

LIFE CYCLE ASSESSMENT OF MATERNITY PRODUCTS: A BIOENGINEERING APPROACH

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ETHICAL DECLARATION

I hereby declare that I am the sole author of this thesis and that I have conducted my work in accordance with academic rules and ethical behaviour at every stage from the planning of the thesis to its defence. I confirm that I have cited all ideas, information and findings that are not specific to my study, as required by the code of ethical behaviour, and that all statements not cited are my own.

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Date: 09.03.2023

ABSTRACT

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Life cycle assessment is analysis that consider the potential environmental impacts of processes or products. It is a type of sustainability assessment tool with various aspects. To perform the life cycle assessment, it is necessary to be complied with ISO 14040 and ISO 14044 which are the standards for the life cycle assessment. In this study, it was aimed to analyze the potential environmental impacts of maternity products which produced by a medical device manufacturer by completing the comparative life cycle assessment. In order to conduct this study, the data needed for the study were directly collected from the manufacturer. For the analysis of the data CCalC2 life cycle assessment carbon footprinting software tool was used. As the output of the comparative life cycle assessment, the potential environmental impacts of two products (breast pump with alkaline battery, breast pump with rechargeable battery) with the same functions were evaluated. According to the literature, since there is no similar study on the life cycle assessment of maternity products, the analyzed potential environmental impacts of these products such as carbon footprint

will be guiding. As a result of this study, it has been determined that the total carbon footprint score and other environmental impact scores are mostly affected by the raw materials. In conclusion, the effect of bio-based plastics on the total carbon footprint was analyzed. It has been confirmed that the use of bio-based plastics instead of plastics made from crude oil reduces the overall carbon footprint scores.

Keywords: Life Cycle Assessment (LCA), Life Cycle Impact Analysis (LCIA), Maternity Products, Carbon footprint.

ÖZET

ANNE-BEBEK ÜRÜNLERİNİN YAŞAM DÖNGÜSÜ ANALİZİ: BİYOMÜHENDİSLİK YAKLAŞIMI

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Yaşam döngüsü değerlendirmesi, süreçlerin veya ürünlerin potansiyel çevresel etkilerini ele alan analizdir. Çeşitli yönleriyle bir tür sürdürülebilirlik değerlendirme aracıdır. Yaşam döngüsü değerlendirmesinin yapılabilmesi için yaşam döngüsü değerlendirmesi ile ilgili standartlar olan ISO 14040 ve ISO 14044'e uyulması gerekmektedir. Bu çalışmada, bir tıbbi cihaz üreticisi tarafından üretilen anne-bebek ürünlerinin karşılaştırmalı yaşam döngüsü değerlendirmesini tamamlayarak olası çevresel etkilerini belirlemek amaçlanmıştır. Çalışmanın tamamlanabilmesi için amaçlanan yaşam döngüsü değerlendirmesi için gereken veriler direkt üretici firmadan sağlanmıştır. Bu veriler CCalC2 yaşam döngüsü değerlendirmesi karbon ayakizi yazılım aracı kullanılarak analiz edilmiştir. Karşılaştırmalı yaşam döngüsü değerlendirmesinin çıktısı olarak, aynı işlevlere sahip iki ürünün (alkalin pil ile çalışan göğüs pompası, şarj edilebilir batarya ile çalışan göğüs pompası) potansiyel çevresel etkileri değerlendirilmiştir. Literatüre göre, daha önce anne-bebek ürünlerinin yaşam döngüsü değerlendirmesi ile ilgili benzer bir çalışma olmadığı için, bu çalışmanın sonucunda bu ürünlerin karbon ayakizi gibi potansiyel çevresel etkileri yol gösterici olacaktır. Bu çalışma sonucunda toplam karbon ayak izi skoru ve diğer çevresel etki skorlarının en çok hammaddelerden kaynaklandığı tespit edilmiştir. Değerlendirme sonunda, biyo-bazlı plastiklerin toplam karbon ayak izi üzerindeki etkisi analiz edildi. Ham petrolden yapılan plastikler yerine biyo-bazlı plastiklerin kullanılmasının genel karbon ayak izi puanlarını azalttığı doğrulandı.

Anahtar Kelimeler: Yaşam Döngüsü Değerlendirmesi, Yaşam Döngüsü Etki Analizi, Annebebek ürünleri, Karbon ayakizi.

Dedicated to my family…

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LIST OF ABBREVIATIONS

LCA: life cycle assessment LCI: life cycle inventory LCIA: life cycle impact analysis BoM: bill of materials PP: polypropylene ABS: acrylonitrile butadiene styrene EVA: ethylene vinyl acetate PC: polycarbonate PE: polyethylene FDA: Food and Drug Administration ISO: International Organization for Standardization MDD: Medical device directive MDR: Medical device regulation kWh: kilowatt-hour MJ: megajoule BPA: bisphenol A BPS: bisphenol S GWP: global warming potential AP: acidification potential EP: eutrophication potential POCP: photochemical oxidants creation potential ODP: ozone layer depletion potential HTP: human toxicity potential

CHAPTER 1: INTRODUCTION

1.1 Life Cycle Assessment

Life cycle assessment, which examines potential environmental impacts of a unit product's life cycle, first appeared in the 1960s, when environmental degradation and resource problems began to appear.

Today, life cycle assessment is defined as a sustainability tool that can cover the entire process of a product from raw material to waste management of the finished product (Figure 1). The LCA, which is estimated to be the first life-cycle assessment focused study, was conducted in 1963 on the energy requirements for the production of chemical intermediates and products (Hauschild, Rosenbaum and Olsen, 2017).

Figure 1. The general flowchart of LCA

Along with the environmental policies of countries and commissions on life cycle assessment the interest in life cycle assessment and sustainability issues began to increase in the early 21st century.

In the late 90's, for standardization of life cycle assessment, ISO 14040, ISO 14041, ISO 14042 and 14043 standards have been published, respectively, by the International Organization for Standardization (ISO). Later, ISO 14041, ISO 14042 and ISO 14043 were combined into a single standard and ISO 14044 was published.

