Celsius® FFT | FFTp with Safecore™ Technology

Simplifying Progress

Sustainability Fact Sheet

SARTORIUS

Overview

Building on more than 20 years of experience in designing single-use solutions, we have developed the bioprocessing solutions with their adapted quality control levels able to support drug handling and transportation steps in frozen state. Discover our product range for cold chain management with Celsius® bags for frozen storage and shipping of bulk drug substance from 30 mL to 75 L.

This fact sheet presents the current sustainability status of Celsius® FFT | FFTp single-use containers, using the 12 L and 2 L versions as examples. 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 sites where feasible.
Bag manufacturing and final assembly are performed in two close countries* in order to reduce the environmental impact of internal transport.

Material Processing
Bags, tubes and other components are manufactured on modern equipment in efficient processes that take material, energy and water consumption into account. Additionally, laser etching is used to brand shells, reducing wastage from misprinting with ink.

At the French production site, plastic scraps are sent to external recycling, and renewable energy is used to manufacture the bag.

Certification
The production sites for Celsius® FFT | FFTp containers in Aubagne, France and M'Hamdia, Tunisia, are ISO 14001 certified. The environmental management system enables our organization to improve the environmental performance, meet legal and other obligations, and achieve environmental objectives.

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

Partnership with Envirotainer for Frozen Shipment
Sartorius and Envirotainer have partnered to develop and qualify new solutions for the transport of frozen pharmaceutical substances, combining industry-leading expertise in biopharmaceuticals and temperaturecontrolled packaging.

Together, we developed a solution to optimize and secure the Celsius® FFT/FFTp Bulk Shipper with ProofTainer, Envirotainer's advanced passive solution available through their global leasing offering.

ProofTainer integrates vacuum insulation panels (VIPs) and phase change materials (PCMs) to deliver stable internal temperatures for over 120 hours, even at conditions as low as -50°C—without relying on dry ice. This eliminates the operational complexity and safety risks associated with dry ice handling, while ensuring product integrity throughout the journey.

As part of Envirotainer's leasing model, ProofTainer supports a circular logistics approach, its light weighted and significantly lower CO_2 emissions across the supply chain. This solution empowers our customers to meet sustainability targets without compromising on performance or reliability.

Celsius® FFT | FFTp Bulk Shipper

*Majority of production occurs in Aubagne, France and M'Hamdia Tunisia. However, there is an additional production site in Beijing, China serving the local market.

Product

	FFT		FFTp	
	12 L	2 L	12 L	2 L
Recyclability	90%	82%	91%	78%

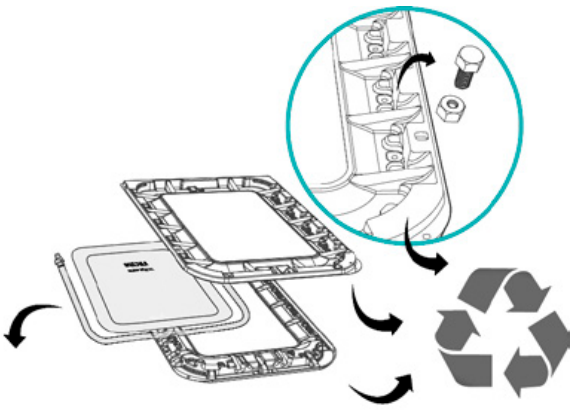
The recyclability of all versions considered starts at a solid 78%, with the FFTp 12 L model achieving an exceptional 91%. This reflects our strong commitment to sustainability and environmental responsibility.

In order to improve the recyclability of the Safecore™ plates used in Celsius® FFT | FFTp, we have removed hot-stamp branding of the containers and implemented the laseretching of HDPE shell. Laser etching prevents the waste of misprinted material that occurs with hot-stamping and does not impact the recyclability of the HDPE shells.This demonstrates our commitment to reduce waste in manufacturing as well as improving the recyclability of our product.

