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Evaluation of recyclable sachet foil material for sustainable packaging

Assessing materials to enhance sustainable packaging solutions

Bachelor's thesis in Chemical engineering

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DEPARTMENT OF CHEMISTRY AND CHEMICAL ENGINEERING

CHALMERS UNIVERSITY OF TECHNOLOGY

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Cover: a Wellspect Primo product next to a constructed prototype sachet

Abstract

Wellspect produces sterile single use urinary catheters, which are activated by a wetting solution before use. The catheters are individually packed in a plastic primary packaging with the enclosed wetting solution. The current Lofric Primo packaging has a sachet for the solution that is composed of a barrier laminate that is currently non-recyclable. This is relevant today as regulations from governmental entities such as EU are to come. The aim of this study was to investigate recyclable barrier materials as suitable replacements for the current non-recyclable aluminum-based barrier material of a sachet. The current Lofric Primo packaging has a sachet for the wetting fluid that is needed for activation of the hydrophilic catheter coating. The present sachet material is integrated into the packaging, which is incinerated after waste handling, and not recycled, in which the latter being the optimal solution for a sustainable world. Several different barrier materials based on polyethylene (PE), polypropylene (PP) and paper were tested for water vapor barrier properties and peel strength after welding. Some of these materials, based on PP and PE showed promising results regarding relevant properties such as water vapor transmission rate (WVTR) and suitable weld strengths via tensile strength tests. However, the paper-based material had too poor barrier properties for realistic applications. These materials, more specifically the Mono PE ones, showed potential to, in the future, replace the current barrier laminate and in turn potentially improve the overall sustainability of the Lofric Primo product. However, the conversion to an alternative material is not guaranteed to improve the sustainability of the product as a life cycle assessment should be carried out to fully conclude if that truly is the case. Further investigation is needed to also determine if the suitability of these materials is still applied when produced in a large-scale operation.

Acknowledgments

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List of Abbreviations

Below is a list composed of abbreviations that have been used throughout this thesis.

PE: Polyethylene

PP: Polypropylene

PS: Polystyrene

PET: Polyethylene terephthalate

HDPE: High-density polyethylene

LDPE: Low-density polyethylene

PVC: Polyvinyl chloride

DNA: Deoxyribonucleic acid

LCA: Life-cycle assessment and/or life cycle analysis

RH: Relative humidity

GPC: Gel permeation chromatography

WVTR: Water vapor transmission rate

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1 Introduction

Wellspect Healthcare is a company that produces sterile single use plastic urinary catheters, which have a hydrophilic coating that is activated by a wetting fluid before use. The catheters are packaged in a plastic primary package with an integrated enclosed wetting fluid in a sachet. The current sachet for the fluid is composed of a barrier laminate that is based on aluminum and not recyclable. As different regulations and recommendations from governmental organizations such as EU are to come, for the purpose of a more sustainable world, Wellspect strives to achieve a more sustainable recyclable packaging by evaluating the possibility of replacing the present sachet foil material with a recyclable one.

1.1 Aim

The aim of this study was to evaluate the possibility of exchanging the current aluminum-based sachet for a more sustainable material that possesses the sufficient technical properties, such as WVTR (Water vapor transmission rate) and suitable weld strengths, with a lower carbon footprint and the ability to be recyclable, whilst preserving the same functions of the current product.

1.2 Limitations

This study did not cover a full-scale Life Cycle Analysis (LCA), however, LCA data from supplier exist for some of the tested materials but is not available to the public due to confidentiality reasons. The results gathered from testing is aimed at the Lofric Primo packaging and cannot be guaranteed to function on the other different types of Wellspect products. It is however important to note that the data gathered from the testing should not be dismissed completely as it has the potential to be useful in future projects. Another limitation to this study was the limited amount of material that was available because of time constraint.

2. Background

EU have conducted new rules regarding packaging with a reduction target of 5% by 2030 and 15% by 2040. These reductions particularly imply plastic packaging. Certain single use plastic packaging will also be banned from 2030, with only particular products, such as medical devices, having a 5-year derogation under certain circumstances [2]. Packaging and packaging waste directive (PPWR) requires all packaging's to be recyclable by 2030 and sets targets on recycled content in packaging materials. Primary packaging for medical devices is, however, which was mentioned before, exempt from these requirements until 2035 [1]. Recyclable packaging for medical devices has the possibility to have a higher ranking in tender processes where the new Nordic criteria for more sustainable packaging for healthcare products are used [1]. As of today, there are two ways of recycling plastics. Mechanical recycling, where the main purpose usually is to regranulate and repurpose the plastic waste and then there is chemical recycling, where the focus lies more on producing chemicals and/or fuels from the plastic waste.

2.1 Recycling

2.1.1 Mechanical Recycling

Mechanical recycling is the most common method for recycling plastic waste as of today. A typical process consists of collection, sorting, washing and grinding of the materials. These steps are not limited to any order and can occur anywhere or not at all throughout the sequence.

- Separation (and sorting): This step is based on the shape, size, density colour or chemical composition of the material.
- Washing: this step is based on the removal of contaminants on the materials.
- Grinding: The material is reduced in size from the original product size to flakes.
- Reprocessing: reprocessing of the flakes occurs, and the material can be granulated and repurposed

The cycle begins by the contents (household waste) being passed through a progressive rotating sieve, which sorts the contents by size, separating the small objects from the bigger ones which go to a residue fraction. The process continues by sorting the contents into two streams, a medium (40-120 mm) and a large one (120-220 mm). A wind sifter is in place to ensure that loose contents are blown out, such as labels and plastic bags. The mixed waste then continues to a magnet for the removal of ferrous metals, which are iron based, and an eddy current for the removal of non-

ferrous metals, which are non-iron based. These mixed plastics are later separated by FT-NIR (Fourier Transform Near Infrared) into PET and HPDE. Optical colour recognition sorts the different PET into corresponding colour sections. After the plastics have been colour sorted it continues on to be manually sorted by operators (if no automated processes are available) as to check for false-positives caused by any automated mistakes. It is to be noted that FTNIR is recognized as the most common method but not an exclusive one in this process. After the mixed plastic has been sorted, it is sent to a crude shredder which shreds the plastic to fist-sized particles. The fist-sized particles are then transported into a silo where it is washed in a rotating drum washer. The particles are then sent to friction washers to remove organic contaminations sticking to the plastic. The particles are then sent to the second round of shredding where the particles are reduced to flakes, sized around 1-12 mm. The flake-sized particles are washed a third time and led to a float-sink separation where different plastic such as PP, PE are separated from denser plastics such as PET, PS and PVC where the latter mentioned will sink. The sunk particles (PET, PS, PVC) are passed through a magnet which removes ferrous remains to a drier and is ready secondary raw material [2]. Secondary raw material is typically used in both closed-loop recycling, where the recycled plastic is used to produce the same product they were originally recovered from, and open-loop recycling where the recycled plastic is used for a different product than the original product it was recovered from. As for the floating particles (PP, PE) they are also dried but continue into a wind sifter that removes the “soft particles”, which is mostly LDPE and PP. The “hard” particles will fall against the airstream from the wind sifter (PP and HDPE) and will be ready as a secondary raw material. The “softer” particles (LDPE and some PP) are too low in density to be used by converters, so it undergoes a granulation step by extrusion making it suitable as a secondary raw material. It is to be noted that the process described above is based on the standard in Belgium which means than an equal or similar process cannot be guaranteed worldwide. [3]

