Application Note

CryoVault® Cold-Chain Shipping Performance & CO_2 Emission Analysis

Meissner evaluates single-use vs. multi-use transport systems for frozen bulk drug substances with a focus on:

- Sub -40 °C Hold-Time Qualification
- Shipper Specifications
- CO_2 Impact Assessment

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Research Questions

Transporting frozen Bulk Drug Substance (BDS) at temperatures of ≤ -40 °C across global supply chains is one of the most demanding logistical challenges in biopharmaceutical manufacturing. This application note evaluates the CryoVault® Freeze & Thaw Platform by Meissner with a specific focus on three questions:

1. What single-use shipper configurations are available for the CryoVault® Freeze & Thaw Platform, and how are they qualified?
2. How long can the single-use shippers from Meissner maintain sub -40 °C conditions during transit?
3. How does the single-use shipping approach compare to traditional multi-use transport systems in terms of CO_2 emissions and costs per shipped CryoVault®?

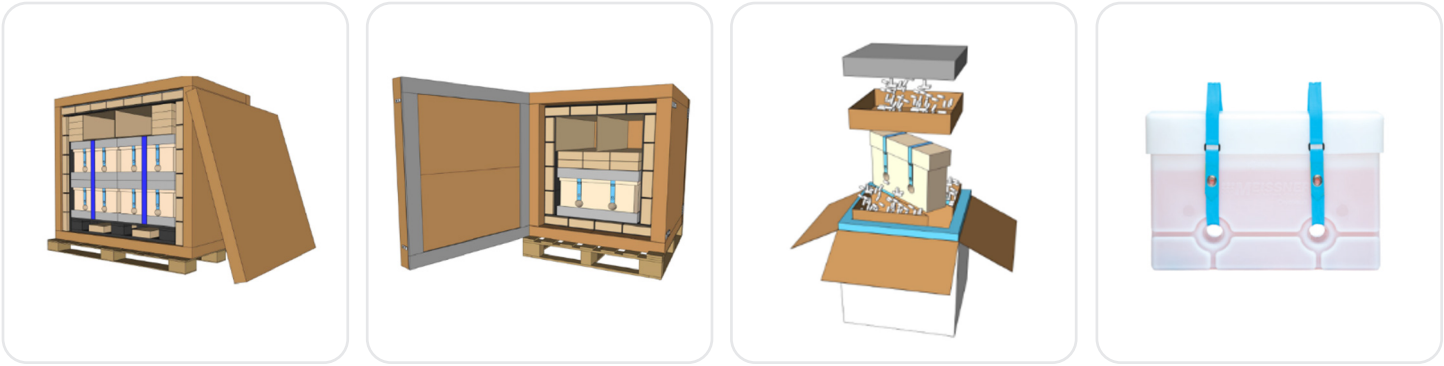
Available single-use shippers for CryoVault®

Meissner offers three single-use shipper configurations as part of the CryoVault® platform:

Shipper Configuration	Total Weight (kg) full load + dry ice	Dry Ice Weight (kg)	External Dimensions (in)	Containers per Shipper (16 L CryoVault®)
20 x 16 L Single-Use Shipper (See figure 1a)	721	200	62.2" x 43.3" x 63.0"	up to 20
5 x 16 L Single-Use Shipper (See figure 1b)	355	176	47.2" x 39.4" x 50.8"	up to 5
1 x 16 L Single-Use Shipper (See figure 1c)	113	83	27.4" x 26.3" x 28.8"	1

Table 1. Specifications of single-use shipper configurations [1] [2] [3].

