PVCFREEBLOODBAG - LIFE CYCLE ASSESSMENT

Environmental strategies

ABSTRACT

BloodBag that is free from PVC, has a promising development in relation to PVC with the plasticizers DEHP. DEHP is classified as toxic to reproduction which means it may damage fertility and may damage the unborn child. To minimize the overall environmental impact and human health hazard one must consider a broad perspective. This LCA compare the life cycle of a bloodbag in PVC with a PVCfree option under development.

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LCA of PVC-free blood bag, Sweden

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Abstract

LCA, Life Cycle Assessment is an international standardised method used to investigate the environmental impact of a product from a life cycle perspective. The purpose with this LCA was to in an objective and scientific way in the European healthcare increase the awareness about the potential environmental and health issues concerned to the materials used in transfusion medicine. This study was partly based on a previous study conducted by Carlson (2012).

The functional unit (FU) was one set of blood bags, consisted of four bags connected with tubes. Needle and filter was excluded. Two different types of blood bags were assessed: A conventional set of blood bags made of PVC (Polyvinyl Chloride) and DEHP (Di-2-Ethylhexyl Phthalate), and a PVC-free set of blood bags made of a PVC-free polymer, mainly polypropylene and synthetic rubber. The scope was from cradle to grave, that is all the way from extraction of raw materials, production, installation, use and service to the waste disposal. A special focus was on DEHP leakage during storage of blood components. This was assessed based on a modified version of USEtox method.

The impact assessment showed that there were no major differences of global warming potential, fossil depletion, and agricultural land occupation of the two set of blood bags. Regarding potential water scarcity and human toxicity, the impacts of PVC/DEHP based set was substantially higher compared to the PVC-free set.

Impact category	**Category indicator**	**Results per FU**		**Method**
		PVC/ DEHP	PVC-free	
Global Warming Potential	Kg CO_2 eq	2,73	2,62	GWP 100a v.1.03
Fossil depletion	kg oil eq	0,05	0,05	ReCiPe Midpoint (H) European v.1.13
Land use, as agricultural land occupation	m^2a	0,5	0,5	ReCiPe Midpoint (H) European v.1.13
Water Scarcity	m^3	0,04	0,02	Hoekstra (2012)
Human toxicity	CTUh, cancer	4,9E-07	3,2E-07	USEtox v.1.04, modified
	CTUh, non-cancer	2,4E-06	4,7E-07	

The most significant aspects of impact on human health for the PVC/DEHP blood bag as identified in the previous study conducted by Carlson (2012), was the phthalate DEHP leaked into the blood during transfusion, and dioxin emitted during incineration of PVC, due to its chlorine content. Based on literature (Doka, 2007), there is no correlation of dioxin formation and incineration of waste with high chlorine content. The conditions during incineration have improved with less emissions of dioxin. However, were incomplete combustion still occur the impact on health remains. Therefore, the most important aspect of human toxicity is the DEHP leakage during storage of blood.

The calculation of DEHP risk is associated with uncertainties, due to assumptions and simplifications. In a sensitivity analysis, the human toxicity for the PVC/DEHP based bag were assessed, based on 50 percent lower DEHP exposure. It showed that even if the DEHP exposure was halved, the potential human toxicity would still be significant.

Based on the result of this LCA, it is possible to lower the toxicity risks for human health by change the PVC/DEHP based blood bag to a PVC-free alterative, without increase other risks environmental risks or risks for human health. The results from this study strengthen the previous results by Carlson (2012) were the unambiguous recommendation was to change the PVC/DEHP based set of blood bag to the PVC-free alternative, considering potential leaching of other substances not shown in this LCA.

Regarding fossil depletion, the use of polymers dominates the use of fossil resources. As Carlson (2012) stated, it is recommended that effort should be taken to use recycled material if possible. Also, alternative to incineration could be considered. According to WHO (2015), alternatives to incineration of healthcare waste are available, such as autoclaving, microwaving, steam treatment integrated with internal mixing and chemical treatment. This could have a potential to lower the global warming impact.

Content

Abbreviations and clarifications

BW	Body weight
DEHP	Di-2-Ethylhexyl Phthalate or Bis(2-ethylhexyl)phthalate, used as plasticiser in PVC.
Erythrocytes	Red blood cells (blood component)
FU	Functional Unit
GWP	Global Warming Potential
HDPE	High density polyethylene
LCA	Life Cycle Assessment
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Assessment
PVC	Polyvinylchloride
Thrombocytes	Platelets (blood component)
WSI	Water Scarcity Index

1 Background

PVCfreeBloodBag is a demonstration project with financial support from EU's Life+ programme. It is a cooperation between healthcare and industry to phase out harmful substances from healthcare.
The project selected PVC-free instead of PVC out of precaution - to avoid risks with new plasticizers.
The companies participating in the project are MELITEK A/S, Wipak Oy, Primo Profile and Haemotronic SpA. They represent the supply chain producing the bag. Karolinska University Hospital has evaluated the bags ability to store red blood cells and Region Jämtland Härjedalen has been responsible for the user tests.
The main objectives are to demonstrate that it is possible to produce a PVC-free blood bag that fulfils requirement specification and to increase demand by cooperation with European healthcare by dissemination knowledge and awareness.
To decrease the environmental impact in future developments a life cycle assessment is very valuable. The LCA will indicate at which steps there are ways to lower the impact on the environment.

Polyvinylchloride (PVC) is a polymer used for a wide range of purposes. Plasticized PVC is used in a wide range of medical devices, mainly because its flexibility, chemical stability, and possibility to sterilise, low cost, wide availability, and the lack of evidence of significant adverse consequences in patients (SCENIHR, 2015).

Phthalates are one of the most commonly used plasticizers and di(2-ethylhexyl) phthalate (DEHP) is one of the commonly used phthalates. The biological properties of DEHP have been the issue in several research studies, where its potential for reproductive and developmental effects, testes toxicity, endocrine disruption, and some forms of cancer. DEHP is classified as toxic to reproduction which means it may damage fertility and may damage the unborn child (ECHA, 2017).

1.1 LCA of blood bags – pre-study

The pre-study to the project was made by (Carlson, 2012).

A comparative LCA of blood bags were performed to provide a quantitative overview of the environmental impacts of the PVC-based blood bags. A PVC/DEHP based blood bag were compared with a fictional bag made of High Density Polyethylene (HDPE).
Climate change, impact on human health and resource use were included. The most significant aspects for the PVC/DEHP based blood bag was

- the phthalate DEHP leaked into the blood during storage of blood and dioxin emissions during combustion of chlorine containing PVC and DEHP
- consumption of fossil oil, while both PVC and DEHP are based of oil, and the used bags are considered as medical waste and are incinerated rather than recycled
- Carbon dioxide emissions during incineration of the fossil based blood bags.

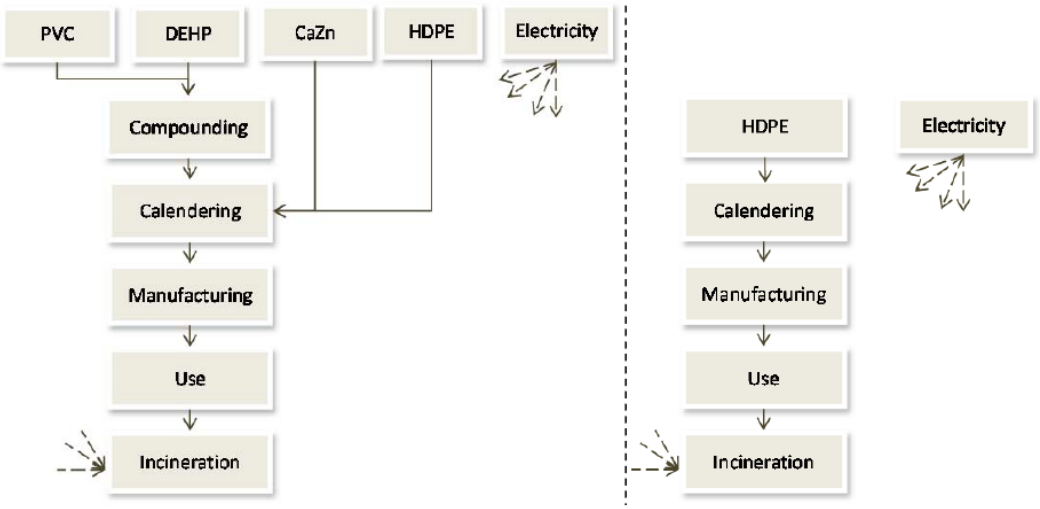

Figure 1 Technical system boundaries of the PVC/DEHP (to the left) and the HDPE (to the right) based blood bags, as included in the previous LCA study taken from Carlson (2012).

The weights were assumed to be the same for both bags. Transports and use were not included, except for the leakage of phthalates during transfusion. The ratio of PVC and DEHP in the PVC based bag were set to 65/35. Both blood bags were assumed to weigh 87,5 grams. The electricity for manufacturing, storage was represented by a generic background electricity production as an average from the OECD countries. The blood was assumed to be stored for 30 days. Two different ways of incineration were assessed for the PVC/DEHP blood bag, an uncontrolled and a controlled incineration.

The PVC-free blood bag showed a potentially higher impact on climate change and resource depletion due to higher content of hydrocarbons. The PVC/DEHP based blood bag had a substantially higher potential to harm human health compared to the HDPE based blood bag. This was explained by the chlorinated substances occurring in production emissions, in phthalates leached to the blood and transferred to the patient during transfusion and due to dioxin emissions during waste incineration. The results are summarized in Figure 2.

The unambiguous recommendation from the study was to change the current PVC/DEHP based blood bags to an PVC-free hydrocarbon based alternative. This was true only if this alternative blood bag fulfils all quality and economic criteria associated with the bags. Else it was recommended that efforts should be made to exchange as many blood bags as possible due to application, such as storage time, patient group, or transportation needs. Also, it was recommended that efforts should be made to use recycled materials when possible, and that bio-plastics may be used if material recycling was an option.

As limitations identified in this study, limited choice of system boundaries was mentioned, as well as the fact that many potential recycling and other synergies were omitted. Also, some data used in the study, for example electricity production data, were old and may not be valid for the current European production systems. Finally, the modelling to compare the life cycle impacts of populations with health risks during blood transfusion was unstable, since the impact on population was based on statistical average, whereas health risks during transfusions is based on the biological sensitivity of individuals. However, sensitivity analysis was carried out to produce a stable result regardless these limitations (Carlson, 2012).

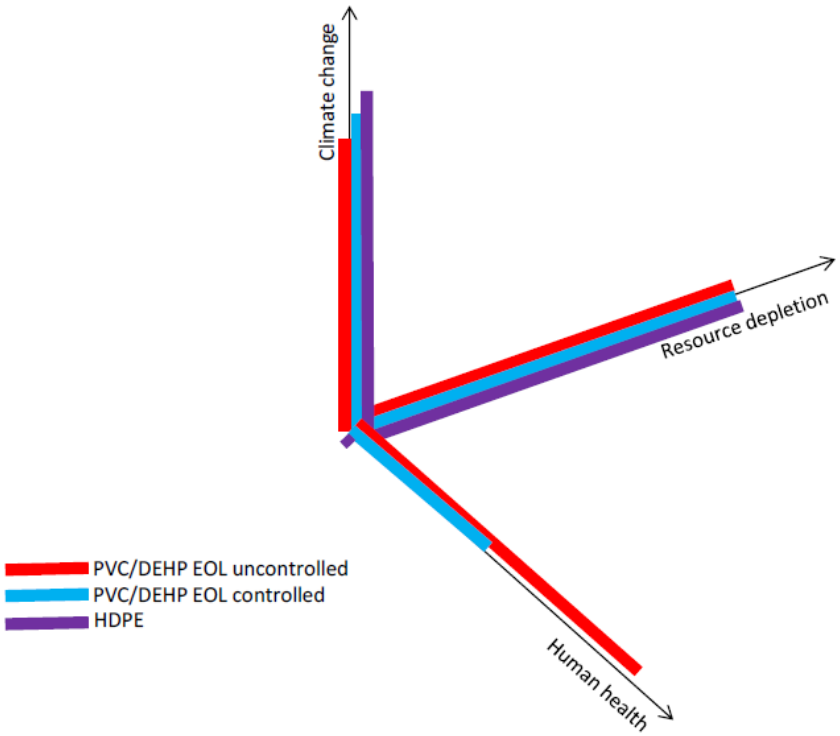

Figure 2 Calculated impacts onto climate change, resource depletion and human health presented as dimensions in a co-ordination system, the 3-axis approach. Figure is taken from Carlson (2012).

1.2 Dioxin emission from health care

However, more recently references state that dioxin formation is not dependent of chlorine content of the waste during incineration of waste. The dioxin formation is rather dependent on process specific parameters, like oxygen concentration, temperatures, and flow velocities. In other words, a decrease of the chlorine content in the incinerated waste will have no perceivable effect on dioxin formation (Doka, 2007).

Historically, incineration of waste containing PVC has been the main source of dioxin emissions due to medical waste. Because of stricter emission limits, the emissions of dioxin from incinerators are declining. However, dioxin is still emitted during production of PVC as well as uncontrolled combustion, such as open burning and building fires (Healt Care Without Harm, 2002).

According to U.S. EPA (2006) the releases of dioxin-like compounds from medical waste incineration in the United States has decreased with 85 percent between the yeas 1987 and 2000. That is 2,570.0 g toxicity equivalence (TEQ) 1987 to 378.0 g TEQ 2000 (U.S. EPA, 2006).

1.3 SCENIHR

DEHP is commonly used as plasticizer in medical devices made of PVC, such as conventional blood bags. Thus, patients undergoing medical treatment, for example transfusions or haemodialysis, can be exposed to this substance. Due to the chronic nature of haemodialysis treatment, haemolysis patients are considered to have the highest exposure.

The release of DEHP from a blood bag made of PVC and DEHP into blood components are affected of at least three factors:

- the content of plasma, while plasma lipids will increase the release
- the temperature, the release of DEHP are significant higher at room temperature than in cold
- time, as the release of DEHP are linear over time (SCENIHR, 2015).

Scientific Committee on Emerging and Newly-Identified Health Risks, SCENIHR, published an updated Opinion on the safety of medical devices containing DEHP and other plasticizers for PVC based components (SCENIHR, 2015). In this opinion, the latest scientific information published was reviewed and evaluated. The focus was on the potential health risks for patients with high exposure to DEHP or other plasticizers, leaching from medical devices. The recent epidemiological studies investigating correlation of DEHP exposure and testosterone production, breast tumour, hypospadias and cryptorchism, decreased anogenital distance, childhood growth and pubertal development and endometriosis, as well as the effect of DEHP metabolites on neurobehavior, obesity, insulin resistance and type 2 diabetes. SCENIHR concludes that results from these studies were either inconsistent and inconclusive. One of the major problems concerning the correlation between exposure and health effects was related to identification of the level of exposure to DEHP. Therefore, this needs further investigations.

2 Life cycle assessment, LCA

In this chapter, a generic description of LCA method are found.

2.1 Introduction

Life cycle assessment (LCA) is a method to investigate the environmental aspects of products or services with a systematic approach. LCA addresses the environmental aspects and potential environmental impacts (e.g. use of resources and environmental consequences of emissions) throughout a product's life cycle from raw material acquisition through to production, use, end-of-life treatment, recycling and final disposal (i.e. cradle-to-grave). A major part of the environmental impact of a product depends on choices taken during the product development phase, e.g. materials, processes, functionality etc. Through increased understanding of the environment impacts of the entire life cycle, the effects of measures can be optimized. LCA conducted according to standardized methods also facilitates comparisons with similar products or services which can be useful for marketing and for developing environmental strategies for the development of products, processes, and business models.

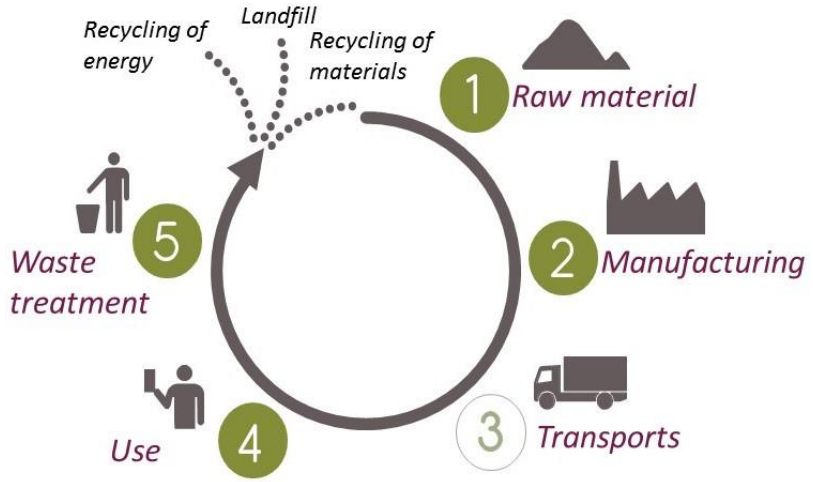

Figure 3 The life cycle of a product.

A life cycle assessment can be designed as either attributional or consequential. An attributional LCA is a retrospective assessment aimed at describing the environmental properties of the life cycles of existing product systems. This can be used for comparative purposes. A consequential LCA is aimed at describing the effects of potential changes within a life cycle, in a forward-looking LCA.

The depth and breadth of an LCA can differ considerably depending on the goal of a LCA.

- Screening (LCA for a product or service on a general level),
- Complete (in-depth LCA),
- Scenario (parametric modelling),
- Organizational (LCA for an organization on an overall level),
- Contributional (analysis of consequences for regions or sectors).

2.2 LCA according to ISO 14044

International Organization for Standardization (ISO) is an independent, non-governmental organization. ISO develops voluntary, market relevant standards with specifications for products, services, and systems, to ensure efficiency and safety.

In 1997, ISO published their first set of international guidelines for the performance of LCAs. This ISO 14040 standard series has become widely accepted amongst LCA experts and is continuously being developed along with advances within the field of LCA (Rebitzer et al. 2003). The guidelines for LCAs are described in two documents; ISO 14040, which contains the main principles and structure for performing an LCA, and ISO 14044, which includes detailed requirements and recommendations (Carlsson & Pålsson, 2011). Other ISO standards concerning LCAs are listed in Table 1.

