

Nordic Ecolabelling for

Disposable bags, tubes and accessories for health care



Version 1.8 ● 13 December 2007 – 31 December 2020

Addresses

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

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Disposable bags, tubes and accessories for health care

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What are Nordic Swan Ecolabelled disposable products for health care?

The Nordic health care sector uses PVC plasticised with phthalates such as DEHP in many disposable products. The incineration of PVC in waste incineration facilities generates large amounts of toxic residue. This residue has to be disposed of in controlled landfills. Many phthalates are problematic to health. DEHP reduces the size of testicles in laboratory animals and is classified as reproductively toxic and teratogenic. It is also known to cause allergy.

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. Nordic Swan Ecolabelled disposable health care products do not contain PVC or harmful plasticisers. The alternative plastic generates much less toxic residue in waste incineration and does not require the same quantity of plasticisers.

In disposable peritoneal dialysis products alone, Nordic Ecolabelling estimates that approximately 100 tons of phthalates can be avoided on a yearly basis in the Nordic countries if they meet the Nordic Ecolabel requirements. Furthermore the amount of problematic waste from this kind of products will reduce significantly.

Why choose the Nordic Swan Ecolabel?

- Manufacturers and distributors may use the Nordic Ecolabel, the Swan trademark, for marketing. The Nordic Swan Ecolabel is a very well-known and highly reputed trademark in the Nordic region.
- The Nordic Ecolabel is a cost-effective and simple way of communicating environmental work and commitment to customers and suppliers.
- Environmentally friendly operations prepare the products for future environmental legislation.
- Environmental issues are complex. It can take a long time and extensive resources to gain an understanding of a specific area. Nordic Ecolabelling can be seen as an aid in this work.
- The Nordic Swan Ecolabel not only covers environmental issues but also quality requirements, since environmental considerations and quality often go hand in hand. In the case of disposable products for PD and IV infusion treatment, the quality requirements are based entirely on the European legislation.

What can carry the Nordic Swan Ecolabel?

Disposable products intended and marketed exclusively for use in:

- intravenous (IV) infusion treatment,
- peritoneal dialysis (PD) treatment,
- treatment of urinary retention and incontinence and also
- ostomy pouches and accessories for treatment following ileostomy, colostomy, or ureterostomy surgery

under the EU Medicinal Products Directive (2001/83/EC) or the Medical Devices Directive (93/42/EEC) with subsequent amendments and adaptations qualify for a Nordic Swan Ecolabel if they are not covered by other Nordic Ecolabelling criteria at the time of application.

Other disposable health care products may be included in the product group if they are governed by the aforementioned directives. If your company is interested, please contact Nordic Ecolabelling.

In Nordic Ecolabelling criteria for sanitary products there is a possibility to ecolabel products such as incontinence care products, underlays, draw sheets, bed linen, wash cloths and surgical gowns for single use.

How to apply

Application and costs

For information about the application process and fees for this productgroup, please refer to the respective national web site. For addresses see in the beginning of 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 R or M and a number. All requirements relevant for the product must be fulfilled to be awarded a licence.

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

Enclose.

 The requirement checked on site.

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

Licence validity

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

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

On-site inspection

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

Queries

Please contact Nordic Ecolabelling if you have any queries or require further information. See for addresses in the beginning of 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

General requirements

R1 Description of the product

Describe the product.

- Appendix 1 duly completed and signed by the applicant.

Environmental and health requirements

Plastic material

R2 Halogenated plastics in the product

Halogenated plastics such as PVC are not allowed in the product (including the packaging).

- Appendix 2 duly completed and signed by the manufacturer of the product.

Plasticisers, other additives and adhesives

The plasticisers and other additives added to the plastic as well as adhesives used in or on the various parts of the product, including the packaging, must fulfil requirements R3 - R5.

R3 Hazardous to health and the environment

No plasticisers, other additives or adhesives may be classified as, or meet the criteria of, any of the following hazard classes or categories with the associated risk and hazard phrases and with the exception of up to 0,1 % by weight of additives classified as dangerous for the environment (the pharmaceutical inside as well as box for secondary packaging and transport packaging shall not be included in the weight of the product):