Each of these single-use shippers is constructed from cardboard and corrugated plastic, and will hold the 16 L CryoVault® containers, which are made from a single polymer HDPE (see Figure 1d). The 16 L containers have a total volume of 20 L and a maximum fill volume of 16 L, which is designed to account for volume expansion during the freezing process. Handling straps can be added to facilitate two-person handling and enable safe and secure transport.



a) 20 x 16 L Single-Use Shipper Meissner PN: KCVS-DS001A

b) 5 x 16 L Single-Use Shipper Meissner PN: KCVS-DS002A

c) 1 x 16 L Single-Use Shipper Meissner PN: KCVS-DS003A

d) 16 L CryoVault® with Handling Straps Meissner PN: KCVM-TE061A

Figure 1. Available single-use shipper sizes and 16 L CryoVault®.

The shroud secures and protects the CryoVault® container's top works. Furthermore, tamper-evidence cable ties can be used to secure the shroud to the container through its bore holes to show clear evidence if the CryoVault® has been opened or tampered with during transportation or storage.

All three single-use shippers are loaded with dry ice to ensure passive cooling during transit. It is possible to re-ice (dry ice replenishment) during transport if necessary. This enhances overall transport stability and reliability, particularly in the event of flight delays or disruptions in flight connections.

Shipping Container Qualification

All CryoVault® shipping containers (shippers) have been qualified according to ASTM D4169 (Standard Practice for Performance Testing of Shipping Containers and Systems) and ISTA 3E (International Safe Transit Association) [1] [4]. The testing program includes frozen drop tests, vibration testing, and sustained temperature monitoring under hot environmental conditions (ISTA 7D Hot). Meissner also provides a documented transport simulation test report (for the 20 × 16 L Single-Use Shipper), validating shipping integrity under real-world transit stress conditions [4]. All tests have been performed in an ISTA certified test facility.

CryoVault® shippers are approved for transport on passenger aircraft—not just dedicated cargo planes. This is significant because passenger aircraft operate far more routes and frequencies than cargo-only flights. For pharmaceutical logistics, this translates directly into shorter transit times, greater route flexibility, and reduced risk of temperature violations caused by extended layovers.

Cold-Chain Hold Time Data: Sub -40 °C and -60 °C

The study evaluated temperature profiles during transport for the three shippers [5]. The temperature log interval was 10 minutes for all experiments. Initially, the CryoVault® containers were stored at -80 °C ±10 °C for 72 hours. Following this period, dry ice was loaded into the shipper. The CryoVault® containers were then placed into the shipper, and the temperature hold study was started. At the start of the study, the temperature briefly increased before decreasing, reflecting the system´s transition toward equilibrium.

For the 20 x 16 L and the 5 x 16 L shipper, two data sets were generated, one under maximum and one under minimum loading conditions. The minimum load scenario intended to demonstrate that even with reduced thermal mass the shippers can maintain regulatory transport conditions.

For the 20 x 16 L and the 5 x 16 L shipper, the thermal environmental profile ISTA-7D Hot was used. For the 1 x 16 L shipper, a constant external ambient temperature of 25° C was applied. Please refer to the temperature records marked as "Amb" in the diagrams.

Shipper Name	Time sub -60 °C (h) Max. Load	Time sub -60 °C (h) Min. Load	Time sub -40 °C (h) Max. Load	Time sub -40 °C (h) Min. Load
20 x 16 L Single-Use Shipper	70	84	>96	>96
5 x 16 L Single-Use Shipper	120	96	144	120
1 x 16 L Single-Use Shipper	>240	-	>240	-

Table 2. Cold chain hold time duration below -40 °C and -60 °C for min/max load conditions.

