

About Swan labelling of

Peritoneal Dialysis (PD) and Intravenous (IV) sets

Draft for review 14 March 2007

Background to ecolabelling



Nordic Ecolabelling

In 1989, the Nordic Council of Ministers decided to introduce an official voluntary ecolabelling scheme, the Swan. The organisations/companies listed below administer the Swan ecolabelling scheme on assignment from their respective national governments.

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Quotations may be made provided that Nordic Ecolabelling is stated as the source.

Swan labelling of peritoneal dialysis and intravenous sets – Background

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	Page
1 Summary	1
2 Introduction	1
3 Other environmental schemes and legislation	2
4 The Market	5
5 Choice of product group	6
6 Background to the delimitation of the product group and the requirements	7
6.1 Definition of the product group (what is eligible for a Swan Label)	7
6.2 Environmental requirements and other requirements	7
6.2.1 Description of the product (K1)	8
6.2.2 Chlorinated plastics in the product or packaging (K2)	8
6.2.3 Plasticisers, other additives and adhesives (K3+K4)	9
6.2.4 Labelling of plastic parts and packaging (K5)	10
6.2.5 Recycling system (K6)	10
6.2.6 SCENIHR Opinions (K7)	10
6.2.7 Safety (K8)	10
6.2.8 Additional requirements that have been discussed	10
6.2.9 Other requirements (M1-M5)	11
6.2.10 Marketing (M6)	11
7 Effects on health and the environment	11
7.1 Life cycle investigations	12
7.2 Health and the environment from the perspective of nature and society	13
7.2.1 Health and working environment	13
7.2.2 Energy consumption	15
7.2.3 Waste	15
7.2.4 Air	16
7.2.5 The aquatic environment	16
7.3 Health and the environment from a technical perspective	16
7.3.1 Plastic	17
7.3.2 Plasticisers and other additives	17
7.3.3 Recycling of plastics	18
7.3.4 Dioxins	19
8 Expected environmental effects	19
9 Future requirements	20
10 References and literature	21
Appendix 1 Description of kidney treatment and infusions	1
Appendix 2 Categorisation of common plastic polymers	3

Abbreviations used in the criteria document and the background document

CMR	Carcinogenic, mutagenic and toxic to reproduction
EC	European Communities
EMAS	Eco Management and Audit Scheme
EN	European Norm
EU	The European Union
ISO	International Standardisation Organisation
IV	Intravenous
LCA	Life Cycle Assessment
NO _x	Nitrogen Oxides
PVC	Polyvinylchloride
RPC	Relevance, Potential and Controllability
SFS	The Laws of Sweden
SIS	Swedish Standards Institute
SO ₂	Sulphur Dioxide
TEQ	Toxic Equivalent
VOC	Volatile Organic Compound

1 Summary

The purpose of this document is to outline the background to the first generation of criteria for the ecolabelling of peritoneal dialysis (PD) and intravenous (IV) sets. This allows applicants, consumers and interest organisations to read Nordic Ecolabelling's reasons and justifications for the requirements imposed in the criteria document.

The document describes the reasons behind the choice of product group and the requirements from the perspective of Nordic Ecolabelling's environmental philosophy. Two of the environmental goals defined in Nordic Ecolabelling's Philosophy are of particular relevance to the life cycle of peritoneal dialysis- and intravenous sets, and relate to the following areas:

- Emissions and effects of substances harmful to health e.g. on sensitive patient groups.
- Waste and waste generation.

In addition to these environmental targets, the environmental philosophy specifies a number of means by which the vision of sustainability should be achieved. For example, nature must not be exposed to systematic increases in the concentration of substances deriving from the ground. There is also reference to the factor 4 and factor 10 -concept, which states that we will need to increase the efficiency of our use of natural resources, materials and energy by a factor of 4 in the short term and a factor of 10 in the longer terms.

Justification for the requirements is also provided by the potential environmental gains offered by the ecolabelling of peritoneal dialysis- and intravenous sets and the scope for controlling and documenting the requirements.

2 Introduction

This background document is the first for this product group, and will serve as a background to version 1 of the criteria document for peritoneal dialysis- and intravenous sets. The criteria were adopted by Nordic Ecolabelling on XXX.

In 2006, Nordic Ecolabelling was contacted by a producer within the health care industry with a request on establishing ecolabelling criteria for peritoneal dialysis (PD) bags. Based on that contact Nordic Ecolabelling conducted a survey into the health care industry in the Nordic countries. In late 2006, it was decided on the basis of the findings of this study that ecolabelling criteria should be drawn up for such a product group. During the development of the criteria intravenous (IV) sets were also included because of interest from industry.

The work on setting requirements was conducted by an internal work group chaired by Ecolabelling Denmark in 2006-07.

Nordic Ecolabelling's procedures require technical data to be compiled from operators in the market. This product category was no exception and data from various producers was processed at the meetings of the working group. Proposals for criteria were drawn up with the aid of the expertise provided by experts contacted on an ad hoc basis.

The purpose of ecolabelling PD/IV products represents a form of sustainability target, although without the social dimension normally concluded in the sustainability concept. The criteria are designed to promote the development of products that:

- do not use substances that are harmful to health and the environment.
- contribute as little as possible to generation of problematic waste.

Since the criteria normally are revised every three to five years, each version of the criteria document represents a step in the direction of achieving the above goals. The goal of this first version of the criteria is to take the first step towards the sustainability target.

Moreover, the background document focuses on discussing the criteria against the background of published life cycle assessments, evaluations of relevance, potential and controllability (RPC), quantitative and qualitative assessments regarding the consequences of the new criteria, etc.

3 Other environmental schemes and legislation

There are, for the moment, no other ecolabelling schemes that have criteria for this product group. The Swedish EKV (Swedish official board for green and public procurement) is however currently developing criteria for dialysis equipment (haemo- and peritoneal dialysis therapy). This work is probably finalised in spring 2007, but seems to be more focused on equipment and additives used rather than the kind of polymer used.