EU Dangerous Substances Directive and Dangerous Preparations Directive 67/548/EEC and 99/45/EC as amended		CLP Regulation 1272/2008	
Hazard class	Hazard designation and risk phrases	Hazard class and category	Hazard phrase
Environmental hazard			
Toxic to the environment	With N: R50, R50/53, R51/53, R59 Without N: R53, R52/53	Toxic to aquatic organisms - acute 1 Toxic to aquatic organisms - chronic 1/2/3/4 Dangerous to the ozone layer	H400 H410, H411, H412, H413 H420 (previously EU 059)
Carcinogenic/mutagenic/toxic for reproduction (CMR)			
Carcinogenic Car1 and Car2	T with R45, R49	Carcinogenicity Carc 1A/1B	H350*
Carcinogenic Car3	Xn with R40	Carcinogenicity Carc 2	H351
Mutagenic Mut1 and Mut2	T with R46	May cause genetic defects Muta 1A/1B	H340
Mutagenic Mut3	Xn with R68	May cause genetic defects Muta 2	H341
Toxic for reproduction Rep1 and Rep2	T with R60, R61	Toxic for reproduction Repr 1A/1B	H360*
Toxic for reproduction Rep3	Xn with R62, R63	Toxic for reproduction Repr 2	H361*
Other toxicological properties			
	R64 (May cause harm to breastfed children) in combination with other R phrases	Toxic for reproduction - effects on or through breast feeding	H362
	R33 (May accumulate in body after repeated exposure) in combination with other R phrases	Specific target organotoxicity - repeated exposure 2	H373*
Acutely deadly effects			
Very toxic	Tx with R26, R27, R28	Acute toxicity 1/2	H330, H310,

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			H300
Toxic	T with R23, R24, R25	Acute toxicity 2/3	H330, H331, H311, H301
Non-mortal permanent injury after a single exposure			
Very toxic or toxic	Tx with R39 in combination with R26, R27, R28 T with R39 in combination with R23, R24, R25	Specific target organotoxicity – single exposure 1	H370*
Harmful to health	Xn with R68 in combination with R20, R21, R22	Specific target organotoxicity – single exposure 2	H371*
Serious harmful effects due to repeated or long-lasting exposure			
Toxic or harmful to health	T with R48 in combination with R23/ R24, R25 Xn with R48 in combination with R20, R21, R22	Specific target organotoxicity - repeated exposure 1/2	H372*, H373*
Harmful to health	Xn with R65	Inhalation hazard 1	H304
Sensitising effects			
Local irritant	Xn with R42	Sensitising - respiration 1, A1 and 1B	H334
Local irritant	Xi with R43	Sensitising - skin 1, A1 and 1B	H317
Other hazards			
Toxic in contact with eyes	T with R39-41		EUH070
Develops toxic gas in contact with water	R29 in combination with other R phrases	Acute toxicity 1/2/3	EUH029
Develops toxic gas in contact with acid	R31 in combination with other R phrases	Acute toxicity 3	EUH031
Develops very toxic gas in contact with acid	R32 in combination with other R phrases	Acute toxicity 1/2	EUH032

**) If definitely proven that the hazard cannot be caused by other routes of exposure, the route of exposure can be stated as part of the hazard designation. Reproductive toxicity must be stated if known (effect on fertility or unborn child). One or two letters indicate the route of exposure (e.g. H350i – May cause cancer by inhalation) and/or type of effect. All additional codes are comprised by the requirement.*

Legally binding classifications of substances within the European Union can be found on the European Commission's ESIS website (European Chemical Substances Information System):

<http://esis.jrc.ec.europa.eu/index.php?PGM=cla>

Proposals for self-classification of environmental hazards for a number of substances can be found on a website compiled by the Nordic Council of Ministers in collaboration with the European Chemicals Bureau:

<http://apps.kemi.se/nclass/>

- ⌘ Typical examples of CMR substances are halogenated organic substances and some phthalates (for instance DEHP, DBP and BBP). Many of these substances are also dangerous to the environment. Other substances hazardous to the environment are lead and lead compounds.
- ☒ Appendix 2 duly completed and signed by the manufacturer of the product. As a help to gather information from suppliers appendices 3 and 4 can be used.

R4 Particularly problematic substances

No plasticisers or other additives added to the plastic or substances used in adhesives may have properties categorised in REACH (Registration, Evaluation and Authorisation of Chemicals) as substances of very high concern (SVHC) and similar substances, i.e.:

1. Category 1 or category 2 CMR substances (1A and 1B in CLP). Moreover category 3 CMR substances (category 2 in CLP) are also included even if they are not classified as SVHC substances in REACH.
2. PBT substances (persistent, bioaccumulative and toxic) and/or vPvB substances (very persistent and very bioaccumulative) in accordance with the criteria in Annex XIII of REACH (regulation 1907/2006/EC).
3. Substances considered to be hormone-disruptive or potentially hormone-disruptive in accordance with the European Union's reports and lists concerning hormone-disruptive substances.
4. Substances recorded on EU's Candidate List and not meeting the requirements in Section 1 - 3.

Regarding CMR classification, see classification requirements above.

As regards PBT or vPvB substances, see the list of substances fulfilling or substances that form substances fulfilling the PBT or vPvB criteria on the ESIS website (European Chemical Substances Information System). Substances that are "deferred" or substances that are "under evaluation" are not considered to have PBT or vPvB properties.