The content of remaining two ISO standards (ISO 14040-Environmental Management-Life Cycle Assessment-Principles and Framework and ISO 14044-Environmental management — Life cycle assessment — Requirements and guidelines) covers, in brief, the principles and framework of life cycle assessment, as well as specifying the requirements and providing guidelines for LCA, such as defining the scope and goal of the LCA, life cycle inventory analysis (LCI), life cycle impact assessment (LCIA), relationships and limitations of LCA (Hauschild, Rosenbaum and Olsen, 2017).

One of the most important results of LCA standardization together with ISO 14040 and ISO 14044 is the formation of the methodological framework of life cycle assessment (Figure 2)(Ekvall, Tillman and Molander, 2005).

Figure 2. The general methodological framework of LCA (Source: ISO 14040, 2009)

1.1.1 The methodology of Life Cycle Assessment

Life cycle assessment is standardized as mentioned in the previous section. According to the ISO 14040 standard, LCA is carried out within the framework of a certain methodology (Figure 2).

Goal definition is defined as the first step of LCA. The goal definition clearly

defines the purpose of the study by setting the limits of the life cycle assessment to be done. Thus, goal definition is important to provide the definition of the 'functional unit' to be carried out in the analysis and to ensure consistency (Hauschild, Rosenbaum and Olsen, 2017) (Curran, 2013).

The second step of life cycle assessment, which determines the scope of the study and specifies how and what to do in the study, is the *scope definition* and explains the main goal and scope of the study in along with the goal definition (Tillman, 2010).

Inventory analysis or *life cycle inventory analysis (LCI)* plays a role in creating a system that covers all processes for the goal and scope determined in the first steps of the life cycle assessment. In this step, all inputs (raw materials, energy, etc.) and outputs (finished product, waste, etc.) can be evaluated (Tillman, 2010).

The purpose of the *impact analysis* or *life cycle impact analysis (LCIA)* is to determine the environmental impacts and environmental impact scores of the flows identified and measured in the previous stages of the life cycle assessment. This assessment can be done using various software tools (Svensson, 2017)(Hauschild, Rosenbaum and Olsen, 2017).

In the *interpretation* stage, which is the final step of the life cycle assessment, the data obtained from the analysis and the important environmental impacts are defined and interpreted. Also, the consistency of the whole life cycle assessment can be checked (Tillman, 2010; Svensson, 2017).

1.1.2 Goal and Scope Definition

According to ISO 14040, regardless of which product or process the life cycle assessment is conducted for, goal and scope definition is essential, which is one of the main requirements of the LCA (ISO 14040, 2009).

The first step of LCA, goal and scope definition, the purpose of the study, why and for whom it was conducted should be clearly stated, taking into account the basic concepts of the study. If comparative LCA is to be conducted, it is aimed to compare the results and reach the final conclusion. The goal and scope of the study guide the correct definition of the functional unit while establishing the main boundaries of the LCA study. The goal and scope of the study should also be consistent with the outcomes of the study (Klöpffer, 1997).

One of the most essential concepts in life cycle assessment is the functional

unit (Klöpffer, 1997). It explains the function of the product being assessed, while also helping to identify the flow as a reference in the life cycle assessment. The most important feature of the functional unit, when defined correctly, is that it forms the basis for comparison in comparative life cycle analysis (Hauschild, Rosenbaum and Olsen, 2017).

1.1.3 Life Cycle Inventory Analysis

Life cycle inventory (LCI) preparation is the second step of the life cycle assessment. It includes all the inputs, outputs and quantities of the process and applied in the life cycle assessment study (ISO 14040, 2009).

During the LCI preparation, which is applied after the goal and scope definition, it is essential to collect detailed data (input and output quantities etc.), determine the process flows (production, transportation, etc.) and determine the system boundaries for the product or process for which the life cycle assessment study is performed. The accuracy and quality of the data obtained and defined in the LCI preparation is extremely important for LCA (Hauschild, Rosenbaum and Olsen, 2017)(Klöpffer, 1997).

While performing the inventory analysis, the bill of material (BoM) created for the product is a guide to have the information about the quantities of all raw materials and materials involved in the process. However, in this step, not only material inputs are considered, resource inputs (energy, water, etc.) should also be included in the inventory. Collecting data for inventory analysis can take quite some time, so different databases are used when performing LCI preparation. However, the information obtained from these databases is based on general data for many processes (Tillman, 2010).

While the system boundaries define which processes are taken into account in the system, it also includes the resources and utilities used in the study. Data on resources used and other processes can be obtained in two ways; directly and indirectly (Hauschild, Rosenbaum and Olsen, 2017).

Figure 3. General schematic representation of system boundaries

In order to establish system boundaries, system outputs should be evaluated as well as system inputs. Wastes and emissions can be handled as output. Thus, the system boundaries of the study will be created with the inventory analysis (Figure 3).

In life cycle assessment, it should be determined how much of the total inputs and waste generated are related to this output. Therefore, the amount energy and material required for the production of each co-product and which environmental emissions associated with the process originate from the production of the co-product are determined by an approached called *allocation*. Allocation is a step of life cycle assessment that covers the decision for attribution of environmental burdens for multiple processes including recycling and disposal (Welford, 2014).

1.1.4 Life Cycle Impact Assessment

In the Life Cycle Impact Analysis (LCIA) phase, the effects of possible environmental releases identified during LCI on human health and environmental values are evaluated. Impact analysis considers human health and environmental values as well as natural resource consumption. Life cycle impact analysis establishes a link between the product/process and its possible environmental impacts.

After listing the data collected in the previous stage, LCI, various software tools are used to identify and interpret the potential environmental impacts, thus ensuring the clarity of the data (Svensson, 2017).

As defined in the ISO 14040 and 14044 standard, there are 6 steps in total divided as mandatory and optional steps that must be applied at this stage (ISO 14040, 2009).

Selection of impact categories, which is the first of the mandatory steps of LCIA, is the step in which environmental impacts are considered in the study. *Classification* is the assignment of data defined in LCI according to impact categories and is done using various LCA software tools. The categories identified may differ in their impact (midpoint and endpoint) and are related to uncertainty. In the next step, *characterization*, each environmental impact category of emissions and resource consumption is modelled with the software tool using data scientific characterization factors classified according to different impact categories (ex. Acidification potential, global warming potential etc.).