Single-Use 20 x 16 L Shipper

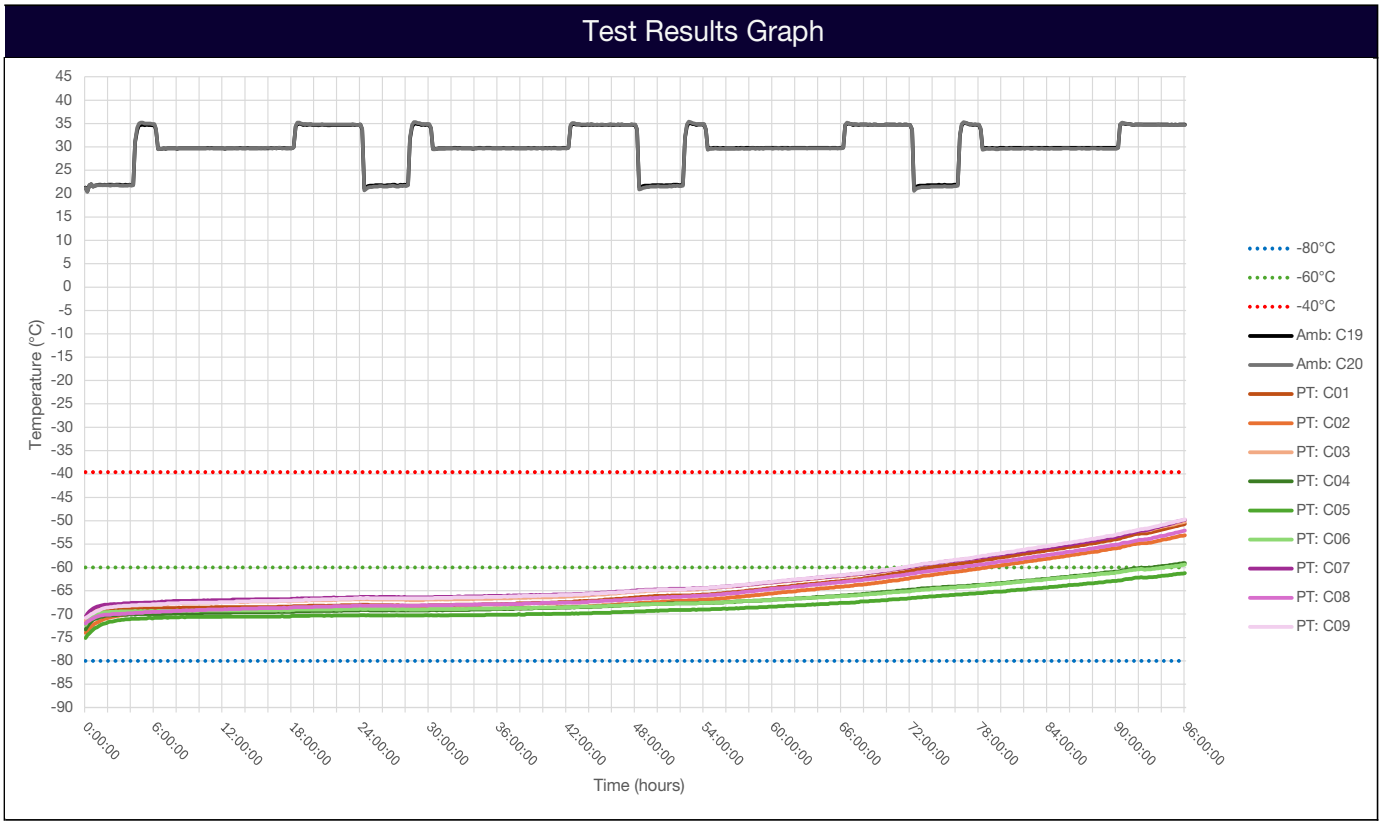


Figure 2. Thermal profile and temperature probe distribution of the 20 x 16 L Single-Use Shipper with maximum load (20 x 16 L CryoVault® Containers).

At the start of the study the minimum measured temperature was -75.1 °C. After 96 hours the maximum measured temperature was -49.7 °C. The diagram (Figure 2.) indicates a vertical gradient within the shipper. For the 20 x 16 L Single-Use Shipper the CryoVault® containers are arranged in two stacked layers (10 above 10), the lower section remains consistently cooler than the upper section. This is due to natural convection, as warmer air rises, making the lower positions thermally more favorable. All 20 CryoVault® containers remained under -40 °C for more than 96 hours (see Figure 2).