2.1.2 Chemical Recycling

Chemical recycling is the second, more uncommon, way of recycling plastic materials and is not limited to a certain specific type of process but several. Some of these processes include but are not limited to; Chemolysis and Pyrolysis

2.1.2.1 Chemolysis

Chemolysis can depolymerize PET into its monomers and this depolymerization is achieved through routes such as glycolysis, methanolysis, hydrolysis, aminolysis, hydrogenation and

ammonolysis. What most of these route's share is the presence of high temperatures and high pressure. The monomers can in a later step be purified and used for polymerization of new PET.

2.1.2.2 Pyrolysis

Pyrolysis is another type of chemical recycling that is suitable for polymers that are harder to recycle such as mixed PE/PP/PS and multilayer packaging. The Pyrolysis process takes place in relatively high temperatures and in absence of oxygen. The process consists of breaking the chemical bonds in its molecules, which in turn becomes smaller molecules which in turn leads to depolymerization or fragmentation of said polymer. Pyrolysis is typically regarded as a method to produce fuels and chemicals. [3]

2.2: Electron beam sterilization

The Wellspect products are sterilized using e-beam sterilization, which is the reason for sterilizing the sachets produced from the test material before evaluation of WVTR properties. E-beam, also known as electron beam, is a type of process which involves using concentrated, highly charged stream of electrons for a wide array of uses, one which includes a sterilization method. An e-beam typically discharges streams of electrons and destroys the bonds between the DNA molecules of living organisms, resulting in death of these organisms, and effectively sterilizing the entity. [5] According to a paper from Harrington et al. electron beam sterilization process is similar to the Gamma one, where the sterilization occurs by producing high-energy electrons (beta particles) from electron accelerators and exposing the product to it. When the material absorbs the beta particles, the DNA is destroyed by altering its molecular bonds. The main differences between these processes are the different radiation sources for each method and the penetration qualities of said methods, the latter having deeper penetration depth. Gray (Gy) is the SI unit of absorbed dose which is the amount of radiation energy stored into the irradiated product. [6,7]

According to Svoboda et al. there are different types of effects of radiating materials depending on what the material is based on, such as polypropylene (PP) or polyethylene (PE), which can be, but is not limited to, chain scission and cross-linking. It is stated that all these reactions coexist and that the predominant effect is determined by factors such as morphology, irradiation conditions and chemical structure. A general rule states that polymers that contain a hydrogen atom at each carbon atom typically cause cross-linking whereas polymers containing a quaternary carbon atom that contains groups other than hydrogen (H) causes chain scission [9].

In the case of PE, the polymer is cross-linked after irradiation which typically improves physical properties such as heat resistance, by having a bond that links one polymer chain to another. [8] Other research, which was conducted by Svoboda et al. continue stating that after e-beam radiation the properties of both PE and PP were studied. It was shown that radiation caused a cross-linking effect in PE and a chain scission effect in PP. With the help of analytical methods such as GPC, a molecular weight for the PE was found to be higher and increase when cross-linked whilst when analyzing PP, a decrease in molecular weight was found [9].

2.3 Water vapor transmission rate (WVTR)

Water Vapor Transmission Rate, also known as WVTR, is typically defined as the ability of water vapor to pass through a solid material, usually measured in the unit $\text{g/m}^2/\text{day}$ [4]. The barrier properties of a water sachet can be measured using WVTR. A sufficiently low value is needed for the sachet to preserve an appropriate volume of water during the shelf life of the product. The WVTR measurements are relevant to the study as Wellspect's catheters must contain a certain amount of fluid in the sachets after a certain amount of time after packaging for it to function properly and as intended. For Wellspect's requirements this usually means a shelf life of 2.5 to 3.5 years after packaging [10]. Different techniques and methods exist for measuring WVTR, which include but are not limited to; ASTM E96, which is a standard test method for WVTR testing that is divided into two methods, the Desiccant method and the water method. For the Desiccant method the test specimen is sealed to a test dish containing a desiccant, which is a hygroscopic substance that is used to induce a state of dryness in its environment and is placed in a controlled environment. Periodic weighing's are to be conducted in order to assess the rate of which the water vapor moves through the test sample into the desiccant. The water method is the second method which is a relatively similar method, with the main difference being that the dish contains distilled water with periodic weighing's being conducted, assessing the rate of the vapor moving through the sample from the water [11]. The second standard, ASTM F1249 is the standard test method for WVTR through plastic film and sheeting using a Modulated Infrared Sensor, and its process is typically executed by a dry chamber being separated from a wet chamber in a controlled environment by the barrier material to be tested. The wet chamber and the dry chamber create a diffusion cell in which the sample is sealed. Water vapor that is diffused through the sample, is mixed with the gas from dry chamber and is carried out to the modulated infrared sensor, which measures the fraction of infrared energy which is absorbed by the water

vapor and in turn produces an electric signal. This information is then used to calculate the WVTR by comparing the signal to other known calibration films [12].

2.4 Tensile test of seal strength

This type of testing was conducted to observe how the different seal temperatures and seal time would affect the strength of the welds of the sachets. This method measures physical properties of materials. Testing carried out with this equipment, which is manufactured by the Zwick Roell Group, includes but is not limited to; tensile, flexure and compression. The suitable testing for this project will be a tensile test of the seal strength of the product. A tensile tester is a system that applies a force to a material to determine the tensile strength and deformation trends until break [13].