Product catalogues for medical devices include some product data, but they often lack information as to whether the material contains PVC. But claims as "PVC-free" or "phthalate-free" on the products or within a product sheet are sometimes communicated. This information may give some guidance to the buyer, but such claims have however some disadvantages in comparison to ecolabelling:

- Claims by a first party are not as credible as third party certifications.
- Marketing agreements and regulations within the health care sector, might conflict with such claims.
- The claim itself might not be an obvious issue or concern for the customer, while a well recognised ecolabel is much easier to understand.

The international coalition *Health Care Without Harm* works in more than 50 different countries and cooperates with more than 440 organisations (hospitals, healthcare staff, environment organisations, etc.). The objective of *Health Care without Harm* is to

transform the market for healthcare materials so that neither people's health nor the environment are harmed. One of *Health Care Without Harm's* work groups in Europe is working in particular for safer materials and is focusing on phasing out PVC, phthalates and mercury. *Health Care Without Harm* has a list of manufacturers and products that are PVC-free.

Environmental certification

Some of the producers of medicinal products and medical devices have certified environmental management systems in place, such as ISO14001 or EMAS. In formulating the criteria, efforts have been made to take account of the environmental management systems already used by manufacturers of peritoneal dialysis and intravenous sets, with a view to reducing the administrative burden.

This forms one of the components in the vision proposed by the authors of the Nordic Council of Ministers report on the role of the Swan Label in relation to environmental management (Edlund et al 2002). According to page 14:

"A significant part of the data necessary to document and confirm the requirements of the eco-labelling scheme is generated by the producer's environmental management system. The environmental management system also organises the necessary documentation and environmental reporting can be used to report to the eco-labelling organisations."

Authorities

The Directive on Medicinal Products, 2001/83/EC on the community code for medicinal products for human use contains provisions about authorisation and control of medicinal products and the companies that manufacture, store or otherwise handle medicinal products.

The liquid and the plastic packaging for peritoneal dialysis and filled IV bags shall be approved by authorised authorities before marketing and use on patients according to the medicinal product directive. Many associated items as bags, gloves, tubings, catheters etc are however regulated according to the Medical Devices Directive.

Medical Devices are regulated by three main Directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), e.g. pacemakers.
- The Council Directive 93/42/EEC on Medical Devices (MDD), also called the general Directive, covers all medical devices except from active, implantable medical devices and in vitro diagnostic devices. The directive became effective on January 1, 1995.
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD), e.g. laboratory equipment.

The directive on Medical Devices, as well as the new rules in the in vitro diagnostic medical devices directive, requires CE-labelling in order to demonstrate conformity of certain standards for safety purposes. The CE marking is a visible sign that the

manufacturer has complied with the procedures of the Directive and that the products fulfil the requirements that apply to them.

One of the standards is the ISO-standard 10993:2003 for Biological evaluation of medical devices. This standard consists of almost 20 parts. The first part of the standard states that the following should be considered for their relevance for the overall biological evaluation of the device:

- materials of manufacture
- intended additives, process contaminants and residues
- leachable substances
- degradation products
- other components and their interaction in the final product
- the properties and characteristics of the final product

In January 2007 ISO voted for a new work in the area of biological evaluation of medical devices. The title of the work is “Technical Specifications for Development of Tolerable Intake Values for Di(2-ethylhexyl)phthalate (DEHP)” (ISO/TC 194 N619). The work is expected to give more specific guidelines as to regulating the use of DEHP in medical devices.

The medical devices are divided into four different classes (I, IIa, IIb and III). In addition, class I is subdivided into devices which are sold in a sterile condition and devices which are sold with a measuring function. The classification reflects the risks involved in the use of the product, the vulnerability of the parts of the body on which the devices are to be applied and the duration of use.

The highest risk class (III) includes products which come into contact with the central nervous system, the heart or the central circulatory system as well as medical devices incorporating medicines. The classification thus ensures that the regulatory control is reasonably proportional to the risk involved in the use of the product.

The actual approval of medical devices in the higher risk classes is carried out by the notified bodies. The following vigilance, which must ensure that products on the market fulfil the requirements of the Directive is, on the other hand, the responsibility of the competent authorities. An example of a notified body is DGM. DS Certification DGM (Danish Medical Devices Certification) is the Danish Notified Body (www.dgm-nb.org).

4 The Market

Medical devices more or less cover all products with some form of medical connection, except for pharmaceuticals – everything from consumables such as dressing materials, syringes and drainage, to implants, x-ray equipment and imaging systems for medical diagnostics.

The medical devices industry is extensive and global with a large number of international manufacturers that are often represented at national level either through subsidiaries or trading companies. From an international perspective, the medical devices industry turns over approximately €184 billion, with approximately €55 billion in Europe. In Sweden, the industry employs roughly 15,000 people distributed among a few very large international companies and many small to medium-sized companies.

Of the total use of PVC in the world, it is estimated that a little less than 1% is used in medical devices. The market for medical devices is global and the conditions may be assumed to be similar in the Nordic countries. Within Stockholm County Council alone, between 1997-2004, more than 200 tons of PVC products were used each year. Most of the PVC was used for gloves, 170 tons (18.8 million units), followed by infusion materials, 15-20 tons (580,000 units), and urine bags, 13 tons (450,000 units).

There are PVC-free alternatives available today on the market for nearly all areas of use (except for blood bags for red blood corpuscles and tubing for haemodialysis). Latex is an alternative to PVC gloves, but especially those with powder are associated with allergy problems.

In the table below the market shares of haemo- and peritoneal dialysis equipment from the three dominating manufacturers in the world are shown.