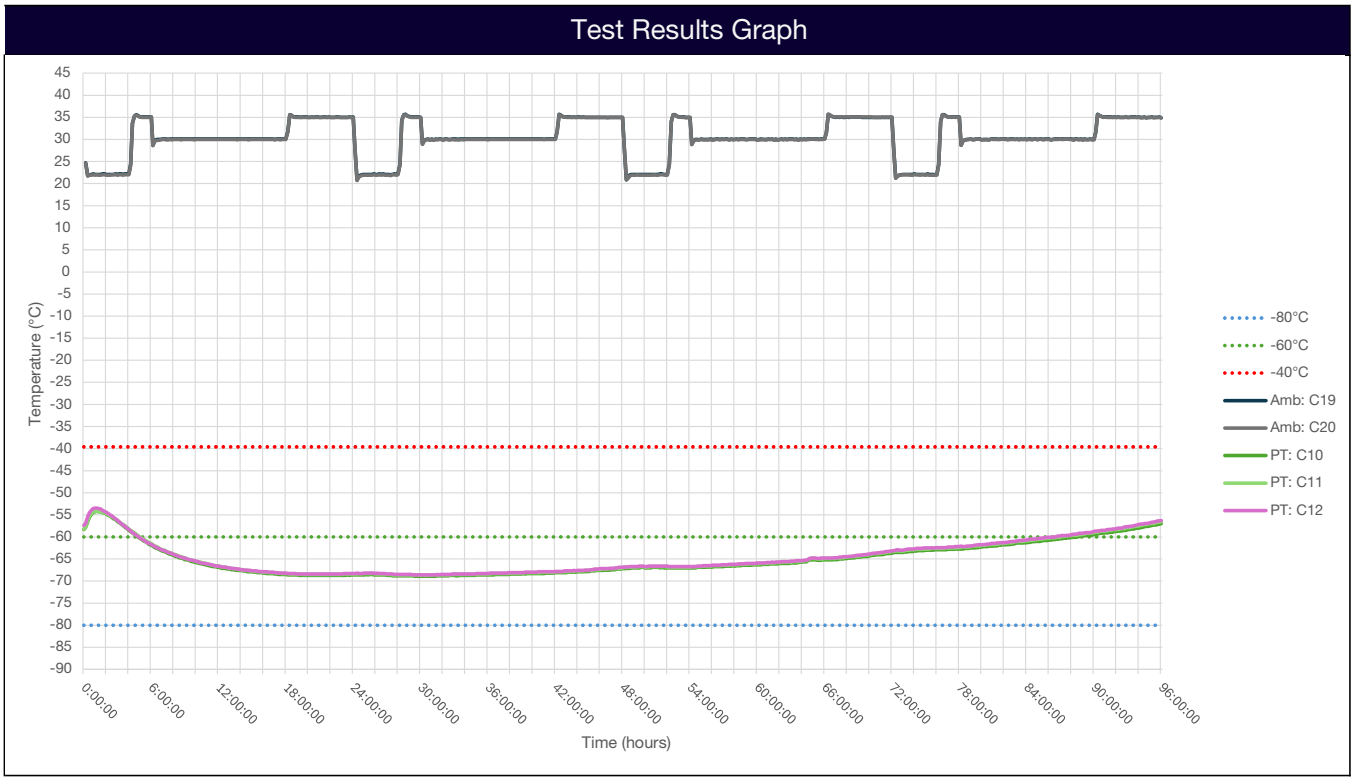


Figure 3. Thermal profile and temperature probe distribution of the 20 x 16 L Single-Use Shipper with minimal load (1 x 16 L CryoVault®).

At the start of the experiment the minimum measured temperature was -68.9 °C. After 96 hours the maximum measured temperature was -56.5 °C. Even in this worst-case scenario with only one CryoVault® container inside the 20 x 16 L shipper, the temperature remained under -40 °C for more than 96 hours (see Figure 3).

