Critical review of the study

"PVCFREEBLOODBAG - Life Cycle Assessment"

Adisa Azapagic

The University of Manchester

August 2017

School of Chemical Engineering and Analytical Science, The University of Manchester
The Mill, Sackville Street, Manchester M13 9PL, UK

Executive summary

This report presents the findings of a critical review of the LCA study "*PVC Free Blood Bag - Life Cycle Assessment*". The LCA study was carried out by Miljögiraff for Region Jämtland Härjedalen within the project "LIFE+ PVCfreeBloodBag". The critical review has been commissioned by the European Council of Vinyl Manufacturers (ECVM) and carried out by Professor Adisa Azapagic at the University of Manchester.

Overall, this critical review has found that the LCA study is not compliant with the ISO 14040 and 14044 standards for the following main reasons:

1. The study fails by a large margin to follow the ISO standard requirements with respect to the public disclosure and comparative assertions, which was the main goal of the study.
2. The definition of the goal of the study is inadequate as the study is not a "complete LCA" as claimed, focusing only on a limited number of environmental impacts. This does not allow for a balanced and informed choice of environmentally more sustainable blood bags.
3. It is not clear if the two types of blood bags have the same performance characteristics and if they can be compared on an equivalent basis.
4. It is not clear or justified why only five environmental impacts are considered in the study and why those have been selected.
5. The use of generic data for PVC bags and specific data for the alternative type of bags represents an inconsistency and does not allow for an equivalent comparison of the two types of bag. Some data are also outdated.
6. The assumptions on DEHP exposure and transfer to humans are questionable and should have been tested through a thorough sensitivity analysis, supported by scientific evidence.
7. Consideration of the maximum storage time of blood in the bags disadvantages PVC bags due to the longer assumed leakage of DEHP into the blood and the subsequent assumed transfer to humans – the shorter storage times actually practiced should have been considered in a sensitivity analysis.
8. The apparent assumption of the equivalent toxicity of DEHP when ingested orally and intravenous is incorrect. Although different transfer ranges have been considered in a sensitivity analysis, it is not clear if these ranges are correct as there is no scientific evidence presented in support of the assumptions.
9. The assumptions on the leakage and uptake of DEHP appear to be incorrect and the estimate does not take into account ambient exposure.
10. Other PVC plasticisers exist which, according to scientific evidence, have lower potential effects on human health and could have been considered alongside DEHP.
11. The omission of gamma-ray sterilisation of "PVC free" bags is potentially significant as it could increase the overall health hazards of these bags. For the PVC bags, the omission of sterilisation underestimates climate change and fossil fuel depletion.
12. The assumptions for incineration should have been tested through a more thorough sensitivity analysis, particularly given its significant contribution to the impacts. The results presented for the limited sensitivity analysis carried out with respect to this are inadequate and incomplete.
13. The study puts a lot of emphasis on the health impacts without considering the large uncertainties associated with these estimates, particularly as

methodologies for estimating health impacts are still in development. An uncertainty analysis should have been carried out for health impacts to test the validity of the assumptions and results.

14. Other tools more suitable for estimation of human health risks and exposure should have been used alongside LCA as, according to the results, the human health impact appears to be the main distinguishing aspect between the two types of bag.

15. The "unambiguous recommendation" that the "PVC-free" option is better than the PVC bag is unfounded as it is based on one highly uncertain aspect - health impact.

16. The sensitivity analysis is inadequate as it is too limited and the interpretation of the results is incomplete.

17. The terminology "PVC free" appears to be biased and may be misleading to the reader implying that it is better and "healthier" than the alternative with PVC (similar to the terminology used in food advertising, such as "sugar free" and "fat free").

18. The claim that human health risks would be lower by switching from PVC to the proposed type of bag is misleading as other factors must be taken into account, such as duration of safe storage of blood.

Therefore, the results of the LCA study should be interpreted with the above in mind.

1. **Background**

This report presents the findings of a critical review of the LCA study "*PVC Free Blood Bag - Life Cycle Assessment*". The LCA study was carried out by Miljögiraff for Region Jämtland Härjedalen within the project "LIFE+ PVCfreeBloodBag". This study is a follow up on a previous study by Carlson (2012).