3. Materials and Methods

3.1 Tested foil materials

In this study following materials were used:

- Metallized Paper (Supplier 1)
- Mono PP superior metallization (Supplier 3)
- Mono PP standard metallization (Supplier 3)
- Mono PE (Supplier 1)
- Upgraded Mono PE (Supplier 1)
- Mono PE (Supplier 2)
- Mono PE with EVOH PE (supplier 2)
- MONO PE glue with EVOH (supplier 2)
- Reference Primo sachet

3.2 Test methods

Two types of major testing were conducted and then analyzed in this thesis. Construction of sachets based of the test material for the purpose of WVTR testing, analyzing how much water that could have evaporated, and the construction of strips which were also based off the test material for the purpose of tensile strength testing, determining the strength of the welds with seal temperature and seal time as parameters. A minor sterilization test was also conducted only to ensure the integrity of the welds so that no leakage would occur and was performed on all

sachets used for WVTR testing. After lab-scale welding had been completed the next phase was to analyze the data and proceed with a large-scale production of the samples with a test run at Wellspect's production department.

3.2.1 Welding sachet samples for WVTR-testing

Welding of the samples were carried out at one of Wellspect's lab-scale weld presses. The welding temperature was chosen from suppliers' recommendation and tested on foils before making the final sachets. Sachets were created with dimensions of 7×11 cm with a total of 4 replicas of each test material. The number of replicas was deemed statistically sufficient for the scope of this testing given the time available. The area of the sachets was then welded to 5×8 cm for practicality and consistency reasons. Three welds were made, leaving one opening for the dispensing of Mili-Q water. Before filling the sachets with Mili-Q water, the weight of the empty sachet, was determined for the purpose of WVTR calculations. After weighing, the sachets were filled with the Mili-Q water with the help of an Eppendorf multipipette E3 manufactured from Mettler Toledo. A setting of 10 ml was set on the multipipette for each dispensing for each sachet as the volume was deemed close enough to replicate the real Primo™ sachet for adequate testing. What should be noted is that a typical Primo™ sachet contains a sodium chloride solution, and not Mili-Q water. The reason for this change was to simplify testing. After the sachet was filled with Mili-Q water, the fourth and last weld was made to seal the sachet. Table 3.1 shows the different welding parameters that were set for each test material.

Table 3.1: Table showing welding parameters and sample pool.

Material	Seal temperature (°C)	Seal time (seconds)	Number of replicas
Metallized paper (Supplier 2)	100	1,5	4
Metallized paper 2 (Supplier 2)	100	1,5	4
Mono PP with superior metallization (Supplier 3)	120	1,5	4
Mono PP equivalent with standard metallization (Supplier 3)	120	1,5	4
Mono PE* (Supplier 1)	125	1,5	4
Upgraded Mono PE* (Supplier 1)	125	1,5	4
Mono PE* (Supplier 2)	110	1,5	4
Mono PE with EVOH PE	105	1,5	4

(Supplier 3)			
MONO PE glue with EVOH (Supplier 3)	105	1,5	4
Reference Primo current sachet*	140	1,5	4

**-marked are prototypes constructed with blue LDPE foil.*

3.2 E-beam sterilization

After the sachets were constructed, they were prepared for processing with the help of E-beam sterilization. For this thesis, a radiation dose of the standard product dose was set out with a minimum of 25 kGy. The sachets were packed in Lofric Sense™ transport boxes taped between two polystyrene plates. This, to even out the radiation dose between all the sachets in order for them to have identical radiation doses. The aim of sterilizing the sachets with the help of an E-beam was to ensure that the welds were fully sealed, and to have the prototype sachets mimic the real primo product, as products going through e-beam is a requirement for all commercial products from Wellspect. Figure 3.1 illustrates the packaging process.



Figure 3.1: Picture depicting how the sachets were packed on one polystyrene plate ready to be enclosed by a second one, in the transport box.

3.3 Water Vapor Transmission Rate (WVTR) testing of sachets

WVTR-testing was carried out to investigate the passage of water vapor through a solid material, which in this case were sachets. The method used to carry out WVTR-testing at Wellspect in this thesis was simple by weighing the samples were periodically a set number of days by using an analytical balance. The samples were placed in a controlled heat cabin with a temperature of 25 °C and a relative humidity (RH) of 35%. The number of days for weighing for this thesis was set to 25 days, weighing them every third day. A glass-based beaker was used as medium to contain the samples during weighing, for the purpose of eliminating the risk of static electricity occurring which could interfere with the readability of the analytical balance. There are several other standard test methods available for Water vapor transmission rate testing such as ASTM E96 and/or ASTM F1249 which can be offered to obtain a more precise result. Figures 3.2 and 3.3 depict how the practical work was performed.



Figure 3.2: Picture illustrating how the sachets were placed during storage in the heat cabin.



Figure 3.3: Picture showing how weighing was performed.

3.4 Tensile test of seal strength

This method measured physical properties of materials. Testing carried out with this equipment, which is manufactured by the Zwick Roell Group, includes but is not limited to; tensile, flexure and compression. The suitable testing for this project was a tensile test of the seal strength of the product. For this testing the samples were made as strips as the sole purpose was to perform tensile tests, which in this case were destructive. The reason for testing the tensile strength of the strips was to measure the amount of force required to open the welds. This was particularly of the essence as the Primo product is required to have different type of weld strengths as for the

product to function properly. A European standard, titled “Packaging for terminally sterilized medical devices” was used for this type of testing, more specifically EN 868-5, annex D, with a slight modification of length parameters of the tensile tester to meet the requirements for the constructed samples.

3.4.1 Welding samples for tensile test of seal strength

The tensile tests were divided into four groups; the current Primo product sachet, Prototype primo sachet, Supplier 1 new test material, and an upgraded version of said test material. This was done for the purpose of determining the tensile strength, calculated in newton (N), and to observe the deformation behavior until breakage. The reason for the choice of Supplier 1’s material for tensile tests was because of its preliminary WVTR-properties and because of the nature of the material being Polyethylene which would be compatible with the sterilization process at Wellspect. Firstly, for the first group, a tensile test was carried out on the current Primo™ products’ weld’s, which meant three types of groups were tested for that group. Figure 3.4 illustrates how the sachets were constructed with 4 layers. From left to right; barrier material, LDPE, LDPE, barrier material. In Figure 3.5 a rough sketch illustrated the three uniquely different welds of the primo product. Afterwards, prototypes made from Wellspect’s aluminum foil were constructed together with the blue LDPE plastic. Figure 3.6 illustrates the tensile test procedure. The third group, which was Supplier 1 barrier foil was also welded together with Wellspect’s blue LDPE based plastic and constructed as strips, which is depicted in Figure 3.7.



Figure 3.4: Picture illustrating how the barrier foil was layered with the LDPE plastic for test group 2, 3 and 4.