Table 4 Kidney Treatment Equipment: Worldwide Market Share 1999 (Gambro 1999).

Type of Dialysis	Baxter (market share, %)	Gambro (market share, %)	Fresenius (market share, %)
Haemodialysis	5%	22%	26%
Peritoneal Dialysis	71%	2%	16%
Both Hemodialysis and Peritoneal Dialysis	23%	17%	23%

Haemodialysis is the dominant kidney therapy in developed countries and accounts for approximately 70% of worldwide dialysis revenues (Dorland's Biomedical, 1998). In developing nations, lower cost peritoneal dialysis dominates. For example, peritoneal dialysis accounts for 90% of the dialysis market in Mexico (Leaversuch 1999).

The three world leading dialysis companies Fresenius, Baxter, and Gambro account for approximately 63% of all dialysis revenues (see Table 4). Other small players in the dialysis market include Aksys Ltd., Althin, B. Braun McGaw, Bard, Horizon Medical Products, Medionics International, Minntech Corp., and Vasca, Inc.

Worldwide revenues from dialysis products and services totaled \$5.45 billion dollars in 1997, with U.S. revenues equalling \$1.39 billion (Dorland's Biomedical 1998). In

the U.S. Baxter dominates the peritoneal market with approximately 85% market share. The haemodialysis market is dominated by Baxter, Gambro, and Fresenius.

The IV (intravenous) therapy solutions market in Europe is dominated by the following competitors, representing 80% of the European market (Frost & Sullivan 1996):

- Fresenius
- Pharmacia & Upjohn (Today Fresenius Kabi)
- B Braun
- Baxter/Clintech

An estimate based on the figures of 1996 and the expected growth rate, will generate revenues of \$950 – 1000 million in 2007.

5 Choice of product group

The idea of ecolabelling of disposable health care products came on the base of an inquiry from a producer. Even if Nordic Ecolabelling had not been operating in the health care sector, the product group was considered interesting because of the simple fact that it comprised single-use products used in large quantities. Nordic Ecolabelling conducted a survey of selected disposable health care products in order to analyse the possibilities of ecolabelling (Bergbom 2006). The study is available from Nordic Ecolabelling. The product group was initiated as a so called environmental pioneer.

The study concluded that potential existed for improvement, particularly:

- Leakage of plasticizers from the polymers, which may affect the long term health of patients, i.e. sensitive groups as newborns, children and dialysis patients
- Reduction of the amount of waste and potential problematic emissions from incineration plants

A decisive factor in the choice of product group was the scope for achieving environmental gains on the most important parameters without shifting environmental problems over onto other areas.

Regarding the quality and security aspect, Nordic Ecolabelling is aware of the extensive legislation in this area. No health care products can be put on the market unless they have been approved by the authorities.

Moreover, Nordic Ecolabelling concluded that professionals within the health care sector wanted more environmentally friendly devices and disposables. One of the problems with PVC that hospitals experienced was made clear when they started to sort waste. It then became particularly apparent that healthcare products usually did not have any markings, except for a CE marking.

The fact that a number of PVC-free products were already on the market indicated that good functionality and quality could be delivered. And lately the prices of the alternatives had become increasingly competitive. Other factors also affect the price considerations:

- Bags: the alternative polymers are 10-20% more expensive, but cost-competitive due to less material needed for the same size and kind of bag (so called downgauging)
- Tubing: can cost more, but may have a longer service life
- Gloves: cost-competitive at large volume and better quality which leads to less discards

6 Background to the delimitation of the product group and the requirements

The background and rationale for the requirements are described in the sections below. Reasons are based on Nordic Ecolabelling's goals and potential for improvements by the health care industry. The cost of fulfilling the requirements is also discussed as is the attitude of various interested parties, where relevant.

Requirements that have been discussed but not included are also discussed where relevant in the context.

6.1 Definition of the product group (what is eligible for a Swan Label)

Peritoneal dialysis and intravenous sets has been chosen as eligible for a Swan label because interest from the industry. Also the existence established and price worthy alternatives on the market for these kinds of health care products have been an important reason.

In the future Nordic Ecolabelling can consider to including other medicinal products or single use medical devices.

6.2 Environmental requirements and other requirements

Nordic Ecolabelling has formulated the requirements with respect to the following features:

- The number of requirements has been kept low
- Templates have been created relating to the procedures and instructions needed at the manufacturers in order to fulfil the requirements.
- Templates have been created for suppliers to make it less time consuming to document requirements to chemicals.

The Working Group has emphasised that the requirements must be easy to document, while at the same time encourage the producer to introduce environmental improvements or rewarding producers that have already done so.

Generally, the requirements have been selected on the basis of an assessment of the effects of the products on health and the environment during its life cycle. In addition an assessment has been performed of the potential for environmental benefits, without gains in one area entailing a problem in a second area.

Other key factors are the importance of formulating clear criteria that are documentable and offer a high degree of credibility. Where the Nordic authorities have legislation in place or have stated goals or attitudes in an area, this will be taken into account since it is intended that the ecolabelling requirements should be stricter than applicable legislation in the area.

6.2.1 Description of the product (R1)

For reasons of credibility, it is required that the applicant describe in which way the product is covered by current legislation. The legislation has strict requirements as to the safety and functionality of the product. See more about the legislation for health care products in section 3.

6.2.2 Chlorinated plastics in the product or packaging (R2)

The requirement as to exclude chlorinated plastics such as PVC has been selected against the background of Nordic Ecolabelling's objective of reducing problems in the waste-handling.

The requirement has also been selected against the background of Nordic Ecolabelling's objective of reducing the risk of health-related problems.

The main waste problems with chlorinated plastics such as PVC are associated with the large amounts of problematic residues from the cleaning process in the incineration plant. This residue has to be deposited under special conditions as landfill (see section 7.2.3 on waste issues). Other plastics are not restricted in the waste incineration plants and therefore less problematic.