Table 1: ISO documents relevant to LCA, a selection.

Area	Document	Basic principles and structure for conducting an LCA
LCA	ISO 14040 (2006a)	Detailed requirements and recommendations
	ISO 14044 (2006b)	Format for data documentation
	ISO/TS 14048 (2002)	Examples of applications: environmental impact assessment
	ISO/TR 14047 (2012a)	Examples of applications: goal and scope description, life cycle inventory
	ISO/TR 14049 (2012b)	Environmental Product Declarations
Other, close to LCA	ISO 14025 (2006c)	Water footprint
	ISO 14046 (2014a)	Carbon footprint
	ISO/TS 14067 (2013)	Basic principles and structure for conducting an LCA

In accordance with ISO 14040 and ISO 14044, an LCA is conducted through four phases: the goal and scope definition phase, the inventory analysis phase (Life Cycle Inventory, LCI), the impact assessment phase (Life Cycle Impact Assessment, LCIA), and the interpretation phase (Figure 4).

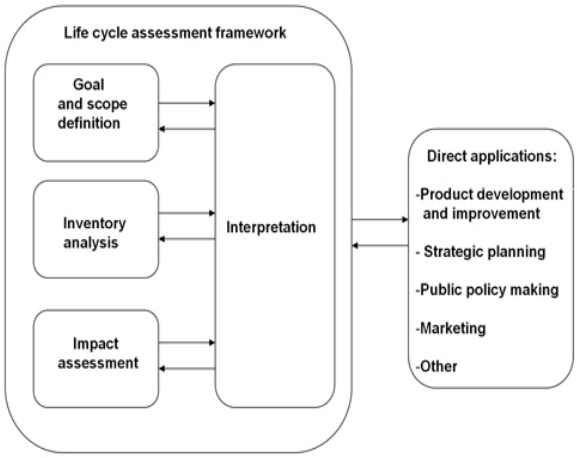

Figure 4. The four phases of Life Cycle Assessment

- During the goal and scope phase, purpose and functional unit are defined. The system boundary is set up, the level of details as well as the intended audience.

- During the life cycle inventory phase (LCI phase), the inputs and outputs of the system are inventoried, including the collection of the data necessary to meet the goals of the defined study.
- The life cycle impact assessment (LCIA) is the third phase of the LCA. The purpose of LCIA is to provide additional information to help assess a product system's LCI results to better understand their environmental significance.
- Life cycle interpretation is the final phase of the LCA procedure, in which the results of an LCI or an LCIA, or both, are summarized and discussed as a basis for conclusions, recommendations, and decision-making in accordance with the goal and scope definition.

In the ISO standard, seven principles of LCA are defined. With a life cycle perspective, the entire life cycle of the studied product will be considered. The assessment shall have an environmental focus, while economic as well as social aspects are usually not considered[1]. With a relative approach, the assessment is structured around a functional unit which defines what is being studied. Each individual phase in an LCA depend on outcomes from the previous phases, hence an iterative approach is necessary. LCA is a complex process, therefore transparency is important to ensure correct interpretation of the results. With comprehensiveness, all attributes, and aspects within one study in a cross-media perspective can be considered. Finally, decisions should be made giving priority to a scientific approach (ISO 2006a; ISO 2006b; Carlsson et al. 2011).

LCA can assist in

- identifying opportunities to improve the environmental performance of products at various points in their life cycle,
- informing decision-makers in industry, government, or non-government organizations (e.g. for strategic planning, priority setting, product or process design or redesign),
- the selection of relevant indicators of environmental performance, including measurement techniques,
- Marketing (e.g. implementing an Eco labelling scheme, making an environmental claim, or producing an environmental product declaration).

[1] Recently, the awareness of and demand for knowledge about the social impacts of a product have increased. Thus, so called social LCAs (S-LCA) have been developed. As an example, the United Nations Environment Program (UNEP) has developed guidelines for social LCAs that can be implemented based on ISO standards ISO 14040 and ISO 14044 (UNEP, 1999).

3 Goal and scope

In this section, the goal and scope of the study are described.

3.1 Goal

The goal was to produce a comparative, complete LCA of the environmental impacts of PVC-based and PVC-free blood bags, with a life cycle perspective.

The purpose with this LCA was to, in an objective and scientific way in the European healthcare, increase the awareness about the potential environmental and health issues concerned to the materials used in transfusion medicine.

The result was intended to be communicated to public.

3.2 Scope

The perspective of the LCA is attributional, which means that the burdens associated with the production and use of the product, at a specific point in time, are assessed.

The scope was from cradle to grave, that is all the way from extraction of raw materials, production, installation, use and service to the waste disposal.

3.2.1 Name and functional unit

The functional unit shall be consistent with the goal and scope of the study. One of the primary purposes of a functional unit is to provide a reference to which the input and output data are related.

The functional unit (FU) was one set of blood bags, consisted of four bags connected with tubes. Needle and filter was excluded. The quality is that at least same share of stored blood can be used after 42 days in storage. (42 days are the guidelines but 21 is praxis. The time required is decreasing.)

Two different types of blood bags were assessed:

- A set of blood bags made of PVC (Polyvinyl Chloride) and DEHP (Di-2-Ethylhexyl Phthalate)
- A PVC-free set of blood bags made of a PVC-free polymer, mainly polypropylene and synthetic rubber.

The assessment on the blood bag with PVC is mainly based on generic data while the assessment of the blood bag without PVC are based on specific data.

3.2.2 System boundary

The system boundary determines which unit processes shall be included within the LCA. The selection of the system boundary shall be consistent with the goal of the study. The criteria used in establishing the system boundary shall be identified and explained.

Raw materials, production, manufacturing use and disposal are included in the study. For the PVC-free blood bag set specific data are used for the material composition, manufacturing and assembly as well as the distances for transports. Generic data are used for acquisition of raw materials, production of material and energy the transport processes.

To verify the bags ability to store red blood cells, meaning an in-vitro study, a PVC-free filter and a needle was required in the set of bags. This filter and needle came from an external source and was not optimised or adopted for the new set of bags. It is not known what filter that will be used in the new set. We have therefor chosen not to include the filter from either of the set of bags in the assessment.

A generic overview of processes included and excluded are presented in (Table 2).

Table 2 Processes included and excluded in the LCA.

Included	Excluded
Upstream • Raw material, energy, and fuels	**Upstream** •
Core • Electricity and material for production of bags and tubing • Packaging material for bags and tubing • Transportation of material	**Core** • Consumables • Labour • Infrastructure and capital goods • Needle and filter • Energy use during assembly • Sterilisation
Downstream • Electricity for component production and storage • DEHP leakage into blood • Transports and infrastructure for waste treatment	**Downstream** • Infrastructure and capital goods for use and storage

3.2.3 Cut off criteria

The broad scope of analysing a whole life cycle of a product and the comprehensive approach demands for clear system boundaries and limits to what should be included and what are not (cut off). To define cut off criteria, a lower limit for the size of flows included is specified. Flows below the lower limit are considered as negligible and are therefore excluded. In this study, the cut off criteria was set to 5 percent of total estimated environmental impacts. This means that LCI data for a minimum of 95 percent of total estimated environmental impact shall include. To reach a goal that not more than 5 percent is excluded, it is required to have an even lower limit on each specific flow. In practical terms, it is not possible to know what is excluded without first doing that assessment. An experienced LCA practitioner can often comprehend and when is doubt using generic data for a reference.

3.2.4 Allocation procedure

While more than one product is produced in the same production system, the use of energy and material and subsequent environmental impacts need to be allocated between the products, to be able to assess the size of the impacts of the specific product. Allocation can be done based on mass, socioeconomic value, or function of the products.

There are a several types of allocation procedures considered in this study:

- The allocation of environmental burden between products
- Allocation to residual material

3.2.4.1 Allocation to products

Allocation of environmental aspects may occur when a process produces more than one product. The basis for this allocation was primarily economic value (economic allocation). Secondarily, allocation was done based on the function of the products.

3.2.4.2 Allocation to residual material

For the allocation of residuals, the model "allocation cut-off by classification (ISO standard) (called "Allocation Recycled Content", alloc rec, by ecoinvent) is used. The underlying philosophy of this approach is that primary (first) production of materials is always allocated to the primary user of a material. If a material is recycled, the primary producer does not receive any credit for the provision of any recyclable materials. Consequently, recyclable materials are available burden-free for recycling processes, and secondary (recycled) materials bear only the impacts of the recycling processes. The concept of allocation to rest material is further described in Appendix 1.

3.2.5 Impact assessment method

The life cycle impact assessment (LCIA) was modelled with SimaPro 8.3 LCA software. In this software, several ready-made methods are included, in principle all recommended by European Commission (EC).

The choice of methods in this LCA is based on impacts being assessed in previous LCA studies and EC guidelines (JRC, 2010) presented in Table 3.

Table 3 Impact categories, indicators and methods used in the study.

Impact category	Category indicator	Method
Global Warming Potential (GWP)	Kg CO_2 eq	GWP 100a v.1.03 (IPCC, 2013)
Fossil depletion	kg oil eq	ReCiPe Midpoint (H) European v.1.13 (Goedkoop, et al., 2009)
Land use	m^2a	ReCiPe Midpoint (H) European v.1.13 (Goedkoop, et al., 2009)
Water Scarcity	m^3	Hoekstra (2012)
Toxicity	CTUh	USEtox v.1.04, modified

3.2.6 Interpretation

Interpretation of the results are made by identifying the data elements that contribute significantly to each impact category, evaluating the sensitivity of these significant data elements, assessing the completeness and consistency of the study, and drawing conclusions and recommendations based on a clear understanding of how the LCA was conducted and the results were developed.

3.2.7 Data requirements

The level of depth (fidelity) depends on the availability of inventory data. In general, the more details you know, the more environmental impact is revealed. That should be balanced by covering the whole perspective of the life cycle. By employing general data from certified organisations, the fidelity and amount of Life Cycle Inventory (LCI) data may increase. It is crucial however, to understand that specific producers may differ significantly from general practice. Only by in depth investigations it can be perfectly determined.

For this study, generic and specific data are used according to following:

- **PVC-free:** In general, specific data are used for material composition and manufacturing (primary flows, system boundary 1).

PVC/DEHP: For the PVC/DEHP based bag, material composition and manufacturing based on generic data. For waste during production and packaging, data corresponding to the PVC-free blood bag are used (primary flows, system boundary 1).

- For production of material, energy, and transports (secondary flows, system boundary 2), generic data are used for both bags.
- For acquisition of raw materials and production of energy (secondary flows, system boundary 3), generic data are used for both bags.

System boundary 1: Material composition for the component, manufacturing and assembly.
System boundary 2: Production of material, energy, and transport.
System boundary 3: Acquisition of raw materials and production of energy.

Generic data are mainly taken from the LCI database ecoinvent v. 3.3 (Wernet, et al., 2016). Specific data are collected by producer. Type of data and data sources are specified in section 4, Life Cycle Inventory, LCI.

3.2.8 Assumptions

Assumptions generic for this study:
Transports:

- For freight transports on road, truck, 16-32 t, EURO class 4 was used.
- Distance for transport within Europe is 1000 km (estimation). This distance is used as a generic transport distance for both blood bags.

Electricity:
- Electricity are assumed to be medium voltage for production processes and low voltage for use processes

Production and assembly:

- During production and assembly of the PVC/DEHP bag, losses of material are based on data for losses during production and assembly of PVC-free blood bags.

Use of blood bags:
- The same number of blood bag sets that are used are also purchased (no shelf times).
- loss of bags with components before and after quality check are assumed to be sent to incineration, as the outdated bags with blood components.
- The storage time for each component is equal to the maximum allowed storage time (that is, erythrocytes: 42 days, thrombocytes: 7 days, plasma: 3 years).
- the total amount of waste during use phase are sent to incineration of hazardous waste.
- During calculation of DEHP transferred to human, fate and exposure factors were set to 1. That is, the total amount DEHP transferred to the blood during storage, are transferred to human. No fate or dispersion is assumed.

3.2.9 Limitations

The broad scope of analysing a whole life cycle of a product and the comprehensive approach can only be achieved at the expense of simplifying other aspects. Thus, the following limitations should be considered as recently summarized by Guinée et al. (2004):

- LCA does not address localized aspects, it is not a local risk assessment tool

- LCA is typically a steady-state, rather than a dynamic approach
- LCA does not include market mechanisms or secondary effects of technological development
- LCA regards processes as linear, both in the economy and in the environment
- LCA focuses on environmental aspects and says nothing on social, economic, and other aspects
- LCA involves several technical assumptions and value choices that are not purely science-based

Limitations specific for this study:

- Energy use during storage of blood components, assumed that all the tree types of components are stored during the maximum recommended storage times, while the storage times varies, depending on the need at the time of each component.
- The amounts of components disposed due to outdating, quality etcetera, are representative for Sweden 2014.
- Generic data for incineration of hazardous waste in Switzerland are used. Incineration of bags filled with blood or blood components, means waste with high water content. The water content in this process is not considered, while generic data for incineration of waste with high water content is missing. That could result that the calculated energy use during incineration is lower than the actual energy requirement during incineration.
- The data for energy use during production of PVC-free granulate is taken from an EPD expired 2006.
- There are different alternatives of packaging solutions for the PVC-free bags, still work in progress. CPD and SAGMAN are assumed to be used in the both bags, that is not true for the PVC-free bag.
- Needle, filter, and sterilisation are not included.

3.2.10 Critical review

A critical review is necessary to allow for external communication and comparison with results from other studies. This is a public study with comparative assertions. The LCA expert Göran Brohammer, LCA-expert at Extracon AB, is engaged to perform the critical review.

4 Life Cycle Inventory, LCI

During the life cycle inventory phase, qualitative and quantitative data need to be collected. The data collection was made by Miljögiraff in cooperation with the costumer, by questionnaires, e-mail, skype meetings and phone calls. Generic data were collected from the LCI-database ecoinvent 3.3 (Wernet, et al., 2016) and literature. Specific data were collected by producer, Table 4 Sources of data.

Table 4 Sources of data

Process	PVC-free	PVC/DEHP
Raw material		
Acquisition and production	Generic, Ecoinvent	Generic, Ecoinvent
Granulate production/compounding		
Energy, source and amount	Specific, MELITEK	Generic process, extrusion
Material loss	Specific, MELITEK	Assumption, same percentage as for the PVC-free
Production of tubes		
Material composition	Specific, Primo	Taken from Carlsson (2012) and assumed
Energy, source and amount	Calculated, based on the production at Primo 2014	Generic process, extrusion of tubes
Material loss	Specific, Primo	Assumption, based on losses for the PVC-free tubes
Packaging materials, types and amounts	Specific, Primo	Assumption, same as packaging for PVC-free tubes
Production of sheets		
Material composition	Specific, Wipak	Taken from Carlsson (2012) and assumed
Energy, source and amount	Specific, Wipak	Generic process, calendaring
Material loss	Specific, Wipak	Assumption, same percentage as for the PVC-free sheets
Packaging materials, types and amounts	Specific, Wipak	Assumption, same as for the PVC-free sheets
Assembly of blood bag sets		
Weights and material types of components and primary packaging	Specific, Haemotronic	Specific weights taken from a commercial PVC/DEHP set. Material types assumed
Energy, source and amount	Data are missing	Data are missing
Material loss	Specific, Haemotronic	Assumption, same percentage as during assembly of PVC-free sets of blood bags
Packaging solutions (liquid)	Same as for PVC/DEHP blood bag are assumed	Specific data (CPD and SAGMAN) taken from safety data sheets of CPD and SAGMAN produced by Fenwal
Sterilization of assembled set of blood bags		
Transport to sterilization site	Specific distance	Same distance as for PVC-free bags are assumed

Sterilization process	Data are missing (gamma radiation)	Data are missing (steam autoclave)
Use		
Transport of blood bags	Specific distance, receiving unit approximated to be in Stockholm	Same distance as for PVC-free bags are assumed
Amounts of blood bag used	Based on statistics for number of blood donations, component productions, transfusions and cassations, valid for Sweden 2014	
Waste and cassations		
Energy for production of blood components	Specific data based on centrifuge and press used at Karolinska	
Storage of blood components	Calculated data based on specific data from Karolinska, effects of specific storage units not used at Karolinska and assumptions	
Disposal		
Transport to waste treatment	Approximated	
Waste treatment	Generic data corresponded to incineration of hazardous waste in Switzerland	

4.1 PVC-free blood bag, production

The PVC-free set of blood bags are made of PVC-free polymer produced by MELITEK, Denmark. The granulate are used for production of plastic film and tubes by suppliers in Finland (Wipak) and Poland (Primo). The tubes and films are assembled with the rest of the components (needle, clamps and filter) and packaged in a primary packaging by Haemotronic, Italy, before the sets are sent to sterilization by gamma radiation by Sterigenics Italy Spa, Italy. A schematic figure of the life cycle of the PVC-free set of blood bag are found in Figure 5.

