances on the Candidate List* ☐ Yes ☐ No

*For D4, D5 and D6 in silicone polymers, see O4.*

Substances that have been evaluated in the EU to be PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative)** ☐ Yes ☐ No

Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects*** ☐ Yes ☐ No

Phthalates**** ☐ Yes ☐ No

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

***PBT and vPvB in accordance with the criteria in Annex XIII of REACH*

**** Substances considered to be potential endocrine disruptors in category 1 or 2, see following link: http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf, see appendix L*

*****Esters of phtalic acid (orthophthalic acid / phthalic acid /1,2-benzenedicarboxylic acid). The prohibition does not include polyethylene terephthalate (PET).*

## Signature

| | |
|---|---|
| Date and place: | Name of company: |
| Responsible person: | Signature of responsible person: |

# Appendix 4 Silicone in the product

*For requirement O4*

Trade name of the silicone material:_____

Do octamethylcyclotetrasiloxane, D4, (CAS 556-67-2), decamethyl cyclopentasiloxane, D5, (CAS 541-02-6) and/or dodecamethyl cyclohexasiloxane, D6 (CAS 540-97-6) form part of the product? ☐ Yes ☐ No

Is the amount of D4, D5 and D6 as impurities* in concentrations below 100 ppm? ☐ Yes ☐ No

** The requirement does not apply to D4, D5 and D6 contained as impurities. Impurities are defined as residual products from the raw material production that can be found in the silicone material in concentrations below 100 ppm for each substance.*

**Signature**

| | |
|---|---|
| Date and place: | Name of company: |
| Responsible person: | Signature of responsible person: |

# Appendix 5 Silicone in small parts

*For requirement O4*

Trade name of the silicone material:_____

Do octamethylcyclotetrasiloxane, D4, (CAS 556-67-2), decamethylcyclopentasiloxane, D5, (CAS 541-02-6) and/or dodecamethylcyclohexasiloxane, D6 (CAS 540-97-6) form part of the product? ☐ Yes ☐ No

Is the amount of D4, D5 and D6 as impurities* in concentrations below 1000 ppm? ☐ Yes ☐ No

* *The requirement does not apply to D4, D5 and D6 contained as impurities. Impurities are defined as residual products from the raw material production that can be found in the silicone material in concentrations below 1000 ppm for each substance.*

**Signature**

| | |
|---|---|
| Date and place: | Name of company: |
| Responsible person: | Signature of responsible person: |