Tensile testing strip samples:

Table 3.2 Test group 1: Current Primo™ product

Group	Temperature (°C)	Seal time (s)	Number of samples
A “diagonal cut of lower weld”	N/A	N/A	5
B “Sideweld”	N/A	N/A	5
C “Topweld”	N/A	N/A	5

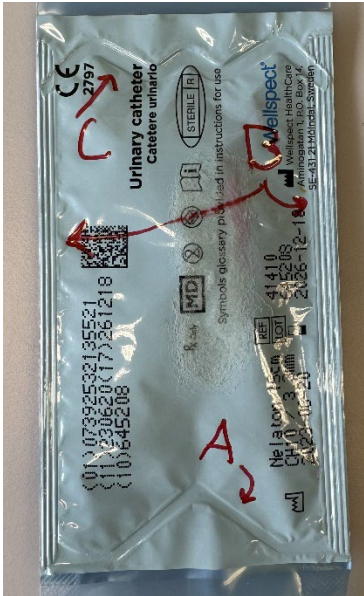


Figure 3.5: Picture depicting the three (A, B, C) different welds for test group 1.

Table 3.3. Test group 2: Prototype present Primo sachet material

Seal temperature (°C)	Seal time (s)	Number of samples
110	1.5	6
120	1.5	6
130	1	6
130	1.5	6
140	1	6
150	1	6
160	1	6

Table 3.4 Test group 3: Mono PE (Supplier 1)

Seal temperature (°C)	Seal time (s)	Number of samples
110	1.5	5 ¹
120	1.5	6
130	1	6
130	1.5	6
140	1	6

1) Only 5 samples for the first group as one sample were destroyed.

Table 3.5. Test group 4: Upgraded version of Mono PE (Supplier 1)

Seal temperature (°C)	Seal time (s)	Number of samples
105	1	6
105	1.5	6
110	1	6
110	1.5	6
120	1	6

120	1.5	6
130	1	6
130	1.5	6
140	1	6
140	1.5	6

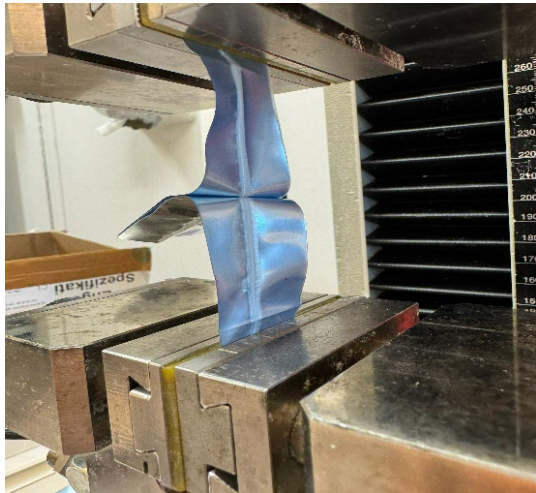


Figure 3.6: Picture of tensile test, mid performance



Figure 3.7: Picture of the constructed strips for the tensile testing

4. Results and Discussion

4.1 Water Vapor Transmission Rate

Table 4.1: Results of measured WVTR

Material	Measured WVTR at Wellspect (25°C, 35% RH) [g/m ² /24h]	Translated WVTR from supplier measured value (38°C, 90% RH) to Wellspect storage conditions [g/m ² /24h]	
Metallized paper (Supplier 2)	65.9384	355	
Metallized paper group 2 (Supplier 2)	42.2952	228	
Mono PP with superior metallization (Supplier 3)	0.0437	0.235	
Mono PP equivalent with standard metallization (Supplier 3)	0.0630	0.339	
Mono PE* (Supplier 1)	0.0365	0.196	

Upgraded Mono PE* (Supplier 1)	0.2768	1.49	
Mono PE* (Supplier 2)	0.0537	0.289	
Mono PE with EVOH PE (Supplier 3)	0.5174	2.78	
MONO PE glue with EVOH (Supplier 3)	0.5988	3.22	
Reference Primo current sachet*	0.0068	0.0366	

* Indicates that the materials were constructed together with the LDPE plastic. See figure 3.2

After E-beam sterilization, visual inspection and WVTR-data analysis showed that leakage had occurred in one of the paper sachets. This was expected with the help of prior knowledge and experience from previous testing of paper materials. Because of this, another 4 replicas were made from the metallized paper, but without sterilizing them through E-beam. As Figure 4.1 shows, an improvement in WVTR properties did not occur and showed similar WVTR abilities as the first group of paper replicas. Figure 4.2 depicts all the potential candidates as an alternative material. The prototype Primo product, was as expected, the material with the best WVTR properties, which can be depicted in Figure 4.3. Supplier 1's Mono PE material, which was projected to be produced in a large-scale environment due to its natural property of being polyethylene (being compatible with the sterilization process), showed relatively good WVTR properties with an average WVTR of $0.0365 \text{ g/m}^2/24\text{h}$ at 25°C , 35% RH. The WVTR conversion from Wellspects storage conditions (25°C , 35% RH) to testing conditions of suppliers' (38°C , 90% RH) was calculated with the help of Professor Steven Abbott's permeability calculations. This translation is done as these are the standardized testing parameters for WVTR. This led to a WVTR translation of $0.196 \text{ g/m}^2/24\text{h}$. This will correspond to an average of 1.144g (9.6%) loss of water after 2 years in packaging. It should however be noted that because of aluminum's excellent WVTR ability, effectively not releasing any vapor, meant that Wellspect had not created any requirements regarding the maximum amount of allowed evaporation in the sachet, but instead have integrity requirements of the welds, analyzing if

leakage has occurred, as micro holes can occur in the welds. This would essentially mean that a minimum volume requirement to compare with does not exist, which would mean that further testing would have to be conducted to confirm a sufficient volume after packaging. The existing internal test requirements were used, and it became evident that the integrity of the welds was not affected. What also should be noted is that the WVTR for the Upgraded Mono PE from Supplier 1 was only measured three times during a period of 13 days due to time constraint. This could potentially influence the result since sufficient data points do not exist. WVTR comparison of the Primo, Supplier 1 and Supplier 2 sachets are depicted in Figure 4.3, showing the WVTR abilities of each material.

