APPENDIX F

ADDITIVES
FOR SENSOR CARDS
LIFE CYCLE ASSESSMENT

NON-CONFIDENTIAL

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Table of Contents

1.0 EXECUTIVE SUMMARY

Intertek has been retained by Instrumentation Laboratory to carry out an environmental Life Cycle Assessment (LCA) of four additives used or potentially used in sensor cards:

- DEHP
- Mineral Oil
- Ester Lubricant
- Acrylic Processing Aid

The three additives Mineral Oil, Ester Lubricant and Acrylic Processing Aid are potential alternatives to DEHP. DEHP is used as an additive on its own, in contrast to the other three additives, which must be used in a combination of all three to match the functional performance of DEHP.

The LCA was performed with guidance from *ISO 14040: Environmental Management – Life Cycle Assessment – Principles* and *Framework and ISO 14044: Environmental Management – Life Cycle Assessment – Requirements and Guidelines* [1].

Instrumentation Laboratory delivers innovative market-leading solutions for Hemostatis and Critical Care *in vitro* diagnostic testing. Sensor Cards are used in Instrumentation Laboratory's blood analyzer equipment. The sensor card is the location of all electrochemical sensors which the systems use for measuring and reporting concentrations of critical care analytes in blood. The LCA study evaluates the environmental impacts at various stages of the life cycle of four additives: DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid. The additives are used to mold and shape the polymer sensor cards. Material and energy inputs, differences and trade-offs are identified through the LCA, permitting quantified data analysis of environmental advantages and identification of opportunities to reduce environmental impacts.

The primary goal of the LCA study is to provide an analysis of the environmental impacts associated with the four additives DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid. The comparison is DEHP additive versus the combination of Mineral Oil, Ester Lubricant and Acrylic Processing Aid additives. This combination is required to match the performance characteristics of DEHP. Results are discussed in detail in the Results section of the report, summarized here (in all cases, a numerically lower result is a preferable result):

- The LCA for DEHP showed a global warming potential or 'carbon footprint' of 3.48 kgCO2eq, Mineral Oil of 2.69 kgCO2eq, Ester Lubricant of 4.05 kgCO2eq and Acrylic Processing Aid of 3.79 kgCO2eq.

- The alternatives to DEHP are required in combination, so the true comparison is DEHP with a carbon footprint of 3.48 kgCO2eq versus the combined alternative additives with a carbon footprint of 10.54 kgCO2eq.

- The USEtox LCA results in the 'Human Toxicity, Cancer' category were 76 nanoCases for DEHP versus 441 nanoCases for the combination of the other three additives.

- The USEtox results in the 'Human Toxicity, Non-Cancer' category were 256 nanoCases for DEHP versus 2130 nanoCases for the combination of the other additives.

- The results for Cumulative Energy Demand (CED) were lower in all cases for DEHP than for the combination of the other additives; for example, in the 'Non-Renewable, Fossil' category, the result for DEHP was 97 Megajoules, while the result for the combination of the other additives was 251 Megajoules.
- The Ecopoint method results showed that DEHP achieved a score of 1.4 mPt versus 5.1 mPt for the combination of the other additives.
- The overall conclusion is that the LCA provides evidence that DEHP is likely to be the preferred solution in terms of environmental impact and human health. The alternative additives when considered individually are within the same order of magnitude, but they must be used in combination in the sensor card to achieve equivalent functional performance, which makes their combined environmental and health impact significantly higher (less desirable) than that of DEHP.
- However, the results should be kept in perspective: all these additives are only used in low concentrations in the sensor card, and their environmental impact is small compared to the environmental impact of the whole blood monitor.

2.0 GENERAL INFORMATION

2.1 Introduction

Intertek has been retained by Instrumentation Laboratory to carry out a Life Cycle Assessment (LCA) for four additives; DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid, which are added to Sensor Cards.

The LCA was performed with guidance *ISO 14040: Environmental Management – Life Cycle Assessment – Principles* and *Framework and ISO 14044: Environmental Management – Life Cycle Assessment – Requirements and Guidelines* [1].

2.2 Organisational Background

Instrumentation Laboratory is a leading manufacturer of equipment used for analysis of critical care analytes in blood used in hospitals and laboratories in all world markets. Instrumentation Laboratory operates under ISO 14001 and is committed to meeting European and country specific environmental requirements.

