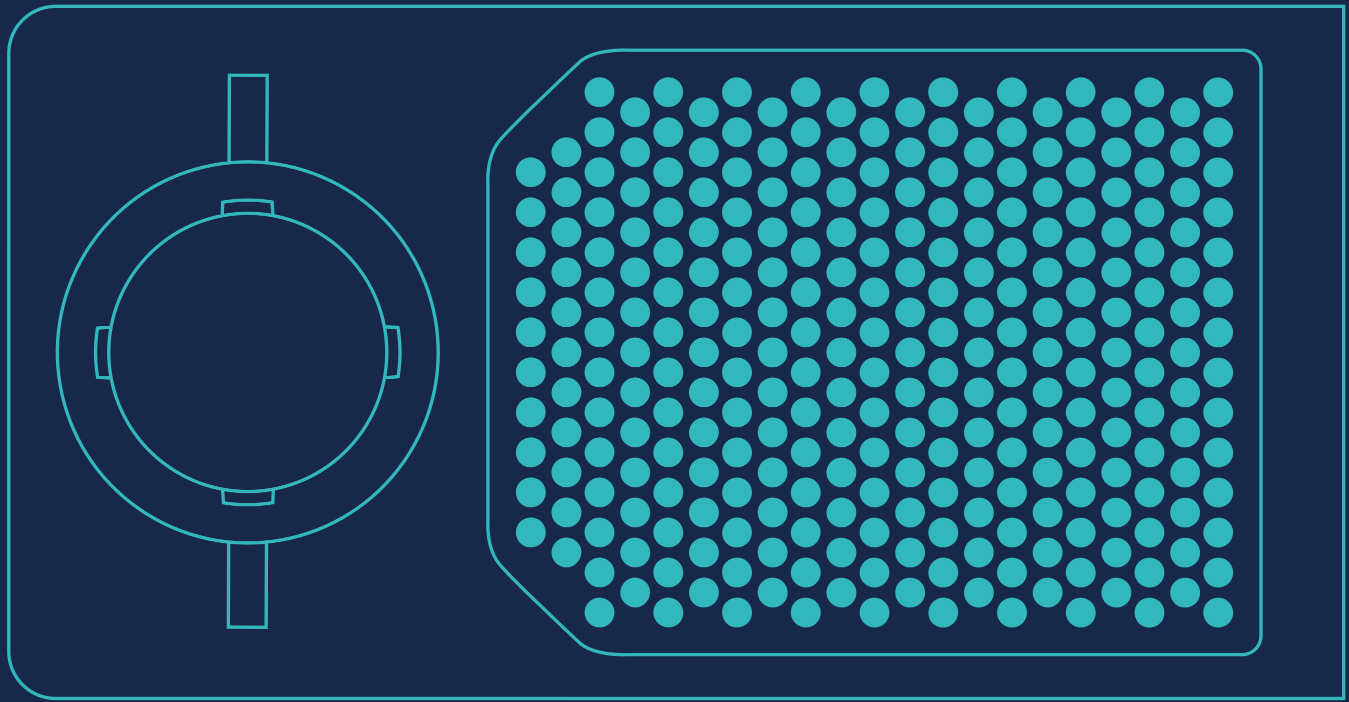


Product Environmental Profile

DPTE-BetaBag® Tyvek 25L

Overview

Getinge sustainability ambitions

Getinge takes steps to empower our customers to reach their sustainability goals. One way to do this is by looking at how we can make our products and solutions as resource efficient as possible. Getinge is committed to reduce their own carbon footprint by setting ambitious targets to become net-zero by 2050 in line with the Science based targets initiative (SBTi).

All manufacturing sites work with Environmental management systems in compliance with ISO 14001.

Read more about Getinge sustainability ambitions on our website here.

Ecodesign efforts

Ecodesign is standard practice at Getinge, focusing on using safer and fewer materials, incorporating circular solutions, and reducing media, energy, and water consumption.

This product is designed and manufactured by Getinge Life Science France, which aims to quickly bring lower-impact products to market using biobased and circularraw materials through a mass balance approach. The new Polycarbonate (PC) Re, which replaces the current/previous Polycarbonate, uses both circular (from waste) and biobased (from biomass) feedstock to reduce the value chain's climate impact.

The main Cradle to grave results are representative for the EU market and indicative only for other markets.

Product climate impact

↓13%

Product description

The DPTE-BetaBag® 190 Tyvek 25L is delivered by the manufacturing unit Getinge Life Science France (GLSF) to rubber components manufacturers, which use the product to steam sterilize their components (Stoppers, plungers, ...). Component manufacturers deliver the filled DPTE-BetaBag® 190 Tyvek 25L to the Pharma industry for transferring the rubber components from the DPTEBetaBag® 190 Tyvek 25L to the isolators (a filling line) in an aseptic way, without any contamination (from external area of isolator).