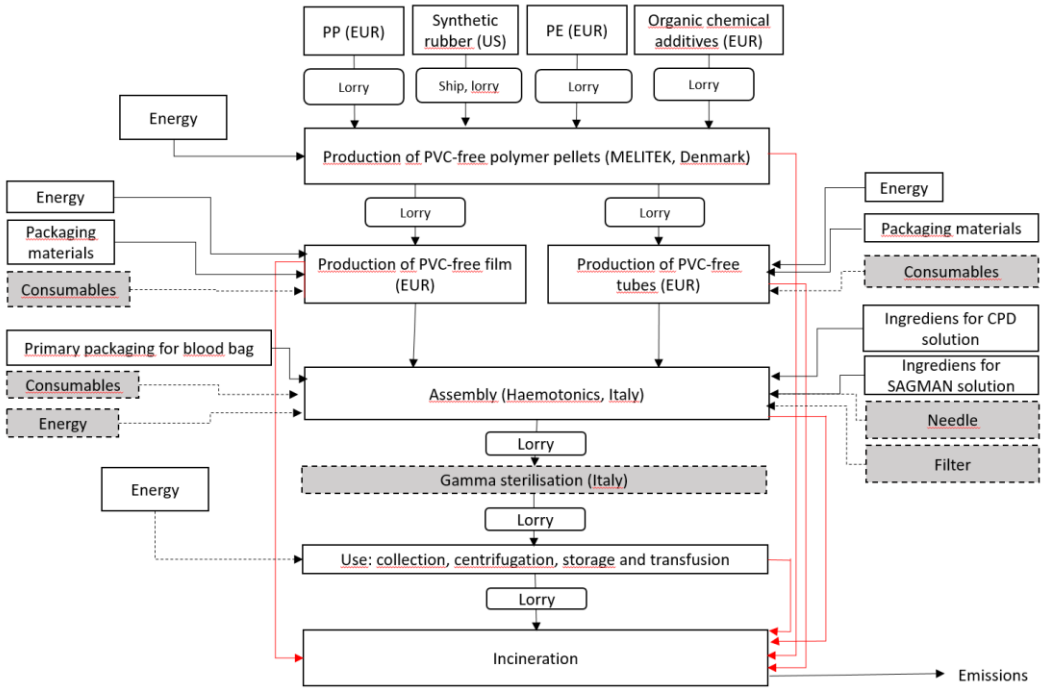

Figure 5. The life cycle of the PVC-free blood bag set. Red lines symbolise loss during the production and use phases. Grey boxes and dotted lines symbolizes processes that are not included.

The PVC-free blood bag is shown in Figure 6. Components, weights, and materials are listed in Table 5.

Figure 6 The PVC-free blood bag

Table 5 components, weights, and material of the PVC-free blood bag set.

	Component	Weight (g)	Material	Comment
1	Filter and plastic sleeve	-		omitted
2	Clamps	2*1,0	Polyethylene, high density	Two clamps á 1,0 g per clamp. Material type is assumed
3	Needle and plastic sleeve	-		omitted
	Bags	4*15,6	Polyolefin (Meliflex)	
	Tubes	33,5	Polyolefin (Meliflex)	
Total	**PVC-free set (without needle and filter)**	**97,9**		The weight of one PVC-free set, without needle, filter, CPD and SAGMAN.
	Primary packaging	17,6	Low density polyethylene	Material type is assumed

4.1.1 PVC-free granulate

Meliflex is a polyolefin-based alloy (compound) that is designed and produced specially for pharmaceutical packaging and medical devices applications by MELITEK, Denmark. The material is both PVC- and latex free and contains neither phthalates nor other plasticisers. The polymer pellets are made of polypropylene (PP), synthetic rubber, polyethylene (PE) and organic chemical additives. These are melted and mixed into a new polymer mixture, designed to have the physical and chemical properties needed to make film and tubes that meets the requirements for blood bags (Melitek, 2006). Losses of materials during processing is one percent, according to the producer. Data

for producing the Meliflex granulate is presented in Table 6. The density of the granulate is 0,9 g/m^3.

Electricity used during production of PVC-free granulate was calculated, based on primary energy data (as CED) taken from EPD (Melitek, 2006). The amount non-renewable energy, as MJ primary, used for production of 1 kg Meliflex granulate was 3,41 MJ. This is assumed to correspond the amount of primary energy used for production and use of electricity. (Also, other kind of energy use can be included in this value, like intern transports, consumables etc.). Based on the CED method (Cumulative Energy Demand V1.09), assumed that electricity, medium voltage, Danish production mix, were used.

Table 6 LCI-data for energy and material used to produce 1 kg Meliflex granulate.

See Appendix 4 LCI-data for energy and material used to produce 1 kg Meliflex granulate.

4.1.2 PVC-free tubes

The tubing is made of three types of resins with different hardness, all produced by MELITEK. The differences between the three types are small and the LCI-data from MELITEK are valid for all three materials (according to Jesper Laursen, personal communication 2016-09-07).

The PVC-free tubes were produced in Poland by Primo, who normally produces plastic devices made of PVC. The tubes produced for the PVC-free blood bag was a test production to make samples of tubes to the prototype PVC-free blood bag. The energy use for extrusion of PVC-free tubes are calculated based on the energy use per kg products produced at the specific production site 2014, which includes tubes and plastic profiles made of PVC.

During production of tubing, the material losses occurs during the startup of machine and on the end of the manufacturing process. No loss of material occurs during running process. During normal production of tubing made of PVC, maximum 10 percent of the material should be lost. According to the producer of the PVC-free granulate (Jesper Laursen, personal communication 2016-09-07), loss during full scale production is 75 percent lower while using the PVC-free granulate compared to the PVC/DEHP-based granulate. Based on that, the loss of material during production of tubing is 2,5 percent. Other kind of waste (like packaging etc.) are not included, nor consumables for the production process. Data for production of PVC-free tubes are presented in Table 7.

Table 7 LCI data for production of PVC-free tubes.

See Appendix 4 LCI-data for energy and material used to produce 1 kg Meliflex granulate.

The tube is sold as reels. Every reel is double plastic bag packed to protect against contamination. The reels are packed to wooden box to protect against mechanical damage during shipment. The wooden boxes are stacked on wooden pallets. The packaging material per 1 kg tubes are estimated, based on data from producer, presented in Table 8.

Table 8 Packing material per 1 kg PVC-free tubes.

Material	LCI-data	Amount	Unit	Comment
Foil bags	Packaging film, low density polyethylene {GLO}| market for | Alloc Rec, U	56,8	g	
Wooden sheets	Fibreboard, soft {GLO}| market for | Alloc Rec, S	2,68E-4	m3	
Wooden frames	Fibreboard, soft {GLO}| market for | Alloc Rec, S	1,17E-3	m3	
pallet	EUR-flat pallet {GLO}| market for | Alloc Rec, S	5,96E-4	piece	

4.1.3 PVC-free sheets

The bags for the PVC-blood bag set are made of PVC-free plastic film produced by Wipak in Finland. The film itself has 3 layers and the film is produced in one step i.e. from granulates to film. Same granulate as for the tubes are used, produced by MELITEK. Data for production of PVC-free sheets are presented in Table 9.

Two types of waste are generated: production start waste and continuous waste. Production start waste is the waste when the product materials are running through the machine, until the material is regarded to be the desired film. Continuous waste is the material when wider reels are cut to narrower customer reels. Material losses during production is 10 percent.

Table 9 LCI-data for production of 1 m2 film.

See Appendix 4 LCI-data for energy and material used to produce 1 kg Meliflex granulate.

Readymade film is slit to reels, width according to the customer's requirement. The weight of the film is 177 g/m2. The film is delivered as double wound (354 g/m2). Each reel is wrapped to double plastic wrap. 6*4 reels are packaged in shrink film wrap, cardboard and put on a wooden pallet. The packaged reels are transported with truck to Haemotronic, Italy.

Table 10 LCI-data for Packaging material used for one pallet of plastic film (430 kg film).

Material	LCI-data	Amount	Unit	Comment
double plastic wrap	Packaging film, low density polyethylene {GLO}| market for | Alloc Rec, U	778	g	
Shrink film wrap	Packaging film, low density polyethylene {GLO}| market for | Alloc Rec, U	72	g	
Cardboard	Corrugated board box {GLO}| market for corrugated board box | Alloc Rec, U	14,2	kg	
EUR pallet	EUR-flat pallet {GLO}| market for | Alloc Rec, U	1	piece	

4.1.4 Packaging solutions (liquids)

At the moment, it is not known what kind of packaging solutions (liquids) that will be used in the PVC-free bag. Therefore, SAGMAN and CPD are assumed, as used in the PVC/DEHP blood bags. The solutions are added in the two of the four bags of the sets during assembly. Data for SAGMAN and CPD are found in section 4.2.3.

4.1.5 Assembly

Tubing, film, donor needle and blood filter is sent to Haemotronic in Italy for assembly of the blood bags. Data for energy use during these processes are missing, and therefore not included. The tubing is cut into specific lengths. Short tubing and film are positioned in the welding mould and bags are welded. During manual assembled the welded bags, tubes and all components are connected to form a set of 4 bags. To avoid damage, the sets are folded and packaged manually.

The filter and needle used in the PVC-free blood bag was taken from an extern producer, not optimised, or adopted for the new set of bags. It is not known what filter that will be used in the new set. Therefore, the filter and needle from either of the set of bags was excluded.

The assembled sets are quality controlled in two ways. A trained operator does visual verification. Functional features (tightness and strength) are also tested according to a sampling plan based on Acceptable Quality Level (AqL) for non-destructive functional testing. This test is performed by a dedicated machine and does not destroy the set that therefore can be sold. The estimated quality control scrap is 0,65% of produced sets (AqL 0,65). For future commercial lots, the estimated industrial scrap of material is negligible when compared to the weight of the device (Alice Ravizza, personal communication 2016-09-20).

4.1.6 Sterilization

The packaged sets of PVC-free blood bags are sterilized by gamma irradiation by Sterigenics Italy Spa. The bags are assumed to be transported to this facility by truck. The irradiation target dose is 25 kg per each sterilization load. The radioactive source is Cobalt 60. All the load receives the same amount of energy. Only small amounts of energy are used during gamma sterilization. Because of lack of LCI data for sterilisation, this is not included.

4.2 PVC/DEHP blood bag, production

The PVC/DEHP based set of blood bags are modelled in the same way as the PVC-free bag. This bag is made of PVC and plasticizer di(2-ethylhexyl) phthalate (DEHP), CaZn and HDPE. Specific weights of the components are taken from a commercial set of blood bag produced by Fenwal. Data regarding the material composition is taken from Carlsson (2012). A schematic figure of the life cycle of the reference PVC/DEHP set of blood bags are shown in Figure 7. The processes are described more clearly in the following.

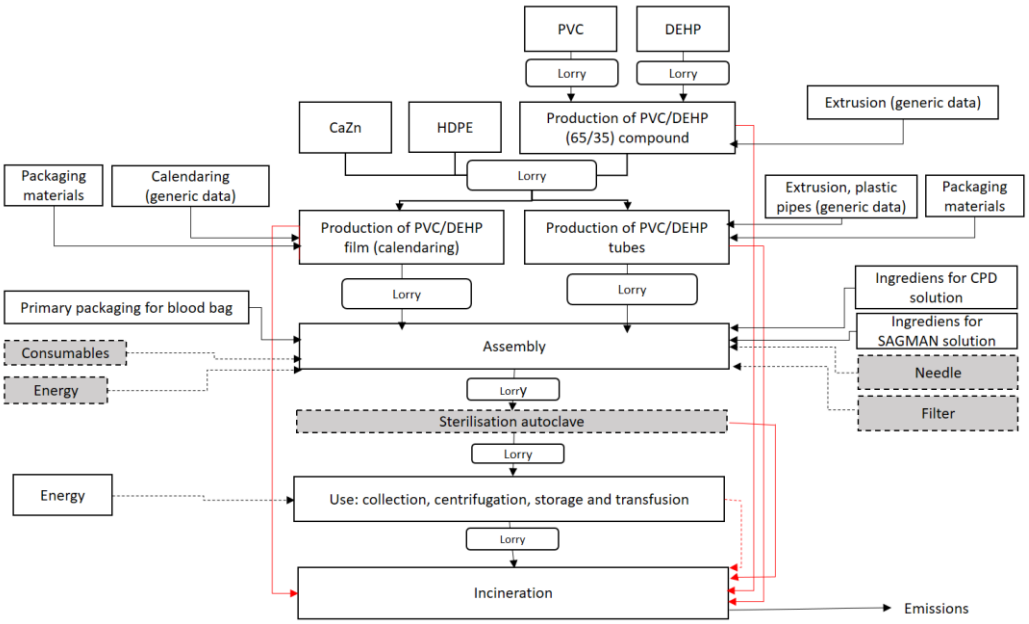

Figure 7 Schematic figure of the production of PVC/DEHP based set of blood bags. Red lines symbolise loss during the production and use phases. Grey boxes and dotted lines symbolizes processes that are not included.

The PVC/DEHP based set are shown in Figure 8. As mentioned before, the filter and needle of both bags was excluded. The PVC-based set of blood bags also included a sampling poush, a small bag and tube, this is excluded from the PVC/DEHP blood bag set in the assessment, while these components are not a part of the PVC-free blood bag (crossed, Figure 8).

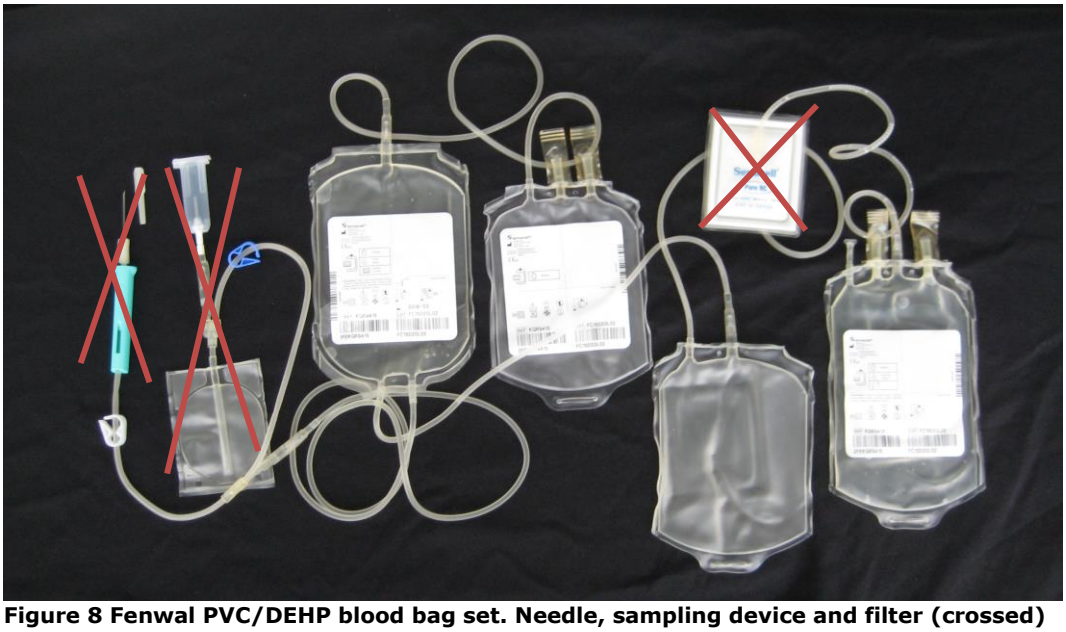

Figure 8 Fenwal PVC/DEHP blood bag set. Needle, sampling device and filter (crossed) are not included.

Figure 9 Components of the PVC/DEHP reference set of bags.

Table 11 Weights and material types of the components in the reference blood bag system. The numbers refers to the numbers in Figure 9.

	Component	Weight (g)	Material	Comment
1	Filter	-		omitted
2	Filter cover	-		omitted
3	Sampling poush	-		omitted
4	Needle cover	-		omitted
5	Needle lid	-		omitted
6	Needle (steel and plastic)	-		omitted
7, 8	Clamps	1,3*2	Polyethylene, high density	Material type is assumed
9	Primary packaging	8,5	Low density polyethylene	Material type is assumed
10	4 bags (mean weight)	25*4	PVC/DEHP	(0,023+0,027)/2. Small bag for sampling is not included
10	tubing	50	PVC/DEHP	Tube connected to sampling device is excluded
	Total weight	**152,6**		Packaging, sampling devices, needle, filter, CPD and SAGMAN excluded

4.2.1 PVC/DEHP compounding

While generic LCI-data corresponded to DEHP were missing, a data set for DEHP was modelled, based on Li (2013). In this process, only the material components are included, represented by generic data from ecoinvent. Production processes, consumables, transports etc. was not included. The inputs are presented in Table 12.

Table 12 Materials used for production of 390 kg DEHP, based on Li (2013).

Process	Material	LCI-data	Amount	Unit	Comment
DEHP (390 kg)	Hydrogen, liquid	Hydrogen, liquid {RER}| market for | Alloc Rec, U	8	kg	
	Carbon monoxide	Carbon monoxide {RER}| market for | Alloc Rec, U	112	kg	
	Propylene	Propylene {GLO}| market for | Alloc Rec, U	168	kg	
	Phthalic anhydride	Phthalic anhydride {GLO}| market for | Alloc Rec, U	148	kg	

PVC and DEHP are mixed into a compound. The ratio PVC/DEHP can differ, in this study a mix of 65 percent PVC and 35 percent DEHP are assumed, taken from (Carlson, 2012). For the compounding process, a general ecoinvent process corresponding to extrusion is used. One percent loss during production was assumed (like production of PVC-free granulate). Data for PVC/DEHP compounding are presented in Table 13.

Table 13 Data for PVC/DEHP compounding.

Material	LCI-data	Amount	Unit	Source	Comment
PVC	Polyvinylchloride, emulsion polymerised {GLO}| market for | Alloc Rec, U	0,65*1,01	kg	ecoinvent	1 % loss assumed
DEHP	Raw material for DEHP (Table 12).	0,35*1,01	kg	Own model based on Li (2013)	1 % loss assumed
Compounding	Extrusion, co-extrusion {GLO}| market for | Alloc Rec, S	1,01	kg	ecoinvent	
Transport	Transport, freight, lorry 16-32 metric ton, EURO4 {GLO}| market for | Alloc Rec, U	1,01*1000	kgkm	ecoinvent	Transport distance within Europe estimated, 1000 km
Waste treatment	Waste incineration of plastics (rigid PVC), EU-27	0,01	Kg	ecoinvent	Material loss

4.2.2 PVC/DEHP tubes and sheets

The PVC/DEHP compound are assumed to be transported to a site for calendaring of plastic film and extrusion of tubing. During these processes, the PVC/DEHP compound are mixed with calcium zinc stabilizer (CaZn) and High Density Polyethylene (HDPE) (Table 14). Production of sheets and tubing are presented in Table 15 and Table 16 respectively. The packaging material for produced tubes and sheets is assumed to be equal to the packaging material used for the PVC-free tubes and sheets.

Based on a technical data sheet for CaZn stabilizer (Norac, 2016), the substance consists of 0,9 percent calcium and 3,2 percent zinc. The CaZn stabilizer is represented with the share of zinc only.