Single-Use 5 x 16 L Shipper

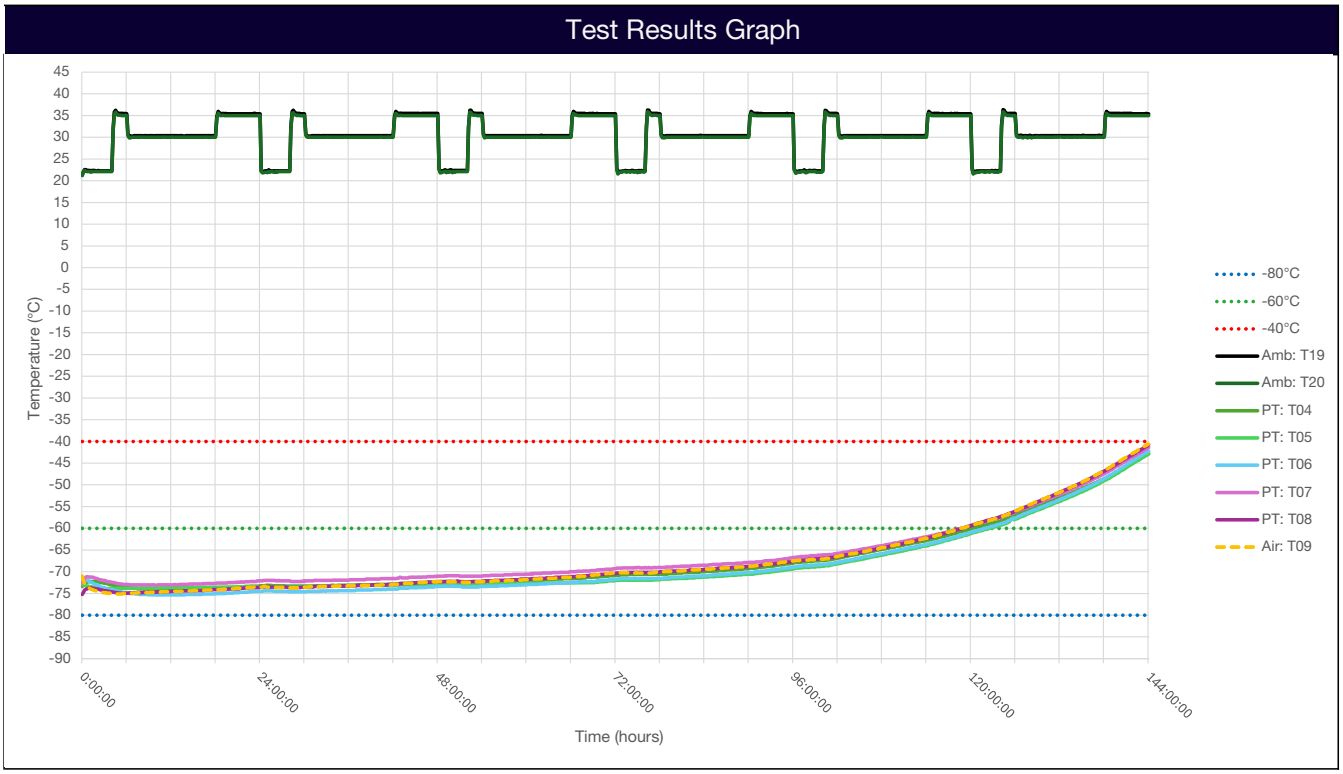


Figure 4. Thermal profile and temperature probe distribution of the 5 x 16 L Single-Use Shipper with maximum load (5 x 16 L CryoVault® containers).

At the start of the experiment the minimum measured temperature was -75.1 °C. After 96 hours the maximum measured temperature was -66.7 °C. All five CryoVault® containers remained under -40 °C for more than 96 hours (see Figure 4).

