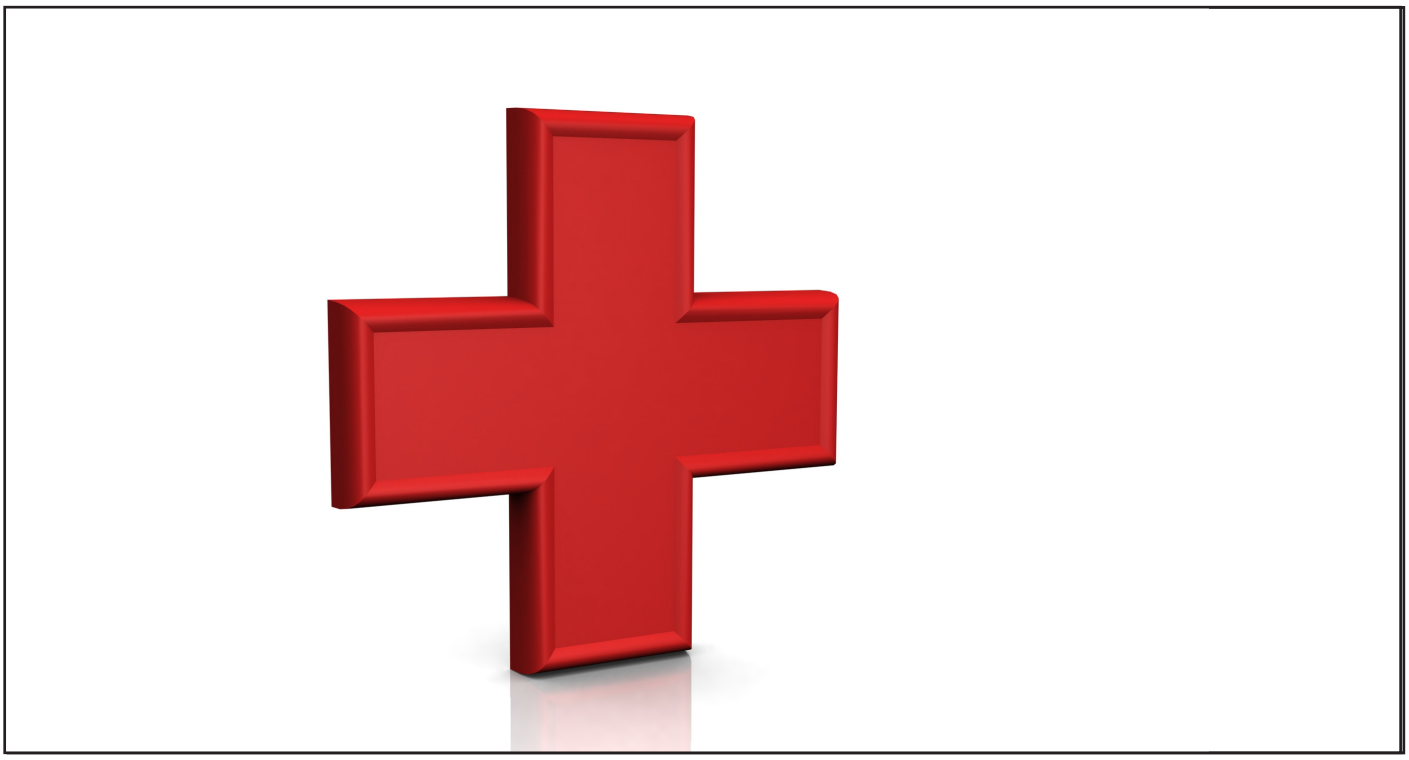
Nordic Ecolabelling of

Disposable bags, tubes and accessories for health care



Version 1.4 • 13 December 2007 – 31 December 2015

Nordic Ecolabelling

Content

098, Disposable bags, tubes and accessories for health care, version 1.4, 9 October 2012

This document is a translation of an original in Danish.
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 Ecocolabelling system on behalf of their own country's government. For more information, see the websites.

Denmark
Ecolabelling Denmark
Danish Standards Foundation
Kollegievej 6
DK-2920 Charlottenlund
Phone +45 72 300 450
Fax +45 72 300 451
E-mail: info@ecolabel.dk
www.ecolabel.dk

Sweden
Ecolabelling Sweden
SE-118 80 Stockholm
Phone +46 8 55 55 24 00
Fax +46 8 55 55 24 01
E-mail: svanen@ecolabel.se
www.ecolabel.se

Norway
Ecolabelling Norway
Tordenskiolds gate 6 B
NO-0160 Oslo
Phone +47 24 14 46 00
Fax +47 24 14 46 01
E-mail: info@ecolabel.no
www.ecolabel.no

Finland
Ecolabelling Finland
Box 489
FI-00101 Helsinki
Phone +358 424 2811
Fax +358 424 281 299
E-mail: joutsen@motiva.fi
www.ecolabel.fi

Iceland
Ecolabelling Iceland
Umhverfisstofnun
Suðurlandsbraut 24
IS-108 Reykjavik
Phone +354 591 20 00
Fax +354 591 20 20
E-mail: svanurinn@ust.is
www.svanurinn.is

What are Nordic 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 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 Ecolabel?