Normalization is associating interrelated impact categories with different impact potentials to a common scale and calculating the results according to the functional unit or reference flow. It also enables each impact category to be compared and evaluated relative to each other. *Grouping* enables the interpretation of impact assessment results by classifying and ranking the impact categories identified in the previous stage.

In the *weighting* phase, it can be determined which of the most significant impacts are based on the different impact categories. This stage must be applied after normalization and it is important that the impact categories are weighted as they should also reflect the objectives of the study and the values of the stakeholders (Tillman, 2010)(Hauschild, Rosenbaum and Olsen, 2017; Svensson, 2017).

The one-dimensional indexes related to the life cycle impact analysis mentioned above are explained in detail in figure 5 below.

Figure 5. The relation between elementary flows, midpoint impacts and endpoint impacts according to ILCD methodology (Source: Hauschild, Rosenbaum and Olsen, 2017)

1.1.5 Interpretation

Interpretation phase is the last step of the life cycle assessment. At this stage, the environmental impacts and significant issues of the evaluated products are identified and interpreted (Hauschild, Rosenbaum and Olsen, 2017).

Life cycle assessment conclusions are specific to the product or process being assessed and interpreted accordingly within previously defined system boundaries. In addition, in this step of the life cycle assessment, it is determined whether the outputs of the assessment are consistent and reliable with the previous stages, goal and scope definition, inventory analysis and impact analysis in the methodology. As a result of the work, limits are set and recommendations for improvement are given (Curran, 1996)(Horne, Grant and Verghese,2009).

At this stage, since the study is completely finished, sensitivity analysis, completeness checks and data quality analyses can be applied to verify the results. Completeness check is conducted to confirm the completeness of the impact assessment and inventory. Data quality analysis is applied to analyse the accuracy of

data that is input or output in life cycle assessment. In the study, the inputs that make up the inventory can be collected from many different sources, such as laboratory test results, books, articles or direct industry reports. Therefore, data quality analysis may be required. If there is uncertainty in the study such as inventory quantities, sensitivity analysis is applied to strengthen the results. In order to carry out a sensitivity analysis, the study must be completely finished. The results obtained may not always meet the goal in the first step, the goal definition. For this reason, the findings obtained as a result of the study are interpreted as recommendations and the points to be improved are determined (Fava et al*.*, 1992; Hauschild, Rosenbaum and Olsen, 2017).

1.2 Medical Devices

Medical device is any device, material, or instrument that, when used in humans, does not provide its essential function by pharmacological, immunological or metabolic effects, but can be supplemented by these effects while performing its function. According to ISO 13485 standard medical device can be defined as any instrument, apparatus, implement, machine, appliance, implant, reagent, software material alone or in combination for humans with one or more specific medical purpose (ISO 13485, 2016).

According to Food and Drug Administration (FDA), medical devices are defined as any instrument, machine, contrivance, implant, in vitro reagent that's intended to treat, cure, prevent, mitigate, and diagnose disease in humans(Bill, 2011).

Medical devices are subject to various standards, directives, or regulations according to the countries where they are produced and sold. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes is the standard to specify the essential requirements for medical device manufacturers (ISO 13485, 2016).

Besides that, there are also medical device directives and regulations for European Union member states. One of the most important is 93/42/EEC Medical Device Directive (MDD) which the medical device manufacturers must consider the directive to sell and export the products to European countries. This directive was published as the 2017/745 Medical Device Regulation in 2017 by expanding its scope and requirements. It is obligatory to consider for medical device manufacturers in European Union member countries or medical device manufacturers exporting to European countries. Additionally, Food and Drug Administration (FDA) is responsible for the regulations and directives in United States of America (USA).

Medical devices are classified according to their risk levels. According to the European legislations, medical devices are divided into four risk classes, with risk levels from low to high, I, IIa, IIb and III, respectively. Besides this classification, according to USA legislations, medical devices are classified into three risk classes with risk levels from low to high, 1, 2 and 3, respectively. While making this classification, the usage period of the device, the intended use, the way of use (invasive or non-invasive), reusability of the device and how it works are taken into consideration. (Aronson, Heneghan and Ferner, 2020).

1.2.1 Maternity Products

Maternity products are products that a woman uses throughout the entire pregnancy and postpartum period as well as additionally to feed the baby, from the time she decides to become pregnant.

When it comes to a sensitive situation such as pregnancy, mothers and expectant mothers always take care to choose the most harmless and appropriate product for their own and baby's health. Thus, maternity product manufacturers should use and produce appropriate products according to some standards and regulations.

Considering these maternity products, there are special products for feeding the baby such types of breast pumps, feeding bottles etc. Breast pumps can be classified as medical devices by their manufacturer based on their intended use. Maternity products produced as medical devices are subject to the medical device standards, regulations and directives mentioned in the previous section. The classification of products is made according to the intended use and risk level. The electric breast pumps are discussed in this study are class IIa active medical devices.

Breastfeeding is important for infant and young child health; as, proper and adequate nutrition of babies greatly affects their development. According to experts, babies should be fed only with breast milk until at least 4-6 months. One of the biggest benefits of adequate breastfeeding is that the baby is immune to infections and has better mental health (Bartels, DiTomasso and Macht, 2020)(Andresen et al., 2022).

Breastfeeding equipment can be used for many different reasons, such as increasing the amount of milk, milking and storing milk for working mothers, or feeding more than one baby. When it comes to infant and maternal health, the materials used in the production of these products should not contain harmful substances such as BPA and BPS, should be suitable for food contact and should not harm human health. In addition, there are standards and regulations related to product safety and safe use of electrical breast pumps. For example, the standard for feeding equipment is EN 14350 Child care articles - Drinking equipment - Safety requirements and test methods (EN 14350, 2020).