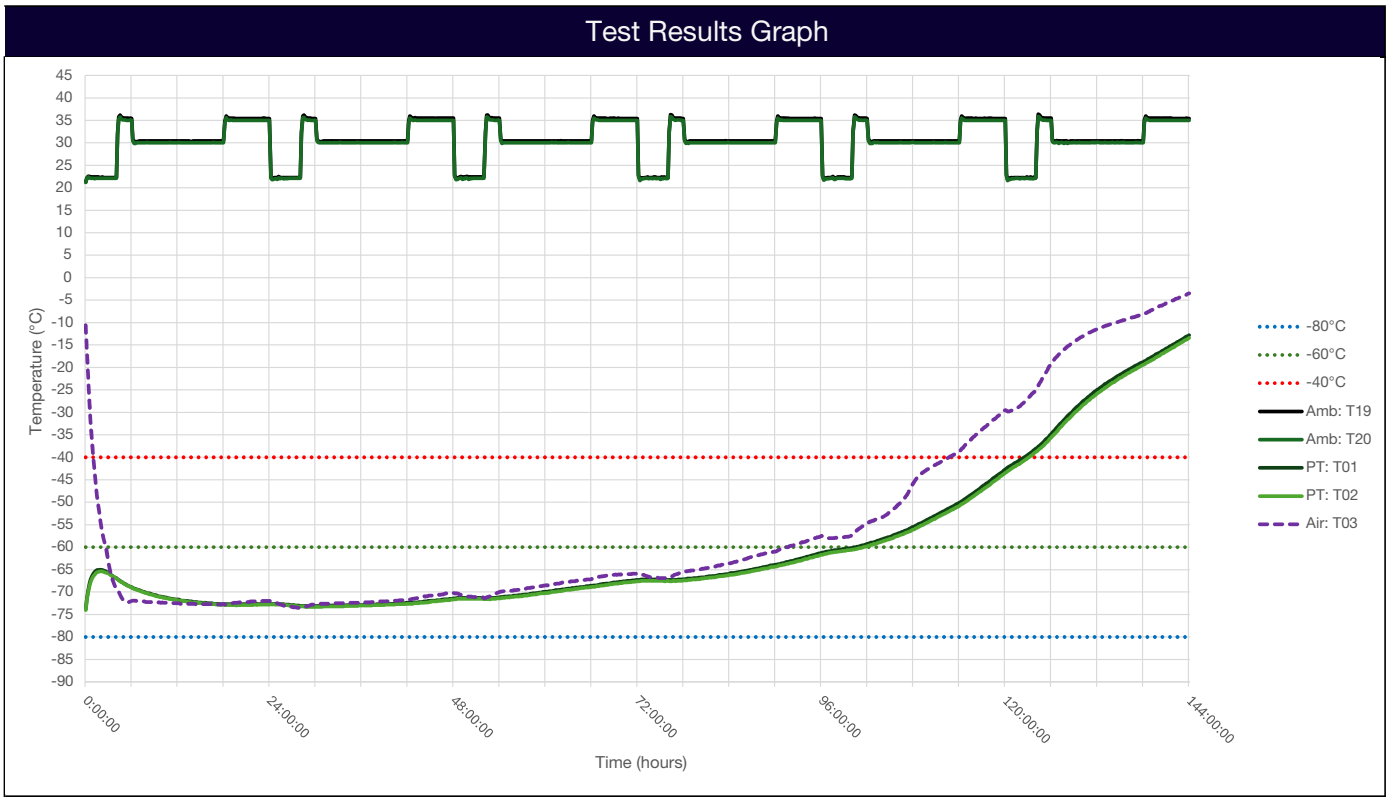


Figure 5. Thermal profile and temperature probe distribution of the 5 x 16 L Single-Use Shipper with minimum load (1 x 16 L CryoVault®).

At the start of the experiment the minimum measured temperature was -75.1 °C. After 96 hours the maximum measured temperature was -62.1 °C (see Figure 5). When comparing the 20 x 16 L shipper to the 5 x 16 L shipper at minimum load, the difference in final temperature as measured in the experiment is caused by the difference in dry ice volume and the difference in geometry of the shippers. Even in this worst-case scenario with only one CryoVault® inside, the 5 x 16 L shipper the temperature remained under -40 °C for more than 96 hours.