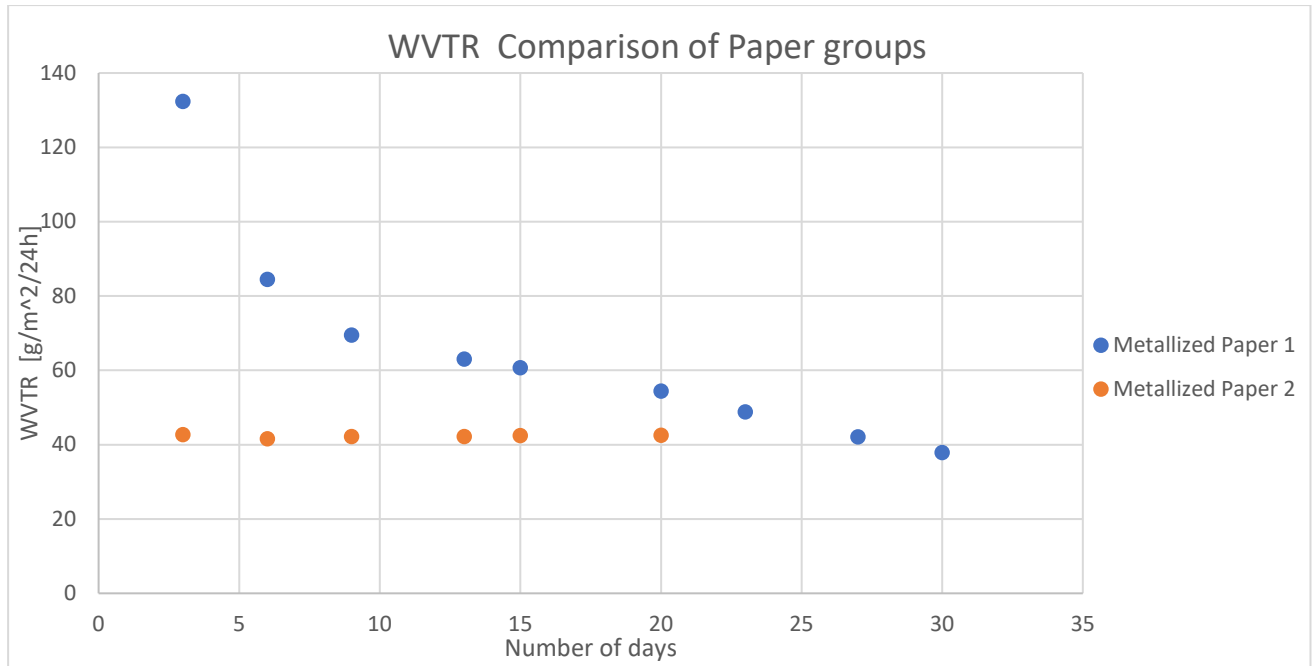


Figure 4.1: Plot depicting the two paper groups.