<http://esis.jrc.ec.europa.eu/index.php?PGM=pbt>

In the event of amendments, the most recently updated version will apply

Typical examples of PBT or vPvB substances are brominated flame retardants

As regards hormone-disruptive effects, see for example the EU's priority list of substances with hormone-disruptive effects in Annex L of the Final Report of the DHI study on:

http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm

Substances in categories 1 and 2 are regarded as hormone-disruptive. Please note that the EU list of hormone-disrupting substances has a class 3, for which the assessment is: "No scientific basis for inclusion on the list. Data available, but do not indicate a scientific basis for inclusion on the list". These substances are not considered hormone-disruptive. In the event of amendments, the most recently updated version will apply

Typical examples of hormone disruptive substances are various phthalates (e.g. DEHP, BBP, DBP, DINP and DNOP).

As regards the "Candidate List", please see the website of the European Chemicals Bureau:

http://echa.europa.eu/chem_data/candidate_list_table_en.asp

For information on monitoring of SVHC, please see the "Intention List". This list is not binding for Nordic ecolabelling purposes, unless the substance appears on some of the other lists above, but it may be useful to stay ahead of developments:

http://echa.europa.eu/chem_data/reg_int_tables/reg_int_curr_int_en.asp

See R3.

R5 Phthalates

The phthalates DEHP, BBP, DBP, DINP, DNOP and DIDP may not be used as plasticisers or other additives, nor may they be used in adhesives.

The requirement is based on the EU Toys Directive. However, Requirements R3 and R4 will already exclude DEHP, BBP, DBP, DINP and DNOP.

See R3.

The product

R6 Recycling system

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

Quality and safety requirements

R7 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 Medical Devices Directive (93/42/EEC) with subsequent amendments and adaptations.

If it is a medical device: A copy of the approval/certificate from a notified body.

If it is a medicinal product: A copy of the market authorisation from the reference member state or national authority.

Other requirements

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

The environmental management requirements are fulfilled when completing and following the instructions in Appendix 5 or when equivalent sections are added to the internal procedures of the organisation. If the applicant wishes to adjust the wording

or format of the procedures in Appendix 5 (without changing their content or meaning) in order to secure a better fit with management systems already established in the company, they may be ordered electronically from Nordic Ecolabelling in an editable format.

M1 Legislation and regulatory requirements

The applicant must ensure compliance with the applicable legislation, including regulations governing safety, the working environment and the external environment plus any permits required by the authorities for the production and handling of the ecolabelled product.

Signed application form.

M2 Organisation and responsibility

The applicant must have procedures and an organisational structure that ensure that the requirements of the ecolabelling criteria are fulfilled at all times. A person responsible for monitoring or quality and a contact person for ecolabelling must be appointed.

Completed and signed Appendix 5. If an environmental or quality management system has been certified (ISO 9001/14001 or EMAS) and if procedures equivalent to those in Appendix 5 already form part of the certified system, copies of the relevant procedures are sufficient.

M3 Documentation of the application

The applicant must ensure that all documentation relating to the application and ongoing supervision of the requirements is collected in one place.

See M2.

M4 Keeping records

The manufacturer must have a system in place for logging and storing documentation of compliance with the ecolabelling requirements.

If the manufacturer has a certified environmental management system (ISO or EMAS) for the production of the eco-labelled product, information from an environmental audit or an environmental report can be used as documentation, if the information meets the requirements in this document.

The same applies if the company issues green accounts, environmental reports or the like.

See M2.

M5 Traceability

Nordic Ecolabelled products must be possible to trace in the manufacturing process so that they are distinguished from other non-labelled products.

See M2.

M6 Information

Unless the product/packaging is provided with additional text and explanatory text from the section about design of the Nordic Ecolabel, the applicant must describe how users of the Nordic Ecolabelled product get equivalent information and which channels are used to provide it.

- Description of how the applicant provides information and which channels that are used.

M7 Marketing

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

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.ecolabel.dk/regulations/ or at www.nordic-ecolabel.org/regulations/

Nordic Swan Ecolabelled disposable health care products

Licensed products can use the Nordic Swan Ecolabel, with the obligatory text and licence number, on the product or on the packaging of the product or in marketing. The products may also be provided with following additional and explanatory text (replace “peritoneal dialysis” with correct term for other product categories):

Danish: Engangsprodukt til peritoneal dialyse - indeholder ikke PVC

Swedish: Engångsprodukt till peritoneal dialys - innehåller ej PVC

Finnish: Kertakäyttötuotteet peritoneaalidialyysissä - ei sisällä PVC:a

Norwegian: Engangsprodukt til peritoneal dialyse - inneholder ikke PVC

Icelandic: Einnota vara til notkunar við kviðskilun - inniheldur ekki PVC

English: Disposable peritoneal dialysis product – does not contain PVC

If the ecolabelled product is a medicinal product one or more of the following explanatory texts may be used:

Danish: Svanens krav dækker emballagen, posen og tilbehøret

Swedish: Svanens krav omfattar förpackningen, påsen och tillbehör

Finnish: Joutsenmerkin vaatimukset kattavat pakkauksen, pussin ja tarvikkeet

Norwegian: krav omfatter emballasjen, posen og tilbehør

Icelandic: Kröfur Svansins ná yfir umbúðir, poka og fylgihluti

English: The Nordic Ecolabel requirements cover the packaging, bag and accessories

If the licence holder wishes to use a designation other than the above-mentioned and or a language other than those specified, advance approval must be secured from Nordic Ecolabelling.

If only accessories are ecolabelled, an alternative designation in the additional text may be used that clearly indicate which kind of accessories they are (e.g. “Tube for IV infusion treatment”). The designation must be approved by Nordic Ecolabel in advance.

Follow-up inspections

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

The licence may be revoked if it is evident that babyproduct with textile does not meet the requirements.

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

How long is a licence valid?

Nordic Ecolabelling adopted the criteria for disposable peritoneal dialysis and intravenous infusion products on 13 December 2007. The criteria are valid until 31 December 2010.

At the Secretariat Directors’ meeting on 25 June 2008 it was decided to introduce a trivial limit for additives classified as hazardous to the environment and to make a few textual adjustments. The change affected the requirement R4 and resulted in criteria version 1.1 valid until 31 December 2010.

The Nordic Ecolabelling Board adopted on 8 June 2009 a change, a few adjustments and prolongation of the criteria. There was also a change to a more widespread name of the product group. The change consisted of expanding the product group. The criteria were prolonged for 2 years; the new criteria version is called 1.2 and is valid until 31 December 2012.

On 15 November 2011 the secretariat managers meeting decided to prolong the criteria until 31 December 2013. The new version is called 1.3.

On 9 October 2012 the Nordic Ecolabelling Board adopted a change, adjustments and prolongation of the criteria. The change affected obligatory text in connection with the logo.

The adjustment relates to an update of the chemical requirements according to REACH and CLP. The criteria were prolonged for two years; the new criteria version is called 1.4 and is valid until 31 December 2015.

On 22 October 2014 the Board of Directors decided to prolong the criteria for two years. The new criteria version is called 1.5 and is valid until 31 December 2017.

On 8 February 2016 the Nordic Ecolabelling Board decided to prolong the criteria for two years. On 17 November 2014 the Board of Directors decided to remove requirement M7 Marketing. The new criteria version is called 1.6 and is valid until 31 March 2019.

On 9 October 2017 Nordic Ecolabelling's Criteria Group decided to remove R6 - Recycling system. On 12 September 2018 Nordic Ecolabelling's Criteria Group decided to prolong the criteria. The new criteria version is called 1.7 and is valid until 30 June 2020.

On 18 June 2019 Nordic Ecolabelling decided to prolong the criteria. The new criteria version is called 1.8 and is valid until 31 December 2020.

Future criteria

In future criteria, Nordic Ecolabelling will, among other things, consider whether to include requirements regarding:

- energy
- recyclability of materials, labelling and design
- process contaminants and residues
- working environment, such as forced ventilation and personal equipment

Terms and definitions

Term	Explanation or definition
Accessories	Disposable medical devices used for PD and IV infusion treatment.
Additive	A chemical substance or preparation intentionally added to the plastic. Additives can be heat stabilisers, antioxidants, UV-stabilisers, flame retardants, dyes, pigments, plasticisers, etc.
Adhesives	Adhesives in their pure form used in or on the product, but also adhesives supplied on prefabricated labels and so on.
BBP	Benzyl butyl phthalate (CAS No. 85-68-7)
Chemicals	Chemical preparations or chemical substances. The authorities have rules for classifying chemical preparations and substances.
DBP	Dibutyl phthalate (CAS No. 84-74-2)
DEHP	Diethylhexyl phthalate (CAS No. 117-81-7)
DIDP	Diisodecyl phthalate (CAS Nos. 26761-40-0 and 68515-49-1)
DINP	Diisononyl phthalate (CAS Nos. 28553-12-0 and 68515-48-0)
DNOP	Di-n-octyl phthalate (CAS No. 117-84-0)
Intravenous (IV) infusion treatment	Intravenous infusion is a method to convey medication fluids and other fluids such as dextrose or electrolyte solutions into the bloodstream of the patient. Blood is not an infusion fluid. An IV set-up includes a bag containing a solution and tubing that conveys the solution from the bag to the catheter inserted into the vein.
Manufacturer	Company that manufactures the product that is to be labelled with the Nordic Ecolabel. Manufacturing comprises the plastic processing such as injection moulding, extrusion, thermoforming, blow moulding, etc. of the parts in the product and assembling of the parts and packaging.
PD (peritoneal dialysis)	A treatment available for patients with kidney disease. The primary components of peritoneal dialysis are the dialysis solution (dialysate) and its container, fill and drain lines, catheter, and drainage bag. In peritoneal dialysis, the patient introduces dialysate into the body through the fill line and a surgically implanted catheter. The peritoneum removes waste products from the blood and discharges them into a drain line that connects to a drainage bag.