Single-Use 1 x 16 L Shipper

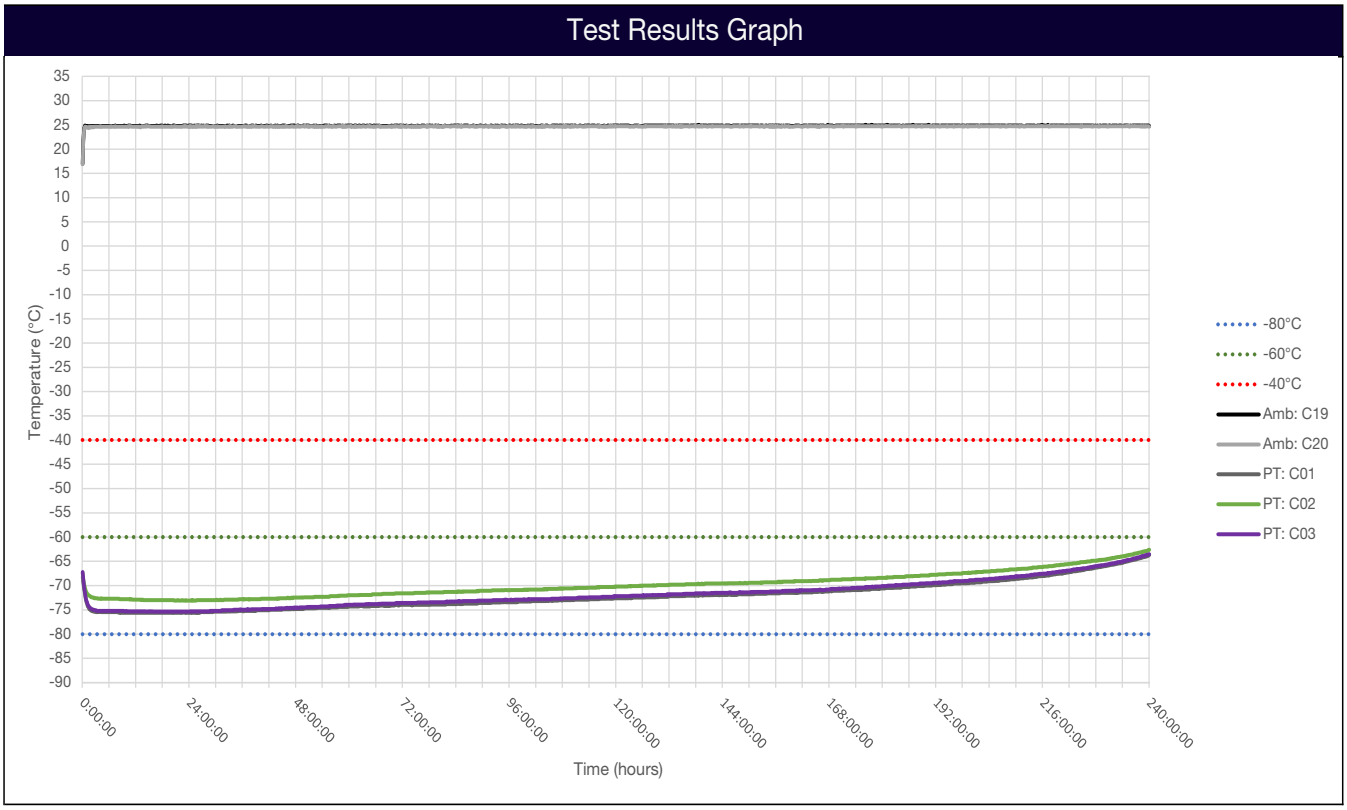


Figure 6. Thermal profile and temperature probe distribution of the single-use shipper 1 x 16 L CryoVault®.