The critical review has been commissioned by the European Council of Vinyl Manufacturers (ECVM) and carried out by Professor Adisa Azapagic at the University of Manchester. She also acted as a critical reviewer (Azapagic, 2012) of the related above-mentioned LCA study carried out by Carlson (2012); the previous critical review was also commissioned by the ECVM.

The reviewer is independent of both the authors of the LCA study and the ECVM.

The critical review is based entirely on the LCA study report that was available in the public domain (Miljögiraff, 2017) and the reviewer had no interactions or discussions with either the authors of the study or ECVM during the critical-review process.

In assessing the LCA study, the critical review followed the main guiding principles for carrying out LCA studies defined in the ISO 14040/44 standards (ISO, 2006a&b) with the aim of finding out if:
- the methods used to carry out the LCA are consistent with these ISO standards;
- the methods used are scientifically and technically valid;
- the assumptions and data used are appropriate and reasonable;
- the interpretation of the results is valid and reflects the findings and limitations of the study; and
- the study is transparent, consistent and impartial.

The findings of the critical review are summarised below, following the phases of the LCA methodology: goal and scope of the study, inventory, impact assessment and interpretation.

2. **Findings of the critical review**

2.1   Goal of the study (section 3 of the LCA report)

i) The goal of the study is defined as: *"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"*.

Thee above definition of the goal of the study is inadequate in two respects:
- "*complete LCA*" – given that the study considers only a limited number (five) of LCA impacts, it cannot be a complete LCA;
- the type of material(s) for the PVC-free blood bags is not specified. This is mentioned in passing later on in section 3.2.1 but it is still not clear what kind of "synthetic rubber" and "organic chemical additives" were assumed. The type of the alternative bags should have been stated clearly in the goal of the study rather than using the term "PVC free" as that could be anything.

ii)   The scope of the study is from cradle to grave, which is appropriate.

iii)   The definition of the functional unit is also appropriate. However, two issues are important as they affect the outcomes of the study:

- it is not clear if the two types of bag have the same performance characteristics and if they can be compared on an equivalent basis; and
- the maximum storage time has been considered based on the guidelines for blood storage, despite much shorter actual storage times. This could disadvantage PVC bags due to the longer time assumed for the potential leakage of DEHP into the blood and a higher estimated human toxicity potential. For this reason, different storage times should have been considered in a sensitivity analysis.

iv) A further issue is noted with respect to the type of data used for the two types of blood bag (section 3.2.1): *"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."*

Using generic data for one system and specific data for another raises the issue of data inconsistency and quality and may lead to a bias in results. Furthermore, data for the "PVC free" granulate have been sourced from an outdated (2006) EPD declaration.

v) The cut-off criteria are discussed but it is not clear if any cut-off has been applied.

vi) Allocation of impacts to products has primarily been carried out on an economic basis which is the last method in the ISO 14040 hierarchy of allocation methods. Therefore, the use of this method should have been justified and used only as a last resort. Furthermore, other allocation methods should have considered in a sensitivity analysis.

vii) The allocation method used for residual materials is unclear, despite being described in the main body of the report and Appendix 1 at some length. This is a typical example of an explanation which leaves the reader none the wiser (Appendix 1): *"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."*

viii) The choice of the impact assessment method has not been justified, beyond the reference to the previous LCA study by Carlson (2012). In addition to the previous three impacts (climate change, fossil fuel depletion and human toxicity), only two additional impacts are considered: land use and water scarcity. The selection of these impacts with relevance to the systems considered has not been justified or explained.

ix) It is assumed that all DEHP in the PVC bags that leaks to blood is transferred to humans, assuming no fate and dispersion (metabolism). This is a significant assumption and should have at least been tested through a sensitivity analysis. Furthermore, DEHP is widely dispersed in the environment and ambient environmental exposure should be considered alongside exposure from PVC blood bags when assessing the risk of DEHP to human health (Lowell Center for Sustainable Production, undated).

