Biosafe® 200 Rapid Transfer Port and Beta-Bags

Simplifying Progress

Sustainability Fact Sheet

SARTORIUS

Overview

The Biosafe® 200 is a Rapid Aseptic Transfer solution featuring a 200mm useful diameter port for installation on isolator panels at Drug Product sites. It enables the aseptic transfer of stoppers and filling repartition bags (Octoplus FF® Rapid Aseptic Fluid Transfer (RAFT), Flexsafe® 2D Advanced RAFT, Transfer set RAFT).

It can also be used at Drug Substance sites for Modular Facility 4.0 to allow an aseptic zone-to-zone transfer between two clean rooms of different classifications, reducing the manufacturing footprint.

Designed to comply with Annex 1 regulations, the Biosafe® 200 mm ensures high cleanliness and alpha-beta compatibility. The Biosafe® 200 meets Contamination Control Strategy requirements by reducing the risk of particle creation through the use of a magnetic technology using pin mechanism opening (without rotation) and by design, protecting the ring of concern. The external opening of the alpha-port meets the requirements for reducing human intervention in critical areas. Additionally, its compact and ergonomic design, featuring a 90° lever, facilitates easy integration.

This fact sheet presents the current sustainability status of Biosafe® 200 Rapid Transfer Port and Beta-Bags. It highlights our commitment to enhancing the sustainability of our products, with continuous improvements being made over time.

Life Cycle Thinking

At Sartorius, we are committed to sustainability and are actively seeking innovative ways to reduce the ecological footprint of our products.

Adopting life cycle thinking is key to enhancing sustainability and considering the environmental impacts from raw materials to end-of-life disposal. We are dedicated to refining our production methods, boosting efficiency, minimizing waste. We also consider the environmental toll of shipping practices and are committed to optimizing logistics to reduce carbon emissions.

Our ongoing research into materials and designs aims to lessen environmental impact and enhance the recyclability of our products. Guided by Product Carbon Footprint (PCF) screenings, we gain valuable insights that drive the development of more sustainable products and deepen our understanding of their ecological footprints.

Integrating life cycle thinking into our operations not only supports the sustainability of our products but also enables our customers to make environmentally conscious decisions with confidence.

Environmental Overview

Material Selection
All materials of construction are selected with care. The polymers used in plastic components and support materials, along with packaging materials like cardboard, are of high quality and largely recyclable.

Raw Material Acquisition
Raw and support materials are supplied from sources close to the manufacturing site, minimizing transportation emissions and supporting local economies. Remarkably, 90% of our hardware components are procured from suppliers within a 500 km radius of our plant, significantly reducing transportation-related impacts.

Material Processing
Bags and other components are manufactured on modern equipment in efficient processes that take material, energy and water consumption into account.

Certification
The production site for Biosafe® 200 Rapid Transfer Port and Beta-Bags is located in Lourdes, France and uses certified green electricity, significantly reducing our carbon footprint and promoting the use of renewable energy.

Distribution
The production and distribution of the ports and containers are managed with logistics solutions allowing for minimized impacts linked to transport to the final customers.

Product

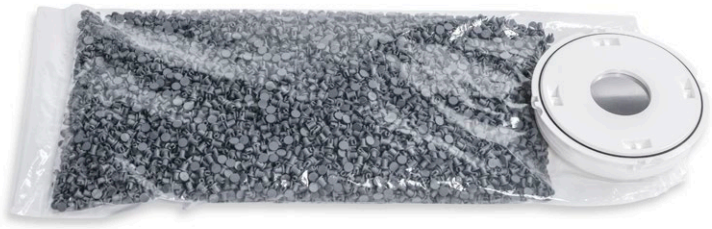
	α-Port	β-Bag	
		Bag	Assembled Connector
Recyclability	99%	100%	7%
Recycled Content	38%	-	4%

The recyclability of the Biosafe® 200 Rapid Transfer Port stands at 99%, and contains 38% recycled material, reflecting our commitment to sustainability and environmental responsibility.

Additionally, the bag films used in the gamma bag version (made of PE/EVOH/PE) and the steam version (made of Tyvek/HDPE) are both 100% recyclable. The film can be separated from the connector by simply cutting it.