Breastfeeding equipment may consist of different materials. If it is talked about breast pumps as an example, the pump contains mainly plastic and silicone materials, while electronic materials, metals and rubber can be found in the breast pumps. There are many different types of breast pumps. Some of these are breast pumps for expressing milk from one breast with or without power supply, while others are breast pumps for expressing milk from both breasts at the same time. In addition to these, there are wearable breast pumps and silicone breast pumps that help collect milk from one breast while the other is milking.

Figure 7. The general representation of electric breast pump (Source: Infihealthcare, 2023)

While this particular study focuses on breast pumps only, the company that manufactures those breast pumps has also other initiatives regarding improving their products' sustainability. These initiatives include topics like eco-design studies such as changing the packaging materials from plastics to cartons.

1.3 Literature Review

When the literature is reviewed, it has been observed that no life cycle assessment studies have been conducted on the aforementioned maternity products. However, there are some studies which focused on LCA of medical devices.

In a study related with the comparative life cycle assessment of breastfeeding and infant formula, five different environmental impacts are evaluated. As a result of this assessment, it was observed that the global warming potential of infant formula is almost 2 times higher than that of breastfeeding. However, it was stated that in this case, the environmental impacts of breastfeeding will vary according to the mother's nutrition (Andresen et al*.*, 2022).

In a study on AA alkaline batteries in the literature, it was determined that the environmental impact of AA alkaline batteries is lower than other batteries with recycling. Significant amounts of energy savings and carbon footprint reduction are envisaged by recycling or remanufacturing AA alkaline batteries (Hamade et al., 2020).

In a comparative life cycle assessment study in the literature, the plastic and glass materials used in the packaging of the contrast media used for X-Ray were compared. In order to achieve the purpose of this study, the functional unit was determined as the packaging of contrast media required to deliver one dose of 96 mL to a patient for an X-ray procedure. In this way, they environmental impacts of the two materials was compared (Dhaliwal et al*.*, 2014).

In another study, life cycle assessment was conducted to face masks used during the Covid-19 pandemic process. In this study, disposable face masks and 5 times re-sterilized face masks were compared. As a result of the life cycle assessment, it was determined that sterilized and re-sterilized face masks have lower environmental impacts. This study has been interpreted as that medical devices should be designed as reusable or with a lower carbon footprint and sustainable, and they should be more sustainable (Straten et al., 2021).

Additionally, in the literature, there is a study about a life cycle assessment for Nanosilver-Enabled Bandages. It has been determined that the environmental impacts of AgNP synthesis, which is included within the system boundaries are much higher than other processes within cradle-to-gate life cycle impacts. Nevertheless, the environmental impacts from bandage production with AgNP are stronger than those from incineration of the bandage after the bandage became medical waste (Pourzahedi and Eckelman, 2015).

In another life cycle assessment study on medical devices, disposable and reusable surgery equipment was examined. Environmental impacts were evaluated in 5 different impact categories, and it was seen that the reusable equipment have higher environmental impacts than disposable ones. This is because that reusable materials have to be sterilized and the environmental impacts of the sterilization process is significantly high (Leiden et al., 2020).

As summarized above, there are very few studies which focused on the LCA of the medical devices and to the best of the authors' knowledge there is no study in the literature which is concern with the LCA of the maternity products. For that reason, this particular work is considered to be original, and it is considered to make a significant contribution to the existing literature on life cycle assessment.

Due to their widespread use, the production and utilization of maternity products have a high impact on the environment, however as it is described above, there are no studies in the literature that focus on the LCA of these products. Therefore, this thesis aims that investigating and quantifying environmental impacts caused by the production and utilization of maternity products. The chosen product is a breast pump which is operated with two different technologies.

CHAPTER 2: MATERIALS AND METHODS

In this chapter, the materials and methods of the life cycle assessment study of the maternity products produced by a medical device manufacturer are mentioned. Due to the confidentiality of the data and the non-disclosure agreement signed with the organization, the name of the manufacturer will not be shared, it will be hereafter referred as the manufacturer.

2.1 Goal and Scope Definition

The main goal of this study is to apply the attributional life cycle assessment to calculate the environmental impacts of two products (having same function) produced by the medical device manufacturer. This LCA study aims to compare the environmental impacts of two different products with the same function.

For these two products to be compared, *the functional unit* has been chosen as *500 hours of operation*, because the expected usage lifetime of these device is 500 hours. The production process flows and functions of these two products which the LCA is applied, are same however the materials used in the production process may differ.

The main scope of this LCA study is the supply of raw materials required for production, the production, assembly and quality control processes at the manufacturer and its shipment to the user. As a result of the study, the supply of products determined to have high environmental impacts and alternatives will be examined.

In the final step of this study, the outputs and the results will be shared with the manufacturer and if improvement is required to be able to decrease the environmental impacts of the materials, the results will support them to take the necessary actions.

2.2 Life Cycle Assessment Methodology

In line with the goal and scope mentioned in the previous section, a life cycle assessment was conducted by evaluating the inputs and outputs of all processes, including the production process, of the aforementioned products.

In this study, life cycle assessment was carried out by applying the CLM 2001

method and using the CCalC2 Carbon Footprinting LCA software tool (Figure 8), according to the general methodological framework determined by the ISO 14040 and ISO 14044 standards shown in Figure 2.

Potential environmental impacts such as global warming potential (GWP), acidification potential (AP), eutrophication potential (EP), photochemical oxidants creation potential (POCP), ozone layer depletion potential (ODP), and human toxicity potential (HTP) can be obtained with the CCalC2 Carbon Footprinting LCA software tool used. Firstly, global warming also called as climate change, or the greenhouse effect is one of the major environmental impacts of LCA that expresses the negative effect of the warming of the terrestrial atmosphere. Acidification is an environmental impact caused by sulphur dioxide (SO2), occurring both on land and in water. It is very harmful and toxic to living organisms when exposed. Eutrophication is an environmental impact that caused by presence of phosphate and nitrogen, which occurs on land, fresh and salt water. This impact is specifically harmful and toxic to aquatic living beings. Photochemical oxidant creation or photochemical smog caused by traffic, motor vehicles and solar radiation in general causes eye irritation, respiratory tract or lung irritation and vegetation damage. Ozone layer depletion is another impact category that is caused by ultraviolet radiation. It is proven that this environmental impact can cause skin cancer on living beings. Finally, human toxicity, which is one of the most important environmental impacts, can be caused by all emissions to air, land and water and cause human morbidity or death (Klöpffer,1997)(Hauschild, Rosenbaum and Olsen, 2017)(SAIC, 2006).