For production of PVC/DEHP tubes and sheets, 10 percent loss are assumed, based on data collected for production of PVC-free tubes and sheets.

Table 14 LCI data for production of 1 kg PVC/DEHP material for sheets and tubing.

Material	LCI-data	Amount	Unit	Source	Comment
PVC/DEHP mix	PVC/DEHP, compounded	0,87	Kg	Own model (Table 13)	
HDPE	Polyethylene, high density, granulate {GLO}| market for | Alloc Rec, U	0,03	Kg	ecoinvent	
CaZn stabilizer	Zinc {GLO}| market for | Alloc Rec, U	0,01*0,032	Kg	ecoinvent	0,01 kg CaZn, represented by the share of zinc (Norac, 2016).
Production	Calendering, rigid sheets {RER}| production | Alloc Rec, U	1,1	kg	ecoinvent	
Transport	Transport, freight, lorry 16-32 metric ton, EURO4 {GLO}| market for | Alloc Rec, U	1,1*1000	Kgkm	ecoinvent	Transport distance within Europe estimated, 1000 km

Table 15 Data for production of 1 kg PVC/DEHP based sheets.

Material	LCI-data	Amount	Unit	Source	Comment
PVC/DEHP/HDPE/CaZn mix	Own model	1,1	Kg	Own model (Table 14)	
Processing	Calendering, rigid sheets {RER}| production | Alloc Rec, U	1,1	kg	ecoinvent	
Waste treatment	Waste incineration of plastics (rigid PVC), EU-27	0,1	kg	ecoinvent	Material loss
Packaging material	See Table 10.				Assumed to be same as packaging for PVC-free sheets

Table 16 Data for production of 1 kg PVC/DEHP based tubes.

Material	LCI-data	Amount	Unit	Source	Comment
PVC/DEHP/HDPE/CaZn mix	Own model	1,1	Kg	Own model (Table 14)	
Processing	Extrusion, plastic pipes {RER}| production | Alloc Rec, U	1,1	kg	ecoinvent	

Waste treatment	Waste incineration of plastics (rigid PVC), EU-27	0, 1	kg	ecoinvent	Material loss
Packaging material	See Table 8				Assumed to be same as packaging for PVC-free tubes

4.2.3 CPD and SAGMAN solutions

In commercial PVC/DEHP sets of blood bags, two types of packaging solutions are added in the blood bag set. These solutions are added during the assembly.

4.2.3.1 CPD solution

In one of the bag, the one which the whole blood are collected during donating, 63 ml of CPD solution (Citrate-Phosphate-Dextrose) is added. The density is 1,0278 g/ml. This is for anti-coagulation, pH regulation and nutrition to the blood cells. While generic LCI-data for this solution were missing, a data set were set up based on the CPD safety data sheet (Fenwal, 2011). Generic data are taken from ecoinvent. Transports or production of the solution is not included in the data set (Table 17).

Table 17 LCI-data for CPD solution, based on Fenwal (2011)

Material	LCI-data	Amount	Unit	Comment
Water	Water, deionised, from tap water, at user {CH}| production | Alloc Rec, U	0,94	kg	
Dextrose	Sugar, from sugar beet {GLO}| market for | Alloc Rec, U	0,025	kg	
Sodium citrate	Sodium {GLO}| market for | Alloc Rec, U	0,025	kg	
Citric acid	Citric acid {GLO}| market for | Alloc Rec, U	0,01	kg	
Monobasic sodium phosphate	Sodium phosphate {RER}| production | Alloc Rec, U	0,01	kg	

4.2.3.2 SAGMAN solution

In the bag where the erythrocytes are stored after the whole blood are decided into components, 100 ml (estimated weight: 0,1 kg) (of SAGMAN solution (Salt-Adenine-Glucose-Mannitol) is added. This is to give nutrition to the erythrocytes during storage. While generic LCI-data for this solution were missing, a data set were set up based on the SAGMAN safety data sheet (Fenwal, 2013). Generic data are taken from ecoinvent. Transports or production of the solution is not included in the data set.

Table 18 LCI data for 1 kg SAGMAN solution, based on Fenwal (2013).

Material	LCI-data	Amount	Unit	Comment
Water	Water, deionised, from tap water, at user {CH}| production | Alloc Rec, U	0,97	kg	
D-Mannitol	Triethylene glycol {RER}| ethylene glycol production | Alloc Rec, U	0,01	kg	
Sodium chloride	Sodium chloride, powder {RER}| production | Alloc Rec, U	0,01	kg	

D-Glucose, monohydrate	Sugar, from sugar beet {GLO}| market for | Alloc Rec, U	0,01	kg	
alpha-D-Glucopyranose	Triethylene glycol {RER}| ethylene glycol production | Alloc Rec, U	0,01	kg	

4.2.4 Assembly of PVC/DEHP blood bag set

Energy and consumables used during assembly is not included for neither of the set of bags, nor transport of components to the site for assembly.

4.2.5 Sterilisation of PVC/DEHP blood bag

The cycle for autoclave sterilization used for the prototypes was 110 Celsius degrees for 150 minutes, in overpressure. The autoclave is a normal free standing autoclave for laboratory use, powered with electrical plug. The sterilisation process is not included in the assessment, due to lack of LCI data.

4.3 Sterilisation processes

As already mentioned, sterilisation is not included in the LCA in a quantitative way, due to lack of data. The impact of sterilisation will only be included in a qualitative way.

However, sterilisation of medical devices was included in a previous study of environmental impact of bioprocess systems (Rawlings & Pora, 2009). In this study, a single-use system, sterilized with steam autoclave, was compared with a reusable system sterilized with gamma. Only energy use was assessed. The steam sterilization was based on a steam generator output of 500 kWh and energy value of 8 MJ/kWh. 100 litre of water was required to provide 130 °C steam during 30 minutes. The energy use for gamma irradiation at 25 kGy for 28 components, based on 90 components per pallet and three pallets per hour, with an output of 28 kWh. The energy use for the sterilisation processes was 2 000 MJ for steam and 32 MJ for gamma sterilization. However, it is not clear what the energy use relates to, and therefore, it could not be used for this study.

4.4 Use

In use phase, component production, storage and transfusion are included (Figure 10).

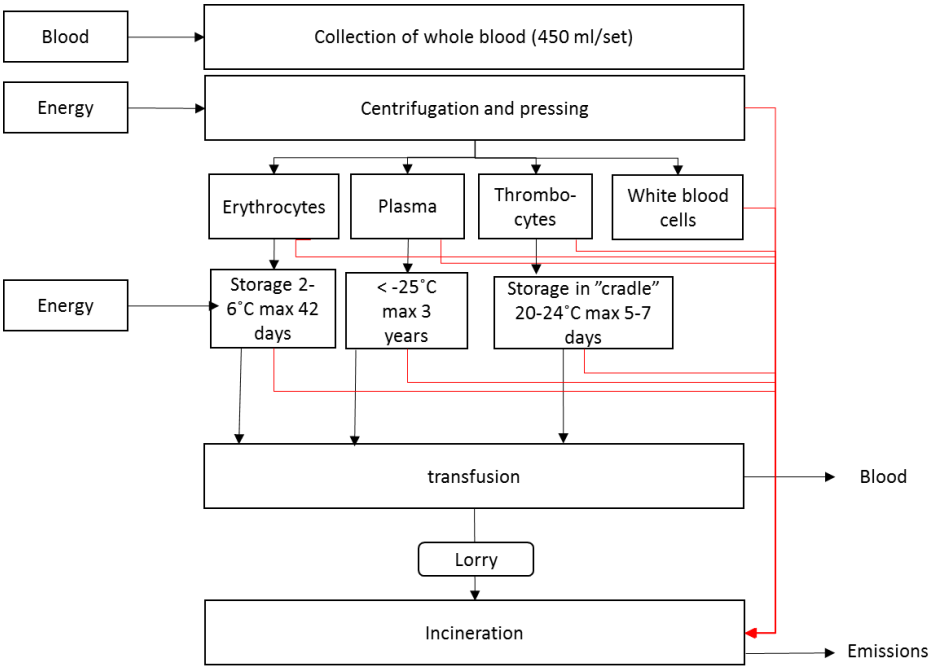

Figure 10 Schematic figure of use and disposal of blood bags.

4.4.1 Component production

The bags are used for collection of blood, production of blood components, and transfusion of components to humans. 450 ml whole blood is collected in the first bag in the blood bag system. This bag is centrifuged, pressed, and divided into the three components (erythrocytes, thrombocytes, and plasma). White blood cells are not used and considered to be sent to incineration as waste. Electricity used during component production (centrifugation and pressing) are taken from Macopharma (2014) and Anette Rodin (personal communication 2016-11-01). Data for electricity use are presented in Table 19, based on generic data from ecoinvent.

Table 19 Data for component production.

Material	LCI-data	Amount	Unit	Comment
Electricity	Electricity, low voltage {SE}| market for | Alloc Rec, S	347	kJ	Centrifugation, 6300 W, 11 min, 12 bags/centrifuge.
Electricity	Electricity, low voltage {SE}| market for | Alloc Rec, S	45	kJ	Press, 300 W, 2-3 min, 1 bag/press.

4.4.2 Storage

The components are stored in different temperature during different number of days before the components are transfused (or, if not used, outdated, and disposed). For calculating of the amount of energy used during storage, the maximum storage times are assumed. To produce one unit of thrombocytes, thrombocytes from four donators (four set of blood bags) are used. Electricity used during storage is based on data from different sources (Kaarlenkaski, 2016; Larsson L. , 2016; Lindman & Wendin, 2013-06-13; Larsson & Gulliksson, 2006; Nüve, 2016). Data for storage are presented in Table 20, based on generic LCI-data from ecoinvent.

Table 20 Energy used for storage of blood components, total per one unit.

Material	LCI-data	Amount	Unit	Comment
Storage, erythrocytes (red blood cells)	Electricity, low voltage {SE}| market for | Alloc Rec, S	0,184	kWh	Cool room, Storage time 42 days, +4 °C.
Storage, thrombocytes (platelets)	Electricity, low voltage {SE}| market for | Alloc Rec, U	0,817	kWh	7 days at 20-24 °C, 18 units/incubator. Consists of thrombocytes from 4-6 donators.
Storage, plasma	Electricity, low voltage {SE}| market for | Alloc Rec, U	4,09	kWh	240 units/freezer, storage time 36 month, - 25 °C.

4.4.3 Usage

In usage phase, number of blood bags required and energy for storage of blood components are included. Usage is based on statistics for blood component productions and transfusions in Sweden 2014 (Svensk Förening för Transfusionsmedicin, 2015). Not all donations (every blood bag used) results in blood component transfusion of blood into humans. A certain percentage of the total amount donated blood are rejected. Also, a certain percentage of all component produced are rejected or outdated. Therefore, more than one set of blood bags are needed to produce the amount of blood components required.

Because of the limitations of number maximum storage time for each component, a certain percentage of the units produced, are outdated and disposed. To cover up for this cassation, more than one set of blood bags are used to produce the amount of one component corresponded to the blood collected in one set of blood bag.

The total number of whole blood collections in Sweden 2014 was 462 629. 450 ml of whole blood are assumed to be collected in each blood bag set. 4,2 % of the total number of whole blood collections were disposed before component production. Number of units produced, transfused, and disposed are presented in Table 21. The component disposed, including the white blood cells not used for transfusion, are assumed to be incinerated (treated as hazardous waste), together with the disposed blood bags. In the model, these components are represented with water.

Table 21 Number of produced, transfused, and disposed units, based on data from Svensk Förening för Transfusionsmedicin (2015).

	Produced and stored units	Transfused (used) units	Outdated units	Rejected units (before + after release)	Disposed, in total	Disposed, of total number produced
Erythrocytes	443 198	442 818	5 373	4683+5667	15 723	4%
Thrombocytes	56 171	48 100	5 236	771+1392	7 399	13%
Plasma	141 159	58 983	10 805	4777+7316	22 898	16%

4.4.3.1 DEHP exposure

The release of DEHP from a blood bag made of PVC and DEHP into blood components are affected of at least three factors:

- the content of plasma, while plasma lipids will increase the release

- the temperature, the release of DEHP are significant higher at room temperature than in cold
- time, as the release of DEHP are linear over time (SCENIHR, 2015).

In a literature review by SCENIHR (2015), it is stated that in human studies, "a maximal and rapid oral absorption of 50 percent was estimated. However, since the amount recovered in the urine depends on the number of urinary metabolites measured, and the amount of excretion via bile is unknown, an almost complete absorption can be used in risk characterisation" (SCENIHR, 2015, s. 83).

Exposure of DEHP are modelled based on Gulliksson (2016), corresponding to adults with assumed bodyweight (BW) 75 kg. Data for DEHP leakage used in this study is presented in Table 22. This is calculated values, not observed, and corresponds to potential exposure. The amounts of DEHP leakage increases linearly over time, and this value corresponds to the maximum storage time. The storage time may be shorter (Hans Gulliksson, personal communication 2017-03-31).

Table 22 Data for DEHP exposure.

Component stored	Storage time	DEHP exposure		Reference
Thrombocytes in plasma	7 days	130	ug/kg BW/day	Gulliksson (2016), based on Sampson & de Korte (2011).
Plasma	7 days	311	ug/kg BW/day	
Erythrocytes	35 days	114	ug/kg BW/day	

4.5 Disposal

After use, the waste bags are incinerated. A waste scenario is modelled in SimaPro for both bags, incinerated as hazardous waste, based on generic data from ecoinvent. The blood bags, as well as the blood and blood components not transfused, are incinerated.

Also, the waste type can be specified in different ways. For the PVC/DEHP based bag, the waste type is set to PVC. For the PVC-free bag, the waste type is set to PP, while PP are the dominant material in the bag. A comparison of correlation of toxic emissions and waste type selected are found in section 6.2.2.2, Waste type and waste treatment process.

The blood is represented by water in the disposal scenario. Each set of blood bag (one of the four bags in each set) are assumed to have a blood content of 0,477 kg blood while incinerated. The blood is represented by drinking water and the waste type are set to water.

4.6 Calculated data

Calculations of data are presented in the specific sections, previous in this chapter.

4.7 Validation of data

A check on data validity is conducted during the process of data collection to confirm and provide evidence that the data quality requirements for the intended application have been fulfilled. A continuous dialogue with responsible people (project leader and producers) was to ensure the validity of data.

5 Life cycle impact assessment, LCIA

During the life cycle impact assessment (LCIA), environmental impacts are evaluated based on the LCIA methods defined and the type of impact categories chosen during the goal and scope phase.

The LCIA phase includes the following mandatory elements:

- selection of impact categories, category indicators and characterization models
- assignment of LCI results to the selected impact categories (classification)
- calculation of category indicator results (characterization).

Emissions of a certain element can have different types of environmental impacts. Nitrogen oxides (NO_X) emitted during combustion of fossil fuels can for example have an impact on acidification as well as eutrophication. In the meantime, different elements emitted, for example both carbon dioxide (CO_2), methane (CH_4) and other so called greenhouse gases, can have an impact on the same environmental category, in this case climate change.

All inputs and outputs throughout the inventory are assigned a classification as well as a characterization of the environmental load they are likely to be associated with. During the classification, the collected data is sorted into different categories of environmental impacts, for example climate change, stratospheric ozone depletion, eutrophication, and acidification (Figure 11). LCIA method is further described in Appendix 2.

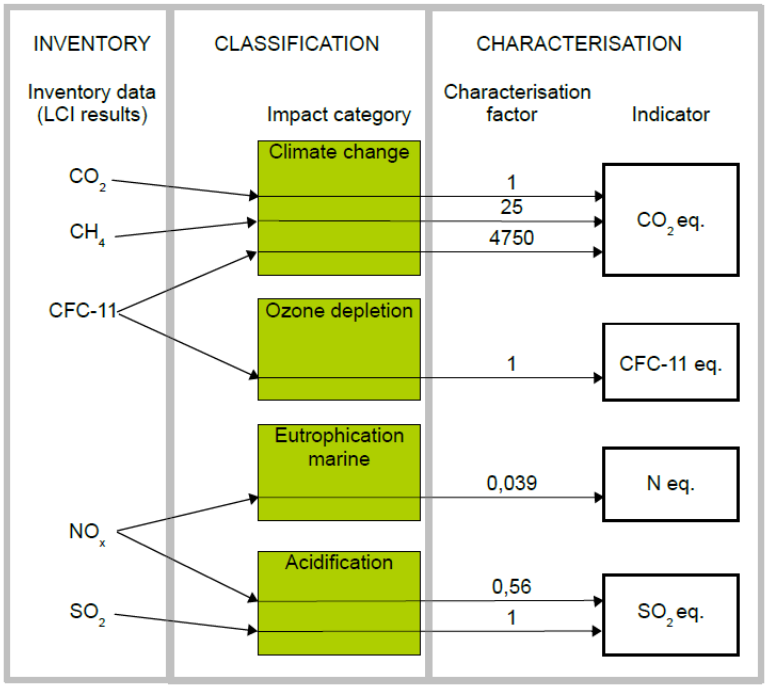

Figure 11 Classification and characterization of a selected numbers of substances and impacts base on the ReCiPe midpoint method (Goedkoop, et al., 2009).

5.1 LCIA methods

There are different methods to be used to assess several environmental impacts. In this LCA, environmental impact as global warming potential, fossil depletion, land use, water scarcity and human toxicity are assessed at a midpoint level. Midpoint results calculates the environmental impact in the middle of the cause-effect chain, based on scientific knowledge which gives a result with low uncertainties. This contrasts with results at endpoint level, were the results are presented as environmental impact at the end of this cause-effect chain, usually as the three different types of damage: human health, ecosystem quality and resources. Endpoint result is easier to interpret, but the uncertainties are higher while data gaps and assumptions stack up along the cause-effect chain (Figure 12).