x) There are other PVC plasticisers that are also used in medical applications, including blood bags and blood tubings, and they should have been considered alongside DEHP. These include butryl tri-n-hexyl citrate (BTHC), tri (2-ethylhexyl) trimellitate (TOTM) and tri-(2-ethylhexyl)-trimellitate) (TEHTM); other possible alternatives are bis (2-ethylhexyl) terephthalate (DEHT). They all exhibit much lower potential human health risks than DEHP (Danish Ministry of the Environment, 2014), as also recognised in the forthcoming revision of the European Pharmacopeia (EDQM, 2017). The other alternatives include diisodecyl phthalate (DIDP) and di-isononyl phthalate (DINP) which also have less discernible human health effects than DEHP (EC, 2001). Furthermore, LCA data for DINP are available via an EPD (ECPI, 2015) and could have been used for comparative purposes.

xi) The study has not followed the specification in ISO 14044 (2006b) on what should be included in the study intended for the public disclosure and comparative assertions. The following requirements are listed in the above ISO standard as necessary (section 5.3.1):

"For LCA studies supporting comparative assertions intended to be disclosed to the public, the following issues shall also be addressed by the report in addition to those identified in 5.1 and 5.2:
a) analysis of material and energy flows to justify their inclusion or exclusion;
b) assessment of the precision, completeness and representativeness of data used;
c) description of the equivalence of the systems being compared in accordance with 4.2.3.7;
d) description of the critical review process;
e) an evaluation of the completeness of the LCIA;
f) a statement as to whether or not international acceptance exists for the selected category indicators and a justification for their use;
g) an explanation for the scientific and technical validity and environmental relevance of the category indicators used in the study;
h) the results of the uncertainty and sensitivity analyses;
i) evaluation of the significance of the differences found."

Out of the above criteria, the following criteria are not satisfied: a), b) [precision and representativeness]; d) [description of the process]; e); f) [justification for use of the selected category indicators]; g); h) [uncertainty analysis and more thorough sensitivity analyses]; and i). Therefore, the study fails by a large margin to follow the ISO standard with respect to the public disclosure and comparative assertions, which was the main aim of the study.

xii) A critical review of the study has been carried out, which is in accordance with the intended public use of the results. However, this is found to be inadequate and not compliant with the above and other ISO 14040/44 guidelines - for details, see a separate report (Azapagic, 2017).

Conclusions: Goal of the study
- The study fails by a large margin to follow the ISO standards with respect to the public disclosure and comparative assertions, which was the main goal of the study.
- The definition of the goal of the study as defined is inadequate as the study is not a "complete LCA" as claimed.
- It is not clear if the two types of blood bag have the same performance characteristics and if they can be compared on an equivalent basis.
- It is not made clear or justified why only five environmental impacts are considered in the study and why those have been selected.
- The use of generic data for PVC bags and specific data for the others is inconsistent. Also, data for the "PVC free" granulate are based on an outdated EPD declaration.
- The assumptions on DEHP exposure and transfer to humans are questionable and should have been tested through a more thorough sensitivity analysis.
- Other PVC plasticisers exist which have less discernible effects on human health and could have been considered alongside DEHP.
- Consideration of the maximum storage time of blood disadvantages PVC bags due to the assumed leakage of DEHP into the blood and the assumed subsequent transfer to humans – the actual shorter storage times should have been considered at least in a sensitivity analysis.

2.2 Life cycle inventory (section 4 of the LCA report)

i) Ecoinvent v3.3 database has been used for generic data which is appropriate. However, it is not clear what data have been used for the background energy mix - European, Swedish, Swiss, Danish (all have been mentioned in some context) or other. The electricity mix for the use stage appears to be Swedish (Table 20). It is not clear why the Swedish mix has been chosen as the European would have been more appropriate given, for example, the use of average European mix of technologies for PVC production. Furthermore, the data for the materials composition are from the previous LCA study (Carlson, 2012) which were largely outdated (including old PlasticsEurope data for PVC).