- Manufacturers and distributors may use the Nordic Ecolabel trademark, the Swan, for marketing. The Nordic Ecolabell 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 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 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 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. See page 2 for contact information.

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

Each requirement is marked with the letter R and a number. R stands for "requirement". All requirements must be fulfilled before a licence can be awarded. Other requirements intended to ensure that ecolabelling requirements are complied with after the licence has been granted are labelled "M" plus a number and must also be fulfilled.

The last section of the document contains a list of definitions and explanations that are central to the proper interpretation and understanding of the requirements. In case of dispute, the definitions and explanations in the list should be taken as authoritative.

Icons in the text

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

✉ Enclose documentation.

🔑 The requirement is checked on site.

Application

Applications are made to the national ecolabelling organisation and the application is valid for 12 months. Applications may be processed by another ecolabelling organisation according to agreement between the organisations. The applicant is notified of this. Companies located outside the Nordic countries make applications to the national ecolabelling organisation of the primary market.

The application must consist of a completed application form together with all of the documentation required to demonstrate compliance with the requirements specified in the criteria document (this is specified for each requirement). The application form must specify in which Nordic countries the products in question are to be sold and the estimated turnover from the products in each country.

Further information and assistance may be available. Visit the relevant national website for information.

Sales in the Nordic region

Once granted, a licence is valid throughout the Nordic region. The licence document specifies in which Nordic countries the products are sold according to the information provided on the application. The products are published on Nordic Ecolabelling's website(s). The licensee undertakes to inform Nordic Ecolabelling of any changes as to where the product is sold. If the product is to be sold in other Nordic countries than those initially specified in the application, the licensee must provide written notification of this and submit any extra documentation required to Nordic Ecolabelling in the country that issued the license.

On-site inspection

In connection with processing an application, Nordic Ecolabelling normally performs an on-site inspection to ensure compliance with to the requirements. For such an inspection, purchase statistics and similar documents that support the application must be available for examination.

An inspection visit might typically involve checks on the following:

- the manufacturer's procedures and instructions for ensuring compliance with the ecolabelling requirements (M2)

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 product.

Enquiries

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

1 General requirements

Are the requirements met?

R1 Description of the product

Yes ☐ No ☐

Describe the product.

✉ Appendix 1 duly completed and signed by the applicant.

Appendix No _____

2 Environmental and health requirements

Are the requirements met?

Plastic material

R2 Halogenated plastics in the product

Yes ☐ No ☐

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.

Appendix No _____

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

Yes ☐ No ☐

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 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*
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. **Appendix no. _____**

R4 Particulary problematic substances

Yes ☐ No ☐

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.

Appendix No _____

R5 Phthalates

Yes ☐ No ☐

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.

Appendix no. _____

The product

R6 **Recycling system** — Yes ☐ No ☐

The relevant national regulations, laws and/or industry-wide agreements on recycling systems for the packaging must be complied with in the Nordic countries in which the Nordic Ecolabelled products are marketed.

Not all countries have established recycling systems. Examples of recycling systems are REPA in Sweden (www.repa.se), PYR in Finland (www.pyr.fi) and Grønt Punkt in Norway (www.grontpunkt.no).

✉ Appendix 1 duly completed and signed by the applicant. — Appendix no. _____

3 Quality and safety requirements

Are the requirements met?

R7 **Safety** — Yes ☐ No ☐

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.

✉ Medical device: A copy of the approval/certificate from a notified body. — Appendix no. _____

✉ Medicinal product: A copy of the market authorisation from the reference member state or national authority. — Appendix no. _____

4 Other requirements

Are the requirements met?

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** — Yes ☐ No ☐

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. — Appendix No _____

M2 **Organisation and responsibility** — Yes ☐ No ☐

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. — Appendix No _____

M3 **Documentation of the application** Yes ☐ No ☐

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

✉ See M2. Appendix No _____

M4 **Keeping records** Yes ☐ No ☐

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 ecolabelled 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. Appendix No _____

M5 **Traceability** Yes ☐ No ☐

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

✉ See M2. Appendix No _____

M6 **Information** Yes ☐ No ☐

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. Appendix no. _____

M7 **Marketing** Yes ☐ No ☐

The Nordic Ecolabel must be marketed and used in accordance with the section on the design of the ecolabel and the "Regulations for the Nordic Ecolabelling of products" dated 22 June 2011 or later, although the Nordic Ecolabel may not reduce the visibility or readability of any CE label.

✉ Outline of how and where the Nordic Ecolabel, the licence number, and the additional and explanatory texts will appear on the product and a completed and signed Appendix 6. Appendix No _____

Design of the Nordic Ecolabel

The ecolabel and the allotted licence number and additional text (in the figure below stated as "Plastic material") must have the following design:

Plastic materials
Licence number

The text "Plastic materials" are obligatory and must appear in connection with the logo. It may be placed under the logo or be printed elsewhere in connection with the logo.