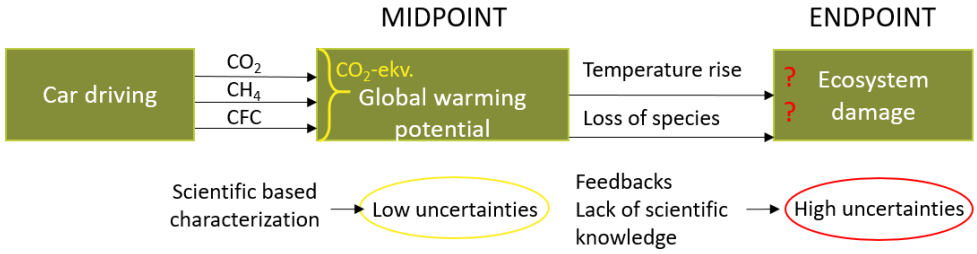

Figure 12 Conceptual model of midpoint and endpoint for climate impact.

5.1.1 ReCiPe

In this LCA, fossil depletion and land use, as agricultural land occupation, are evaluated based on the ReCiPe Midpoint method (Goedkoop, et al., 2009). ReCiPe is a methodological tool used to quantify the environmental impact on 18 categories at midpoint level and 3 categories, or harmful effects, at endpoint level. The method is created by RIVM[2], CML[3], PRé Consultants[4], and Radboud Universiteit Nijmegen[5], and recommended by European Commission (JRC, 2010). The method is further described in Appendix 3.

5.1.1.1 Fossil depletion

The term fossil fuel refers to a group of resources that contain hydrocarbons. The group ranges from volatile materials (like methane), to liquid petrol, to non-volatile materials (like coal) (Goedkoop, et al., 2009). The characterization factor of fossil depletion in ReCiPe Midpoint is the amount of extracted fossil fuel extracted, based on the lower heating value. The unit is kg oil equivalent (1 kg of oil equivalent has a lower heating value of 42 MJ) (PRé, 2016).

5.1.1.2 Land use

Land is a finite resource. Production of food, materials and biofuels compete with areal for buildings, infrastructure, and recreational opportunities of the earth's limited land resources. Sustainable land use is essential for the conservation of biodiversity, ecosystem functioning and ecosystem services.

The land use impact category reflects the harm to ecosystems because of occupation and transformation of land. Although there are many links between the way land is used and loss of biodiversity, this category concentrates on the following mechanisms:

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[2] http://www.rivm.nl/milieuportaal/dossier/lca/recipe/
[3] http://cml.leiden.edu/
[4] http://www.pre-sustainability.com/
[5] http://www.ru.nl/environmentalscience/

1. Occupation of a certain area of land during a certain time;
2. Transformation of a certain area of land.

Both mechanisms can be combined, often occupation follows a transformation, but often occupation occurs in an area that has already been converted (transformed). In such cases, the transformation impact is not allocated to the production system that occupies an area.

For the evaluation of occupation of land, the ReCiPe Midpoint offers the opportunity to show separately *Land occupation as* agriculture and *Land occupation as urban*. Transformation of agricultural land is accounted for as loss of land availability that could have been used for cultivating food crop as an alternative livelihood. By studying the weighted result by ReCiPe Single Score, agricultural land use came up to be the category of land use with the greatest impact, and therefore the kind of land use category assessed in this study. In this study, focus was on agricultural land occupation, expressed as m2 agricultural land used per year.

5.1.2 Global Warming Potential, GWP

Direct solar radiation heats the earth. The heated crust emits heat radiation which partially are absorbed by gases, known as greenhouse gases, in the Earth's atmosphere. Some of this heat radiation rays back to earth and heat the earth. This natural greenhouse effect is essential for life on Earth. However, because of human activity, the presence of greenhouse gases in the atmosphere, such as carbon dioxide, methane, and nitrous oxide, have increased. This affects the natural radiation balance, which leads to global warming and climate changes.

Potential impact on the climate is calculated using the IPCC 2013 GWP 100 v.1.03 (IPCC, 2013), model Global Warming Potential, GWP. The impact of climate gases is expressed as carbon dioxide equivalents, CO2 eq. It is the most established scientific method. It has been implemented in other methods, such as GHG protocol and ReCiPe, but then with adaptions.

5.1.3 Human toxicity

For calculations of toxicity, the USEtox (recommended + interim) V1.04 (Rosenbaum, Bachmann, & Gold, 2008) method is used. However, this toxicity perspective can only be covered in a rudimentary way with the broad LCA perspective.

The toxicity model USEtox has been developed with support of the UNEP-SETAC Life Cycle Initiative to provide recommended characterisation factors for human toxicity and freshwater ecotoxicity in life cycle impact assessment. USEtox is a scientific consensus model that is parsimonious and contains only the most influential model elements based on current best practice in the context of LCA. Intermediary variables such as intake fraction, fate (residence time in each media) and inter-media transfer factors are also provided as intermediary results (JRC, 2010).

In this method, three impact categories are included:

- Human toxicity, cancer
- Human toxicity, non-cancer
- Ecotoxicity

The characterisation factor for human toxicity (Human Toxicity Potential) is expressed in Comparative Toxic Units (CTUh/kg), providing the estimated increase in morbidity in the total human population per unit mass of a chemical emitted (cases/kg), assuming equal weighting between cancer and non-cancer due to a lack of more precise insights into this issue.

In the USEtox model, the emissions to air, water and ground are included, it is not possible to model the effects of direct exposure to human. Because of that the model was modified. New characterisation factors were added for DEHP, corresponding to inhalation and ingestion (same factors for both). These factors were taken from USEtox version 1.01, organic "Human EF" (based on Raul Carlson, personal communication 2017-02-02).

Based on Carlson (2012) the fate and exposure factors were set to 1. The fate factor was set to 1 while there is no dispersion of the DEHP as transferred to the blood system. Exposure factor was set to 1 while the person exposed to the transfused blood also will receive the total amount DEHP. Please note that this assumption is very simplified and therefor associated with uncertainties. Appendix 5

5.1.4 Water scarcity

Water is a scarce resource in many parts of the world, but also very abundant in others. In other words, the effects if water use depends on from where the water is taken. In this study, water scarcity is assessed based on Hoekstra (2012). This water scarcity method takes into account not only the amount of water used, but also the amounts of water availability at the geographical location. Consumption of ground water, surface water and rain water as well as freshwater polluted, are taken into account. The unit is m^3 water.

5.2 Results

The results per impact category are summarised in Table 23. This is then further elaborated in the subchapters below.

Table 23 Results per one set of PVC/DEHP and PVC-free set of blood bag, respectively, as impact assessment per category.

Impact category	Category indicator	Results per FU		Method
		PVC/ DEHP	PVC-free	
Global Warming Potential	Kg CO_2 eq	2,73	2,62	GWP 100a v.1.03 (IPCC, 2013)
Fossil depletion	kg oil eq	0,05	0,05	ReCiPe Midpoint (H) European v.1.13 (Goedkoop, et al., 2009)
Land use, as agricultural land occupation	m^2a	0,5	0,5	ReCiPe Midpoint (H) European v.1.13 (Goedkoop, et al., 2009)
Water Scarcity	m^3	0,04	0,02	Hoekstra (2012)
Human toxicity	CTUh, cancer	4,9E-07	3,2E-07	USEtox v.1.04, modified
	CTUh, non-cancer	2,4E-06	4,7E-07	

5.2.1 Global Warming Potential, GWP

Based on IPCC 2013 100a, the climate impact of production, use and disposal of one set of PVC/DEHP based blood bag was 2,73 kg CO2 eq. The climate impact of PVC-free set was 2,62 kg CO2 eq. For both types of bags, the major impact (about 70 percent) is due to disposal (incineration of hazardous waste) of used bags, and the rest (almost 30 percent) is due to production (mainly material use). Only a minor part is due to usage (Figure 13).

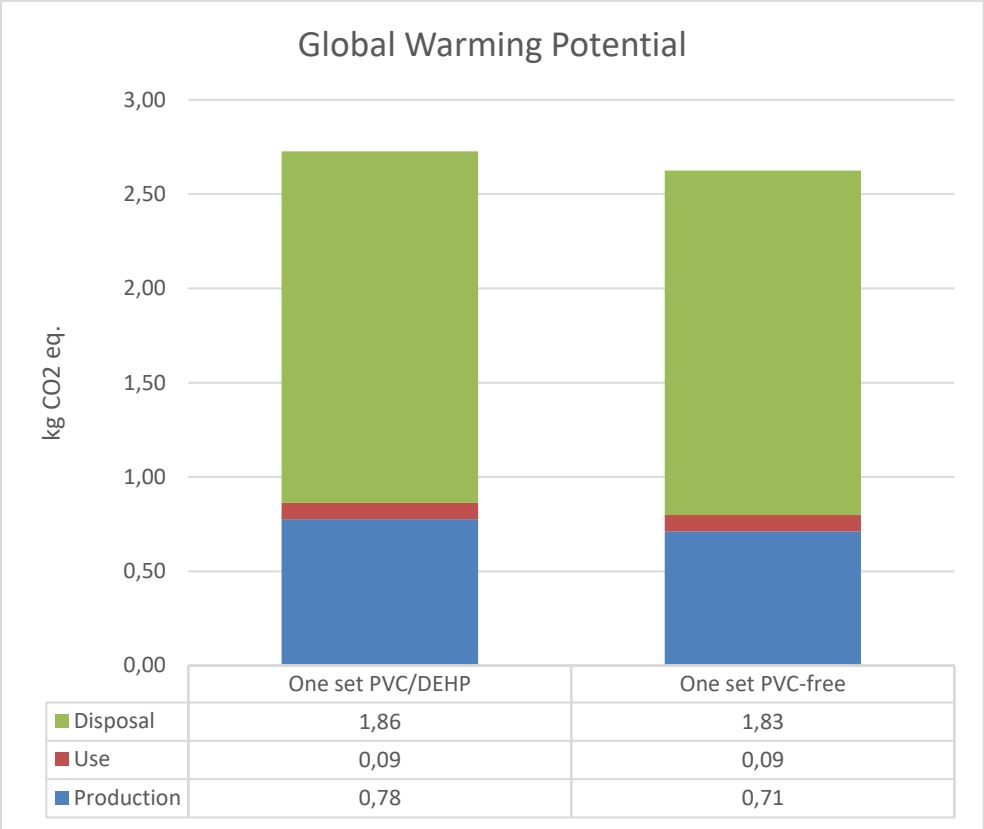
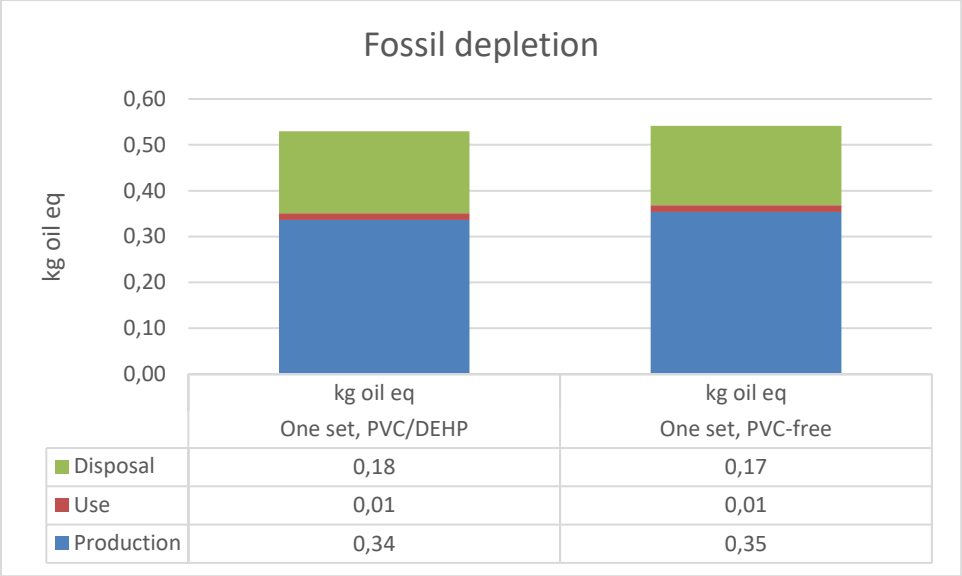


Figure 13 Characterisation result, GWP as kg CO2 eq. per one set of blood bag, based on IPCC 2013 100a.

5.2.2 Fossil depletion

Based on ReCiPe Midpoint, the fossil depletion of production, use and disposal of both types of blood bags (PVC/DEHP based and PVC-free) was 0,5 kg oil eq. per set. The major impact (about 65 percent) was due to production of the bags, mainly material use. The rest was mainly derived to the waste treatment (about 34 percent). Only a minor part was due to usage (Figure 14).



	kg oil eq One set, PVC/DEHP	kg oil eq One set, PVC-free
Disposal	0,18	0,17
Use	0,01	0,01
Production	0,34	0,35

Figure 14 Characterisation result, fossil depletion, as kg oil eq. per one set of blood bag, based on ReCiPe Midpoint (H), V.1.13.

5.2.3 Land use

Based on ReCiPe Midpoint, the agricultural land occupation of production, use and disposal of one set of PVC/DEHP based blood bag and one PVC-free set was 0,5 m2 agricultural land per year. About the half of that impact are due to use of blood bags (electricity use during storage), and the rest are due to production and disposal (Figure 15).

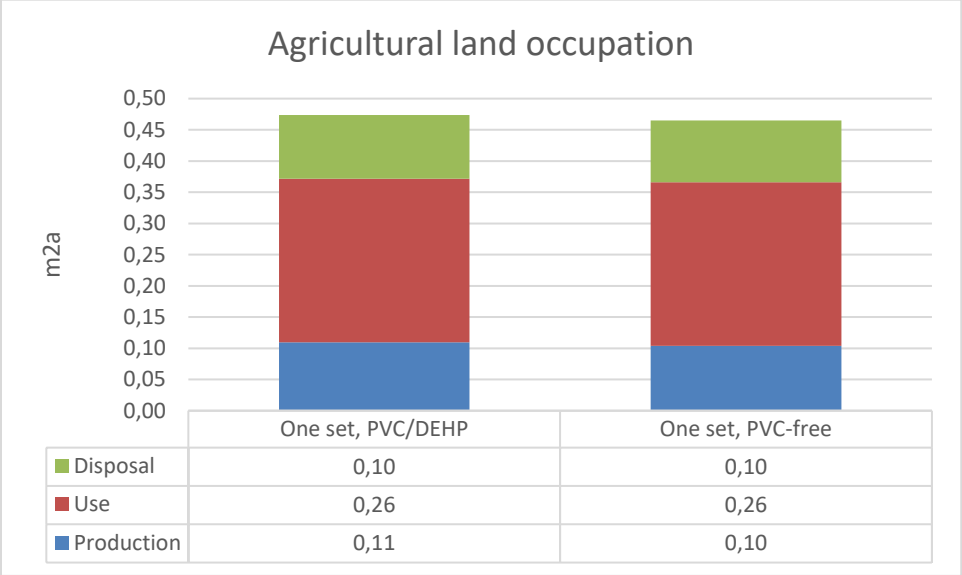


Figure 15 Characterisation result, agricultural land occupation, as m2a, per one set of blood bag, based on ReCiPe Midpoint (H), V.1.13.

5.2.4 Water Scarcity

Based on Water Scarcity (Hoekstra, 2012) the water scarcity as m3 was about twice as large for one PVC/DEHP based blood bag (0,04 m3), as for the PVC-free (0,02 m3). The main difference is due to production (Figure 16). The larger WSI for the PVC/DEHP is mainly due to the material used.

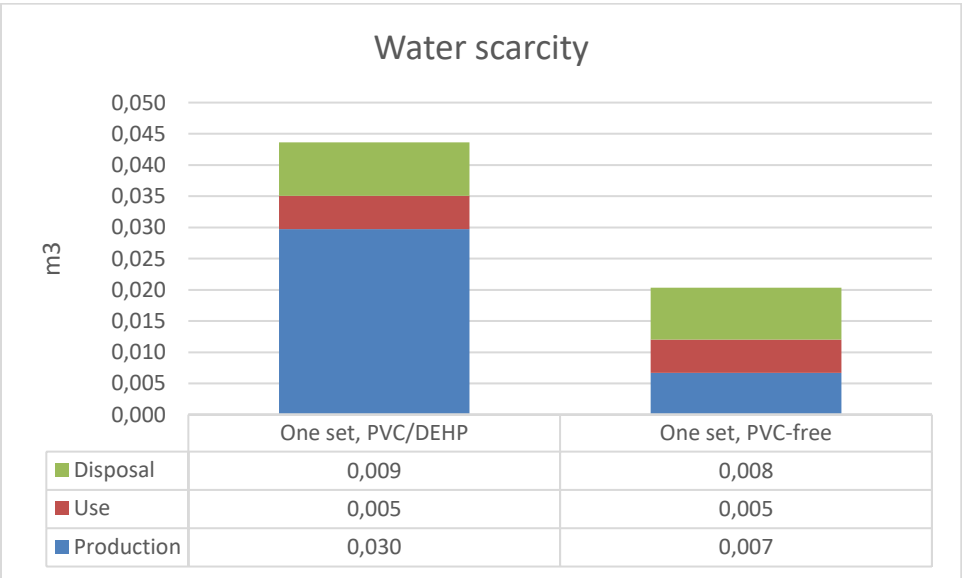


Figure 16 Characterisation result, Water Scarcity, as m3 water, per one set of blood bag, based on Hoekstra et al. (2012) V.1.02.

5.2.5 Human toxicity

The human toxicity, based on a modification of USEtox method (section 5.1.3) are presented as CTUh (Comparative Toxic Units) for cancer and non-cancer effects, as shown below.

Table 24 Characterisation result of human toxicity, non-cancer effects, per set of blood bags, based on a modified USEtox method.

Effect	Product	Unit	Amount
Non-cancer	One set, PVC/DEHP	CTUh	2,4E-06
Non-cancer	One set, PVC-free	CTUh	4,7E-07
Cancer	One set, PVC/DEHP	CTUh	4,9E-07
Cancer	One set, PVC-free	CTUh	3,2E-07

		Amount
PVC/DEHP, non-cancer		2,4E-06
PVC-free, non-cancer		4,7E-07
		Amount
PVC/DEHP, cancer		4,9E-07
PVC-free, cancer		3,2E-07

The impact, per stage of the life cycle, are presented in Figure 17 (non-cancer) and Figure 18 (cancer). Based on the modified USEtox method, the results are presented as non-cancer and cancer effects. Based on this method, the DEHP leakage do affect the non-caner effects the most. For cancer effects, the effects are mainly due to the incineration of hazardous waste (60 and 88 percent for PVC/DEHP and PVC-free respectively). About 31 percent of the cancer effects are due to use phase of PVC/DEHP blood bag. Compared to use of PVC-free blood bag, 4 percent are derived to the use phase.