Recyclability is defined as the characteristic of products that retain useful physical or chemical properties after serving their original purpose. Once these products are separated and sent to recycling, they can be reintroduced into manufacturing as raw materials[1]. In this context, we refer to the technical recyclability of a material or component, meaning that technological solutions exist to recycle them, either mechanically or through advanced recycling methods.

Recycled content refers to the percentage of recycled material in relation to the total mass of the product.[2]



Elements of the α-Port : Options at the End-Of-Life

Component	Material	Recyclable
Metallic components	SS, Al	Yes
Multi-material components	SS, PET	No
Seal	Sil	No
O-rings	EPDM	No
Sleeve	PEEK	No

Elements of the β-Bag: Options at the End-Of-Life

Component	Material	Recyclable
Pin	SS	Yes
Connector	SS, PBT, HDPE	No*
Gasket	Sil	No
Blister	PC	Yes
Bag	PE film	Yes

Al = Aluminum, EPDM = Ethylene Propylene Diene Elastomer, HDPE = High Density Polyethy, PBT = Polybutylene terephthalate, PC = Polycarbonate, PE = Polyethylene, PEEK = Polyether ether ketone, PET = Polyethylene terephthalate, Sil (Pt) = Platinum Cured Silicone, SS = Stainless Steel

Definitions: [1]Based on European Environmental Agency GEMET – Environmental thesaurus
[2]Only recycled post-industrial and recycled post-consumer materials shall be considered as recycled content. The numbers provided herein are the best available approximations.

Disclaimer
The recyclability of the product may be influenced by its use, such as the presence or absence of agents defined as hazardous, as well as local regulations and the capabilities of local companies to manage those materials. Data refers to one Biosafe® 200 Rapid Transfer Port and beta-bag.

*Connector materials are recyclable but parts need to be disassembled

Packaging

	α-Port	β-Bag
Recyclability	100%	100%
Renewable Content	84%	56%
Recycled Content	23%	14%

Recyclability[1]
Characteristic of products that still have useful physical or chemical properties after serving their original purpose and, after being separated and sent to recycling, can be reintroduced into manufacturing as raw materials.

We refer here as technical recyclability of a material | component | packaging material if technological solutions exist to recycle them (mechanically or via advanced recycling).

Renewable Content[2]
Materials that are derived from resources that are quickly replenished by ecological cycles or agricultural processes, so that the services provided by these and other linked resources are not endangered and remain available for the next generation. In our product packaging, we refer specifically to cardboard and paper.

Recycled Content[3]
Percentage of recycled material in relation to the total mass of the packaging.

Elements of the Primary and Secondary Packaging of the α-Port: Options at the End-Of-Life

Category	Packaging Element	Material	Recyclable
Plastics	Foam	PE	Yes
Paper and Cardboard	Box	Cardboard	Yes

Elements of the Primary and Secondary Packaging of the β-Bag: Options at the End-Of-Life

Category	Packaging Element	Material	Recyclable
Plastics	Overpouches	LDPE	Yes
	Bubble foil	HDPE	Yes
Paper and Cardboard	Box	Cardboard	Yes
	Labels	Paper	Yes

PE = Polyethylene, HDPE = High Density Polyethylene, LDPE = Low Density Polyethylene

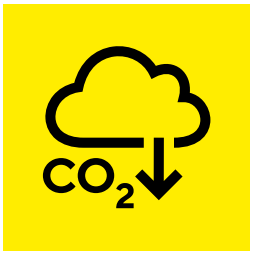
Definitions: [1]Based on European Environmental Agency GEMET – Environmental thesaurus | [2]Corporate Sustainability Reporting Directive (CSRD) | [3]Only recycled post-industrial and recycled post-consumer materials shall be considered as recycled content. The numbers provided herein are the best available approximations.

Disclaimer
The recyclability of the packaging may be influenced by local regulations as well as the capabilities of local companies to manage those materials. Data refers to one Biosafe® 200 Rapid Transfer Port and Beta-Bag

Sustainability at Sartorius

Sartorius is dedicated to shaping a future where improved medicine is more accessible to many. Concurrently, we acknowledge and address the impacts of our operations globally.

Taking into account the concerns of its stakeholders, Sartorius has defined six strategic sustainability topics:



Climate Action

Resources and Circularity

Water and Effluents

Supply Chains

Social Responsibility

Corporate Governance

For further information, visit
sartorius.com/en/company/sustainability

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