ii) Data on sterilisation of blood bags have not been considered due to unavailability. For "PVC free" bags this is an issue as gamma radiation is used for sterilisation, which represents a health hazard. Given the emphasis on the potential health risks of PVC bags, this is a significant omission. For the PVC bags, the issue with sterilisation is mainly related to energy use (steam) which could increase the energy-related impacts, such as climate change and fossil fuel depletion.

iii) The component materials used for the production of "PVC-free" bags are (finally) mentioned in section 4.1.1. While it is appreciated that the data on their amounts are confidential, at least the type of synthetic rubber and organic additives should have been specified, particularly as Ecoinvent data have been used for the component materials.

iv) Data for DEHP were not available and its impacts were modelled by the authors of the LCA study. Given the importance of these data for the overall goal of the study, this represents a potentially significant limitation of the study. To alleviate this and test the significance of these data, a sensitivity analysis should have been carried out, particularly with respect to the type of the allocation method used. Furthermore, the LCA results for DEHP should have been compared with those for DINP (ECPI, 2015) to validate the results as both plasticisers have similar composition (both are phthalate esters with on carbon atom difference) and production process (both are produced from phthalic anhydride and an alcohol).

v) The study appears to assume that the exposure to and the health impact of DEHP via blood transfusion are equivalent to that of oral ingestion (page 32, 2nd paragraph). If so, this is incorrect as the latter is more hazardous than intravenous exposure. This is due to the avoidance of the digestive tract, where DEHP is metabolised to MEHP, which is responsible for much of the DEHP's toxicity (Lowell Center for Sustainable Production, undated).

vi) The leakage rate assumed for DEHP is not specified. In any case, this ranges widely during blood transfusion and different ranges should have been considered in a sensitivity analysis.

vii) Disposal by incineration considers only one type of ("predominant") material in the bags. Given the very significant contribution of incineration to the impacts, this assumption should have been tested through a more thorough and extensive sensitivity analysis.

> **Conclusions: Inventory**
> - The use of generic data for PVC bags and specific data for the other type of bag is inconsistent and in some cases data are too old.
> - The LCA results for DEHP could have been compared with DINP to validate the findings as they have similar chemical composition and are produced in a similar way.
> - The omission of gamma-ray sterilisation of "PVC free" bags is potentially a significant omission as it could increase the overall health hazards of these bags. For the PVC bags, the omission of sterilisation underestimates climate change and fossil fuel depletion.
> - The apparent assumption of the equivalent toxicity of DEHP when ingested orally and intravenous is incorrect. Although different transfer ranges have been considered in a sensitivity analysis, it is unclear if these are correct.
> - The assumptions for incineration should have been tested through a more thorough sensitivity analysis, particularly given its significant contribution to the impacts. The results presented for the limited sensitivity analysis carried out with respect to this are inadequate and incomplete.

2.3   Life cycle impact assessment (section 5 of the LCA report)

i) As commented previously, the study uses only five environmental impacts to compare the blood bags. This is insufficient to make informed and balanced recommendations for the use of either type of the bag as the information is far too limited. A full range of impacts should have been considered to show how the blood bags compare across all the categories.

ii) The results for climate change, fossil fuel depletion and water scarcity are presented to the second decimal place. Given the uncertainties in the data, assumptions and the models, this is inappropriate and the results should have been rounded off.

iii) The USEtox model has been used to assess potential human toxicity. This is acknowledged by the authors of the LCA study as a limitation as the model does not allow for consideration of all substances in the life cycle of the two types of blood bag and thus has limited value for use in LCA. Particularly, the data for DEHP are not available and the authors have apparently assumed (incorrectly; see above) that the ingestion and inhalation impacts are equivalent to those by transfusion. Furthermore, the authors should have used the ReCiPe method (Goedkoop et al., 2008) alongside the USEtox model to compare and contrast the findings.

iv) All human toxicity models are uncertain and an uncertainty analysis should have been carried out to test the reliability of the results. This is particularly important given that the study puts a lot of emphasis on the health impacts and that methodologies for estimating health impacts are still in development.

v) As the main difference in the results between the two types of bag appears to be in potential human toxicity, other tools should have been used to assess this aspect more accurately, as LCA is not well suited for such analyses.