Soft PVC, in contrast to other polymers, requires a significant amount of plasticizer, which has the potential to migrate and enter the patient's body. A precautionary approach is therefore to avoid such polymers. Going further than the current legislation by using the precautionary principle is supported by the fact that an EU scientific committee on newly identified health risks has taken up the discussion on harmful PVC-plasticisers again (see section 7.2.1 on health effects).

PUR is an optional material for tubing, but the potential health risk from exposure of isocyanates are far less than that from plasticisers from PVC tubing because of the simple fact that the amount present in the plastic is very small. Any amount present in PUR is unintended as opposed to the amount of plasticisers in PVC.

Polycarbonate is a stiff material used in small parts of catheters and connections etc. The potential health risk from exposure of bisphenol A is also here much smaller for the same reasons as for isocyanates in PUR. See more about the environmental profile of PUR and polycarbonates in section 7.3.1 and Appendix 2.

The potential health risk from both PUR and polycarbonate in this type of products is assessed to be ministered by the legislation (see section 3).

PD and IV bags, made of alternatives to PVC, are e.g. made of a laminate consisting of polyamide and polyolefin or pure polyolefins. The environmental profiles of these materials are dealt within section 7.3.1 and Appendix 2.

6.2.3 Plasticisers, other additives and adhesives (R3+R4)

As PVC is not allowed it may seem unnecessary to have requirements to plasticisers and additives. Normally little plasticisers or additives are used in other plastic materials than PVC.

But almost all plastics contain additives which may cause an exposure humans or the environment. However, the legislation discussed in section 3 is aimed to protect humans from any unwanted exposure. The requirement is therefore mostly set for credibility reasons to catch possible harmful chemicals used in other plastics than PVC.

The legislation discussed in section 3 is aimed to protect humans from any unwanted exposure from health care products. Most of the waste from disposable plastic health care products is incinerated and used adhesive will not be exposed to the aquatic environment. The requirement is therefore mostly set for credibility reasons to catch possible harmful chemicals.

Environmental harmfulness

The requirement that the chemical added to the plastic must not be classified as environmentally harmful is based on the EU classification legislation in order to make it easy to verify.

Health-related requirements

The chemicals to which restrictions apply are those that have or should be allocated a risk phrase indicating that the chemical is carcinogenic, mutagenic or toxic to reproduction (what are termed the CMR effects), is allergenic, toxic or very toxic according to the EU classification legislation. All chemicals with CMR R phrases are excluded, irrespective of whether they cover category 1, 2 or 3 CMR effects. The exclusion of substances that are harmful to health will minimize possible health issues related to the use of the product, but it will also improve the chemical working environment during the manufacturing of the product.

Endocrine disruption

Some of the phthalates used as plasticisers are endocrine disruptors. The requirement is based on EU Scientific Committee's list of these kinds of substances:

http://europa.eu.int/comm/environment/docum/01262_en.htm

6.2.4 Labelling of plastic parts and packaging (R5)

The requirement as to the labelling of plastic parts and packaging has been selected on the background of Nordic Ecolabelling's objective of better waste handling.

The labelling of plastic parts will facilitate sorting when plastic is recycled. For example, the labelling might help personnel at hospitals and other health care units to identify the material during the waste handling process. However, actual recycling in a larger scale of disposable health care products is not yet developed. Therefore the requirement shall be seen as a preparation for future systems in this area.

6.2.5 Recycling system (R6)

The requirement as to recycling system for plastic parts and packaging has been selected on the background of Nordic Ecolabelling's objective of better waste handling.

This is a standard requirement in most of Nordic Ecolabelling's criteria documents. The participation in a recycling system will contribute to a more optimal waste handling. However, not all Nordic countries have these systems in place.

6.2.6 SCENIHR Opinions (R7)

For reasons of credibility it is required that the applicant comply with directives from the EU scientific SCENIHR committee. If such recommendations should conflict with the some of the requirements Nordic Ecolabelling will consider revising the criteria in order to stay updated with the development.

6.2.7 Safety (R8)

For reasons of credibility, it is required that the applicant submit a copy of the authorization to market the product. The legislation has strict requirements as to the safety of the products. See more about the legislation for health care products in section 3.

6.2.8 Additional requirements that have been discussed

A number of requirements were discussed during the criteria development process. Some of them have not been included as part of the criteria. These are discussed below.

Energy

Nordic Ecolabelling considered the possibility of including requirements as to energy consumption in the production of plastics (see about energy consumption in section 7.2.2). But due to the limits in the scope of the criteria development project this was not done. However this can be a future requirement.

Recycling

Some materials and products on the market are better suited for recycling than others. Simple polymers with small amount with additives combined with a system for identification can make recycling possible. See more about the recyclability of different plastic materials in section 7.3.3. Requirements as to the choice of material and product design to enhance recycling can be a future demand.

Process contaminants and residues

In some plastics there are small amounts of process contaminants or residues such as traces of catalyst material and monomers from the production of the polymer. These substances can be problematic themselves, but are only present in very small amounts. See the discussion and examples in section 6.2.2.

In the most common thermoplastics the content of free monomer is around 1-10 or less ppm (Schmidt 2006). See also the legislation on this area in section 3. The area is complex because of many different production methods and materials and therefore requirements as to process contaminants and residues from production can be a future demand.

6.2.9 Other requirements (M1-M5)

This set of requirements is common to most of Nordic Ecolabelling's criteria documents. They are set to ensure that the requirements are complied with during the validity of the license and to give Nordic Ecolabelling a possibility to withdraw a license if legislation is not complied with.

6.2.10 Marketing (M6)

The marketing directions are to secure the optimal value for the applicant of the Swan-label and to avoid misunderstandings. The requirements comprise among other things design directions for the Swan logo.