Figure 8. The interface of CCalC2 Carbon Footprinting LCA Software tool (Source:CCalC2 Carbon Footprinting Tool)

2.3 Life Cycle Inventory Preparation

As mentioned previously, since a non-disclosure agreement was signed with the organization in order not to share information about the manufacturer, critical data and to protect the confidentiality of data and information, the bill of materials (BoM) used in the production process and information about the suppliers is not explicitly shared in this section but is grouped.

2.3.1 System Boundaries

In this study, the processes for the two products, for which life cycle assessment is applied, take place in 11 main stages in total. The first step is the procurement of raw materials or materials to be used in production or assembly. When the raw material or material reaches the manufacturer, it is first analysed in the incoming quality control. Then the raw material or material is stored until it is used. The material to be used in production or assembly is transferred to the area to be used and the production process begins. Process quality control is applied during production/assembly. The finished product is made ready for shipment, passes the final quality control and the shipment is completed (Figure 9).

Figure 9. The general illustration of the process flow

System boundaries have been determined according to the manufacturer's preparation, production, assembly and shipping process flows (Figure 10).

Because of the manufacturer carries out the waste management process with third party organizations, *waste management* is not included in the system in this LCA study.

Figure 10. System Boundary diagram of the LCA of production of breast pumps

2.3.2 Life Cycle Inventory

This section shares data on all materials and processes included in system boundaries. The weight information of the raw materials or materials used in the production of the two selected products and their equivalents in the database in the CCalC2 software tool are presented in Table 1 and Table 2.

Table 1. Inventory data of the breast pump with alkaline battery

*(a)** Thermoplastic elastomer (TPE) that is not defined in CCalc and Ecoinvent database is defined in CCalC with reference to a website whose carbon footprint score has been calculated before(KTPE, 2019).

*(b)** A new input has been defined for the AC Adapter by considering the 'connector, computer, peripherical' carbon footprint score in the CCalC database.

*(c)** Since there is no data on foam or EPDM in the CCalc and Ecoinvent database, a new carbon footprint score was created by using the carbon footprint score of the EPDM raw material found on a website and calculated according to the thickness of the foam used in this study. (Rubberbond, 2015)

*(d)** While defining Ice Pack to the CCalC database, a previous study on gel packs was taken as reference and the carbon footprint score was obtained by calculating the weight. (Soulliere and Corporation, 2020)

*(e)** For the polyethylene plastic bag, it was defined as PE Plastic Bag in the CCalC database by taking the carbon footprint score from a study of LCA for plastic supermarket bags. (Edwards and Fry, 2011)

*(f)** Since the number of components for the solenoid valve cannot be calculated separately, the carbon footprint scores previously calculated for a different solenoid valve with the same function was taken into consideration and the new carbon footprint score was calculated based on the product weights and reference values by applying the 0.6 rule (scaling approach) according to another study as following, $1.81 \times (19/354)^{0.6}$. It is defined as 0.31 kg CO2 eq./kg in the CCalC database(Atilgan and Azapagic, 2016; SMC, 2019). The environmental impact of a product may not be directly proportional to its capacity, in addition, the 0.6 rule (scaling approach) can be applied since energy consumption will also be different.

*(g)** Since the carbon footprint scores for the cooler bag are not available in the CCalC or Ecoinvent database, a new carbon footprint score has been defined by considering the values of the components separately that make up this product. Since the components that make up this product are polyester and Ethylene-vinyl acetate (EVA), the carbon footprint scores of these two components were evaluated according to the percentages of the components that make up the product(Yan et al., 2016). *(h)** Since this product can work with both electricity and alkaline battery, it has been added to the usage part. Since there is no carbon footprint score for alkaline batteries in the CCalC or Ecoinvent database, a new value was defined based on the life cycle assessment study for alkaline batteries. It was calculated based on consumption in 500 hours of use. (Hamade et al., 2020)

Table 2. Inventory data of breast pump with rechargeable battery

*(a)** Thermoplastic elastomer (TPE) that is not defined in CCalc and Ecoinvent database is defined in CCalC with reference to a website whose carbon footprint score has been calculated before (KTPE, 2019).

*(b)** A new input has been defined for the AC Adapter by considering the 'connector, computer, peripherical' carbon footprint score in the CCalC database.

*(c)** Since there is no data on foam or EPDM in the CCalc and Ecoinvent database, a new carbon footprint score was created by using the carbon footprint score of the EPDM raw material found on a website and calculated according to the thickness of the foam used in this study. (Rubberbond, 2015)

*(d)** While defining Ice Pack to the CCalC database, a previous study on gel packs was taken as reference and the carbon footprint score was obtained by calculating the weight. (Soulliere and Corporation, 2020)

*(e)** For the polyethylene plastic bag, it was defined as PE Plastic Bag in the CCalC database by taking the carbon footprint score from a study of LCA for plastic supermarket bags. (Edwards and Fry, 2011)

*(f)** Since the number of components for the solenoid valve cannot be calculated separately, the carbon footprint scores previously calculated for a different solenoid valve with the same function was taken into consideration and the new carbon footprint score was calculated based on the product weights and reference values by applying the 0.6 rule (scaling approach) according to another study as following, $1.81*(19/354)^{0.6}$. It is defined as 0.31 kg CO2 eq./kg in the CCalC database(Atilgan and Azapagic, 2016; SMC, 2019). The environmental impact of a product may not be directly proportional to its capacity, in addition, the 0.6 rule (scaling approach) can be applied since energy consumption will also be different.

*(g)** Since the carbon footprint score for the cooler bag are not available in the CCalC or Ecoinvent database, a new carbon footprint score has been defined by considering the values of the components separately that make up this product. Since the components that make up this product are polyester and Ethylene-vinyl acetate (EVA), the carbon footprint scores of these two components were evaluated according to the percentages of the components that make up the product(Yan et al., 2016). *(h)** The amount of energy (in MJ) required for 500 hours of use has been calculated based on Turkish electricity.