Technical specification

Useful volume	25 L
Bag size (mm)	1,045 x 420
Alpha Port	190
Shelf life	18 months

Applicable directives and standards compliance for the product

FDA 21 CFR 177.1520 regulation	HDPE film; Tyvek® film
FDA 21 CFR 177.2600 regulation	Lipseal (Silicone)
Biocompatibility USP <88> Class VI	HDPE film ; Tyvek® film; Lipseal (Silicone); Flange; Door; Clamp collar
BSE/TSE: EMEA 410/01 compliant	
Ph. Eur. 3.1.5	HDPE film
BSE/TSE: EU N°722/2012 compliant	Tyvek® film
BSE/TSE: the material contains no substances of animal origin	Flange, Door, Clamp collar
	Lipseal (Silicone)

Main assumptions of the LCA study (LCI parameters)

The Life Cycle Assessment (LCA) results are calculated for one unit of DPTE-BetaBag® Tyvek 25L. A reference is made to a previous model with an alternative feedstock for the Polycarbonate raw material but identical technical specifications and performance.

The product is designed and manufactured by Getinge Life Science France. The composition is derived from the BOM and all raw material are modeled with specific data for the material flows and processes used for manufacturing and supply of parts. Regional approach has been used for choice of energy, transport, and raw material datasets, as well as the outbound transport, use scenario and end-of-life.

In this study all transport have been modelled as road transport, all packaging is recycled, and all product material is assumed to be incinerated after use. Emissions from incineration of materials are allocated to the materials and no benefits of energy recovery are included. More information on the scope of study in the appendix.

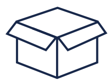
Product

Total weight (net): 1,033 kg

Packaging

Total weight (gross): 1,247 kg

Impact category indicator



1,033 kg
Total mass of
the product (net)

0,214kg
Total mass of
the packaging

Recyclability

Recycled materials

The following materials are considered recyclable: Steel, Alu, Bronze, Brass, Copper (except cables), Cardboard, Paper, Thermoplastics (PMMA, PVC, ABS, PC, PS, PET, PE, PA, PP, POM). Thermosetting plastics, elastomers and other materials not listed are considered non recyclable. Recycled content evaluated in the study but requires documented trail in the value chain.

The effect of changing the feedstock for the polycarbonate raw material, from PC to PC Re, is 13.2 – 11.4 = 1.8 kg CO_2eq over the whole life cycle of the DBTE Betabag, which represents 13.3% reduction.

Note that the PC Re includes polycarbonate material where the feedstock partly comes from biogenic rest products. The biogenic carbon is assumed to be neutral over the life cycle of the material. The biogenic carbon uptake of the biomass has therefore not been included in the data for the raw material (cradle to gate results) and the biogenic emissions from incinerating the polycarbonate material are not either accounted in the end-of-life. The difference between the product models over the full life cycle is therefore mainly in lower fossil resource use and climate impact from fossil emissions from the incineration of the product.

Note also that in the Getinge manufacturing impact energy use for the cleanroom at the GLSF site is included (1 kg CO_2eq). Note though that the energy use at GLSF site is modelled conservatively with fossil natural gas and regular grid electricity in the study but is in fact sourced as renewable with guarantees of origin. The study additionally evaluated the impact of alternative transport mode for delivery, the choice of surrounding packaging for transport from component manufacturer to users as well as end-of-life treatment for the product and packaging.

Recommendations to reduce the Climate impact

Recommendations to customers and end-users to further reduce the Climate impact of their sterile transfer activities:

- Solutions for surrounding packaging and recycling
- Recycling of the product

Climate impact of alternative transport and packaging solutions

↓12%

Recycled plastic materials

The potential of reduced impact by enabling recycling of plastic materials (HDPE, Polycarbonate) is significant (up to 12% reduced disposal emission). Additionally, there is an indirect benefit of enabling recycling by making recycled material available for the market, possibly decreasing the need for virgin/ fossil feedstock.

↑5%

Cardboard transport box

The climate impact for a transport box in cardboard, as Getinge recommendations are, weighing ~400 g, assuming single use and incineration of the box is 0.6 kg CO_2eq, adding that to the product life cycle of PC Re increases the impact by 5%. Recycling the box after use would decrease this additional impact significantly.

↑28%

Polypropylene transport box

The climate impact for a transport box in PP, weighing ~600 g, assuming single use and incineration of the box is 3.16 kg CO_2eq, adding that to the product life cycle of PC Re increases the impact by 28%. Recycling the box after use would decrease this additional impact significantly.