Plastic	<p>Organic material composed of polymers made by modification of natural materials or polymerisation of primary substances from oil, natural gas or coal. The plastic may contain other substances to improve performance.</p> <p>Based on properties and structure plastics are divided into three main categories: thermoplastics, thermosets and elastomers.</p>
Plasticiser	<p>Additive which, when added to the plastic, produces a product that is flexible, resilient and easier to handle.</p>
Producer of plastic raw material	<p>Company that manufactures the plastic raw material. The production process comprises polymerisation and compounding. Compounding is the process of mixing the basic polymer with additives.</p>
Product	<p>The pharmaceutical, its container and other connected parts, as well as any inner and outer packaging, carton or transport packaging. There are different understandings as to what primary and secondary packaging are, but both kinds are always part of the product in this context, as well as any carton and the transport packaging. The last is often made of cardboard. Accessories and their connected parts used in PD and IV infusion treatment and their packaging are also considered to be products.</p>
Supplier	<p>Company that supplies goods or services to the manufacturer. The definition is based on the definition in ISO 9000:2000.</p>

Appendix 1 Applicant's declaration

For use in applications for a licence for a Nordic Swan Ecolabel for disposable bags, tubes and accessories for health care. In signing this form, the applicant undertakes to keep the submitted information updated as long as the criteria are valid. The form may be obtained electronically in an editable format from Nordic Ecolabelling.

Name of the product(s): _____

1. Description of the product

Parts and packaging	Function	Weight of part (g)*	Manufacturer (if external)	Material	Legislation**
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
					<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device

*) Approximate weight in grams.

**) The implementation of the EU Medicinal Products Directive (2001/83/EC) and the Medical Devices Directive (93/42/EEC), with subsequent amendments and adaptations.

2. Recycling system

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

3. Safety

The product and parts are be safe to use and function well in accordance with the EU Medicinal Products Directive (2001/83/EC) and or the Medical Devices Directive (93/42/EEC) with subsequent amendments and adaptations.

- If it is a medical device:* A copy of the approval/certificate from a notified body.
- If it is a medicinal product:* A copy of the market authorisation from the reference member state or national authority.

Signature

We declare that the requirements have been met and that the information provided is accurate and correct.

Date and place	Company
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Signature, contact person

Name of contact person, printed	Phone
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If the contact person changes, a new declaration must be submitted to Nordic Ecolabelling.

Appendix 2 Manufacturer's declaration

For use in applications for a licence for a Nordic Swan Ecolabel for disposable bags, tubes and accessories for health care. In signing this form, the manufacturer undertakes to keep the submitted information updated during the validity period of the criteria.

The form may be obtained electronically in an editable format from Nordic Ecolabelling.

The manufacturer can use Appendices 3 and 4 as a help to gather information from suppliers.

Name of the product(s): _____

1. Plastics for the product including packaging

Neither the parts of the product nor the packaging consists of halogenated plastics such as PVC.

Part of the product and packaging	Name*) of plastic raw material

*) Indicated as for instance PP, PE and so on.

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

If yes, add the part/packaging name and the additives in the table in section 2.

2. Additives in the plastic

Part/packaging	Name of plastic raw material	Additives (chemical name and or CAS No.)	Function	Additives comply with requirements in Appendix 4
				Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/>

- Enclose EU material safety data sheet or other technical data sheet for each additive. If there are several different suppliers of the additive it is enough to supply a material safety data sheet from one of the suppliers.

3. Adhesives

Are any adhesives used in the product? Yes No

If yes, fill in the table:

Name of adhesive	Adhesive comply with requirements in Appendix 4
	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Yes <input type="checkbox"/> No <input type="checkbox"/>

- Enclose EU material safety data sheet or other technical data sheet for each adhesive. If there are several different suppliers of the adhesive it is enough to supply a material safety data sheet from one of the suppliers.

Signature

We declare that the requirements have been met and that all information provided is accurate and correct.

Date and place	Company
----------------	---------

Signature, contact person

Name of contact person, printed	Phone
---------------------------------	-------

If the contact person changes, a new declaration must be submitted to Nordic Ecolabelling.