Instrumentation Laboratory manufactures the GEM Premier diagnostic medical analyzers for the EU Market. These instruments are used to measure the blood of patients and provide clinicians with accurate measurements of specific analytes, vital to medical diagnosis and patient treatment.

This study was conducted to provide Instrumentation Laboratory with the environmental impacts associated with four additives:

- DEHP
- Mineral oil
- Ester Lubricant
- Acrylic Processing Aid

The LCA study evaluated the environmental impacts at all stages of the life cycle of additives. Material and energy inputs, differences and trade-offs are identified through the LCA, permitting quantified data analysis of environmental advantages and identification of opportunities to reduce environmental impacts.

3.0 GOAL AND SCOPE

The primary goal of the study is to provide an analysis of the environmental impacts associated with four additives DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid, using LCA methods.

The LCA study is intended to identify the key environmental impacts for the additives. The results may be used internally to assist new product designers in future designs and re-designs of this and similar products. The study is not intended for disclosure to the public as described in the ISO 14040 series or to represent an Environmental Product Declaration (EPD).

4.0 PRODUCT INFORMATION

Instrumentation Laboratory delivers innovating market-leading solutions for Hemostatis and Critical Care *in vitro* diagnostic testing. Sensor Cards typically used in its blood analyzer equipment. The sensor card is the primary unit of the cartridge and is the location of all electrochemical sensors which the systems use for measuring and reporting concentrations of critical care analytes in blood. The LCA study evaluates the environmental impacts at various stages of the lifecycle of four additives: DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid. The additives are used as an additive in order to mold and shape the Sensor Cards. Material and energy inputs, differences and trade-offs are identified through the LCA, permitting quantified data analysis of environmental advantages and identification of opportunities to reduce environmental impacts.

The four additives DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid are added to aid the molding of the polymer in the sensor cards. DEHP – di-2-ethylhexyl phthalate, $C_6H_4(CO_2C_8H_{17})_2$ – is commonly added to plastics to make them malleable. Mineral oil, Ester Lubricant and Acrylic Processing Aid can act in a similar capacity when used in combination.

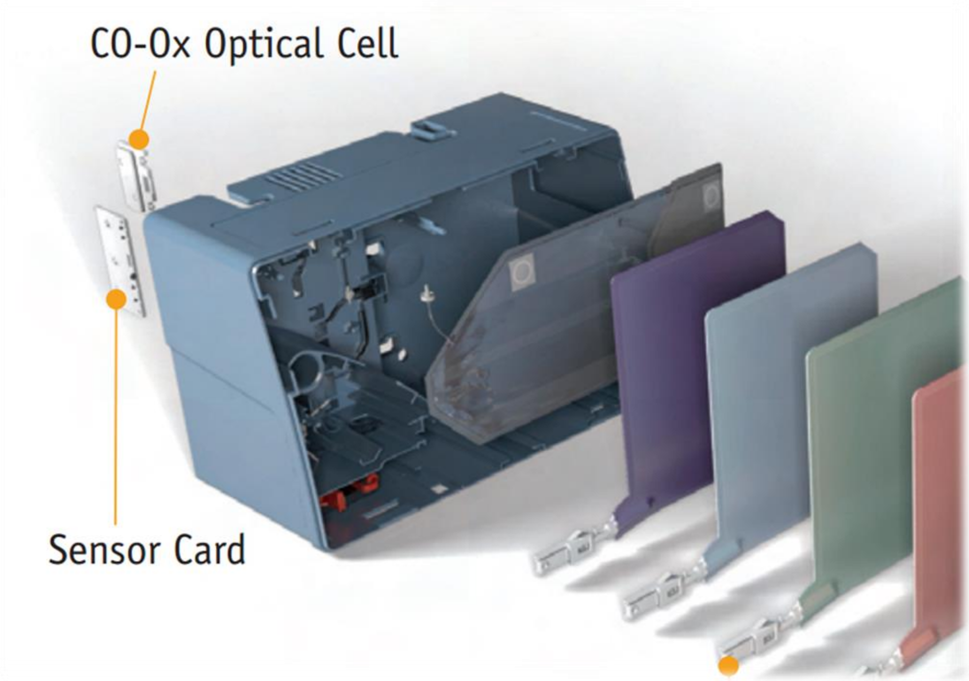

Figure 1. A small quantity of additive is used in the polymer of the Sensor Card

5.0 FUNCTIONAL UNIT & REFERENCE FLOW

For the purposes of this study, the functional unit is defined as one kilogram of DEHP additive. Each additive requires different amounts in order to achieve similar results of molding the sensor card. The sensor card polymer would typically contain:

- DEHP: %

or

- Mineral Oil: %
- Ester Lubricant: %
- Acrylic Processing Aid: %

Therefore, a normalization factor was used. The comparative reference flows as prescribed in ISO 14040 are:

Additive	Unit	Factor
DEHP	kg	1.00
Mineral Oil	kg	1.228
Ester Lubricant	kg	1.404
Acrylic Processing Aid	kg	1.404
Combination of above three additives	kg	4.036

6.0 SYSTEM BOUNDARY

The LCA system boundary for the additives includes cradle-to-grave life cycle stages. This boundary considers raw material extraction, pre-production processes, production, transport and final disposal of the product (the additive). Aspects assigned to the card and its operation, such as electricity use during blood analysis, are not included.

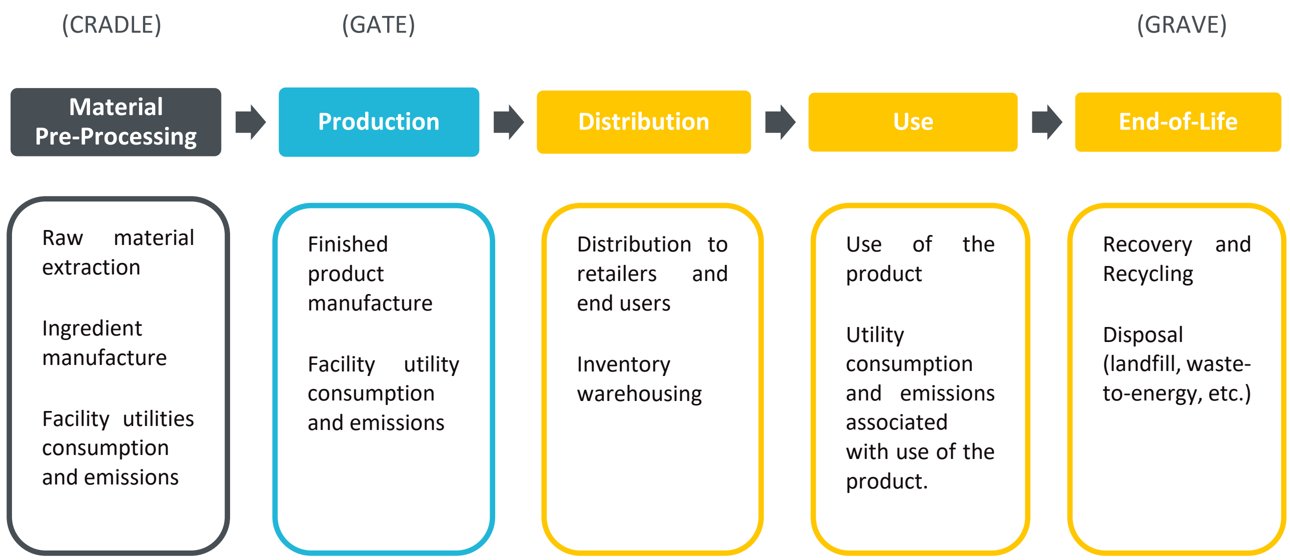

Figure 2. System boundary for the additives

6.1 Assumptions

The Ecoinvent 3.6 database is one of the most comprehensive and reliable resources for LCA data available globally. Instrumentation Laboratory provided the additives that are categories as one material or substances, minimal assumptions were made on the composition of the additives.

While raw material and sub-component data sets within the Ecoinvent 3.6 database [2] typically include raw material extraction, transport, infrastructure, emissions, waste and energy use, they do not include any packaging and/or palletizing that is applied to sub-components in their transport to the finished product manufacturer. All input information is assumed to be as accurate as possible at the time of the study.