The shipping distances and transportation types of the products with the inventory data table above are shown in Table 3 and Table 4. Suppliers located in the same city as the manufacturer are not included in the table. In accordance with the non-disclosure agreement, the location information of the suppliers was not shared.

Stage	Inputs	Distance (km)	Type of Transportation (Ecoinvent dataset/CCalC Library)
Production	ABS	15119	Freighter
	Master Batch	14536 444	Freighter Lorry > 16t
	Polycarbonate	2446	Freighter
	Polypropylene	11932 339	Freighter Lorry > 16t
	Silicone	11932	Freighter
	Solvent	14536	Freighter
	Thermoplastic Elastomer (TPE)	2957	Lorry > 16t
Assembly	AC Adapter	12841	Freighter
	Ice Pack	14536	Freighter
	User Manual, Insert	490	Lorry > 16t
	Cartons	537	Lorry > 16t
	PE Plastic Bag	512	Lorry > 16t
	Silicone Products	13097	Freighter
	Solenoid Valve	13454	Freighter
	Rubber Products	13097	Freighter
	Motor	15186	Freighter
	Cooler Bag	14536	Freighter
	Bumperstop	497	Lorry > 16t
	Product Bag	13454	Freighter
Use	Finished Product	9493	Freighter

Table 3. Transportation information of breast pump with alkaline battery

Stage	Inputs	Distance (km)	Type of Transportation (Ecoinvent dataset/CCalC Library)
Production	ABS	15119	Freighter
	Master Batch	444	Lorry > 16t
	Polycarbonate	2446	Freighter
	Polypropylene	11932	Freighter
	Silicone	11932	Freighter
	Solvent	14536	Freighter
	Thermoplastic Elastomer (TPE)	2957	Lorry > 16t
Assembly	AC Adapter	15243	Freighter
	Rubber Products	13097	Freighter
	Ice Pack	14536	Freighter
	Printed Circuit Board	13749	Freighter
	User Manual, Insert	490	Lorry > 16t
	Cartons	537	Lorry > 16t
	PE Plastic Bag	512	Lorry > 16t
	Silicone Products	13097	Freighter
	Solenoid Valve	13454	Freighter
	Motor	15186	Freighter
	Cooler Bag	14536	Freighter
	Bumperstop	497	Lorry > 16t
	Battery	14501	Freighter
Use	Final Product	9493	Freighter

Table 4. Transportation information of breast pump with rechargeable battery

The energy consumption amounts of all processes that are included in the system boundaries and have energy consumption are listed in Table 5 and Table 6 as kWh and MJ.

Stage	Consumption/unit product	Consumption/unit product
	(kWh)	(MJ)
Production	1.255	4.52
Assembly	0.285	1.02
Quality Control	0.142	0.514

Table 5. Energy consumptions of breast pump with alkaline battery

Table 6. Energy consumptions of breast pump with rechargeable battery

CHAPTER 3: RESULTS AND DISCUSSION

3.1 Life Cycle Impact Analysis

The comparison of two products with the same production processes specified in the target and scope of this LCA study and the evaluation of their environmental impacts are presented in this section.

The life cycle impact analysis was calculated by the CCalC2 Carbon Footprinting LCA Tool by entering the material inventory data, transportation data and energy consumption data presented in the previous sections for the products. In this section, the environmental impacts of two different breast pumps are examined under 5 headings.

3.1.1 Carbon Footprint Results

When the two products are compared, it has been determined that the total carbon footprint scores per unit are very close to each other. (Table 7)

Product Total Carbon Footprint/Functional Unit (kg CO² eq/fu) Breast Pump with Alkaline Battery 78.48 Breast Pump with Rechargeable Battery 78.19

Table 7. Total carbon footprint of two products

Since the alkaline batteries of the breast pump with alkaline battery are defined for use from the "raw material" part, they are included in the raw material on the graphics. On the other hand, the "use" phase can be seen on the graph since the breast pump with rechargeable battery consumes electricity.

First of all, the carbon footprint of the breast pump with alkaline batteries, in other words the global warming potential, was investigated. Here, it has been determined that the ratio of raw materials to the whole value is 98.24%. However, when the carbon footprint score of production and transportation are compared to the total score, they have a ratio of 1.11% and 0.65%, respectively (Figure 11).

Carbon Footprint of Breastpump with Alkaline Battery

Figure 11. The carbon footprint ratios of breast pump with alkaline battery

When the components that make up the total carbon footprint score are examined, it is seen that the component with the highest carbon footprint score of 97.58% of the breast pump with rechargeable battery is because of raw materials (Figure 12).

Figure 12. The carbon footprint ratios of breast pump with rechargeable battery

Carbon footprint (kg CO2 eq./f.u.)

Figure 13. The comparison of carbon footprint scores of both breast pumps

When the carbon footprint scores for both breast pumps were compared, it was observed that the total score for both was very close to each other. Besides, the score of raw materials makes up almost the entire score (Figure 13). It has been determined that the carbon footprint score of the production and transportation involved in the process is very low. When the raw materials were examined in detail, it was noticed that the two products with the highest carbon footprint scores were integrated circuit board and motor (Figure 14 and Figure 15).

Figure 14. Impact of raw materials on total carbon footprint score for the breast pump with alkaline battery

Raw materials carbon footprint

Figure 15. Impact of raw materials on total carbon footprint score for the breast pump with rechargeable battery

3.1.2 Acidification Potential Results

The acidification potential results and scores of breast pump with alkaline battery were analysed. Compared to the carbon footprint score, it has been determined that the acidification potential of production and transport is higher than carbon footprint scores. However, raw materials have 86.88% of the total acidification potential (Figure 16).

Acidification Potential of Breastpump with

Figure 16. The acidification potential ratios of breast pump with alkaline battery

The acidification potential results of breast pump with rechargeable battery are shown in the Figure 17. Similar to the breast pump with alkaline battery, the acidification potential score of manufacture and transport is higher than the carbon footprint score.