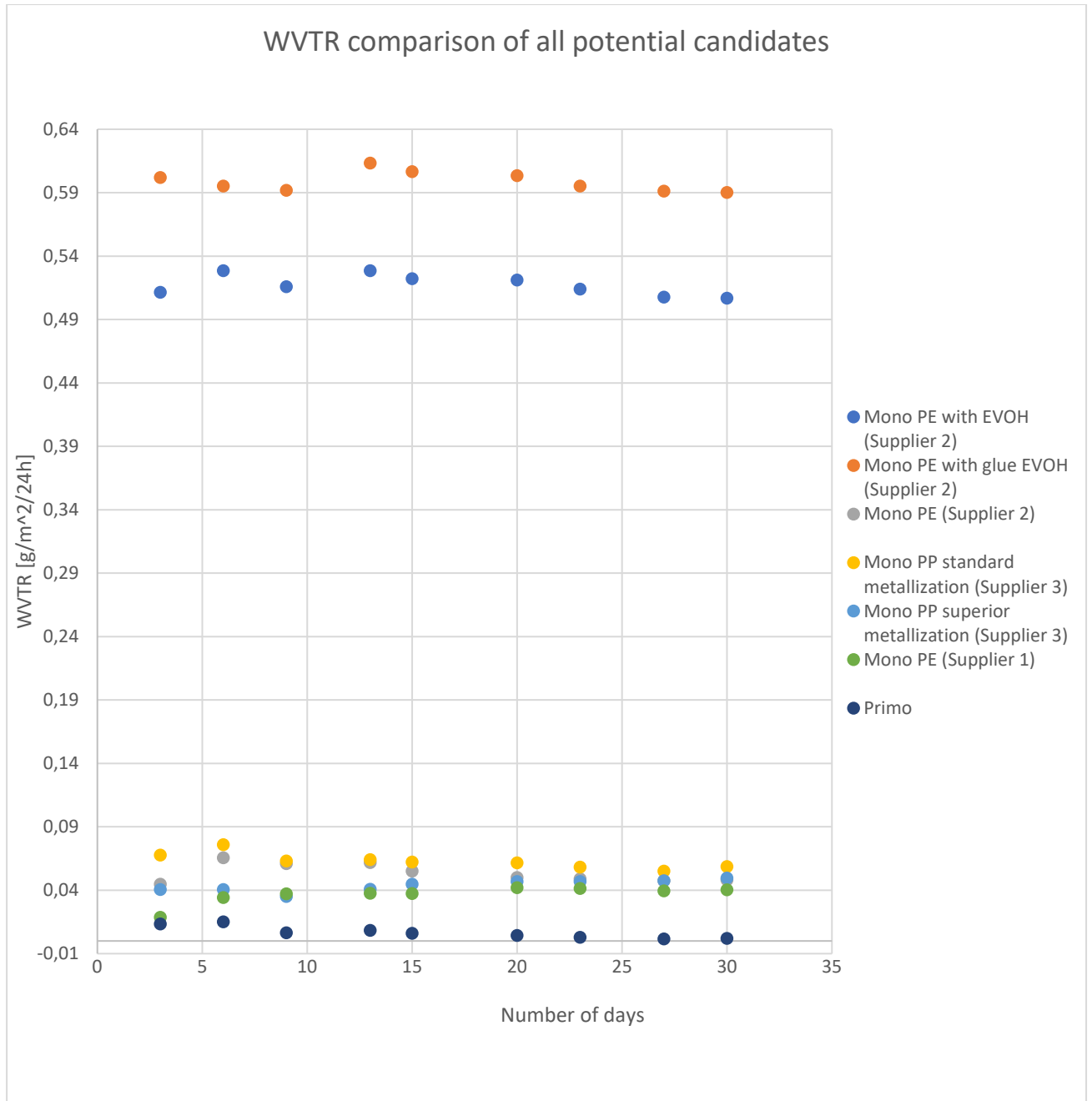


Figure 4.2: Plot of all potential candidates

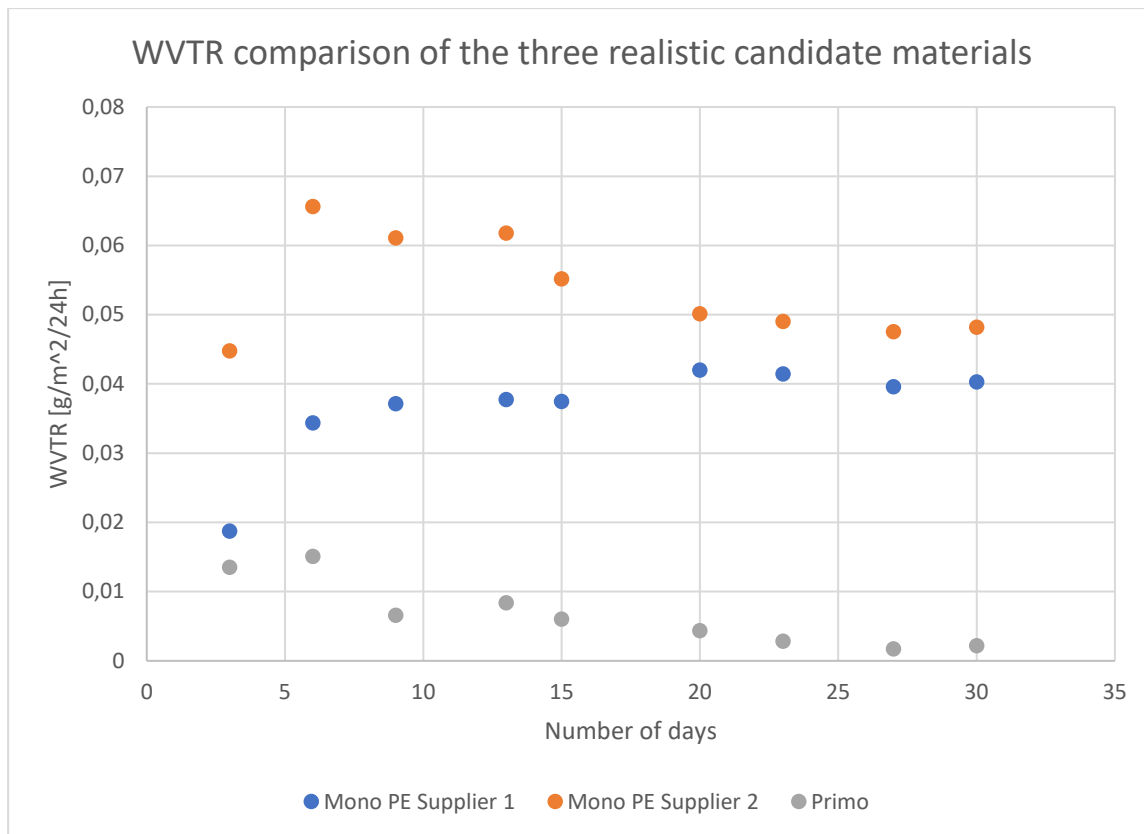


Figure 4.3: Plot depicting WVTR of three different materials.

4.2 Peel strength

The peel strength results measured with the tensile tester showed the different ranges of force required to peel the welds. As depicted in Figure 4.4, one can see from the prototype Primo samples the average force for the different groups. An important factor to keep in mind is the importance of having different weld strengths in the Primo product as the three welds serve different purposes for the product to function as intended. As depicted in Figure 3.5, one can see the different weld patterns of the side, bottom, and top weld of the Primo product. The bottom weld must be weak enough to burst when activated but strong enough to hold the weld together whilst the top weld's purpose should be strong enough to withstand activation, so that it does not "splash" upwards. The two side-welds are supposed to be the strongest welds, as they should not cause any leakage when stored or activated. We can see that supplier 1's material reached similar forces to the prototype Primo but with different parameters. What should be noted is that the sample pool was very small, which means that these test results may or may not be representative of what can qualify as an approved requirement. What should also be noted is that the prototypes were constructed in lab-scale environment with the instruments available. This would essentially mean that it is practically difficult to recreate prototype welds with laboratory equipment that

mimic the real Primo product welds, as the real process, when mass produced, is vastly different with different fixtures used, that factor into the weld’s functionalities. The plot in Figure 4.4 showed that Supplier 1’s material had similar adequate weld strengths as the Primo prototypes at different parameters, for the lower required peel force strength. However, the Mono PE material did not reach an adequate maximum weld strength as can be observed in the plot. This is due to the Mono PE welds melting after exceeding a seal temperature of 140 °C, essentially affecting the integrity of the weld which essentially meant that a seal temperature of 140 °C was the highest possible testing-temperature achieved, that would grant actual results and not misleading ones. Figure 4.5 showed the same plot but with error bars included. When observed, it showed a relatively large deviation. A general reason for this could be due to the simple fact that there were not enough tests performed. A more specific reason for the deviation may be due to the construction of the strips which may not have been replicated in the exact same way due to the natural curling of the blue LDPE plastic which in turn made the welding more difficult. This may have led to inconsistencies in the construction of the strips. One should note that this data is not sufficient to base an absolute conclusion of any sorts and needs to be further evaluated with more testing.