6.2 Study Limitation

The study limitations are as follows:

- Due to the inherent limitations of LCA methodology, this study should not be used as the sole source of environmental data on the materials and processes modelled. This LCA has been performed according to best practices in modelling and allocation.
- Due to the limitation of some substances that were not available within the EcoInvent database, these were created based on composition information and desktop research.

7.0 DATA SOURCE

The Instrumentation Laboratory provided primary data for the substance level bill of material of the four additives DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid, with weights and material composition.

Additionally, Intertek used data from the Ecoinvent 3.6 database [2] to incorporate the processing of additives materials.

8.0 UNCERTAINTY

The LCA study for tablets involved data, flow, and modelling assumptions, which can potentially introduce uncertainty into study results. Some possible contributors to uncertainty in this LCA study, include:

- Secondary data that is derived from the Ecoinvent database.
- Geographical representation of secondary or background data from Ecoinvent is primarily routed in European research but used in this LCA study to represent production globally. Note, energy data used in the study is a global average or in the case of the production phase, specific to where the manufacturer is located.
- Mistakes imposed by human error in primary and secondary data, research and modelling.

9.0 METHODOLOGY

9.1 LCA Framework

The LCA and report were prepared in reference to the ISO 14040 series of standards as guidance, primarily; *ISO 14040: 2006 Environmental Management – Life Cycle Assessment – Principles and Framework* and *ISO 14044: 2006 Environmental Management – Life Cycle Assessment – Requirements and Guidelines* [3]. Additionally, guidance from the ILCD Handbook was used for the study [4].

9.2 Software

To facilitate the LCA and perform the impact assessment, Intertek utilized SimaPro 9.1 LCA software [5], with data primarily from the Ecoinvent 3.6 database [2]. The data in these built-in resources were applied for commonly used materials, products and processes when internationally accepted generic information or secondary data is required for the study.

9.3 Methodology and Impact Indicators

The LCA and impact category results are presented following the ReCiPe [6], CED and Ecopoint methods.

ReCiPe is a method used for LCIA that was developed through cooperation between RIVM, Radboud University Nijmegen, Leiden University and PRé Sustainability. The primary objective of the ReCiPe method is to transform the long list of life cycle inventory results into a limited number of indicator scores.

These indicator scores express the relative severity on an environmental impact category. In ReCiPe indicators are determine at two levels, 18 midpoint indicators and 3 endpoint indicators. Each method (midpoint, endpoint) contains factors according to the three cultural perspectives. These perspectives represent a set of choices on issues like time or expectations that proper management or future technology development can avoid future damages.

USEtox is a scientific consensus model endorsed by the UNEP/SETAC Life Cycle Initiative for characterizing human and ecotoxicological impacts of chemicals.

Cumulative Energy Demand (CED) is based on the method published by Ecoinvent version 1.01 and expanded by PRé for energy resources available in the SimaPro database. CED represents the direct and indirect energy use throughout the life cycle.

Ecopoints are produced by the IMPACT 2002+ assessment method. Ecopoints should be read with caution since they are based on societally agreed weighting factors.

LCA results do not predict impacts on category endpoints, exceeding of thresholds, safety margins or risks; they provide an estimate of potential impacts.

The impact categories are based on ReCiPe, USEtox, CED and Ecopoints, and the reported impact categories include: global warming potential, stratospheric ozone depletion, ionizing radiation, ozone formation, human health, fine particulate matter formation, ozone formation, terrestrial ecosystems, terrestrial acidification, freshwater eutrophication, marine eutrophication, terrestrial ecotoxicity, freshwater ecotoxicity, marine ecotoxicity, human carcinogenic toxicity, human non-carcinogenic toxicity, land use, mineral resource scarcity, fossil resource scarcity, water consumption, nonrenewable - fossil, nuclear, biomass, renewable – biomass, wind, solar, geothermal and water. All results are calculated using SimaPro v9.1.

10.0 MATERIAL INPUT

The material inputs form part of the LCA and shows the inputs and flows for the four additives DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid. Instrumentation Laboratory provided material inputs for the the four additives DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid. The raw material inputs are entered into the LCA model in kilograms per additive, with normalization factors applied to make each additive as functionally equivalent as possible (1.000 kg DEHP, 1.228 kg Mineral Oil, 1.404 kg Ester Lubricant, 1.404 kg Acrylic Processing Aid).