Appendix 3 Declaration by producer of plastic materials

For use as a help to the manufacturer to gather information from suppliers when applying for a licence for a Nordic Swan Ecolabel for disposable bags, tubes and accessories for health care.

In signing this form, the producer of the plastic material undertakes to keep the submitted information updated during the validity period of the criteria.

The form may be obtained electronically in an editable format from Nordic Ecolabelling.

Name on the plastic material/name of polymer: _____

Additives in the plastic material

Additives (chemical name and or CAS No.)	Function	Supplier and location of supplier

Signature

We declare that the information provided is accurate and correct.

Date and place Company

Signature, contact person

Name of contact person, printed Phone

If the contact person changes, a new declaration must be submitted.

Appendix 4 Requirements for plasticisers and other additives in the plastic material and for adhesives

This form is for use as a help to the manufacturer to gather information from suppliers when applying for a license for Nordic Ecolabel for disposable bags, tubes and accessories for health care.

In signing this form, the supplier or manufacturer undertakes to keep the information submitted up to date during the validity period of the criteria.

Nordic Ecolabelling is, however, entitled to seek information on the full composition of the chemical from the chemical manufacturer/supplier in order, where necessary, to check the contents of the chemical.

The final section of the criteria document contains explanations and definitions of words and terms that may be difficult to interpret. If you are unsure, always check the Nordic Ecolabel definition.

The form may be obtained electronically in an editable format from Nordic Ecolabelling.

Please complete the form for chemical identification below.

Country	Trade name (where applicable, fill in CAS No.)	Or group designation*), where applicable	Product number, where applicable
Internationally			
Sweden			
Norway			
Iceland			
Finland			
Denmark			

∅ *) A group designation is a trade name covering a group of similar chemicals.

☒ Enclose EU material safety data sheet or other technical data sheet.

Function of the chemical:

Plasticiser Other additive, specify: _____

Adhesive

1 Hazardous to health and the environment

Neither the additive nor the adhesive is classified as belonging to, or meet the criteria of, any of the following hazard classes or categories with the associated risk and hazard phrases:

EU Dangerous Substances Directive and Dangerous Preparations Directive 67/548/EEC and 99/45/EC as amended		CLP Regulation 1272/2008	
Hazard class	Hazard designation and risk phrases	Hazard class and category	Hazard phrase
Environmental hazard			
Toxic to the environment	With N: R50, R50/53, R51/53, R59 Without N: R53, R52/53	Toxic to aquatic organisms - acute 1 Toxic to aquatic organisms - chronic 1/2/3/4 Dangerous to the ozone layer	H400 H410, H411, H412, H413 H420 (previously EU 059)
Carcinogenic/mutagenic/toxic for reproduction (CMR)			
Carcinogenic Car1 and Car2	T with R45, R49	Carcinogenicity Carc 1A/1B	H350*
Carcinogenic Car3	Xn with R40	Carcinogenicity Carc 2	H351
Mutagenic Mut1 and Mut2	T with R46	May cause genetic defects Muta 1A/1B	H340
Mutagenic Mut3	Xn with R68	May cause genetic defects Muta 2	H341
Toxic for reproduction Rep1 and Rep2	T with R60, R61	Toxic for reproduction Repr 1A/1B	H360*
Toxic for reproduction Rep 3	Xn with R62, R63	Toxic for reproduction Repr 2	H361*
Other toxicological properties			
	R64 (May cause harm to breastfed children) in combination with other R phrases	Toxic for reproduction - effects on or through breast feeding	H362
	R33 (May accumulate in body after repeated exposure) in combination with other R phrases	Specific target organotoxicity - repeated exposure 2	H373*
Acutely deadly effects			
Very toxic	Tx with R26, R27, R28	Acute toxicity 1/2	H330, H310, H300
Toxic	T with R23, R24, R25	Acute toxicity 2/3	H330, H331, H311, H301
Non-mortal permanent injury after a single exposure			
Very toxic or toxic	Tx with R39 in combination with R26, R27, R28 T with R39 in combination with R23, R24, R25	Specific target organotoxicity - single exposure 1	H370*

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Harmful to health	Xn with R68 in combination with R20, R21, R22	Specific target organotoxicity – single exposure 2	H371*
Serious harmful effects due to repeated or long-lasting exposure			
Toxic or harmful to health	T with R48 in combination with R23/ R24, R25 Xn with R48 in combination with R20, R21, R22	Specific target organotoxicity - repeated exposure 1/2	H372*, H373*
Harmful to health	Xn with R65	Inhalation hazard 1	H304
Sensitising effects			
Local irritant	Xn with R42	Sensitising - respiration 1, A1 and 1B	H334
Local irritant	Xi with R43	Sensitising - skin 1, A1 and 1B	H317
Other hazards			
Toxic in contact with eyes	T with R39-41		EUH070
Develops toxic gas in contact with water	R29 in combination with other R phrases	Acute toxicity 1/2/3	EUH029
Develops toxic gas in contact with acid	R31 in combination with other R phrases	Acute toxicity 3	EUH031
Develops very toxic gas in contact with acid	R32 in combination with other R phrases	Acute toxicity 1/2	EUH032