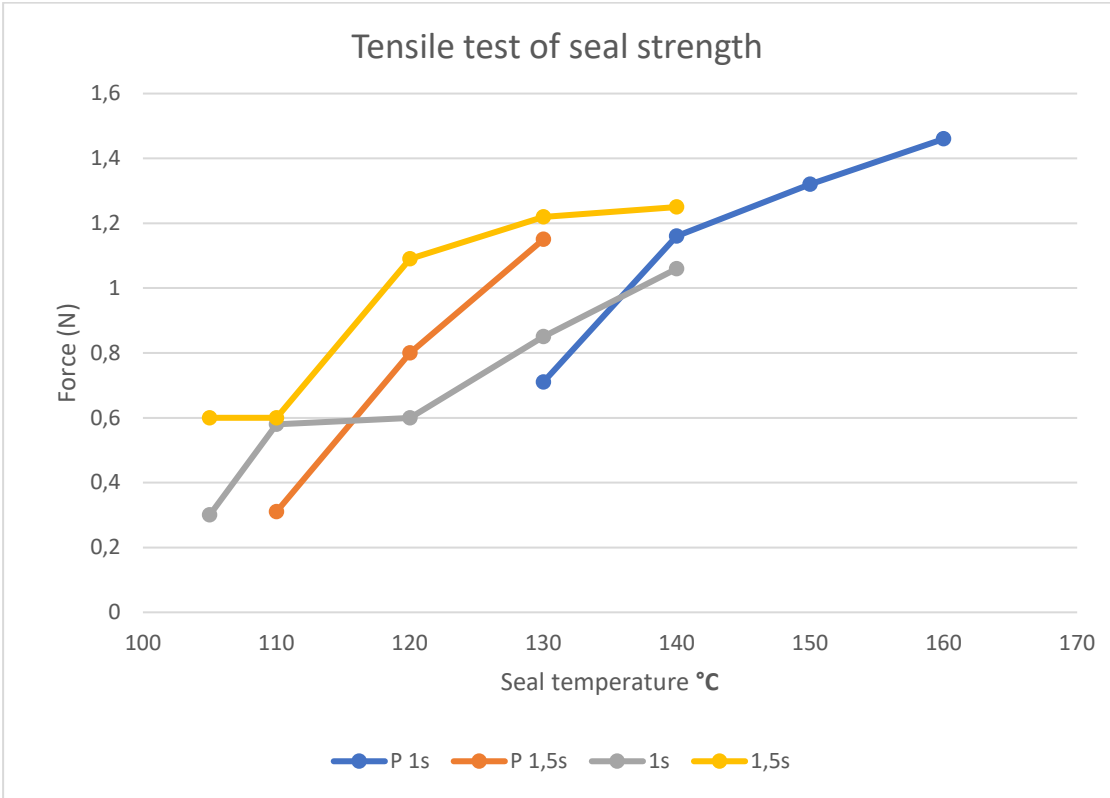


Figure 4.4: Plot depicting values of tensile testing. “P 1s” and “P 1.5” being the Primo prototypes (test group 2) and “1s” and “1.5s” the Supplier 1 prototypes (test group 4)

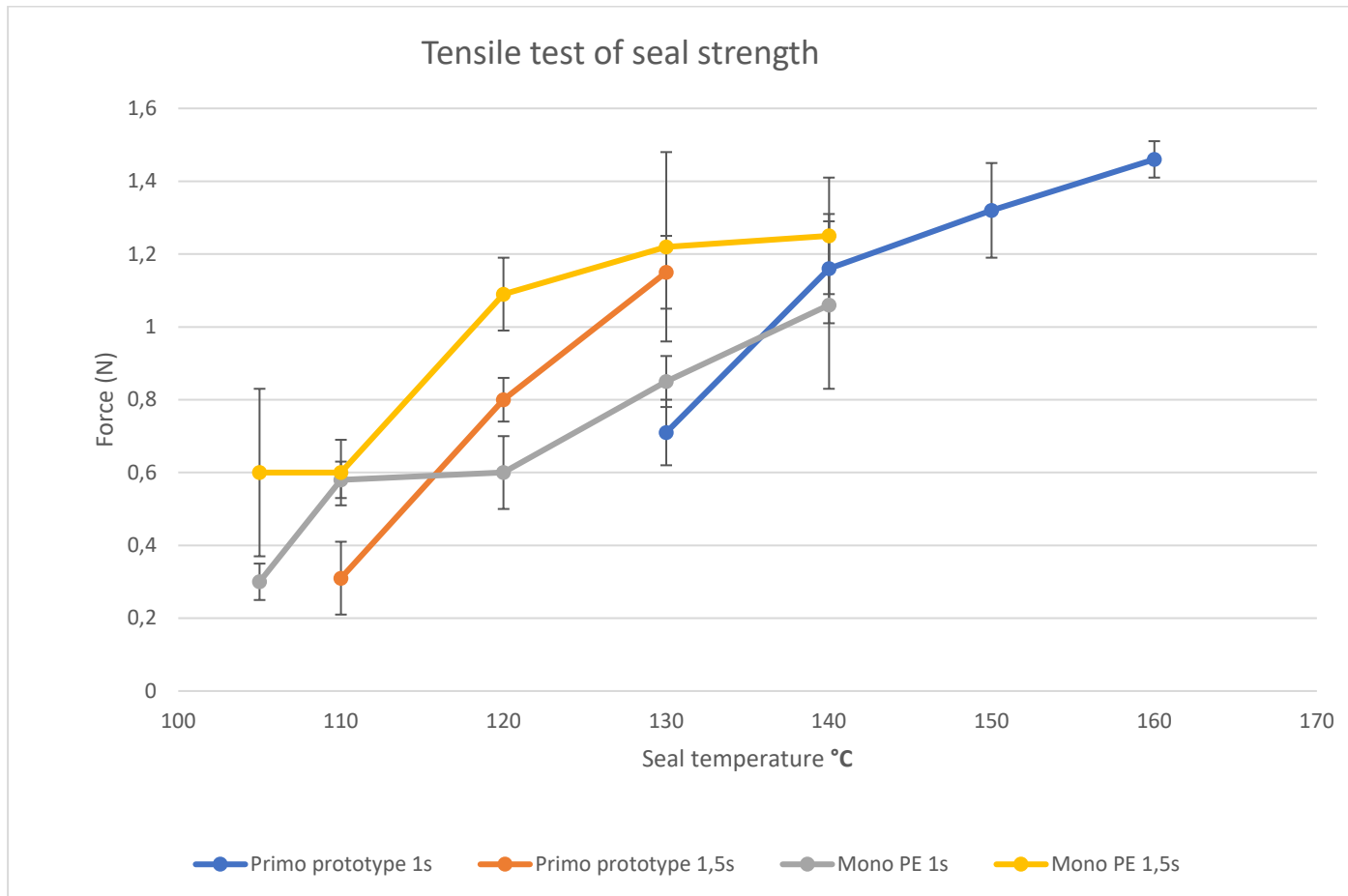


Figure 4.5: Plot showing results from the tensile strength testing with seal temperature plotted against the force

5. General discussion

When making substantial changes in a product it is important to list the different pros and cons. Functionality is one of these factors that can be compromised after a material change. A material change would potentially lead to a reduction or sometimes a complete loss of the functions that are intended for the product. Another factor that may play a role is the safety of the modified product after the material change. Examples of this may be the compromise of the biocompatibility and/or mechanical properties, including strength, flexibility, and durability. These two factors play a huge role in this evaluation as users would most likely prefer the product that is both safer and more functional than the product that is more sustainable. Regarding the selection of the available material that was tested, the Mono PP materials would most likely be ruled out due to the nature of the material being polypropylene, even with relatively good WVTR

properties, as it undergoes a chain scissoring at radiation doses from 20 kGy, which reduce materials properties. [9] This would maybe be the case for Wellspect sterilization doses. In addition, this leaves the Mono PE as one of the more suitable materials in regards both to the test results and its natural structure. The tested PE foils have also shown to be possible to weld with similar peel strengths at the present Primo sachet material.

6. Conclusions

The results of this study showed that alternatives to aluminum as a barrier foil exists and could potentially replace the existing foil. Further research should be conducted to ensure clear results, as the current results only show a small pool of samples and restricted types of testing. Furthermore, a full scale LCA is needed to conclude if a change from aluminum to an alternative barrier material is more sustainable. However, one should be aware that this may not even be realistically possible to execute due to potential confidential specifications. An example of classified specification can be the carbon footprint of the adhesive that is used which the supplier might not want, or even be legally obliged, to release to clients. A natural complication of this would be that the given information would not be sufficient to base an LCA of the product leading to an inconclusive result.