11.0 RESULTS

The purpose of conducting an LCA is to determine the actual impacts from the material and energy inputs. This is accomplished through assigning the mass and energy inputs into flows that are then classified by the environmental impact categories to which they contribute. To compare emissions from various pollutants on the same scale, the methodology characterizes emissions from various substances to enable comparison in common equivalence units.

The tables overleaf show the LCA results per functional unit using four environmental impact assessment methods: ReCiPe, USEtox, CED and Ecopoints. ReCiPe is the most commonly used LCA impact assessment method. ReCiPe reports global warming (carbon footprint) and a variety of other environmental impact metrics. UEStox reports human health impact. CED, Cumulative Energy Demand, reports life cycle energy requirements. Ecopoints, produced by the IMPACT 2002+ method, are a single number result that combines various environmental metrics. Ecopoints are subjective, because the scoring is based on notional weightings set by a panel of experts. Nevertheless, the results can be informative, so they are included here for comparison with the other results.

Table 1. Cradle-to-grave ReCiPe LCA results for additives per functional unit

Impact category	Unit	DEHP 1kg	Mineral Oil 1.228kg	Ester Lubricant 1.404kg	Acrylic Processing Aid 1.404kg	Combined Additives 4.036kg
Global warming	kg CO2 eq	3.48	2.69	4.05	3.79	10.54
Stratospheric ozone depletion	kg CFC11 eq	0.000000552	0.000000134	0.000007520	0.000001368	0.00000902
Ionizing radiation	kBq Co-60 eq	0.111	0.000	0.163	0.460	0.623
Ozone formation, Human health	kg NOx eq	0.00499	0.00960	0.00809	0.00894	0.0266
Fine particulate matter formation	kg PM2.5 eq	0.00317	0.00586	0.00551	0.01219	0.0236
Ozone formation, Terrestrial ecosystems	kg NOx eq	0.00540	0.01005	0.00849	0.00922	0.0278
Terrestrial acidification	kg SO2 eq	0.00799	0.01880	0.01222	0.03707	0.0681
Freshwater eutrophication	kg P eq	0.000431	0.000000	0.001076	0.001834	0.00291
Marine eutrophication	kg N eq	0.0000419	0.0000152	0.0001207	0.0002291	0.000365
Terrestrial ecotoxicity	kg 1,4-DCB	3.01	0.67	10.05	12.78	23.496
Freshwater ecotoxicity	kg 1,4-DCB	0.0286	0.0099	0.0811	0.1850	0.276
Marine ecotoxicity	kg 1,4-DCB	0.0410	0.0136	0.1143	0.2586	0.387
Human carcinogenic toxicity	kg 1,4-DCB	0.0553	0.0033	0.1279	0.1818	0.313
Human non-carcinogenic toxicity	kg 1,4-DCB	0.968	0.466	2.423	5.262	8.151
Land use	m2a crop eq	0.0273	0.0000	2.9880	0.1536	3.142
Mineral resource scarcity	kg Cu eq	0.00410	0.00000	0.00786	0.15318	0.161
Fossil resource scarcity	kg oil eq	1.99	2.30	1.82	1.37	5.489
Water consumption	m3	0.0307	0.0000	0.0496	0.1008	0.150

Table 2. Cradle-to-grave USEtox LCA results for additives per functional unit

Usetox Impact Category	Unit	DEHP 1kg	Mineral Oil 1.228kg	Ester Lubricant 1.404kg	Acrylic Processing Aid 1.404kg	Combined Additives 4.036kg
Human toxicity, cancer	cases	0.0000000761	0.0000000023	0.0000001752	0.0000002637	0.000000441
Human toxicity, non-cancer	cases	0.000000256	0.000000370	0.000000636	0.000001120	0.00000213
Freshwater ecotoxicity	PAF.m3.day	6641	913	22047	33319	56279