**) If definitely proven that the hazard cannot be caused by other routes of exposure, the route of exposure can be stated as part of the hazard designation. Reproductive toxicity must be stated if known (effect on fertility or unborn child). One or two letters indicate the route of exposure (e.g. H350i – May cause cancer by inhalation) and/or type of effect. All additional codes are comprised by the requirement.*

Legally binding classifications of substances within the European Union can be found on the European Commission's ESIS website (European Chemical Substances Information System):

<http://esis.jrc.ec.europa.eu/index.php?PGM=cla>

Proposals for self-classification of environmental hazards for a number of substances can be found on a website compiled by the Nordic Council of Ministers in collaboration with the European Chemicals Bureau:

<http://apps.kemi.se/nclass/>

Typical examples of CMR substances include halogenated organic substances and certain phthalates (e.g. DEHP, DBP and BBP). Moreover, many of these substances are environmentally harmful. Other environmentally harmful substances include lead and lead compounds.

2 Particularly problematic substances

The additive or any substance used in the adhesive is not regarded as having properties categorised in REACH (Registration, Evaluation and Authorisation of Chemicals) as substances of very high concern (SVHC) and similar substances, i.e.:

1. Category 1 or category 2 CMR substances (1A and 1B in CLP). Moreover category 3 CMR substances (category 2 in CLP) are also included even if they are not classified as SVHC substances in REACH.
2. PBT substances (persistent, bioaccumulative and toxic) and/or vPvB substances (very persistent and very bioaccumulative) in accordance with the criteria in Annex XIII of REACH (regulation 1907/2006/EC).
3. Substances considered to be hormone-disruptive or potentially hormone-disruptive in accordance with the European Union's reports and lists concerning hormone-disruptive substances.
4. Substances recorded on EU's Candidate List and not meeting the requirements in Section 1 - 3.

Regarding CMR classification, see classification requirements above.

As regards PBT or vPvB substances, see the list of substances fulfilling or substances that form substances fulfilling the PBT or vPvB criteria on the ESIS website (European Chemical Substances Information System). Substances that are "deferred" or substances that are "under evaluation" are not considered to have PBT or vPvB properties.

<http://esis.jrc.ec.europa.eu/index.php?PGM=pbt>

In the event of amendments, the most recently updated version will apply

Typical examples of PBT or vPvB substances are brominated flame retardants

As regards hormone-disruptive effects, see for example the EU's priority list of substances with hormone-disruptive effects in Annex L of the Final Report of the DHI study on:

http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm

Substances in categories 1 and 2 are regarded as hormone-disruptive. Please note that the EU list of hormone-disrupting substances has a class 3, for which the assessment is: "No scientific basis for inclusion on the list. Data available, but do not indicate a scientific basis for inclusion on the list". These substances are not considered hormone-disruptive. In the event of amendments, the most recently updated version will apply

Typical examples of hormone disruptive substances are various phthalates (e.g. DEHP, BBP, DBP, DINP and DNOP).

As regards the "Candidate List", please see the website of the European Chemicals Bureau:

http://echa.europa.eu/chem_data/candidate_list_table_en.asp

For information on monitoring of SVHC, please see the "Intention List". This list is not binding for Nordic ecolabelling purposes, unless the substance appears on some of the other lists above, but it may be useful to stay ahead of developments:

http://echa.europa.eu/chem_data/reg_int_tables/reg_int_curr_int_en.asp

3. Phthalates

The additive is not DEHP, BBP, DBP, DINP, DNOP or DIDP, and none of these phthalates have been used in the adhesive.

⚙ The requirement is based on the EU Toys Directive. However, the requirements in sections 1 and 2 will already exclude DEHP, BBP, DBP, DINP and DNOP.

Signature

We declare that the requirements have been met and that the information provided is accurate and correct.

Supplier: _____

Producer: _____

Company name:	
Address:	
Tel.:	Date:
E-mail:	
Signature, contact person:	
Name (printed):	

If the contact person changes, a new declaration must be submitted.

Appendix 5 Procedures and instructions (M1-M5)

This form is to be used to document the fact that the manufacturer is able to meet Nordic Ecolabelling's requirements for as long as the licence is valid.