An important factor to also note is that, due to the packaging being based off different materials, in Primo's case being aluminum, PET and LDPE based, means that when recycled, the sachet may be incinerated with other waste. If the sachet was based of a single material, such as Mono PE, it would open for discussions regarding the ability to recycle the whole packaging, instead of the current waste handling which is via incineration. If this was fulfilled it could lead to a more sustainable process regarding the Primo packaging and increase sustainability of the product in total.

Another aspect to consider in this thesis is that the tests were done in lab-scale. Different challenges may occur when attempting to conduct the substitution of barrier material in a large-scale environment with automated machines as added factors. These challenges may be handling of a smaller processing window for a Mono PE material, which may lead to more scrap during production. Also, more complex complications such as sensors in the large scale equipment may not register the material due to, for example, the blankness of the material. One should keep in mind these kinds of challenges when aiming for an acceptable and continuous large-scale operation.

7. Future outlook

To further evaluate the possibility of replacing the current aluminum-based barrier foil, additional testing in the form of a larger sample pool should be performed. A distinctive indication of this was for the tensile strength testing where the sample pool was too small, which led to an inconclusive result regarding the comparison of sufficient weld strength. An interesting parameter that was not covered in this thesis was the aging of the product. This parameter would show if, and how significantly, the materials are affected by aging. Another interesting factor would be to mimic the product completely, that is by filling the sachets with a sodium chloride solution rather than Mili-Q water, and to evaluate if this has any substantial effect on the material and different properties. Another aspect that was not analyzed in this thesis was the effect on the material substitution when one uses increased osmolality, by using sodium chloride and other also other additives. To know if a new and recyclable foil could be used in future updated packaging, test runs in the manufacturing packaging machine must be made. The performance of peel seals made with the production welding tools will show if the sachets could be made with the recyclable foil. Furthermore, an evaluation regarding the economic incentive should be performed for the purpose of confirming if a change in material is financially sustainable.

8. References:

[1] Nordic Council of Ministers. *Nordic criteria for More Sustainable Packaging*. March 2022 <https://www.regioner.dk/media/21537/nordic-criteria-for-more-sustainable-packaging-in-healthcare.pdf>

[2] [New EU rules to reduce, reuse and recycle packaging | News | European Parliament \(europa.eu\)](#)

Cairns, C. N. “E-Waste and the Consumer: Improving Options to Reduce, Reuse and Recycle.” Proceedings of the 2005 IEEE International Symposium on Electronics and the Environment, 2005., IEEE, 2005, pp. 237–42. DOI.org (Crossref), <https://doi.org/10.1109/ISEE.2005.1437033>.

[3] [Mechanical and chemical recycling of solid plastic waste \(sciencedirectassets.com\)](#)

Ragaert, Kim, et al. “Mechanical and Chemical Recycling of Solid Plastic Waste.” Waste Management, vol. 69, Nov. 2017, pp. 24–58. DOI.org (Crossref), <https://doi.org/10.1016/j.wasman.2017.07.044>.

[4] [Determination of the water vapor transmission rate of cellulose-based papers by multiple headspace extraction analysis \(sciencedirectassets.com\)](#)

Dai, Yi, et al. “Determination of the Water Vapor Transmission Rate of Cellulose-Based Papers by Multiple Headspace Extraction Analysis.” *Journal of Chromatography A*, vol. 1710, Nov. 2023, p. 464404. DOI.org (Crossref), <https://doi.org/10.1016/j.chroma.2023.464404>.

[5] Ethide Laboratories. “What is Electron Beam Sterilization?” Ethide Labs, [Ethide Laboratories - What is electron beam sterilization? \(ethidelabs.com\)](#) Accessed 13 April 2024

[6] Harrington, Roger E., et al. “3.1.4 - Sterilization and Disinfection of Biomaterials for Medical Devices.” Biomaterials Science (Fourth Edition), edited by William R. Wagner et al., Academic Press, 2020, pp. 1431–46. ScienceDirect, <https://doi.org/10.1016/B978-0-12-816137-1.00091-X>.

[7] “Radiation Exposure and Contamination - Injuries; Poisoning.” Merck Manual Professional Edition, <https://www.merckmanuals.com/professional/injuries-poisoning/radiation-exposure-and-contamination/radiation-exposure-and-contamination>. Accessed 19 May 2024. [Radiation Exposure and Contamination - Injuries; Poisoning - Merck Manual Professional Edition \(merckmanuals.com\)](https://www.merckmanuals.com/professional/injuries-poisoning/radiation-exposure-and-contamination/radiation-exposure-and-contamination)

[8] Sumitomo Electric Industries, Ltd. “Development of Long-length High Temperature Superconducting Power Cables.” SEI Technical Review, no. 75, October 2012 [Electron beam Processing System and Its Application \(global-sei.com\)](https://www.global-sei.com/en/technical-review/75-10-2012)

[9] Svoboda, Petr, et al. “Study of Crystallization Behaviour of Electron Beam Irradiated Polypropylene and High-Density Polyethylene.” Royal Society Open Science, vol. 8, no. 3, Mar. 2021, p. rsos.202250, 202250. DOI.org (Crossref), <https://doi.org/10.1098/rsos.202250>

[10] Wellspect Healthcare. “Lofric Primo.” [LoFric Primo - Wellspect](https://www.wellspect.com/lofric-primo)

[11] Kelechava, Brad. “ASTM E96: Explaining Water Vapor Transmission Rate Testing - ANSI Blog.” The ANSI Blog, 2 Feb. 2022, <https://blog.ansi.org/explaining-water-vapor-testing-astm-e96/>. [ASTM E96: Water Vapor Testing Explained \[Video\] - ANSI Blog](https://www.youtube.com/watch?v=Kj8qKj8qKj8)

[12] ASTM International. “ASTM F1249-20: Standard Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor.” iTeh Standards Store, [ASTM F1249-20 - ASTM F1249-20 \(itih.ai\)](https://www.itih.ai/astm-f1249-20)

[13] Tensile Testing: Machine and Tester.” Tensile Testing: Machine and Tester, <https://www.zwickroell.com/products/static-materials-testing-machines/universal-testing-machines-for-static-applications/tensile-tester/>. Accessed 5 May 2024. [Tensile Testing: Machine and Tester | ZwickRoell](https://www.zwickroell.com/products/static-materials-testing-machines/universal-testing-machines-for-static-applications/tensile-tester/)

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