Table 3. Cradle-to-grave CED LCA results for additives per functional unit

CED Impact Category	Unit	DEHP 1kg	Mineral Oil 1.228kg	Ester Lubricant 1.404kg	Acrylic Processing Aid 1.404kg	Combined Additives 4.036kg
Non renewable, fossil	MJ	97.3	105.4	83.1	62.7	251.2
Non-renewable, nuclear	MJ	3.48	0.00	4.11	8.96	13.07
Non-renewable, biomass	MJ	0.0000801	0.0000000	0.0004003	0.0006745	0.00107
Renewable, biomass	MJ	0.263	0.000	17.537	2.642	20.179
Renewable, wind, solar, geothermal	MJ	0.884	0.000	0.270	0.693	0.963
Renewable, water	MJ	0.545	0.000	1.203	2.045	3.248

Table 4. Cradle-to-grave Ecopoint LCA results for additives per functional unit

Ecopoints Damage Category	Unit	DEHP 1kg	Mineral Oil 1.228kg	Ester Lubricant 1.404kg	Acrylic Processing Aid 1.404kg	Combined Additives 4.036kg
Total	mPt	1.388	1.413	2.121	1.532	5.066
Human health	mPt	0.421	0.472	0.876	0.602	1.951
Ecosystem quality	mPt	0.025	0.009	0.309	0.098	0.416
Climate change	mPt	0.311	0.241	0.361	0.359	0.961
Resources	mPt	0.631	0.691	0.574	0.473	1.739

The following graph shows a summary of the global warming potential or carbon footprint for the additives modelled in the LCA study.