7 Effects on health and the environment

Because several manufacturers have taken active steps on environmental issues in recent years, there is a growing potential for improvement on health and environmental impacts. This is true not least in light of the size of the industry.

There are a number of sources of information on effects on health and the environment. Life cycle assessments are amongst the published sources. The most well known in this area are discussed below. A further source of published information is the reference document on Best Available Technology (BAT) in the production of polymers. It was published in October 2006 and contains generic BAT for all polymers and specific BAT for each polymer.

A further source is comments by experts contacted during the process on health and the environment in the health care industry. Industry players including buyers of the products also represent a source of information on the effects on health and the environment. Surveys of interested parties may also represent a means of finding out what these interests regard as important

For the sake of simplicity, a number of general areas have been selected in the following sections and the most relevant effects within each area are described.

7.1 Life cycle investigations

There is a compilation of the existing Life Cycle Assessments (LCA's) of PVC and its competing materials commissioned by the EU-commission (European Commission 2004). The authors however, underline that comparisons between the plastic materials are made on application level, and can not be used on a general material level. The report also states that there are no public available LCA's concerning medical applications.

The PVC industry concludes from the compilation that PVC is as good a material as any other **as long as there are special precautions taken in the different stages in the lifecycle (Vinyl2010 2004).**

The Commission's LCA report can be regarded as an approach to deliver answers to concerns and questions that were raised within a green paper by the Commission four years earlier. Most of the questions, raised by the green paper, remain however unanswered. As a matter of fact the LCA report has been heavily criticised as non-conclusive. Here for example by Mark Rossi in 2004:

“Through a combination of omitting key data and policy decisions, engaging in the selective citation of studies (or poorly conducting research), and relying upon a method -- quantitative life cycle assessment (LCA) -- unsuited for the task, the result is a study whose conclusions must be read with a healthy dose of scepticism. Given these problems it is impossible to know the validity and relevance of the conclusions reached by the authors. We conclude from this review that the study -- Life Cycle Assessment of PVC and of Principal Competing Materials -- is fundamentally flawed and that it should not be used or considered as a relevant comparative analysis of the life cycle problems associated with PVC and its competing materials.”

Rossi explains the limitations and part of the reasons why the study is not conclusive by the fact that many life cycle studies are limited to measurable figures such as energy and raw material use. For i.e. hazardous chemicals it is much more complicated to express different risk scenarios and take the precautionary principle in account. He argues that taking the precautionary principle in account is relevant for the majority of existing chemicals.

There is, on the other hand, a good comprehensive and transparent presentation of polymers and environmental issues by Lars Pedersen (in Danish). This is a kind of qualitative LCA, followed by an environmental classification considering mainly content of health or environmental hazardous substances, energy consumption and waste treatment, see Appendix 2.

7.2 Health and the environment from the perspective of nature and society

In order to gain an overview of environmental and health effects from the perspective of nature and society, Nordic Ecolabelling has opted to describe the effects on health and the environment in the following general areas:

- Health and working environment
- Waste
- Energy consumption
- Air
- Aquatic environment

These areas are particularly relevant for health care products discussed in this document.

7.2.1 Health and working environment

A general overview of exposure of chemicals in the production of the most common plastics can be seen in Schmidt's survey from 2006. He lists different types of plastics and manufacturing methods together with measurements of degradation products.

Polyvinyl chloride or vinyl (PVC) is a polymer in which more than half of the content by weight consists of chlorine. Plasticizers are added to PVC to make the plastics soft and pliable which are the most desirable properties for disposable medical devices/medicinal products.

A problem with plasticizers is that they do not bind to the PVC matrix and can leach out of the product into liquid transferred from medical devices to the patient's body. In general, medical procedures that last for hours or days, such as haemodialysis, blood transfusion, extra-corporeal membrane oxygenation (ECMO), total parenteral nutrition (TPN), or enteral feeding result in higher plasticizer exposure than brief procedures.

Phthalates are the most commonly used plasticisers in PVC plastic. Phthalates have been in focus by the authorities because of their CMR and endocrine disruption effects on human health. Patients that use PVC products internally (tubes, etc.) may be subjected to raised exposure from phthalates because the phthalates are not bound to the polymer. The potential for DEHP exposure is also higher when the PVC/DEHP product is used invasively and/or when fat containing liquids like blood or nutritional formulas are transferred.

Research results on the risks associated with plasticizers and PVC are not unequivocal and a general prohibition of PVC does not exist. The EU's Scientific Committee on Medicinal Products and Medical Devices examined the issue of PVC in 2002 but did not find any evidence of carcinogenic effects in humans and therefore did not provide any specific recommendation on limiting the use of DEHP. This issue has however been taken up again by the EU's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2006). The committee is discussing the

safety of medical devices containing DEHP-plasticised PVC or other plasticisers on neonates and other groups possibly at risk.

Chemical preparations containing DEHP must be labelled with the “skull and cross-bones” symbol within the EU. Medical products are not regarded as “chemical preparations” according to chemicals legislation and are therefore not covered by the general restrictions in the chemical legislation despite the likelihood of high exposure. But these products are covered by other medical device and medicinal products legislation taking risk assessment into account (see section 3).

There is specific regulation of the use of phthalates in toys. Toys that can be placed in the mouth by children under the age of three must not contain six specific phthalates. But recently the legislation was updated: phthalates classified as reproductive toxins – DEHP, DBP and BBP are prohibited in all children products. The other three phthalates – DINP, DODP and DIDP are banned from products intended for children under the age of three.

It is prohibited to use DEHP in cosmetics, adhesives, paint and other consumer products.

Several PVC products that contain DEHP plasticizer are used in health care. Common products include feeding tubes, tubes and catheters, as well as infusion bags for nutrients or dialysis fluids.