Conclusions: Impact assessment

- The limited number of impacts (five) considered does not allow for a balanced and informed choice of environmentally more sustainable blood bags.
- The study puts a lot of emphasis on the health impacts without considering the large uncertainties associated with these estimates, particularly as methodologies for estimating health impacts are still in development.
- The assumptions on the leakage and uptake of DEHP appear to be incorrect and the estimate does not take into account ambient exposure.
- An uncertainty analysis should have been carried out for health impacts to test the validity of the assumptions and results.
- Other tools more suitable for estimation of human health risks and exposure should have been used alongside LCA as the human health impact appears to be the main distinguishing aspect between the two types of bag.

2.4   Interpretation (section 6 of the LCA report)

i)   The study states that there is no difference between the two types of blood bags for three impacts (climate change, fossil fuel depletion and land use) and that there is a more significant difference for water use and human toxicity. Based on the results obtained, this interpretation is correct.

ii) However, the results for human toxicity should be interpreted with utmost care due to some incorrect and unclear assumptions, as well as a lack of an uncertainty analysis (see also the previous related comments). While the study refers to some of the uncertainties (section 6.2.1), a quantitative uncertainty analysis would have improved significantly the reliability of the study.

iii) The study states that *"PVC/DEHP based set of blood bag has a substantially higher potential impact on human health, compared to the PVC-free alternative."* While the absolute figures suggest a substantial difference between the two, it is not clear how *significant* the impact is in the first instance, as the figures are small (of the order of 10^{-6} and 10^{-7} CTUh for both bag types). For context, the average total daily ambient exposure to DEHP in the US is estimated at 0.27 mg per day, of which exposure through food is 0.25 mg per day (Lowell Center for Sustainable Production, undated). It would have helped to interpret the results in a more informed and impartial way if they were put in a similar context. A context is also missing for the other impacts.

iv) The study correctly points out the erroneous assumption on the contribution of PVC to dioxin formation during incineration that was made in the previous study by Carlson (2012) and criticised in the subsequent critical review (Azapagic, 2012).

v)   A sensitivity analysis has been carried out considering two major assumptions: the "worst-case" scenario for the transfer of DEHP to humans and the type of waste incinerated. This is both appropriate and necessary. While the human toxicity results are still substantially higher for PVC bags for a 50% lower transfer rate, it is still unclear how significant the absolute values are when put into context or whether 50% is still too high. The study makes no mention of the importance of considering this. Furthermore, the explanation of the results provided for the sensitivity analysis related to incineration is unclear. The graphical results referred to in the report are missing so that the effect of the assumptions on incineration on the overall results remains unknown.

vi) The study states that "… *the results from this study strengthen the previous results by Carlson (2012) were* [sic] *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." This statement is unfounded for several reasons:

- the previous study was fundamentally flawed (for details, see Azapagic (2012));
- the results of the current study suggest that the "PVC free" blood bag is a better alternative for human toxicity but, as acknowledged by the authors, "*the uncertainties about the effects of human toxicity are high*";
- making "unambiguous" recommendations on the basis of one highly uncertain impact goes against both good practice in LCA and a robust scientific approach.

Conclusions: Interpretation
- The study concludes that there is no difference between the two types of blood bags for climate change, fossil fuel depletion and land use. It also finds that the difference for water use and human toxicity is substantially higher for PVC bags. These conclusions are appropriate based on the presented results.
- However, the "unambiguous recommendation" that the "PVC-free" option is better than the PVC bag is unfounded as it is based on one highly uncertain criterion – health impact – for which LCA is not the best tool.
- It is difficult to interpret the results for health impacts and check their validity as the results have not been put in perspective and there is no uncertainty analysis.
- The sensitivity analysis is inadequate as it is too limited and the interpretation of the results is incomplete.

