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PLA for Drug Delivery Devices

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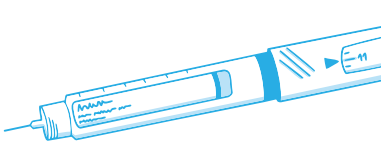


PLA for Drug Delivery Devices

Abstract. *As the healthcare sector faces growing pressure to eliminate critical substances and reduce carbon emissions, a paradigm shift in material choice is inevitable: In this short paper, we'll explore PLA –a biobased polymer– as a flexible material solution for drug delivery devices. Topics addressed in this paper are its suitability, the relevant regulatory environment for materials in the field of drug deliver and the transition to a circular economy for autoinjectors. In this regard we will shed light on common myths around PLAs recyclability.*

1. Why Healthcare Plastics Must Evolve

Various external factors influence the choice of materials in drug delivery devices: patient safety, climate goals and substance regulations, to name a few. Marketing Authorization Holders (MAH) need to re-think the material contents of their devices. Cur-

rently used plastics will not meet the demands of the future. Four main drivers can be identified:

1.1. Market demand

The healthcare market demands reasonably priced products. That much is certain. Aside from patient safety and performance, ensuring a safe supply of healthcare products is of the utmost importance, and this is becoming increasingly difficult as the phase-out of raw materials requires frequent product recertification. Therefore, material risks must be mitigated by using long-term, stable raw materials that do not contain critical precursors or ingredients. Another dynamic in the market is new compared to the aforementioned: Sustainability. When it comes to products where patients are involved in the decision-making process, such as autoinjectors and powder inhalators, having the more environmentally friendly product gives you an advantage over the competition. Medical professionals are increasingly considering this when making purchases, as are procurement teams in clinics.

1.2. Patient Safety

First on the list is the need to eliminate the use of substances that harm human health. While it may seem self-evident, the healthcare sector has a fundamental responsibility to prioritize patient safety, liabilities are tied to that. This includes eliminating critical substances such

as Bisphenol A in Polycarbonates (PC) or styrene in ABS, both commonly used in drug delivery devices. Or Phthalates such as DEHP, used as a plasticizer in PVC which we commonly find in infusion kits and similar products. And, in some applications, PFAS, be it as high performance polymer part, or as part of a processability optimized polyethylene formulation. Critical substances like these can cause a range of health issues: endocrine disruptors like BPA or DEHP cause cause hormonal imbalances, e.g. regarding reproductive health. Emerging research indicates that micro- and nanoplastics, where ultra-persistent materials contribute to the problem, can cross the blood-brain barrier, potentially contributing to neurodegenerative diseases such as Alzheimer's[1].

1.3. Upcoming Regulations

The threat posed by critical substances is increasingly being addressed through legislation. Examples include limitations of chemical substance marketing access due to the REACH regulation. Novo Nordisk, Sanofi, Merck and Eli Lilly already recycle insulin pens together in Denmark in the Returpen initiative, while RECYPEN (Sanofi, Eli Lilly, Dastri) does pretty much the same in France, for example. This sure is innovatve, but in the end these companies follow what the regulatory trajectory in the EU points out: A strong push towards a circular economy utilizing recycled material content in all sorts of new products as pushed be the EU (including the Packaging and Packaging

Waste Regulation PPWR) or the European Climate Law restricting the carbon emissions. Besides that, the PFAS ban already entered into forcce in Minnesota – while ECHA proposed a similar, EU-wide restriction. All these initiatives, and many more, are pushing all industries—including healthcare—towards circularity and lower carbon emissions.

1.4. Planetary Health

There is no human health without planetary health. The effects of environmental degradation manifest directly in public health, including increased mortality during prolonged heatwaves, respiratory issues caused by air pollution, health risks associated with toxic or persistent substances in soil and drinking water [2,3] making climate change the single greatest environmental threat to human health [4]. Moreover, endocrine-disrupting chemicals not only affect human health but also disrupt aquatic ecosystems, impacting wildlife reproduction [5]. Of course, climate change also lets ecosystems collapse, endangering biodiversity greatly. A trustworthy healthcare sector cannot afford to ignore the irreversible environmental damage that ultimately undermines the very health we aim to protect.