Under the EU’s risk assessment process the risks of different types of DEHP exposure have been evaluated. In the case of medical devices the conclusion is drawn that risk reduction measures are necessary to decrease the exposure of patients who come into contact with DEHP.

The phthalate DEHP leads to a reduction in the size of testicles on laboratory animals and is classified as reproductive toxic and teratogenic. The risk of harm to health is greatest among children and patients who have experienced long-term exposure.

Non-phthalate plasticisers as trimetallates, citrates etc. are often used as alternatives to phthalates. They might have an advantage in toxicological profile or/and less leakage. Also treated castor-oil is marketed as an alternative to phthalates. The alternative plasticiser consists of acetylated monoglycerides and diglycerides of hardened castor oil. The alternative has been investigated for hydrolysis, absorption, metabolism and excretion in rats. The results show that the oil is hydrolysed and is quickly metabolised and excreted (Vang Sparsø et al 2007).

7.2.2 Energy consumption

The table below demonstrates the energy balance for common polymers used for peritoneal dialysis or IV bags within the health care sector (Pedersen 1999). It can be seen that the plastics are energy demanding materials to produce. From energy point of view, polyamide seems to be disadvantageous compared to other plastic materials. This is however only one of many environmental aspects, and when considering a total judgement this material will have much better relative environmental profile.

Table 7.2.2 Energy demand and recovery for different plastics.

	<i>Energy demand, Mj/kg</i>	<i>Energy recovery from incineration Mj/kg</i>	<i>Difference</i>
PVC	66,8	17,8	49
Polyamide	156	28,7	127,3
Polyolefins	80-82	43,5-42,3	36,5-39,7
Polyurethanes	89	27	62

Anders Schmidt (2006) has more detailed figures for the mentioned plastics as well as for other plastics. Figures for energy consumption can also be found in the EU BAT report (European Commission 2006).

7.2.3 Waste

A large amount of plastic waste ends up in incineration plants, where the energy content is used to produce electricity and heat (see the previous section). This is also the case for disposable health care products made of plastic. Most of the larger waste incineration plants are constructed to handle and minimize emissions originating from the plastics.

Experience shows that no more dioxin is produced by an extra kilo of PVC in an incineration plant than by one kilo of any other equivalent chlorine-free material. It appears that chlorine is not the limiting factor for dioxin emissions during incineration.

Even if the emissions from the incineration of PVC can be controlled in the bigger plants, burning PVC generates a large amount of problematic residues because of the content of chlorine. The amount is between 0.4-1.7 kg/kg PVC depending on the purification process used (Schmidt 2006). The most common processes used generates more problematic residues than the amount of PVC incinerated. These residues are categorized as dangerous waste by the authorities and have to be deposited as landfill under special conditions. If PVC itself is deposited as landfill it can not be excluded that the plasticisers are released in time.

For that reason the Danish authorities since 1999 have had a strategy to avoid PVC in the waste incineration process. Therefore focus has been to limit the use of PVC

products that not easily will be collected after use and because of that will end up in the waste incineration process (Miljø- og Energiministeriet 1999).

This strategy shall be seen in the light of the general waste policy in Denmark that waste that can be incinerated, including most of the plastics, shall not be deposited as landfill. Instead it should be recycled or incinerated in order to recover the energy content.

7.2.4 Air

The most problematic emissions to air are the gases originating from energy production such as carbon dioxide (CO₂), nitrogen oxides (NO_x), sulphur dioxide (SO₂), and volatile organic compounds (VOC).

Emissions of nitrogen oxides and sulphur dioxide cause environmental problems such as acidification resulting in fish death in lakes and air pollution that is harmful to health. Nitrogen oxides that are emitted to air also cause environmental problems such as over-fertilisation and oxygen depletion. Carbon dioxide and volatile organic compounds cause climate change in the form of the greenhouse effect.

7.2.5 The aquatic environment

The effluent water from the Karolinska hospital in Sweden is contaminated, such as with phthalates. The levels of DINP are today double that of DEHP (A. Vesterberg, personal communication January 2007). This probably reflects the shift of plasticisers within the PVC-industry from DEHP to DINP.

All phthalates used to a large extent in PVC can be found throughout our environment today, partly since they are released from PVC products (European Commission 2000). In the environment, the phthalates DEHP, DINP and DIDP decompose slowly and are highly bioaccumulable, which is why "it cannot be excluded that they accumulate in the food chain" (Danish Environmental Protection Agency 2003).

7.3 Health and the environment from a technical perspective

To gain an overview of environmental and health impact viewed from a technical perspective, Nordic Ecolabelling has chosen to describe the environmental effects of the following elements:

- Plastic
- Plasticisers and other additives
- Recycling of plastics
- Dioxins

These areas are particularly relevant for health care products discussed in this document. The production of polymers in general is extensively described in the European Commission BAT document from 2006 and the different manufacturing processes in the Danish EPA's report from 2006 (Schmidt 2006).

7.3.1 Plastic

Initially, PVC products were developed to replace natural rubber and glass. The advantages associated with products made from PVC are that they are easy to sterilise, they are transparent, soft, physically strong, chemically stable and relatively cheap. Plasticized PVC often has important functional characteristics, such as ease-of-use, softness and flexibility which prevent sensitive tissue from being subjected to injury. It also minimises discomfort for the patient and ensures free passage through catheters and tubes. PVC also facilitates the collection of whole blood by preventing coagulation.

The alternative materials, besides softened PVC, in medical devices or packaging of medicinal liquids are the following. After the plastic it is indicated which category they belong to according to Appendix 2.

- Polyamide In category 2
- Polyolefins In category 1 (polypropylene/polyethylene)
- Polyurethanes In category 3
- Silicone In category 2
- EVA In category 1
- Latex/rubber In category 3

There are many aspects in favour for alternative polymers to PVC, as described in by Lars Pedersen in Appendix 2. PVC softened with DEHP belongs to the worst class (category 4). But, other softened PVC belongs to class 3 together with materials such as polyurethane (PUR) and polycarbonate which can also be relevant in health care disposables.