Effect	Product	Unit
Non-cancer	One set, PVC/DEHP	CTUh
Non-cancer	One set, PVC-free	CTUh
Cancer	One set, PVC/DEHP	CTUh
Cancer	One set, PVC-free	CTUh

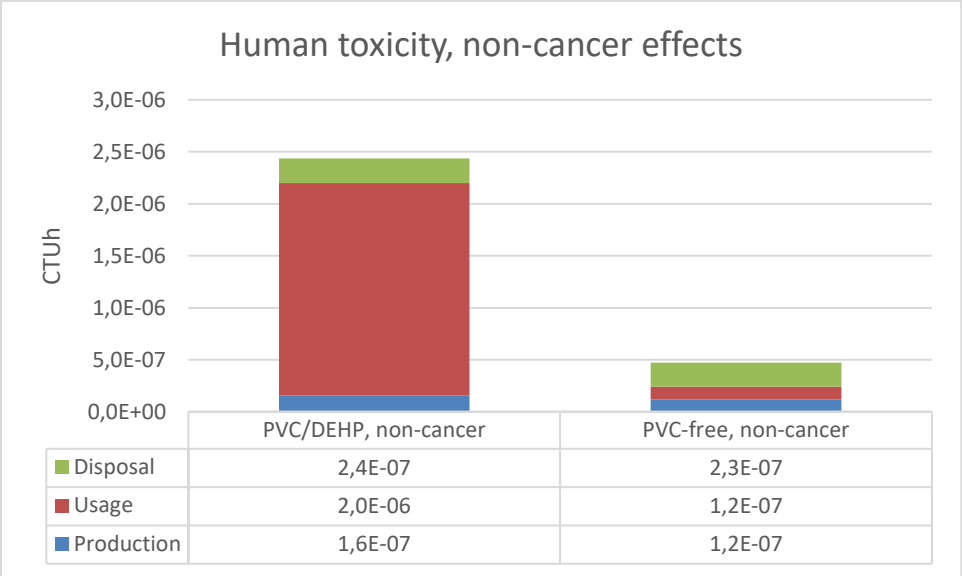


Figure 17 Characterisation result of human toxicity, non-cancer effects, per set of blood bags, based on a modified USEtox method.

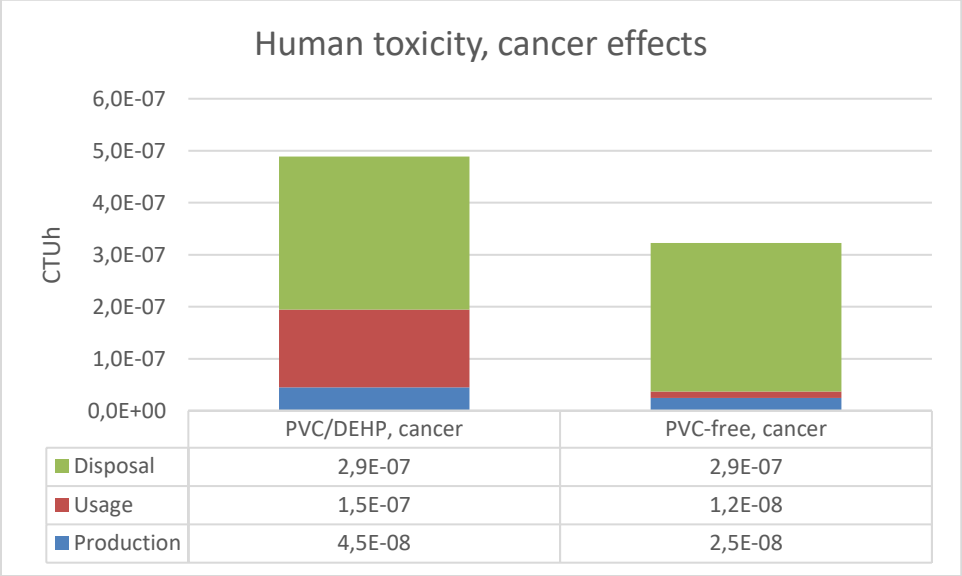


Figure 18 Characterisation result of human toxicity, cancer effects, per set of blood bags, based on a modified USEtox method.

In Figure 20 and Figure 23, the human toxicity of one PVC/DEHP based set and a PVC-free set are presented with European normalisation corresponding to the year 2004, based on USEtox v.1.04. The normalisation factors for Europe 2004 was 3,08E4 and 1,23E3 for cancer and non-cancer respectively. Based on this normalisation, the cancer effects are more important.

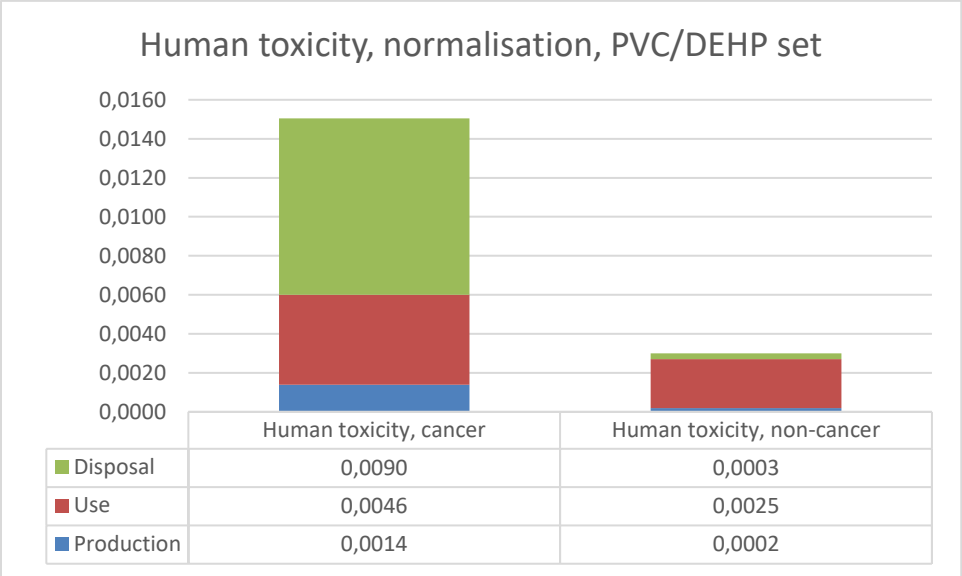


Figure 19 Human toxicity, per one PVC/DEHP based set, normalised to Europe 2004 based on USEtox v. 1.04 (modified).

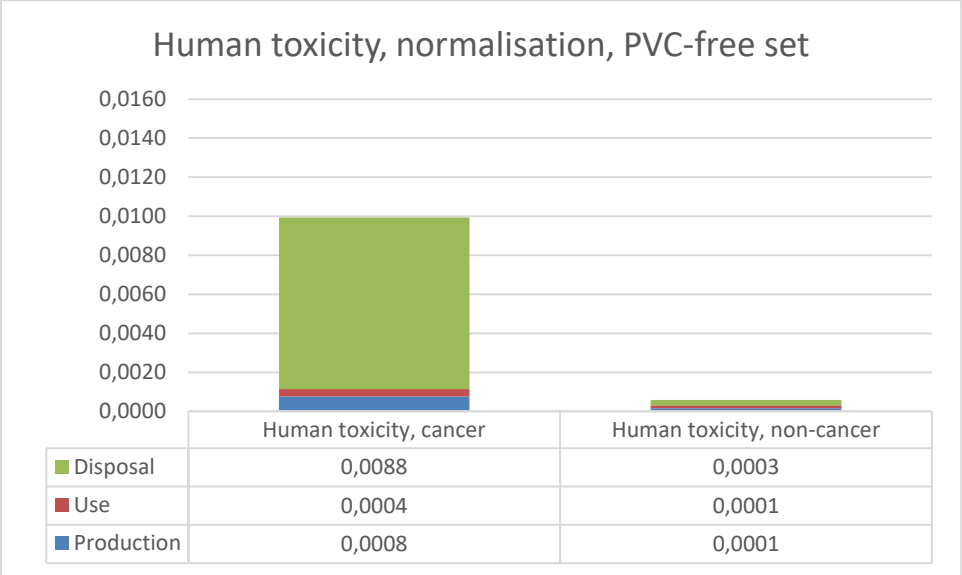


Figure 20 Human toxicity, per one PVC-free set, normalised to Europe 2004 based on USEtox v. 1.04 (modified).

The substances contributed the most to the human toxicity of the PVC/DEHP based set of blood bag, are presented in Table 25 (non-cancer) and Table 26. It shows that DEHP is the substance contributing the most to the human toxicity, non-cancer effects, and the second largest contributor to non-cancer effects, both during use of PVC/DEHP based blood bag.

Table 25 Inventory table of characterized results of human toxicity, non-cancer, with analysing 1 p LC PVC/DEHP blood bag. Based on the modified USEtox method.

No	Substance	Compartment	Unit	Total	Production PVC/DEHP 2014	Usage Set Bloodbag 2014 of PVC	Disposal of SET blood bag PVC/DEHP 2014
	Total of all compartments		CTUh	1.13	0.07	0.94	0.11
	Remaining substances		CTUh	0.01	3.8E-3	3.75E-3	4.56E-3
1	DEHP	Air	CTUh	0.89	x	0.89	x
2	Zinc	Water	CTUh	0.08	0.02	0.02	0.05
3	Arsenic	Water	CTUh	0.05	0.01	0.02	0.02
4	Zinc	Air	CTUh	0.04	0.02	0.01	0.01
5	Mercury	Air	CTUh	0.03	0.02	1.39E-3	0.01
6	Zinc	Soil	CTUh	0.02	2.12E-3	0.01	0.01
7	Lead	Air	CTUh	0.01	2.06E-3	2.1E-3	1.63E-3

Analysing 1 p 'LC PVC/DEHP blood bag'; Method: USEtox (recommended + interim) MB blood bag V1.04 / Europe 2004 / Characterization

Table 26 Inventory table of characterized results of human toxicity, cancer, with analysing 1 p LC PVC/DEHP blood bag. Based on the modified USEtox method.

No	Substance	Compartment	Unit	Total	Production PVC/DEHP 2014	Usage Set Bloodbag 2014 of PVC	Disposal of SET blood bag PVC/DEHP 2014
	Total of all compartments		CTUh	0.23	0.02	0.07	0.14
	Remaining substances		CTUh	1.26E-3	4.87E-4	2.84E-4	4.87E-4
1	Chromium VI	Water	CTUh	0.16	0.02	3.4E-3	0.13
2	DEHP	Air	CTUh	0.06	x	0.06	x
3	Chromium VI	Soil	CTUh	2.13E-3	7.93E-5	1.94E-3	1.1E-4
4	Nickel	Water	CTUh	1.39E-3	2.26E-4	5.38E-5	1.11E-3

Analysing 1 p 'LC PVC/DEHP blood bag'; Method: USEtox (recommended + interim) MB blood bag V1.04 / Europe 2004 / Characterization

6 Interpretation

In this chapter, the result is interpreted and evaluated. Also, conclusions and recommendations are presented.

6.1 Hot spots

The impact assessment shows that there are no major differences of global warming potential, fossil depletion, and agricultural land occupation of the two set of blood bags, produced of PVC/DEHP and PVC-free material respectively. Regarding potential water scarcity and human toxicity, the impacts of PVC/DEHP based set was substantially higher compared to the PVC-free set.

6.1.1 Human toxicity

The most significant aspects of impact on human health for the PVC/DEHP blood bag as identified in the previous study conducted by Carlson (2012), was the phthalate DEHP leaked into the blood during transfusion, and dioxin emitted during incineration of PVC and DEHP, due to its chlorine content. Based on literature (Doka, 2007), there is no correlation of dioxin formation and incineration of waste with high chlorine content. Therefore, the most important aspect of human toxicity is the DEHP leakage during storage of blood.

However, the results show that the PVC/DEHP based set of blood bag has a substantially higher potential impact on human health, compared to the PVC-free alternative. This is due to the DEHP leakage during storage of blood components. The result is associated with uncertainties, due to assumptions and simplifications. In a sensitivity analysis (section 6.2.2.1), the human toxicity for the PVC/DEHP based bag were assessed, based DEHP exposure. It showed that even if the DEHP exposure was halved, the potential human toxicity would still be significant.

6.1.2 Water scarcity

Based on Hoekstra (2012), the water scarcity is about the double for the PVC/DEHP based blood bag compared to the PVC-free. This is mainly due to the type of polymer used. Water scarcity of 1 kg of PVC/DEHP based material and 1 kg PVC-free material are compared in Figure 19, which shows that the WSI of production of PVC/DEHP material (CaZn and additives included) are about five times higher compared to the PVC-free polymer.

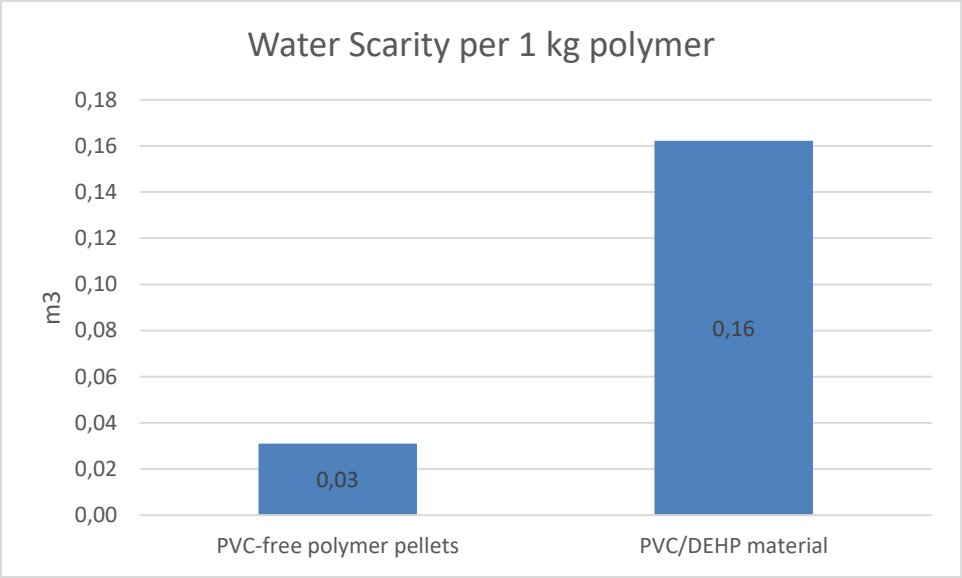


Figure 21 Water Scarcity as m3 water/kg PVC-free and PVC/DEHP material respectively, based on Hoekstra et al. (2012) V.1.02.

6.2 Evaluation

6.2.1 Completeness check

As already mentioned, the modelling of DEHP are based on simplified assumptions. Also, the amount DEHP leakage into blood depends on different factors (as content of plasma lipids, temperature, and storage time), which increases the uncertainties. The leakage of DEHP is modelled with the fate and exposure factors set to 1, which can be seen as a "worst case" scenario. To this, the uncertainties of the effects of DEHP transferred to human should be considered.

The sterilisation for both bags are excluded. Based on a precious study by Rawlings & Pora (2009), the amount of electricity used for sterilisation was considerably higher for autoclave sterilization compared to gamma sterilization.

However, sterilisation of medical devices was included in a previous study of environmental impact of bioprocess systems (Rawlings & Pora, 2009). In this study, a single-use system made of polymer, sterilized with steam autoclave, was compared with a reusable system made of stainless steel, sterilized with gamma. Only energy use was assessed. The steam sterilization was based on a steam generator output of 500 kWh and energy value of 8 MJ/kWh. 100 litre of water was required to provide 130 °C steam during 30 minutes. The energy use for gamma irradiation at 25 kGy for 28 components, based on 90 components per pallet and three pallets per hour, with an output of 28 kWh. The energy use for the sterilisation processes was 2 000 MJ for steam and 32 MJ for gamma sterilization. The high-energy use of the autoclave sterilisation was partly explained by high cost of steam generation. However, in this case the design of the two devices was not identical, while the device sterilised with autoclave was made of stainless steel, in contrast to the system sterilised with gamma, made of polymer. The high-energy consumption was due to the high cost of steam generation as well as the heat capacity of the metal material used.

Beside electricity consumed, there are other aspects that may be relevant to consider. Gamma sterilisation may consume less electricity, but on the other hand, the use of a radiative material (cobalt 60), may be associated with other kinds of aspects. This may be important aspects, that is not considered in this LCA. To increase the robustness of

the results, the environmental effects of the sterilisation processes could be further investigated.

6.2.2 Sensitivity analysis

6.2.2.1 DEHP transferred to human

The results of this LCA are based on the assumption that the total amount DEHP leakage during storage of blood are transferred to human. This is associated with uncertainties and can be considered as a worst-case scenario. If the amount DEHP transferred to human were decreased with 50 percent, the effects would decrease. However, it will still be considerably higher compared to the PVC-free set (Figure 22).