2. Exploring PLA as a Solution

Chapter 1 shows: Devices in pharmaceutical applications need materials that truly address the market needs, planetary health, patient safety, and upcoming

regulations. Otherwise, market access is at risk. All that must be considered while long-term formulation consistency, supply chain security and quality control, as defined in the VDI 2017, is ensured. A small range of bioplastics offer the potential to meet the future requirements discussed in the previous section. We want to focus on PLA here, because in our opinion, it has the best balance of technical performance, ergonomical benefits, environmental footprint including various best-in-class end-of-life options and costs. With its recyclability, biocompatibility and a low carbon footprint, PLA is indeed a future-proof solution, and in this chapter we will explain why in more detail.

2.1. Product Performance in Drug Delivery Devices

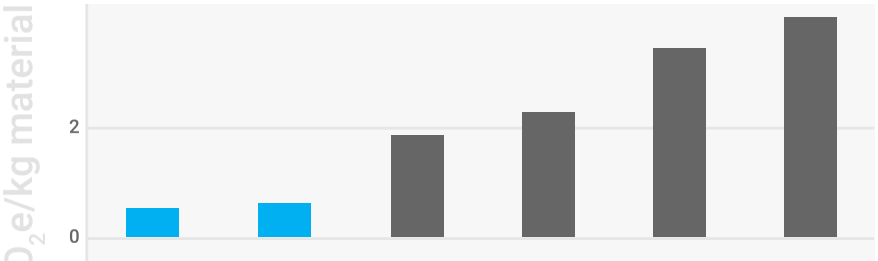
In particular the PLA-based BIOVOX MedEco ICB and BIOVOX MedEco IGH offer properties that are perfectly suited to the autoinjectors and inhalers of the future. Their high mechanical strength and stiffness ensure durable, reliable and material-efficient designs that reduce the use of plastics without compromising device integrity. Both MedEco grades have higher stiffness than PC or ABS and are easy-flowing, enabling thinner parts that reduce cycle times, save material, lower costs and environmental impact. Low processing temperatures - approximately 50°C lower than ABS and 100°C lower than PC - also save energy. [See page 11 for full datasheet] All grades feature low shrinkage, high surface hardness and detail

reproduction enable the production of highly precise components, which are critical for consistent performance of drug delivery devices. BIOVOX MedEco ICB also offers very good crystal-clear transparency up to 1.5 mm wall thickness, making it ideal for components that require visual control of the drug or the dialed-in dose. If you need excellent transparency also at high wall thicknesses, MedEco ICB C1 with lower crystallization tendencies is a suitable choice.

The haptics of the material further enhance perceived quality. Particularly, BIOVOX MedEco IGH offers a very premium tactile feel plus excellent grip with vinyl and nitrile gloves, both wet and dry, and a premium experience when patients handle autoinjectors directly —clearly outperforming the waxy feel of conventional polypropylene.

2.3. Environmental Aspects

PLA requires minimal energy to produce the polymer, with a cradle-to-gate footprint of only about 0.6 kg CO_2e per kg of BIOVOX MedEco ICB. The materials are fossil-free, which also reduces dependence on fossil resources from politically critical regions. [Figure 1] This means up to 85% lower carbon emissions, including the currently most common incineration at the end of their life, compared to materials like fossil based virign PP, ABS or PC. Recycling and circular economy are a broader topic that we look at in the following chapter.



	MedEco ICB	MedEco IGH	HDPE	PP	PC	ABS
Sum	2,43	2,27	5,04	5,42	6,17	7,25
Incineration	1,83	1,54	3,14	3,14	2,77	3,13
Cradle-to-Gate	0,60	0,73	1,90	2,28	3,40	4,12

BIOVOX MedEco | Conventional Plastics

Figure 1: Carbon footprints of plastics used in drug delivery devices
(Updated data with further reduced CO_2 values will be available soon – contact us!)

3. End-of-Life & Recycling Myths

PLA is one of the most versatile polymers when it comes to disposal. It performs very well in all end-of-life scenarios compared to the currently used polymers in drug delivery devices, making it resilient against regulation dealing with the end of the product life cycle.