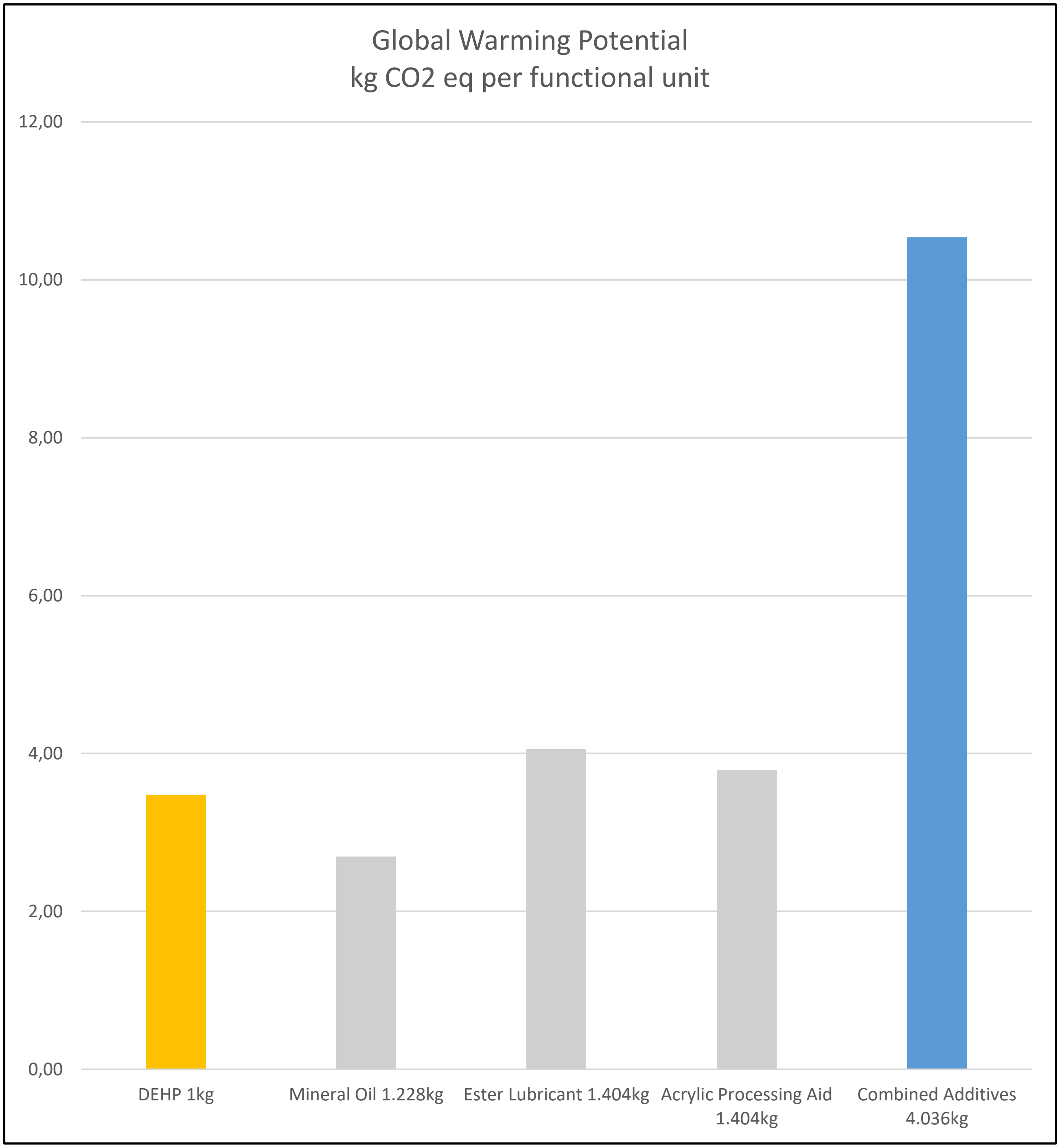

Figure 3. Carbon footprint results for additives DEHP, Mineral Oil, Ester Lubricant and Acrylic Processing Aid, and the combination of the three alternative additives

11.1 Environmental Impact Drivers and Results

The LCA results are further discussed below.

ReciPe Results

Global warming potential is usually considered to be one of the most important environmental impact metrics. The highest contributor for global warming potential was the Ester Lubricant at 4.05 kg CO2 eq, compared to Mineral Oil at 2.69 kgCO2eq as the lowest. DEHP at 3.48 kgCO2eq and Acrylic Processing Aid 3.79 kgCO2eq provided results in between. Allowing for uncertainties, the results could be considered to be broadly similar. The combination of the three alternative additives resulted in a result of 10.54 kgCO2eq.

In terms of the other ReCiPe metrics, in all cases the DEHP impacts were significantly lower than the impacts of the combined alternative additives.

USEtox Results

In all cases the DEHP impacts were significantly lower than the impacts of the combined alternative additives.

CED Results

In all cases the DEHP impacts were significantly lower than the impacts of the combined alternative additives.

Ecopoint Results

In all cases the DEHP impacts were significantly lower than the impacts of the combined alternative additives.

12.0 INTERPRETATION

The primary goals of the LCA for the additives were developed at the beginning of the project with Instrumentation Laboratory and are outlined in the Introduction of this report. The Interpretation section serves as a discussion of the results and their relationship to the initial goals of the study.

The LCA are summarized here:

- The LCA for DEHP showed a global warming potential or 'carbon footprint' of 3.48 kgCO2eq, Mineral Oil of 2.69 kgCO2eq, Ester Lubricant of 4.05 kgCO2eq and Acrylic Processing Aid of 3.79 kgCO2eq.
- The alternatives to DEHP are required in combination, so the true functional comparison is DEHP with a carbon footprint of 3.48 kgCO2eq versus the combined alternative additives with a carbon footprint of 10.54 kgCO2eq.
- The USEtox LCA results in the 'Human Toxicity, Cancer' category were 76 nanoCases for DEHP versus 441 nanoCases for the combination of the other three additives.

- The USEtox results in the 'Human Toxicity, Non-Cancer' category were 256 nanoCases for DEHP versus 2130 nanoCases for the combination of the other additives.
- The results for Cumulative Energy Demand (CED) were ower in all cases for DEHP than for the combination of the other additives; for example, in the 'Non-Renewable, Fossil' category, the result for DEHP was 97 Megajoules, while the result for the combination of the other additives was 251 Megajoules.
- The Ecopoint method results showed that DEHP achieved a score of 1.4 mPt versus 5.1 mPt for the combination of the other additives.

12.1 Conclusions

The overall conclusion is that the LCA provides evidence that DEHP is likely to be the preferred solution in terms of environmental impact and human health. The alternative additives when considered individually are within the same order of magnitude, but they must be used in combination in the sensor card to achieve equivalent functional performance, which makes their combined environmental and health impact significantly higher than that of DEHP.

13.0 REFERENCES

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