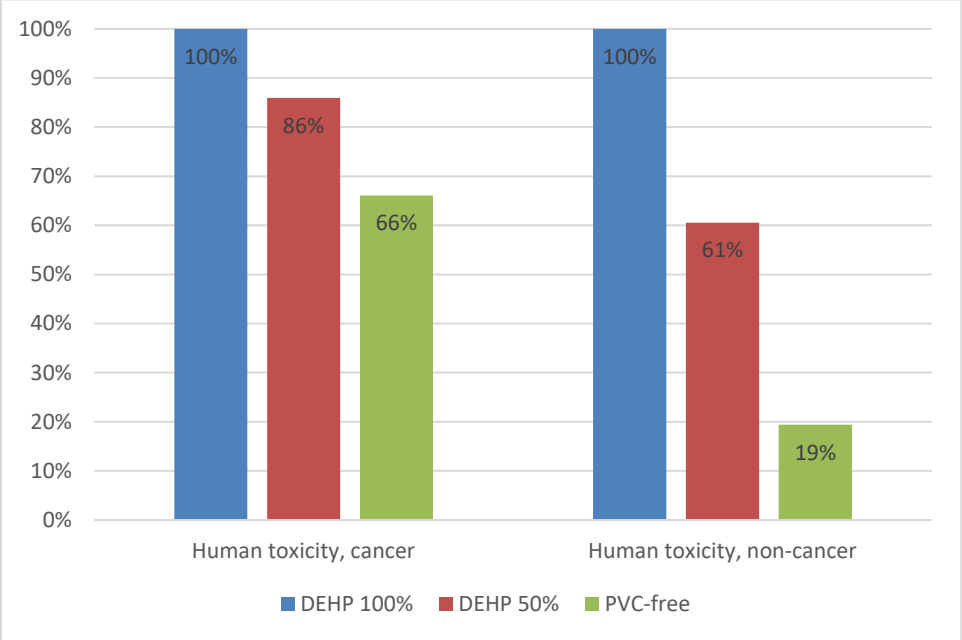


Figure 22 Comparison of characterisation results with a scenario where only half of the amount DEHP leakage during storage are transferred to human. Based on the modified USEtox 1.04 method.

6.2.2.2 Waste type and waste treatment process

After use, the waste bags are incinerated. A waste scenario is modelled in SimaPro for both bags. There are several options available for this process, which affect the result in different ways. The incineration can be modelled as hazardous waste treatment, or incineration of municipal solid waste, in Sweden, both based on generic data from ecoinvent. In this LCA, the waste treatment process for hazardous waste is used for both bags. Waste type "PVC" was chosen for the PVC/DEHP material and waste type "PP" for the PVC-free material, while polypropylene is the dominate material for this material.

However, the modelling, as selected waste treatment process and waste type chosen, may affect the result of the LCA. To investigate the potential differences, human toxicity as kg 1,4 DB eq (based on USEtox, implemented in ReCiPe Midpoint), was calculated per 1 kg of both materials. The result of this comparison is shown in **Table 28 Comparison of characterisation result per 1 kg PVC/DEHP and 1 kg PVC-free polymer, with different waste types and incineration processes. Based on ReCiPe Midpoint.**
. Based on the comparison, following are concluded:

- Incineration of PVC-based material: With municipal incineration, the dioxin emissions are higher compared to incineration of hazardous waste. The waste type does not affect the amount of dioxin emitted.
- Incineration of PVC-free material: With municipal incineration, the dioxin emissions are higher compared to incineration of hazardous waste. Waste type does not affect the amount of dioxin emitted during incineration of hazardous waste. For municipal incineration, the waste type does affect the amounts of dioxin emitted. However, waste type "plastic" and waste type "PP" gives the same amount of emissions.

A comparison was made of characterisation result per 1 kg PVC/DEHP and 1 kg PVC-free polymer, with different waste types and incineration processes. Based on ReCiPe Midpoint. See Appendix 6.

6.2.3 Consistency check

Consistency check has been done to secure that life cycle modelling and methodological choices are used in the same way throughout the model and following the defined goal and scope. No deviations have been found.

6.3 Conclusions, limitations, and recommendations

In this study, global warming potential, fossil depletion, land use, water scarcity and human toxicity were assessed for a PVC/DEHP as well as a PVC-free blood bag. The results show that the global warming potential, fossil depletion, and agricultural land occupation is on the same range for both bags. Further, the PVC/DEHP based blood bag has a substantially higher potential impact on human toxicity, due to leakage of DEHP during storage of blood. Also, water scarcity, due to the material choice, is higher during production of PVC/DEHP based blood bag compared to the PVC-free.

Based on the result of this LCA, it is possible to lower the toxicity risks for human health by change the PVC/DEHP based blood bag to a PVC-free alterative, without increase other risks environmental risks or risks for human health. The uncertainties about the effects of human toxicity are high. Despite that, the results from this study strengthen the previous results by Carlson (2012) were the unambiguous recommendation was to change the PVC/DEHP based set of blood bag to the PVC-free alternative, considering potential leaching of other substances not shown in this LCA.

Regarding fossil depletion, the use of polymers dominates the use of fossil resources. Plastics (such as PP) are available as bio based from sugerstraw residues (i.e. From Braskem) but not common yet. As Carlson (2012) stated, it is recommended that effort should be taken to use recycled material if possible. The amount of material required for the PVC free bag is 36% less which can counterbalance that PVC include less fossil content per kg, due to the content of chlorine. Due to new technology in production, it is possible to have PP plastic that is much softer in itself. That will reduce the amount of rubber needed, and consequently reduce environmental impact.

Also, alternative to incineration could be considered. According to WHO (2015), alternatives to incineration of healthcare waste are available, such as autoclaving, microwaving, steam treatment integrated with internal mixing and chemical treatment. This could have a potential to lower the global warming impact.

Please note that the scope of this study is Swedish conditions on a pilot scale. Controlled burning has been assumed but globally also uncontrolled combustion is likely to be common. It would lead to more formation of dioxins from PVC. Some of the technics used in production of PVC free, will be more efficient in a larger scale.

6.3.1 Need of further investigation

Incineration of hazardous waste: The incineration process is represented by generic data corresponding to incineration of hazardous waste in Switzerland. Specific data from the incineration processes in Sweden would give a more valid result for the specific case.

Polypropylene (PP) used in the PVC-free granulate corresponds to generic data set, for PP at the global market. A smaller part of the PP in this data set corresponds to PP from the European market and the rest to PP from the global market. The origin of the PP is of importance for the environmental impact of the PP, if the origin of the PP used could be specified, the results regarding to the PP process could be more precise.

The synthetic rubber used in the PVC-free polymer granulate is represented by a generic process for synthetic rubber. This process consists of a mixture of several different kinds of rubber. If this data could represent the specific type of rubber used in the specific case, the uncertainties regarding the impact from the PVC-free polymer could be smaller.

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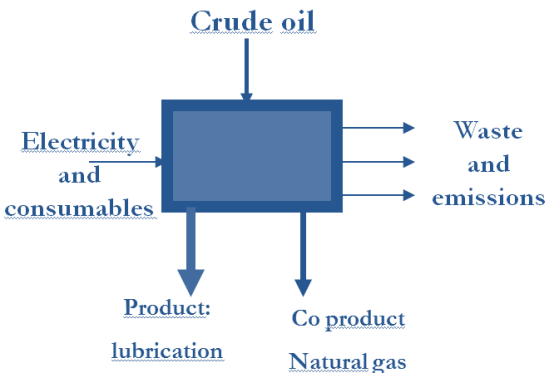
Appendix

Appendix 1 The concept of allocation of waste

The inputs and outputs shall be allocated to the different products according to clearly stated procedures that shall be documented and explained together with the allocation procedure. The sum of the allocated inputs and outputs of a unit process shall be equal to the inputs and outputs of the unit process before allocation.

Whenever several alternative allocation procedures seem applicable, a sensitivity analysis shall be conducted to illustrate the consequences of departure from the selected approach.



Allocation of environmental aspects may occur when a process produces more than one product. The basis for this allocation is primarily economic value, secondarily physical properties. If the allocation has low importance, it may be "cut-off", not considered and instead, all load is assigned to the studied product. The method chosen for the allocation is the cut-off method. The cut-off method assigns the loads caused by a product to just that product. When the cut-off method is used, environmental aspects or processes which can be assumed to contribute less than 1% do not have to be included in the study [Baumann H. & Tillman A-M. (2004)].

Figure 23:Allocation example

The study shall identify the processes shared with other product systems and deal with them according to the stepwise procedure, presented below:

1. Wherever possible, allocation should be avoided by dividing the unit process to be allocated into two or more sub-processes and collecting the input and output data related to these sub-processes, or expanding the product system to include the additional functions related to the co-products.
2. Where allocation cannot be avoided, the inputs and outputs of the system should be divided between its different products or functions in a way that reflects the underlying physical relationships between them; i.e. they should reflect the way in which the inputs and outputs are changed by quantitative changes in the products or functions delivered by the system.
3. Where physical relationship alone cannot be established or used as the basis for allocation, the inputs should be allocated between the products and functions in a way that reflects other relationships between them. For example, input and output data might be allocated between co-products in proportion to the economic value of the products.

"Allocation cut-off by classification" (ISO standard).
Recycled Content:
The underlying philosophy of this approach is that primary (first) production of materials is always allocated to the primary user of a material. If a material is recycled, the primary producer does not receive any credit for the provision of any recyclable materials. As a consequence, recyclable materials are available burden-free for recycling processes, and secondary (recycled) materials bear only the impacts of the recycling processes. For example, recycled paper only bears the impacts of waste paper collection and the recycling process of turning waste paper into recycled paper.

It is free of any burdens of the forestry activities and processing required for the primary production of the paper.

Furthermore, producers of wastes do not receive any credit for recycling or re-use of products resulting from any waste treatment. For example, heat from the incineration of municipal solid waste can be used to heat houses or offices, and therefore has a value. Nevertheless, the incineration is allocated completely to the treatment of the waste, and therefore the burdens lay with the waste producer. The heat comes burden-free. This approach to by-product allocation has also been used in ecoinvent versions 1 and 2, where it was the only available system model.

In the ISO standards, boundaries with other systems, and the allocation of environmental burdens between them, are based on the recommendations of the international EPD system[6], which are also in line with the requirements and guidelines of ISO14040 and ISO14044 standards (IEC, 2008). In accordance with these recommendations, the Polluter Pays (PP) allocation method is applied. For allocation of environmental burdens when incinerating waste, this implies that all of the processes in the waste treatment phase, including emissions from incineration, are allocated to the life cycle in which the waste is generated. Following procedures for refinement of energy or materials used as the input in a following/receiving process, such burdens are allocated to the next life cycle.

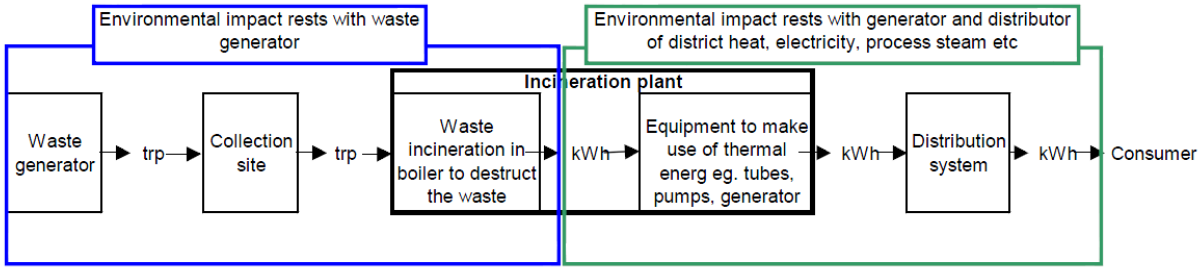


Figure 24:Allocation of environmental impacts between two life cycles according to the PP allocation method. Regarding in this case the incineration of waste and resulting energy products (Image from IEC, 2008, p14).

In the case of recycling, environmental burdens are accounted for outside of the generating life cycle, and have thus been allocated to the subsequent life cycle which uses the recycled materials as input.
In this LCA, the heat and electricity recovered from the incineration of waste has been taken into account, but modelled as an empty energy process which does not affect the inputs of the life cycle. Recovered energy from waste incineration has been presented and discussed in the results in comparison to cumulative energy demand. Avoided materials due to recycling of cardboard and plastics have not been taken into account, as in accordance with the EPD recommendations.

Allocation recycled content (Cut-Off approach recommended by ecoinvent)

Specifically, in the allocation-based system models, all marketable by-products yielded in treatment activities are moved into the activities producing the treated material for treatment as waste in a process called allocation at the point of substitution. Similarly, in the case of Speciality Productions, the reference product of the activity will be handled from now on as a by-product of an ordinary treatment activity.

[6] EPD (Environmental Product Declarations) by the International EPD Cooperation (IEC)

Then, all multi-output activities are allocated (using the allocation criteria defined for the specific System Model). This allocation happens at the point of substitution, and the marketable by-products produced in treatment activities get allocated in the activities they have been moved into.

Appendix 2 Method for impact assessment, general description

Classification
Classification means that all categories of data are sorted into different categories of environmental impacts. Ready-made methods for this have been used in order to evaluate a broader perspective and to find the most potential categories.
The aim of characterization is to quantify each element's contribution to the different categories of environmental impact respectively. To do this, each category of environmental impact is multiplied by characteristic factors which are specific for the data and the category of environmental effect. The result from characterization gives answers as to what or which emissions that have significant environmental effect. For each characteristic factor calculates the potential environmental effect which could arise if an element is released into the environmental or if a resource is consumed. Classification and characterization is where all items in the inventory are assigned to the effect it is likely to have on the environment (Baumann & Tillman, 2004).

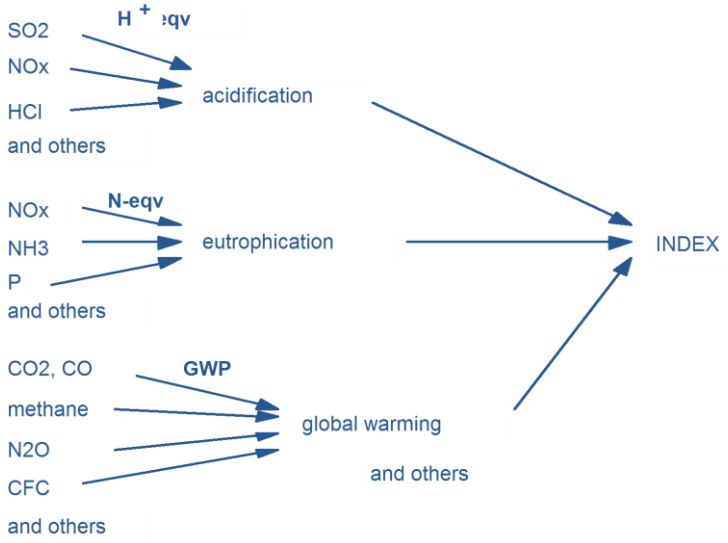


Figure 25 Illustration of the Impact Assessment of an LCA

When this link is determined, we call it an environmental aspect. This environmental aspect has to be linked between the environment and the process before you can say that it is established and that the process is unsustainable. In the early stages of Life Cycle Assessment, substances that were found in the inventory was assigned to environmental aspects. In order to reach the ultimate goal of sustainability, it is important to describe the local and global environment too. Environmental aspects that may have an impact are located and after that, the link to the inventory and to the process path features may be analyzed and established.

Weighting
The results of an LCA may depend on the method for impact assessment. There are a few different models to assist in the assessment of environmental impacts connected to a life cycle e.g. ecological scarcity (ECO), the environmental theme method (ET), ECO indicator (EI), ReCiPe and the Environmental Priority Strategies in Product Design (EPS) method.
The weighting method implies that all of the data classes are weighted together so that only one number is expressed for the weighting method. To do a weighting, different data categories are weighed based on some form of valuations principle. The basis of a valuation could be either individual or a community's political and/or morality valuations. The weighting expresses the relationship between values in the community and variations in the nature of the environmental aspect. The more effect or deviation an environmental aspect has from its valuations, the higher the weighting value the environmental aspect gets [Lindahl et al. (2002)].

The basis of valuations which are used to develop a weighting method could be; political decisions, technical-financial conditions, environmental conditions, effects on health, panels and studies of behavioural patterns. In a weighting method, there is either only one of these valuation factors or a combination of them. Since the basis of valuations varies for each weighting method, a comparison between different methods will give a shifting result [Lindahl et al. (2002)].
The mostly used weighting methods are collected in the book "The Hitch Hiker's Guide to LCA", written by Baumann H. & Tillman A-M. (2004), and the most important are presented below:

Ecoindicator'99: is a weighting method based on the distance-to-target principle and the target is established as environmental critical loads 5% ecosystem degeneration, or similar. Ecoindicator'99 is determined from three different cultural perspectives; hierarchism, egalitarian and individualistic. An average value from the three cultural perspectives has been calculated and is used in this study. Ecoindicator'99 is based on Goedkoop and Spriensma (1999) (Baumann & Tillman, 2004).

EPS 2000 is different from the other two weighting methods above as it is not based on the distance-to-target principle. Instead this method is based on the willingness-to-pay for avoiding harm to environmental safeguard subjects. The EPS method is especially suitable for assessment of global impacts, such as climate change potential and resource depletion. The EPS indices are prepared by a group at Chalmers University of Technology and a steering committee from the industry in Sweden.

EPD 2007: This method is to be used for the creation of Environmental Product Declarations or (EPDs), as published on the Swedish Environmental Management Council (SEMC) website www.environdec.com. The original document is entitled: "Revision of the EPD® system into an International EPD®". In the standard EPDs, one only has to report on some specific impact categories. Specific product category guidelines may require extra information.

The ReCiPe method is the most recently updated, the most comprehensive and best adapted to the environmental impacts that are relevant in the area (Europe). ReCiPe is a life cycle impact assessment method which comprises harmonized category indicators at the midpoint and endpoint levels.

Appendix 3 ReCiPe Method

ReCiPe LCIA Methodology Life cycle assessment (LCA) is a methodological tool used to quantitatively analyze the life cycle of products/activities. ISO 14040 and 14044 provide a generic framework. After goal and scope have been determined and data has been collected, an inventory result is calculated. This inventory result is usually a very long list of emissions, consumed resources and sometimes other items. The interpretation of this list is difficult. An LCIA procedure, such as the ReCiPe method, is designed to help with this interpretation. The primary objective of the ReCiPe method is to transform the long list of inventory results into a limited number of indicator scores. These indicator scores express the relative severity of an environmental impact category. In ReCiPe, we determine indicators at two levels:

Eighteen midpoint indicators
Three endpoint indicators

ReCiPe uses an environmental mechanism as the basis for the modelling. An environmental mechanism can be seen as a series of effects that together can create a certain level of harm to, for instance, human health or ecosystems. For instance, for climate change, we know that a number of substances increases radiative forcing, which means heat is prevented from being radiated from the Earth into space. As a result, more energy is trapped on Earth, and temperature increases. As a result of this, we can expect changes in habitats for living organisms, and as a result of this, species may become extinct.
From this example, it is clear that the greater the scope of this environmental mechanism, the higher the uncertainties get. Radiative forcing is a physical parameter that can be relatively easily measured in a laboratory. The resulting temperature increase is less easy to determine, as there are many parallel positive and negative feedbacks. Our understanding of the expected change in habitat is also not complete, etc.