According to Lars Pedersen PUR is critical mainly due to the use of isocyanates, which is an allergenic raw material in the production of the PUR. In the same way, the suspected endocrine disruptor; bisphenol A, is used as a raw material in the production of polycarbonate. The amount of these materials, however, is small in peritoneal dialysis and IV sets.

Manufacturers have reacted to purchasers' requests for PVC-free products and increasing numbers of new products are being introduced. There are many manufacturers on the market. The environmental impact of plastic medical devices such as examination gloves, tubes and bags in this context is often associated with the question as to whether PVC is used in the product or not.

Even today, renewable plastic is not yet an alternative for these types of products. Protective gloves have by tradition been made from natural rubber latex, but synthetic rubber has become more common due to the allergic problems associated with latex. Gloves are also available in for example polyethylene and nitrile.

7.3.2 Plasticisers and other additives

Disposable medical devices and packaging for medicinal products made from PVC normally contain 20–40 percent plasticizer by weight. The content can be as high as 80 percent in feeding tubes. There are at least 15 different phthalates, all with similar

properties often used to as plasticisers in PVC. Trimetallates, citrates etc. are used as alternatives to phthalates.

The most widely used phthalate is DEHP (di-ethyl-hexyl-phthalate). See more about health issues and phthalates in section 7.2.1. 9 Alternatives to DEHP in PVC for medical devices have been investigated by the Danish EPA and the conclusion found was that none of the substances was rejected as alternatives to DEHP. However the report states, much more data are needed before DEHP can seriously be substituted in medical devices (Danish EPA 2003).

Apart from plasticisers there are thousands of other additives that can be added to the plastics. They have different functions such as stabilizers, antioxidants, UV-stabilizers, flame retardants, dyes, pigments, etc. (Schmidt 2006).

7.3.3 Recycling of plastics

As an example of the difficulty of recycling PVC, especially closed-loop recycling, the automobile industry has targeted PVC for elimination. Driven by end-of-life vehicle directives in Europe and Japan to increase recycling rates for automobiles, automakers are evaluating their use of plastics and selecting plastics that can be recycled back into the same product.

The European automaker, Opel, for example, classified plastics according to their recyclability. PVC was next to last on the list in terms of recyclability, with PVC only more recyclable than a “mixture of incompatible products” (see Table 7.3.3 below). All of the automakers have reached the same conclusion as Opel: that polypropylene and polyethylene are the easiest plastics to recycle and PVC is among the most difficult.

▲	Polypropylene, Polyethylene
▲	Polyoxymethylene (POM), Polyamide, Thermoplastic Urethane (TPU)
▲	Acrylonitrile Butadiene Styrene (ABS), Polymethylmethacrylate, Styrene Maleic Anhydride (SMA) copolymer, Acrylonitrile Styrene Acrylate (ASA), Styrene Acrylonitrile (SAN)
▲	Polycarbonate, Polyethylene Terephthalate (PET), Polybutylene Terephthalate (PBT)
▲	Thermoplastic Elastomer (TPE)
▲	Polyurethane
▲	Sheet Moulding Compound (SMC)
▲	Elastomer
▲	Polyvinyl Chloride (PVC)
▲	Mixture of incompatible materials

Table 7.3.3 Opel Priority List for Plastics with regard to Recycling Aspects (Opel 2000).

7.3.4 Dioxins

If the technology and safety of the production plant is up to scratch, the PVC information council in Denmark claims that the majority, but not all, of dioxin emissions are purified. The information council notify that the Swedish environmental protection agency has determined that PVC raw materials account for roughly 1% of the total dioxin emissions in the country (Dammand Nielsen 2005). In small, less modern facilities, dioxin emissions to the environment and humans are more common (European Commission 2004). Dioxins are also released when PVC is incinerated. Refer also to the section on waste (sectin 7.2.3).

The Nordic countries are bound by the "Stockholm Convention on Persistent Organic Pollutants (POPs)" to omit waste containing POPs at source so that POPs are destroyed or pacified without impacting on the environment (www.pops.int). The convention considers that the incineration of PVC, for example, is a source of POPs, in particular dioxins.

Furthermore, it is always a risk of POP emissions (dioxins) in the case of uncontrolled fires that involve PVC and other materials containing chlorine, e.g. houses, hotels and hospitals.

There are many other sources of dioxin emissions to air. In addition to air emissions, dioxins are released to water and the ground, and can be found in waste products. The following sources are listed in a background document for a meeting of the OSPAR Commission in June 2002 (www.ospar.org):

- Incineration of waste and sludge
- Heating of buildings with coal and biomass (straw and wood)
- The metal industry – in particular sintering processes and the recycling of metal waste

Statistics Norway estimated the dioxin emissions to air as 29 g TEQ in 2003 (www.miljostatus.no). 10.5 g originated from households, which were the primary source. Industrial emissions were 8.1 g, of which 7.75 g came from metal processing and 0.01 g from the chemical industry. Industrial emissions in 1990 were 86 g TEQ, while household emissions were 8.1 g. The emissions of dioxins from incineration and waste were 0.6 g TEQ (17.6 g in 1990). It is estimated that the burning of wood accounted for ¼ of dioxin emissions in 2003.

8 Expected environmental effects

The criteria are intended to encourage producers to:

- avoid substances that are harmful to health and the environment
- avoid materials that are problematic in the waste handling

Nordic Ecolabelling expects to support and speed up the emerging development of reducing health and environmental impact from health care products by ecolabelling.

Ecolabelling is specially expected to contribute to the reduction of harmful phthalates and unsustainable waste generation.