Figure 17. The acidification potential ratios of breast pump with rechargeable battery

When the acidification potential results are examined in detail, it has been noticed that the environmental impacts of plastics, silicone or packaging materials used in the production or assembly of breast pumps are negligible.

Acidification potential (kg SO2 eq./f.u.)

If both breast pumps are compared, it can be said that the total acidification potential score of the breast pump with rechargeable battery is 0.03 higher than other breast pump, there is almost no difference between the two pumps (Figure 18).

3.1.3 Eutrophication Potential Results

When the eutrophication potential results for the breast pump with alkaline battery are evaluated, it has been determined that raw materials account for 99.81% of this environmental impact, and the impact of production and transportation is very small (Figure 19).

Eutrophication Potential of Breastpump with Alkaline Battery

Figure 19. The eutrophication potential ratios of breast pump with alkaline battery

Likely to the breast pump with alkaline battery, almost the total eutrophication potential score produced by the raw material. The impacts of the production, transport and use is very low (Figure 20).

Figure 20. The eutrophication potential ratios of breast pump with rechargeable battery

Similar to the carbon footprint scores and acidification potential scores, the eutrophication potential results were found to be 0.04 higher for the breast pump with rechargeable battery, with no significant difference between them. When the potential environmental impact results in this section were examined in detail, it was realized that it was completely sourced from the raw material and determined that the source was caused by the integrated circuit board and the motor (Figure 21).

Eutrophication potential (kg PO4 eq./f.u.)

3.1.4 Photochemical Smog Potential Results

Photochemical smog potential results were evaluated for both breast pumps. It was seen that 93.91% of the total photochemical smog score for the breast pump with alkaline battery is due to raw materials (Figure 22). The reason why this impact is mostly caused by raw materials is the integrated circuit board and motor, as mentioned before.

Photochemical Smog Potential of Breastpump with

Figure 22. The photochemical smog potential ratios of breast pump with alkaline battery

When this photochemical smog potential impact of the breast pump with rechargeable battery was examined, it was seen that the effect of the raw materials was 93.35% (Figure 23). When the photochemical smog impact is compared for both breast pumps, it can be said that the difference between them is very small.

Figure 23. The photochemical smog potential ratios of breast pump with rechargeable battery

Photochemical Smog Potential results of both breast pump with rechargeable and alkaline battery is shown in the Figure 24. For this potential environmental impact, it can be interpreted as there is no impact caused by the production and the transport. Also, in overall, it was seen that the entire photochemical fog potential score of the raw materials was formed, and it was noticed that the score was very low.

Photochemical Smog Potential (kg C2H4 eq./f.u.)

Figure 24. The comparison of eutrophication potential scores of both breast pumps

3.1.5 Ozone Layer Depletion Results

The ozone depletion potential results of breast pump with alkaline battery were analysed and it was seen that the impact of raw material constituted 98.90% of the total ozone layer depletion score (Figure 25).

Figure 25. The ozone layer depletion potential ratios of breast pump with alkaline battery

Similar to breast pump with alkaline battery, the ozone layer depletion results shows that the raw materials of breast pump with rechargeable battery consist of the 98.37% of the total score (Figure 26).

Figure 26. The ozone layer depletion potential ratios of breast pump with rechargeable battery

If both breast pumps are compared, the ozone layer depletion potential scores of production and transport are higher for breast pump with rechargeable battery. In overall, the ozone layer depletion potential scores of both breast pumps are lower than the other environmental impacts as expected (Figure 27).

Ozone layer depletion potential (kg R11 eq./f.u.)

Figure 27. The comparison of ozone layer depletion potential scores of both breast pumps

3.1.6 Human Toxicity Potential Results

When the human toxicity impacts of the breast pump with alkaline battery is examined, as with other environmental impacts, raw materials have the highest rate with 99.84%, and production and transportation are seen to be very low with a rate of 0.15% and 0.01%, respectively (Figure 28).

Human Toxicity Potential of Breastpump with **Alkaline Battery** $0.15\% - 0.01\%$ Raw materials Production 99.84% - Transport

Figure 28. The human toxicity potential ratios of breast pump with alkaline battery

The human toxicity potential results for the rechargeable battery breast pump show that raw materials accounted for 99.77% of the total score, when production, transport and use accounted for 0.17%, 0.01% and 0.05% of the total score (Figure 29).

Figure 29. The human toxicity potential ratios of breast pump with rechargeable battery

When the total scores for both breast pumps are compared, it can be said that

the human toxicity potential of the breast pump with rechargeable battery is higher than other breast pump. However, for both breast pumps, the highest value belongs to raw materials, as seen in other environmental impacts. When detailed raw material analysis was made, it was observed that the integrated circuit board and motor increased this impact score (Figure 30).

Human toxicity potential (kg DCB eq./f.u)

Figure 30. The comparison of human toxicity potential scores of both breast pumps

As a conclusion of the life cycle impact assessment, the environmental impacts of the two products were compared and in overall it has been determined that the biggest factors that increase the total carbon footprint are the raw materials. When a detailed analysis was made, it was understood that the materials with the highest carbon footprint score were electronic components.

The acidification potential (AP) eutrophication potential (EP), photochemical oxidants creation potential (POCP), ozone layer depletion potential (ODP), and human toxicity potential (HTP), which are one of the most important potential environmental impacts, were observed to be higher for the product with a rechargeable battery, although there was not much difference between the two products.

3.2 Sensitivity Analysis

The carbon footprint of the raw materials of the breast pump with rechargeable battery, in other words, the global warming potential constitutes 97.58% of the total

carbon footprint. Likewise, 98.24% of the total carbon footprint for breast pump with alkaline battery consists of raw materials.

When the carbon footprint score of the raw materials of the breast pump with rechargeable battery is examined in detail, it has been determined that the carbon footprint of the integrated circuit board and the motor constitutes 94.9% of the total score. Additionally, in the same way when the carbon footprint score of the raw materials of the breast pump with alkaline battery is examined in detail, it has been shown that the carbon footprint score of the integrated circuit board and the motor constitutes 91.8% of the total score.