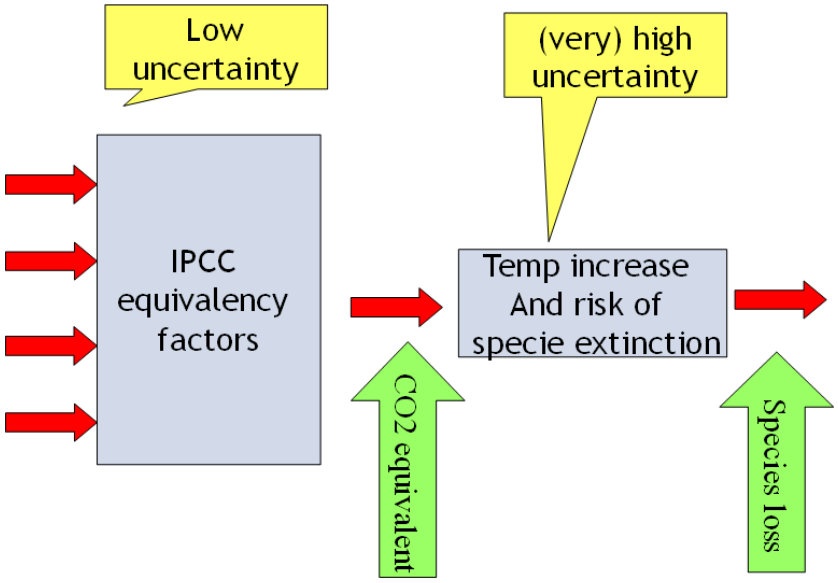


Figure 26:Example of a harmonized midpoint-endpoint model for climate change, linking to harm to human health and ecosystem.

So the obvious benefit of taking only the first step is the relatively low uncertainty.
ReCiPe combines mid- and endpoints
In ReCiPe, we indeed not only calculate eighteen such midpoint indicators, but also three much more uncertain endpoint indicators. The motivation to calculate the endpoint indicators is that the large number of midpoint indicators is very difficult to

interpret, partly as there are too many, partly because they have very abstract interpretations. How to compare radiative forcing with base saturation numbers that express acidification? The indicators at the endpoint level are intended to facilitate easier interpretation, as there are only three, and they have a more understandable definition.

The idea is that each user can choose at which level they want to have the result:

Eighteen robust midpoints, that are relatively robust, but not easy to interpret

Three easy to understand, but more uncertain endpoints:

Harm to Human health

Harm to ecosystems

Harm to resource availability

The user can thus choose between uncertainty in the indicators, and uncertainty as to the correct interpretation of indicators.

The figure below provides the overall structure of the method.

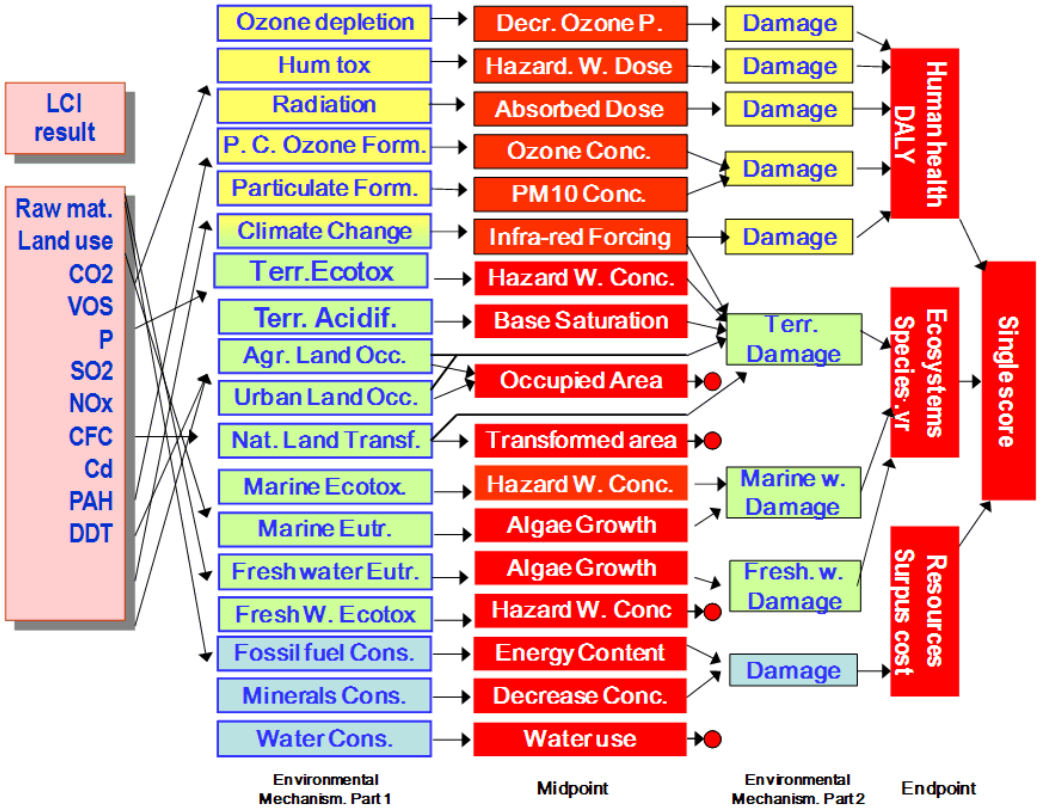


Figure 27: ReCiPe Characterization links.

Table 27: Impact category name and unit in ReCiPe (Goedkoop, et al., 2009)

Impact category name	Indicator name	Unit
Climate change CC	infra-red radiative forcing	kg (CO2 to air)
Ozone depletion OD	stratospheric ozone concentration	kg (CFC-115 to air)
Terrestrial acidification TA	base saturation	kg (SO2 to air)
Freshwater eutrophication FE	phosphorus concentration	kg (P to freshwater)
Marine eutrophication ME	nitrogen concentration	kg (N to freshwater)
Human toxicity HT	hazard-weighted dose	kg (14DCB to urban air)
Photochemical oxidant formation POF	Photochemical ozone concentration	kg (NMVOC6 to air)
Particulate matter formation PMF	PM10 intake	kg (PM10 to air)
Terrestrial eco toxicity TET	hazard-weighted concentration	kg (14DCB to industrial soil)
Freshwater eco toxicity FET	hazard-weighted concentration	kg (14DCB to freshwater)
Marine eco toxicity MET	hazard-weighted concentration	kg (14-DCB7 to marine water)
Ionizing radiation IR	absorbed dose	kg (U235 to air)
Agricultural land occupation ALO	Occupation	m2×yr (agricultural land)
Urban land occupation ULO	Occupation	m2×yr (urban land)
Natural land transformation NLT	Transformation	m2 (natural land)
Water depletion WD	amount of water	m3 (water)
Mineral resource depletion MRD	grade decrease	kg (Fe)
Fossil resource depletion FD	upper heating value	kg (oil)

At the endpoint level, most of these midpoint impact categories are further converted and aggregated into the following three endpoint categories:

Harm to human health (HH)
Harm to ecosystem diversity (ED)
Harm to resource availability (RA)

Climate change: Climate change causes a number of environmental mechanisms that affect both the endpoint for human health and ecosystem health. Climate change models are in general developed to assess the future environmental impact of different policy scenarios. For ReCiPe 2008, we are interested in the marginal effect of adding a relatively small amount of CO2 or other greenhouse gases, and not the impact of all emissions.
Ozone layer: The characterization factor for ozone layer depletion takes into account the destruction of the stratospheric ozone layer by anthropogenic emissions of ozone depleting substances (ODS). These are recalcitrant chemicals that contain chlorine or bromine atoms. Because of their long atmospheric lifetime, they are the source of Chlorine and Bromine reaching the stratosphere. Chlorine atoms in chlorofluorocarbons (CFC) and bromine atoms in halons are effective in degrading ozone due to heterogeneous catalysis, which leads to a slow depletion of stratospheric ozone around the globe.

Acidification: Atmospheric deposition of inorganic substances, such as sulphates, nitrates and phosphates, cause a change in acidity in the soil. For almost all plant

species, there is a clearly defined optimum of acidity. A serious deviation from this optimum is harmful for that specific species and is referred to as acidification. As a result, changes in levels of acidity will cause shifts in species occurrence (Goldcorp and Spriensma, 1999, Hayashi et al. 2004). Major acidifying emissions are NOx, NH3 and SO2

Eutrophication: Aquatic eutrophication can be defined as nutrient enrichment of the aquatic environment. Eutrophication in inland waters as a result of human activities is one of the major factors that determine its ecological quality. On the European continent, it generally ranks higher in severity of water pollution than the emission of toxic substances. Aquatic eutrophication can be caused by emissions to air, water and soil. In practice, the relevant substances include phosphorus and nitrogen compounds emitted into water and soil as well as ammonia (NH3) and nitrogen oxide (NOx) emitted into the air.

Toxicity: The characterization factor of human toxicity and eco toxicity accounts for the environmental persistence (fate) and accumulation in the human food chain (exposure), and toxicity (effect) of a chemical. Fate and exposure factors can be calculated by means of 'evaluative' multimedia fate and exposure models, while effect factors can be derived from toxicity data on human beings and laboratory animals (Hertwich et al., 1998; Huijbregts et al., 2000).

Particulate matter formation:Fine Particulate Matter with a diameter of less than 10 µm (PM10) represents a complex mixture of organic and inorganic substances. PM10 causes health problems as it reaches the upper part of the airways and lungs when inhaled. Secondary PM10 aerosols are formed in the air from emissions of sulphur dioxide (SO2), ammonia (NH3) and nitrogen oxides (NOx) among others (World Health Organization, 2003). Inhalation of different particulate sizes can cause different health problems.

Land occupation: The land use impact category reflects the harm to ecosystems due to the effects of occupation and transformation of land. Although there are many links between the way land is used and loss of biodiversity, this category concentrates on the following mechanisms:
1. Occupation of a certain area of land during a certain time;
2. Transformation of a certain area of land.
Both mechanisms can be combined, often occupation follows a transformation, but often occupation occurs in an area that has already been converted (transformed). In such cases, the transformation impact is not allocated to the production system that occupies an area.

Ionizing radiation: This describes the harm to Human Health related to the routine releases of radioactive material into the environment.

Water depletion: Water is a scarce resource in many parts of the world, but also a very abundant resource in other parts. Unlike other resources, there is no global market that ensures a global distribution. The market does not really work over long distances as transport costs are too high. Extracting water in a dry area can cause very significant harm to ecosystems and human health.

Fossil depletion: The term fossil fuel refers to a group of resources that contain hydrocarbons. The group ranges from volatile materials (like methane), to liquid petrol, to non-volatile materials (like coal).
There is a highly politicized debate on the availability of conventional (liquid) oil, and this makes it difficult to obtain reliable unbiased data. The spectrum of views ranges from the Peak-oil movement (www.aspo.org or peak-oil.com) to international organizations like the International Energy Agency (IEA), or commercial organizations like the Cambridge Energy Research Agency (CERA). Therefore, it is hard to determine

the seriousness of the depletion of oil, and which model to use; for this category the IEA model is used.

In ReCiPe 2008, it was decided to group different sources of uncertainty and different choices into a limited number of perspectives or scenarios, according to the "Cultural Theory" by Thompson 1990.
Three perspectives are discerned:

Individualistic (I)
Hierarchism (H)
Egalitarian (E)

These perspectives do not claim to represent archetypes of human behaviour, but they are merely used to group similar types of assumptions and choices. For instance:

Perspective I is based on short-term interest, impact types that are undisputed, technological optimism as regards human adaptation.
Perspective H is based on the most common policy principles with regards to time-frame and other issues.
Perspective E is the most precautionary perspective, taking into account the longest time-frame, impact types that are not yet fully established but for which some indication is available.

Appendix 4 LCI-data for energy and material used to produce 1 kg Meliflex granulate:

This information is not public and has therefor been put in a separate appendix that is distributed only to the parties that have an NDA[7] with the producer.

Please contact MELITEK to arrange with an agreement and then Miljögiraff can provide the file with the data.

[7] Non-Disclosure Agreement

Appendix 5 Method adaption

In the USEtox model, the emissions to air, water and ground are included, it is not possible to model the effects of direct exposure to human. Because of that the model was modified. New characterisation factors were added for DEHP, corresponding to inhalation and ingestion (same factors for both). These factors were taken from USEtox version 1.01, organic "Human EF" (based on Raul Carlson, personal communication 2017-02-02).

Based on Carlson (2012) the fate and exposure factors were set to 1. The fate factor was set to 1 while there is no dispersion of the DEHP as transferred to the blood system. Exposure factor was set to 1 while the person exposed to the transfused blood also will receive the total amount DEHP. Please note that this assumption is very simplified and therefor associated with uncertainties.

The USE tox method was copied and saved in a new version to create a modified method where we can correct the values for DEHP. DEHP is named in the method "Phthalate, dioctyl".

Impact category	Unit
Human toxicity, cancer	CTUh
Human toxicity, non-cancer	CTUh
Freshwater ecotoxicity	CTUe

Compartment	Subcompartment	Substance	CAS number	Factor	Unit
Air		Phthalate, dioctyl-	000117-81-7	1,14E-7	CTUh / kg
Air	low. pop.	Phthalate, dioctyl-	000117-81-7	8,34E-8	CTUh / kg
Air	low. pop., long-term	Phthalate, dioctyl-	000117-81-7	8,34E-8	CTUh / kg
Air	high. pop.	Phthalate, dioctyl-	000117-81-7	1,45E-7	CTUh / kg
Air	stratosphere + trop	Phthalate, dioctyl-	000117-81-7	8,34E-8	CTUh / kg
Water		Phthalate, dioctyl-	000117-81-7	8,76E-8	CTUh / kg
Water	ocean	Phthalate, dioctyl-	000117-81-7	3,54E-9	CTUh / kg
Soil		Phthalate, dioctyl-	000117-81-7	1,93E-11	CTUh / kg
Soil	agricultural	Phthalate, dioctyl-	000117-81-7	2,57E-9	CTUh / kg

Figure 28 DEHP represented by Phthalate, doctyl in Use tox.

A factor for inhalation and ingestion of DEHP, cancerogenic and non-canerogenic effects, was proposed in the Pre-study (Carlson, 2012).

	1	2	3	4	5	6	7
2	2	**ID #**	**Name**	***Human health Effect factor [cases/kgintake]***			
3	3			*Inhalation*		*Ingestion*	
4	4			cancer	non-canc.	cancer	non-canc.
91	91	117-81-7	di-(2-ethylhexyl)-phthalate (DEHP)	2,9×10^-03	4,1×10^-02	2,9×10^-03	4,1×10^-02

Figure 29 DEHP added to USEtox.

Appendix 6: Comparison of characterisation result per 1 kg PVC/DEHP and 1 kg PVC-free polymer, with different waste types and incineration processes. Based on ReCiPe Midpoint.

Table 28 Comparison of characterisation result per 1 kg PVC/DEHP and 1 kg PVC-free polymer, with different waste types and incineration processes. Based on ReCiPe Midpoint.

		1 kg PVC/DEHP material (waste type: PVC)						1 kg PVC free material (waste type: rubber)					
		Hazardous waste			Municipal solid waste, incineration (SE)			Hazardous waste			Municipal solid waste, incineration (SE)		
		total	material	waste treatment	**total**	material	waste treatment	**total**	material	waste treatment	**total**	material	waste treatment
Impact assessment	Human toxicity, kg 1,4-DB eq.	**0,746**	0,53	0,216	**1,1**	0,53	0,574	**0,663**	0,448	0,216	**0,647**	0,448	0,2
Inventory, amount	Dioxin, ng	**3,57**	,	3,17	**8,15**	0,403	7,74	**3,46**	0,298	3,17	**0,339**	0,298	0,0414
Characterization, Human toxicity	Human toxicity, dioxin, kg 1,4-DB eq.	**0,0003 62**	4,24E-05	0,00032	**0,000825**	4,24E-05	0,000782	**0,000351**	3,06E-05	0,00032	**3,48E-05**	3,06E-05	0,0000042

		1 kg PVC/DEHP material (waste type: plastic)						1 kg PVC free material (waste type: plastic)					
		Hazardous waste			Municipal solid waste, incineration (SE)			Hazardous waste			Municipal solid waste, incineration (SE)		
		total	material	waste treatment	**total**	material	waste treatment	**total**	material	waste treatment	**total**	material	waste treatment
Impact assessment	Human toxicity, kg 1,4-DB eq.	**0,746**	0,53	0,216	**1,1**	0,53	0,574	**0,663**	0,448	0,216	**0,671**	0,448	0,223
Inventory, amount	Dioxin, ng	**3,57**	0,403	3,17	**8,15**	0,403	7,74	**3,46**	0,298	3,17	**7,86**	0,298	7,57
Inventory, characterization	Human toxicity, dioxin, kg 1,4-DB eq.	**0,0003 62**			**0,000825**			**0,000351**			**0,000795**	3,06E-05	0,000764

		1 kg PVC/DEHP material (waste type: PVC)						1 kg PVC free material (waste type: PP)					
		Hazardous waste			Municipal solid waste, incineration (SE)			Hazardous waste			Municipal solid waste, incineration (SE)		
		total	material	waste treatment	**total**	material	waste treatment	**total**	material	waste treatment	**total**	material	waste treatment
Impact assessment	Human toxicity, kg 1,4-DB eq.							**0,663**	0,448	0,216	**0,708**	0,448	0,261
Inventory, amount	Dioxin, ng							**3,46**	0,298	3,17	**7,86**	0,298	7,56
Inventory, characterization	Human toxicity, dioxin, kg 1,4-DB eq.										**0,000794**	3,06E-05	0,000763