3.1. Incineration

With 100% bio-based carbon, today's standard End-of-Life for medical devices — incineration — is climate neutral. The CO2 emitted has already been captured during the growth of the feedstock plants from which the polymer is made, closing the carbon cycle over one growth period, usually one year instead of millions of years as with fossil carbon.

3.2. Deposition

Fortunately, the depositing of waste is on the decline. Nevertheless, there are markets where this is still a relevant disposal scenario. PLA does not release harmful substances, and even if it gets carried out of a landfill, it is biodegradable. Biodegradation can be quite slow in uncontrolled conditions, the main factor here is hydrolysis in water. Microparticles are broken down down quicker than with non-degradable plastics [6] such as the polymers used today – not releasing toxins and being biocompatible, minimizing the impact of microplastics compared to ABS, PC or PP.

3.3. Mechanical Recycling

Recycling, already being set up e.g. in Denmark and France for insulin auto-injectors, is a necessity to achieve circular economy in healthcare. It further reduces the consumption of energy and raw materials, thereby reducing carbon emissions. PLA has faced several misconceptions in the past regarding recycling. First, that "PLA cannot be recycled." and second, that "PLA disrupts recycling flows". Both are misleading. Facts are that PLA is recyclable using existing industrial processes. Post-industrial PLA is already being mechanically recycled, and while post-consumer recycling remains limited due to low volumes, this will change as PLA usage grows. PLA also does not disrupt recycling systems, as it can be reliably identified via near-infrared (NIR) sorting and separated without issue. Like other materials, cross-contamination is part of any recycling process. This means that PLA is no more and no less problematic than conventional polymers.[7]

3.4. Chemical Monomer Recyling

PLA is not chemically recycled in pyrolysis processes, as for example polyolefins are. Being a Polyester, depolymerization is performed through hydrolysis – with catalytic or enzymatic assistance or just by hot steam or acids, depending on the technology. Depolymerization produces Lactide as the monomer of PLA and is much more efficient compared to pyrolysis that produces a wide variety of resulting

hydrocarbons that require refining/steam cracking afterwards. With chemical recycling, PLA delivers full performance and safety at just half the footprint compared to virgin PLA — thanks to >90% polymer yield and ~50% lower energy use [see page 11 for full recycling factsheet] — significantly outperforming conventional materials, but also PP and ABS and making PLA an ideal material to future-proof drug delivery devices.

4. What about the costs?

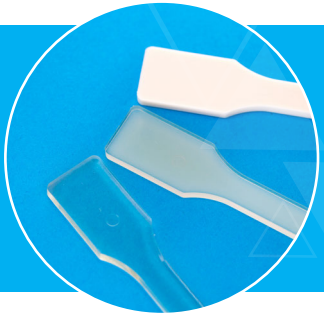
Even though some perceive PLA as an expensive niche polymer, the facts tell a different story: In most of our projects, we observe only a minor 5-10% increase in parts cost while reducing the carbon footprint by 60-85% and eliminating regulatory risks due to critical substances such as BPA and others. Having mitigated several health- and market access risks while contributing to the MAH's ESG ratings and gaining marketing opportunities is a very good investment in our eyes.

5. In a Nutshell

The need for change comes from different sources/reasons like patient safety, the markets pharmaceutical companies operate in and Planetary Health, but also a lot of new legislation. Those who wait too long to change might stay behind and risk their market access in progressive countries. New solutions have to be found and bioplastics in Medical Grade quality are a suitable option. By implementing sustainable

materials such as BIOVOX MedEco ICB or IGH, manufacturers can future-proof their products and stay ahead of the competition. With EU regulations driving sustainability and the industry already moving towards circularity, now is the time to innovate.

Find out more about BIOVOX MedEco and take a look at the factsheets referenced in the text for further information:



BIOVOX MedEco Datasheet ICB

BIOVOX MedEco Datasheet IGH

BIOVOX MedEco Recycling

Further questions? Contact us!

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–THE END–

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Future-Proof Plastics for Healthcare

WHO WE ARE

At BIOVOX, we are a team of experts for renewable plastics for healthcare with great expertise for biobased materials and recycling.

WHAT WE DO

With our MedEco series, we offer a range of high-quality plastics for MedTech, pharma & lab applications. Rigid, durable, soft or transparent? We find the perfect solution for your individual application!

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