The Celsius® FFT | FFTp portfolio is designed to facilitate and ecourage the recycling and responsible disposal of the used containers. For post-use disposal Sartorius encourages the following:

1. Before disassembling the shell, be sure that the CelsiusFFT/FFTp Container is fully drained

2. After draining, the bag and its polyester plates assembled together have to be removed from the shells. To remove the shells, remove the screws and nuts with standard M10 socket wrenches.



3. Once the shells are removed, put on safety glasses and protective gloves and cut the snap button using a cutting tool (e.g. pneumatic scissors, sheet metal cutter), cutting parallel to the bag edges in order to prevent cutting the bag.

4. Disassemble the bag from the polyester plates and set the bag aside for testing or discard according to your internal procedure.

5. The protective shell as well as the label placard are made of polyethylene and can be recycled after disassembly.

6. The plates as well as the sample bag cover are made of polyester and can be recycled after disassembly

Elements of the Product: Options at the End-Of-Life

Component	Material	Recyclable
Plates	PET	Yes
Shells	HDPE	Yes
Bag chamber and tube	EVA	Yes
Tubes	TPE	No
Mono-material fluid contact component (i.e. elbow, press in plug)	PP	Yes
Multi-material fluid contact components (i.e. coupling, sealing cap)	PC/Sil	No
Non-fluid contact components (i.e. screws, cable ties, nuts)	PUR, PA	No
Non-fluid contact components such as clamps	PBT	Yes

EVA = Ethylene vinyl acetate, PA = Polyamide, PBT = Polybutylene terephthalate, PC = Polycarbonate, PET = Polyethylene terephthalate, PP = Polypropylene, PU/PUR = Polyurethane, Sil = Silicone, TPE = Thermoplastic elastomer, HDPE = High Density Polyethylene

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 Celsius® FFT | FFTp 12 L and 2 L.

Packaging

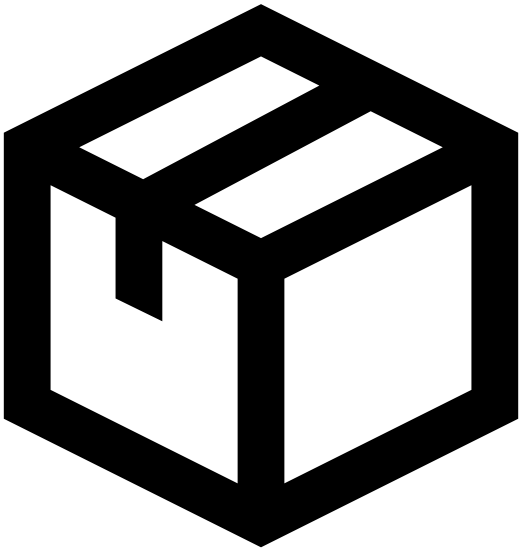
	FFT		FFTp	
	12 L	2 L	12 L	2 L
Recyclability	70%	51%	69%	34%
Recycled Content	16%	41%	50%	28%
Renewable Content	68%	48%	67%	33%

Recycled Content[2]
Proportion of the mass of recycled material on the total mass of the product or packaging.

Renewable Content[3]
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.

Recyclability[1]
Characteristic of products that still have 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.

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



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

Category	Component	Material	Recyclable
Plastics	Tearable pouches, labels	PE/PA/PE film, ACR/PE/PP	No
	Polybag	LDPE	Yes
	Reverse cable tie	PA	No
Paper and Cardboard	Box and case separator	Cardboard	Yes

ACR = Acrylic, PA = Polyamide, PE = Polyethylene, PP = Polypropylene, LDPE = Low Density Polyethylene

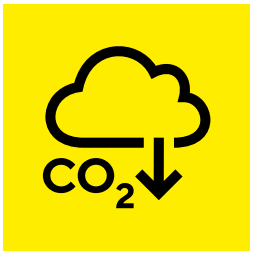
Definitions: [1]Based on European Environmental Agency GEMET – Environmental thesaurus | [2]Only recycled post-industrial and recycled post-consumer materials shall be considered as recycled content. The numbers provided herein are the best available approximations | [3]Corporate Sustainability Reporting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

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 Celsius® FFT | FFTp 12 L and 2 L.

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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