If the applicant wishes to adjust the wording or format of the procedures (without altering their content or meaning) to achieve a better fit with management systems already established in the company, this appendix is available electronically in an editable format from Nordic Ecolabelling.

Physical location of copy of application and any other information used in the application: _____

Physical location of records and documentation for annual reports (see M4): _____

1 Legislation and authorities (M1)

Name of regulatory environmental authority: _____

Address: _____

Contact person, where applicable: _____

Name of regulatory working-environment authority: _____

Address: _____

Contact person, where applicable: _____

2 Organisation and responsibility (M2)

Contact person for Nordic Ecolabelling: _____

Person responsible for environmental matters: _____

Person responsible for quality matters: _____

Person responsible for marketing matters: _____

Person responsible for day-to-day operations: _____

In the event of changes in staff areas of responsibility, the contact person must notify Nordic Ecolabelling as soon as the change has been implemented.

3 Procedure for documenting, processing and reporting non-conformities, claims/complaints and changes (M4)

The purpose of this procedure is to ensure that Nordic Ecolabel requirements are met in the event of non-conformities, complaints and changes.

The procedure covers all production of ecolabelled products by the manufacturer.

- The contact person is responsible for documenting and processing unforeseen non-conformities and changes (for instance on plastic raw materials, additives and adhesives) and for all reporting to Nordic Ecolabelling. This responsibility may be delegated to others.
- _____ (name) is responsible for documenting and processing claims/complaints. This responsibility may be delegated to others.

Changes

- In the event of changes to the information on which the original application for the Nordic Ecolabel was based, the contact person must notify Nordic Ecolabelling in writing before the change is implemented. This could, for example, involve changes in the ecolabelled product or applicable changes in the law, i.e. in the Medicinal Products Directive or Medical Devices Directive.
- The contact person will determine whether a change affects compliance with the criteria.
- In a letter to Nordic Ecolabelling, the contact person must state the nature of the change and how it affects the ecolabelling criteria. In addition, the contact person must attach a completed and signed application form for a change and/or extension of the licence.
- The change will be implemented only when a reply has been received from Nordic Ecolabelling. The contact must ensure that all correspondence with Nordic Ecolabelling is documented and filed together with the original application.

Non-conformities

- In the event of non-conformities that affect compliance with the ecolabelling criteria, the contact person must notify Nordic Ecolabelling in writing immediately after the non-conformity has taken place.
- First of all, the contact person is to determine whether or not a non-conformity affects compliance with the criteria. Whether or not it does, the contact person must always file a non-conformity report if he/she is requested to do so by Nordic Ecolabelling.

- A non-conformity report contains a description of the nature of the non-conformity, an account of its scope, a description of how the non-conformity occurred, a description of the steps taken to remedy the non-conformity and a plan for avoiding similar non-conformities in the future.
- If the plan encompasses changes relative to the original application, the contact person will treat this in the same way as a change.
- The contact person must ensure that all correspondence with Nordic Ecolabelling is documented and filed together with the original application.

Complaints

- In the event of written complaints or claims, the person with responsibility for this area will reply to the party making the complaint. The reply must contain a clear decision on the complaint or claim and, if applicable, also information about compensation and a clear specification of the reasons underlying the decision.
- The person responsible will ensure that all written complaints and claims are documented and filed together with the original application.
- If the complaint results in changes in the internal working method, the contact person for Nordic Ecolabelling must be notified.

4 Procedures for ensuring traceability (M5)

The purpose of this procedure is to ensure that ecolabelled products are kept separate from products not labelled.

The procedure covers all production by the manufacturer.

- The contact person for Nordic Ecolabelling is responsible for ensuring that products that are to be ecolabelled are marked clearly so that they can be kept separate from other products. This responsibility may be delegated to others. For this purpose, the following information must follow the product throughout the manufacturing process:
 - Plastic material used and name of supplier
 - Information to the effect that PVC must not be used as a material

Production sheet or similar.

5 Procedures for recording and storing information in records (M4)

The purpose of this procedure is to ensure that records are maintained and stored.

The procedure covers all production of ecolabelled products by the manufacturer.

The Nordic Ecolabelling contact person is responsible for keeping these records. This responsibility may be delegated to others.

- The contact person investigates whether any changes have occurred in relation to the application and whether the ecolabelling criteria are still fulfilled.
- If such major changes have occurred that the criteria are no longer fulfilled, a non-conformity is involved (see section 2 above).
- The contact person ensures that the documentation, such as invoices, reports, measurements or excerpts from the accounting system, and operating logs are stored together with the original application for inspection by Nordic Ecolabelling as long as the ecolabelling licence remains in force.

Appendix 6 Marketing of disposable products for health care (M7)

The appendix is removed as decided by the Board of Directors 17 November 2014.