For this reason, it was decided to perform sensitivity analysis only for these two materials (integrated circuit board and motor). In this sensitivity analysis, the effect of integrated circuit board and motor suppliers on the total carbon footprint score was examined by both reducing and increasing the distances by 10%. As a result of this sensitivity analysis, it has been observed that although the carbon footprint score of the mentioned materials is high, the total carbon footprint score almost does not change when the supplier distances are both decreased and increased (Figure 31).

Carbon Footprint (kg CO2 eq./f.u.)

Figure 31. Sensitivity analysis results of both breast pumps

This figure shows that, even if the supplier locations change in the coming years the transportation distance is not likely to affect the final carbon footprint scores of these two products. Therefore, the uncertainty about the location of the supplier and the transportation mode and distance of the raw material will not affect the results in the future.

3.3 Effect of using bio-based plastics

In recent years, the use of bio-based plastics for the manufacture of different types of products has become quite common due to the environmental friendliness of these products. (Walker and Rothman, 2020) Therefore, it was decided to investigate the effect of the use of bio-based plastics instead of plastics produced from petroleum on the impacts of these particular maternity products. The result of this analysis can be found below (Figure 32).

1 in figure 3indicates that all plastic materials were excluded from the analysis, 2 represents the original carbon footprint score and 3 shows the carbon footprint score when all plastics are replaced by bio-based plastics.

Carbon Footprint (kg CO2 eq./f.u.)

Figure 32. Comparison of carbon footprint scores of plastics and bio-based plastics

Since no data was available in the CCalC Carbon footprinting software tool on the impact mitigation potential of using bio-based plastics for the potential environmental impacts such as acidification potential, eutrophication potential etc., this analysis was conducted only for carbon footprint.

In this analysis on the use of bio-based plastics, all plastic products entering the process as raw materials were replaced with LLDPE from wheat grain in the CCalC database.

First, the carbon footprint scores of the breast pumps obtained before in this study, the carbon footprint score obtained when all plastic materials were removed from the raw materials section, and finally the carbon footprint score by replacing all plastics with bio-based plastics (LLPDE from wheat grain) were reanalysed and all scores were compared.

As a result of this analysis, it was seen that the total carbon footprint score for the breast pump with rechargeable decreased from 78.19 to 77.09 when all plastics were excluded from the analysis, while the use of bio-based plastics reduced the total carbon footprint score from 78.19 to 76.69.

Likely to the analysis of the breast pump with rechargeable battery, the breast pump with alkaline battery was analysed and it was seen that the total carbon footprint score is decreased from the 78.47 to 77.07 when all plastics were removed from the analysis. Furthermore, it was clearly seen that the usage of bio-based plastics reduces the total carbon footprint score from the 78.47 to 76.38.

Based on these analysis results, it can be said that bio-based plastics reduce the total carbon footprint score. Compared to the sensitivity analysis made before, there was little or no change in the carbon footprint score, even if the distance was reduced by changing suppliers. However, as a result of this analysis, although there is a small decrease in the carbon footprint score, it can be said that the use of bio-based plastics has more positive impact than the change of supplier.

CHAPTER 4: CONCLUSION

A life cycle assessment is a sustainability tool applied to analyse the potential environmental impacts of a product or process. In order for this assessment to be implemented, the target and scope of the study should be determined, an inventory analysis should be made, and an impact analysis assessment should be made.

Manual breast pumps (non-powered) work with human power and do not consume electricity. Since it is known that the environmental impacts of manual breast pumps are much lower than those of electric breast pumps, environmental impact comparisons of electric breast pumps were made in this study.

In this assessment, the potential environmental impacts of maternity products, which is the main purpose of the study, were investigated. First of all, the goal and scope of the evaluation were determined. Afterwards, the system boundaries were determined by making an inventory analysis of the study. Life cycle assessment was performed with the CCalC2 LCA software tool. Inventory data in the database of the CCalC2 software used during the life cycle assessment was used. For materials that are not in the database of the software used, allocation was applied by reviewing the literature.

As a result of this study, it was determined that the total carbon footprint scores of the two products evaluated were very close to each other. However, the potential environmental impacts (acidification potential, eutrophication potential, photochemical oxidants creation potential, ozone layer depletion potential (ODP), and human toxicity potential) are pretty much the same.

Another output of this study is that the materials that have the most impact on the total carbon footprint of the evaluated products are the electronic components supplied from the supplier.

At the end of the analysis, it is clear that the inputs that have the highest contribution to the impacts are the integrated circuit board the motor used in the device. However, the motor used in this product is imported from a distance about 15000 km and then the supplier company of the motor is contacted, it was found out that they have no experience and knowledge when it comes to measuring environmental impacts such as carbon footprint.

This is a clear example of how important it is to choose the correct suppliers in

order to be able to adapt to the upcoming European Union Green Deal and the Green Transition. As this particular example shows in many cases the environmental impact of a final product is mainly determined by the raw materials that the manufacturing company does not produce itself but obtains from another external supplier. Hence, it is the suppliers' processes that actually determine the value of the environmental impact for a given product and that is why either the suppliers should conform to the regulations regarding to the calculation of environmental impacts or the manufacturing companies would have to consider changing their suppliers and finding one that actually calculates the environmental impacts of the processes.

If the suppliers cannot provide any information, it would not be possible for the manufacturer of the final product to be able to accurately determine their carbon footprint or environmental impacts. In order to avoid such situations, manufacturers may refer to work with suppliers who have the technical capability to measure their environmental impacts. Nonetheless, it also should be mentioned that in medical device industry changing the supplier is not easy according to directives, regulation and standards such as Medical Device Directive (MDD) and Medical Device Regulation (MDR). According to the requirements of this standard and regulation, when the critical material supplier is to be changed, it is mandatory to notify the notified body.

On the other hand, instead of shortening the distance by changing suppliers, the use of bio-based plastics will be more beneficial for breast pump production, as the use of bio-based plastics has been observed to reduce the overall carbon footprint score.

To summarize, this study clearly shows the importance of using LCA approach for the determination of the environmental impacts of a product, so that the contribution of different manufacturing stages can be determined, and appropriate actions can be taken. The approach developed in this study is not restricted to medical device industry, it can be used for any manufacturing industry.

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