2.5 Other comments

i) Terminology: The non-specific "PVC-free" terminology is used throughout the report. This could be interpreted as if the study is suggesting that, because the other type of bag is "PVC free", it is by implication 'better' and 'healthier' (compare, for example, the implication of related terms used in food advertising: "sugar-free", "fat-free", etc.). Therefore, the type of the other blood bag should have been specified clearly at the outset (including in the title of the study) and that terminology used throughout.

ii) Abstract and Conclusions: The same comments apply as in section 2.4 above. In addition:
- It is claimed that it is possible to lower the toxicity risks for human health by using "PVC-free" bags, without increasing risks to human health. The authors make this statement without any comparison of the technical performance of the PVC and the proposed type of bag, particularly as existing evidence (Sang et al., 2001) shows that PVC/DEHP bags can store blood products for much longer than bags made of polyolefins, which are used in the proposed "PVC free" bag. This means that blood may need to be used quicker or it would be spoiled and could lead to blood shortages, or otherwise larger blood banks may be needed. Therefore, the claim that human health risks would be lower by switching to the proposed type of bag is at best misleading as other factors must be taken into account.
- A reference is made to reducing global warming by considering other methods for waste management of blood bags instead of incineration. The study fails to mention that the potential health impact it estimated for the PVC bags could also be reduced if such alternative methods were to be used.

Conclusions: Other comments
- The terminology "PVC free" appears to be biased against PVC and may be misleading to the reader.
- The claim that human health risks would be lower by switching from PVC to the proposed type of bag is misleading as other factors must be taken into account, such as duration of safe storage of blood.

References

Azapagic, A. (2012). Critical review of the study "Life Cycle Assessment, LCA, study of PVC blood bag". www.pvc.org/upload/documents/Critical_review_statement.pdf.

Azapagic, A. (2017). Critical review of the critical review of the study "PVCFREEBLOODBAG - Life Cycle Assessment". TO ADD THE LINK WHEN KNOWN.

Carlson, R. (2012). Life Cycle Assessment, LCA, study of PVC blood bag. eco2win AB.

Danish Ministry of the Environment (2014). Alternatives to classified phthalates in medical devices. Danish Environmental Protection Agency, Environmental Project No. 1557, 2014. http://www2.mst.dk/udgiv/publications/2014/03/978-87-93178-27-4.pdf.

EC (2001). Opinion on the results of the Risk Assessment of: 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-"isononyl" phthalate. Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), European Commission, 2001. http://ec.europa.eu/health/ph_risk/committees/sct/documents/out120_en.pdf.

ECPI (2015). Di-isononyl phthalate (DINP). Eco-profiles and environmental product declarations of the European Plastics Manufacturers. ECPI, 2015. http://www.plasticisers.org/wp-content/uploads/2017/03/21872-ecpi-eco-profile-dinp-2015-02-05.pdf.

EDQM (2017). Ph. Eur. seeks feedback on alternatives to DEHP for blood bags. European Directorate for the Quality of Medicines and Health Care, The Council of Europe, 16 May 2017, https://www.edqm.eu/sites/default/files/pheur_enquiry_on_plastised_pvc_04052017_en.pdf.

ISO (2006). ISO 14040 - environmental management - life cycle assessment - principles and framework. Geneva; 2006.

ISO (2006). ISO 14044 - environmental management - life cycle assessment - requirements and guidelines; 2006. Geneva.

Goedkoop M.J., Heijungs R, Huijbregts M., De Schryver A.;Struijs J.,; Van Zelm R, ReCiPe 2008, A life cycle impact assessment method which comprises harmonised category indicators at the midpoint and the endpoint level; First edition Report I: Characterisation; 6 January 2009, http://www.lcia-recipe.net.

Lowell Center for Sustainable Production (undated). Health risks of DEHP. www.chemicalspolicy.org/downloads/DEHP.pdf.

Miljögiraff (2017). PVC free blood bag - life cycle assessment. Report no. 93. Södra Miljögiraff, Gothenburg, Sweden, www.pvcfreebloodbag.eu/?p=1188.

Sang et al. (2001). The effects of polyvinyl chloride and polyolefin blood bags on red blood cells stored in a new additive solution. PubMed 81(3):161-6. https://www.ncbi.nlm.nih.gov/pubmed/11703858.