Furthermore may an additional and an explanatory text appear in connection with the logo.

The licence number may also be placed under the logo or be printed elsewhere in connection with the logo. The text above the logo may also be omitted or written elsewhere in connection with the logo. The text above the logo varies from country to country. See the "Regulations for the Nordic Ecolabelling of products" dated 22 June 2011 or later versions for the correct text above the logo in various languages and for selection of colour.

The size of the ecolabel including the text above the logo, obligatory text and licence number must always be such that they are clear and legible.

Nordic Ecolabelled disposable health care products

Licensed products can use the Nordic 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 tilbehøren
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 Ecolabelling may decide to check whether the ecolabelled product fulfils the Nordic Ecolabel requirements during the licence period. This may involve a site visit or random sampling.

According the "Regulations for the Nordic Ecolabelling of products" 22 June 2011, the cost of this is not to be borne by the licensee unless it turns out that the requirements are not complied with.

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

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.

The ecolabel licence is valid, providing the criteria are fulfilled, 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 must be published at least one year prior to the expiry of the present criteria. The licensee is then offered the opportunity to renew its licence.

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	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. Based on properties and structure plastics are divided into three main categories: thermoplastics, thermosets and elastomers.
Plasticiser	Additive which, when added to the plastic, produces a product that is flexible, resilient and easier to handle.
Producer of plastic raw material	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.
Product	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.
Supplier	Company that supplies goods or services to the manufacturer. The definition is based on the definition in ISO 9000:2000.

Appendix 1 Applicant's declaration

For use in applications for a licence for a Nordic Ecolabel for disposable bags, tubes and accessories for health care consisting of tubes and bags with accessories. 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 ****	**Material**	**Legislation*****
					☐ Medicinal product ☐ Medical device
					☐ Medicinal product ☐ Medical device
					☐ Medicinal product ☐ Medical device
					☐ Medicinal product ☐ Medical device
					☐ Medicinal product ☐ Medical device
					☐ Medicinal product ☐ Medical device
					☐ Medicinal product ☐ Medical device
					☐ Medicinal product ☐ Medical device
					☐ Medicinal product ☐ Medical device

**) Approximate weight in grams.*

***) Manufacturer does only need to filled in if Appendix 1 is not signed by the manufacturer.*

****) 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 relevant national regulations, laws and/or industry-wide agreements on recycling systems for the packaging are fulfilled in the Nordic countries in which the Nordic Ecolabelled products are marketed.

Not all countries have established recycling systems. Examples of recycling systems are REPA in Sweden (www.repa.se), PYR in Finland (www.pyr.fi) and Grønt Punkt in Norway (www.grontpunkt.no).

Name of recycling system(s): _____

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.

✉ **Medical device:** A copy of the approval/certificate from a notified body. Appendix No _____

✉ **Medicinal product:** A copy of the market authorisation from the reference member state or national authority. Appendix No _____

Signature

We declare that the requirements have been met and 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 to Nordic Ecolabelling.

Appendix 2 Manufacturer's declaration

For use in applications for a licence for a Nordic Ecolabel for disposable bags, tubes and accessories for health care consisting of tubes and bags with accessories. 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? Yes ☐ No ☐

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	Complies with requirements in Appendix 4
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐

✉ 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.

Appendix No _____

3 Adhesives

Are any adhesives used in the product? Yes ☐ No ☐

If yes, fill in the table:

Name of adhesive	Complies with requirements in Appendix 4
	Yes ☐ No ☐
	Yes ☐ No ☐
	Yes ☐ No ☐
	Yes ☐ No ☐

✉ 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.

Appendix No _____

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 Ecolabel for disposable bags, tubes and accessories for health care consisting of tubes and bags with accessories.

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/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 consisting of tubes and bags with accessories.

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. Appendix No ____

Function of the chemical:

☐ Plasticiser

☐ Adhesive

☐ Other additive, specify: _____

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 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*
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..

2 Particulary 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	Date
Addess	
Phone/Fax	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 appli

cation: _____

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)

We hereby certify that we are well acquainted with the regulations governing the use of the Nordic Ecolabel as detailed in the "Regulations for the Nordic Ecolabelling of products" dated 22 June 2011 or later versions. We agree to follow these regulations when marketing the Nordic Ecolabelled disposable bags, tubes and accessories for health care and to ensure the Nordic Ecolabel does not reduce visibility and readability of any CE label.

Furthermore, we confirm that we are familiar with the criteria document on the Nordic Ecolabelling of disposable bags, tubes and accessories for health care.

We undertake to advise the individuals in the company who are involved in marketing the Nordic Ecolabelled health care product of the criteria for the Nordic Ecolabelling of disposable bags, tubes and accessories for health care with accessories and of the "Regulations for the Nordic Ecolabelling of products" dated 22 June 2011 or later versions.

Date and place

Company

Signature, contact person

Name of contact person, printed

Phone

Signature, marketing director

Name of marketing director, printed

Phone

If there is any change in the above-mentioned personnel, a new declaration must be submitted to Nordic Ecolabelling.