↑30%

Airfreight transport

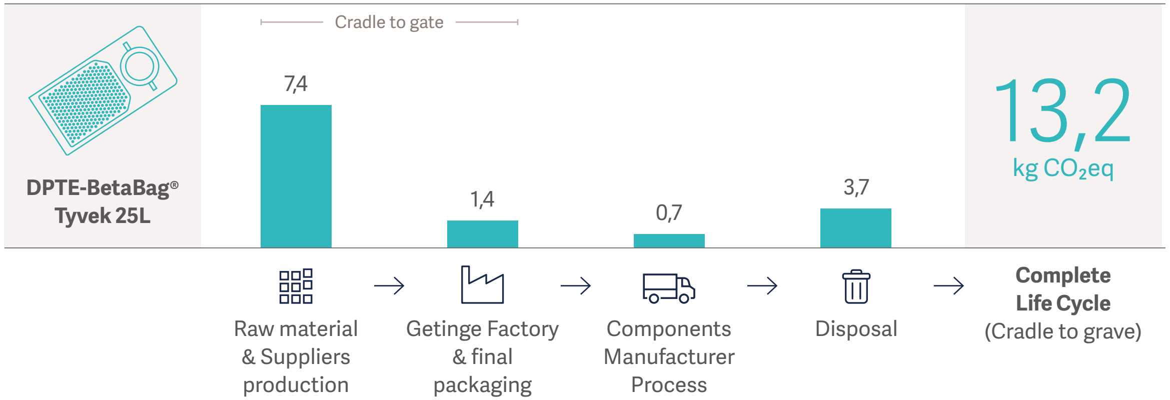
Intercontinental transport by airfreight to component manufacturers or from component manufacturer to end user, which represents the worst-case scenario for transport is estimated to increase the transport impact by about factor 10, from 0.38 to 3.8 kg CO_2eq, making it a the second most significant activity contribution, and increasing the total impact by 30%.

Product environmental impact with focus on Climate impact

The cradle to gate results are representative for all products delivered from GLSF. The main Cradle to grave results are representative for the EU market and indicative only for other markets. This as the results are sensitive to key parameters that are within the customer and end-user control and dependent on their geographical location such as choice of transportation mode and distances and waste handling of product and packaging.

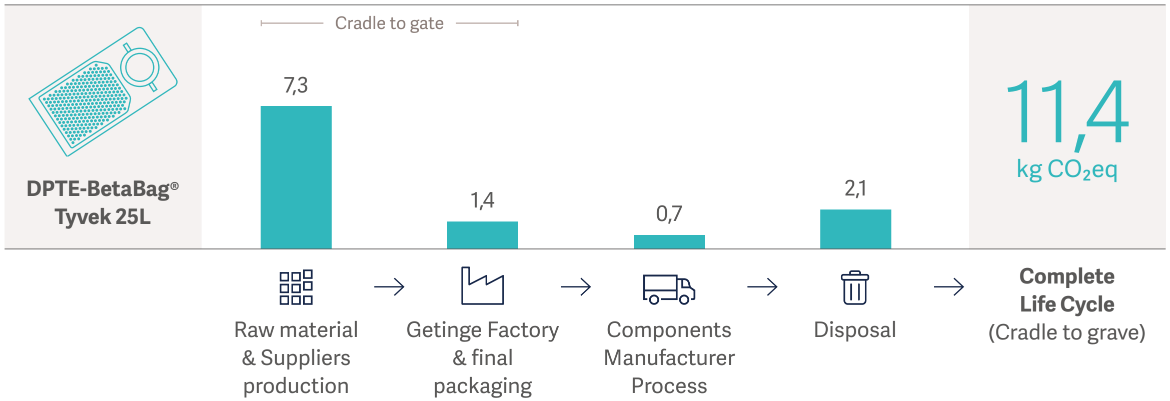
Global warming Potential (GWP100a)
kg CO_2eq

Previous version



↓1,8
kg CO_2eq

New version



The LCA and Ecodesign methods

Product Environmental Profile (PEP) communicates the results of a Life Cycle Assessment (LCA). This is a methodology for assessing environmental impacts associated with all the stages of the life cycle of a product, process, or service. I.e. for a product environmental impacts are assessed for the raw material extraction (cradle) followed by the whole value-chain further processing, through the product's manufacturing (gate), distribution and use, to the recycling or final disposal of the materials it is composed of.

The LCA study follows requirements in ISO 14040 and ISO 14044 and has been 3rd party verified by AFRY. The SimaPro software version 9.5.0.1 and the EcoInvent 3.9.1 allocation, cut-off by classification has been used. Environmental impact has been calculated with the "CML-IA baseline V3.09 / EU25" method as implemented in SimaPro with minor adjustments. All LCA studies include holistic analysis of all relevant environmental impacts used for eco-design input. Further details can be available upon request, contact responsible PLM/R&D team.

GETINGE

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 12,000 people worldwide and the products are sold in more than 135 countries.

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