Nordic Ecolabelling estimates that if the dialysis bags on the Nordic market did not contain PVC, between 175-350 tons of phthalates could be avoided on a yearly basis, and the harmful residues formed when PVC is burned could also be avoided.

9 Future requirements

In future requirements Nordic Ecolabelling will among other things consider whether to:

- Include requirements as to energy
- Include requirements as to recyclability of materials
- Include requirements as to process contaminants and residues

See more in section 6.2.8.

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Appendix 1 Description of kidney treatment and infusions

Peritoneal Dialysis and Hemodialysis (by Mark Rossi 2000)

Peritoneal dialysis and hemodialysis are the two treatments available for patients with kidney disease who do not receive a kidney transplant. The primary difference between the two treatments is how waste products are separated from the blood: in peritoneal dialysis the body's peritoneum separates waste products from the blood whereas in hemodialysis a machine does the separating. Some patients are not candidates for peritoneal dialysis because it requires some residual renal function: patients with end-stage renal disease, very little to no renal function, require hemodialysis.

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. The two primary peritoneal dialysis techniques are continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD). In CAPD the patient introduces dialysate into the peritoneum four times per day. In CCPD the patient connects the catheter to a machine, which cycles solution in and out of the peritoneum while the patient sleeps.

The primary components of hemodialysis are the hemodialysis machine, blood lines (tubing that carries blood from and to the body), anticoagulants, and dialysate. In hemodialysis a machine pumps blood out of the patient through blood lines, mixes it with dialysis solution and anticoagulants (primarily heparin to keep the blood from clotting), runs it through a dialyzer, and returns cleansed blood to the patient. A "dialyzer" is an artificial kidney: it separates waste products and excess water from the blood. Patients usually receive three, two to six hour, treatments per week at a dialysis center.

Peritoneal dialysis is much less disruptive than hemodialysis because a patient does not travel to a dialysis center three or more times per week. But peritoneal dialysis requires some renal function and does increase the risk of peritonitis, an infection of the peritoneum.

Infusions (www.noharm.org)

In addition to blood infusions, patients may receive medications, nourishment (such as total parenteral nutrition), and other fluids, such as dextrose or electrolyte solutions through infusion. 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 patient's vein. Approximately 80% of IV sets are manufactured with DEHP-plasticised PVC bags and tubes.

The leaching of DEHP into IV medications and products is well established. Trissel for example, has in 1998 identified a range of drugs, including the cancer drug Taxol, that have been shown to increase DEHP leaching. DEHP leaching into standard IV products -- such as glucose (sugar) solutions, or electrolyte (saline) solutions -- is more likely when the bags have been agitated or warmed. DEHP concentrations have been found as high as 0.36 mg/l in glucose solutions and 0.16 mg/l in electrolyte solutions. An infusion of one litre of glucose solution could result in 0.005 mg DEHP/kg bw.

Appendix 2 Categorisation of common plastic polymers

The following table categorizes common plastic polymer materials (Lars Pedersen, 1999).

Category	Description	Material
1	<p>The substances added or generated in the production, use or disposal phase do not require any special precautions or result in significant health or environmental impact.</p> <p>The energy consumption during manufacturing of the raw material and in further processing is relatively low while the energy generated by incineration (heat of combustion) of the polymer material is high</p>	Polypropylene – PP
		Polyethylene – PE
		Cellulose acetate – CA
		Poly (isobutylene) – PIB
		Ethylene vinyl acetate – EVA
2	<p>The polymer materials in this category contain health or environmental hazardous substances, which are crucial for the manufacturing or for the properties in use of the polymer.</p> <p>The substances added or generated in the production, use or disposal phases may not according to law, require any special end-of pipe treatment or special for protective equipment but might have health or environmental impacts.</p> <p>The polymer materials, which fulfil the first criteria in Category 1 but require large energy consumption to manufacture or which generate relatively low levels of energy upon incineration, are also listed in Category 2.</p>	Polyamide – PA or Nylon
		Styrene ethylene butylene styrene co-block polymer – SEBS
		Styren isoprene block polymer
		Polymethyl methacrylate – PMMA
		Polyethylene terephthalate – PET
		Polyacetal or polyoxymethylene– POM
		Aminoplast – MF, UF
		Phenolformaldehyd – PF
		Polystyrene – PS
		Styrene co-polymer and ter-polymer – SAN and ABS
Silicone		

Category	Description	Material
3	<p>The polymer materials in this category contain particularly health or environmentally hazardous substances, which are crucial for the manufacturing or for the properties in use of the polymer.</p> <p>The substances added or generated in the production, use or disposal phase may require special end-of-pipe precautions or protective equipment and may result in significant health or environmental impacts.</p> <p>It should be noted that where the necessary end-of-pipe precautions and protective equipment are adequately installed during manufacturing, the impacts on health and environment can be made negligible.</p>	<p>Latex/Natural rubber (cis-polyisoprene) – NR</p> <p>Polytetrafluorethylen – PTFE</p> <p>Polyvinyl chloride – PVC (hard)</p> <p>Polyvinyl chloride not plasticized with DEHP – PVC (soft)</p> <p>Thermoplastic Polyurethane – TPU</p> <p>Polyurethane foam – PUR foam</p> <p>Polysulfon – PSU</p> <p>Polycarbonat – PC</p> <p>Epoxy – EP</p>
4	<p>The polymer materials in this category are regarded as particularly hazardous to health and environment. This category includes polymer materials that otherwise would be in category 1-3 but which contain additives considered as hazardous to health and environment.</p>	<p>Polyvinyl chloride plasticized with DEHP – PVC(soft)</p> <p>Halogenated additives</p> <p>Additives with heavy metals</p> <p>Fire-retardant based on bisphenols or diphenyl</p> <p>Plasticizers based on DEHP</p> <p>Other additives with the ability to act as endocrine disrupters</p>