At the start of the experiment the minimum measured temperature was -75.6 °C. After 96 hours the maximum measured temperature was -62.6 °C (see Figure 6).

CO_2 Emission Analysis

The CO_2 impact analysis of two shipping systems, presents comparative results between the single-use shipper and a conventional multi-use shipper, based on a representative intercontinental 7500 km flight from Basel, Switzerland, to Louisville, Kentucky, USA [6]. The analysis accounts for CO_2 generated during air freight transport as a function of each shipper's weight.

The CO_2 impact of producing the single-use shipper is approximately 250 kg CO_2, including the end-of-life disposal. For the representative multi-use shipper, the corresponding value is roughly 3000 kg CO_2. To obtain the CO_2 impact per shipment, this value must be divided by the number of uses [6].

Due to the high complexity involved, production-related emissions are not included in the calculation in this application note (see Figure 7).

Should you be interested in a more detailed discussion of these production emissions, a Meissner representative can be contacted at any time.

	Single-Use Shipper 20 × 16 L CryoVault®	**Multi-Use Shipper 12 x 16 L CryoVault®**
Empty weight (for reverse logistics)	131 kg	428 kg
Shipping weight (including product and 200 kg dry ice)	721 kg	980 kg
CO_2 transport air freight *	2920 kg CO_2	3969 kg CO_2
CO_2 reverse logistics (air)	(531 kg CO_2)**	1733 kg CO_2
Total CO_2 impact per shipment	**2920 kg CO_2 / 20 Cryovault® containers**	**5702 kg CO_2 / 12 Cryovault® containers**
Total CO_2, impact/L incl reverse logistics	**9.1 kg CO_2 /L**	**29.7 kg CO_2 /L**

* Based on the flight from Basel, Switzerland to Louisville, Kentucky, USA (7500 km) and 0.54 kg CO_2, per ton-km, according to DEFRA / GLEC.

** For reference only. The value 486 kg CO_2, is not included in the calculation (single-use shipper).

Figure 7. Total CO_2 Impact of single-use and multi-use shippers.

The total CO_2 Impact of shipment, including reverse logistics, for the multi-use shipper (5702 kg CO_2) is almost 90% higher than the single-use shipper (2920 kg CO_2). Because the two shippers have different capacities (20 CryoVault® containers for a single-use shipper versus 12 CryoVault® containers for a multi-use shipper) the total CO_2 impact per liter is more than 3 times higher for the multi-use shipper than for the single-use shipper.

The calculations were conducted according to DEFRA / GLEC (0.54 kg CO_2 per ton and km) [7].

	Single-Use Shipper 20 × 16 L CryoVault®	Multi-Use Shipper 12 x 16 L CryoVault®
Shipping weight (including product and dry ice)	721 kg	980 kg
Transport costs Air Pharma Service (at € 4,- per kg)	€ 2884	€ 3920,
Number of CryoVault® Containers	20	12
Transport cost per CryoVault®	€ 144	€ 327

Figure 8. Transport cost per CryoVault® Single-Use Shipper against Multi-Use Shipper

Shipping a 16 L CryoVault® from Basel, Switzerland, to Louisville, Kentucky, USA, costs €144 with the single-use shipper and €327 with the multi-use shipper—more than 2 times higher. The calculations assume a transport cost of €4 per kilogram for this route.

An additional advantage regarding CO_2 impact relates not to the shipper, but to the single-use CryoVault® container itself. CryoVault® containers are made from a single polymer (HDPE) making them mechanically recyclable after appropriate decontamination. Conventional 2D bioprocess bags on the other hand, use bonded multi-layer films that cannot be separated and are therefore effectively not recyclable. According to a life-cycle impact study conducted by Franklin Associates on behalf of the Association of Plastic Recyclers, using recycled HDPE requires 88% less energy and generates 71% less greenhouse gas than virgin resin [8]. These figures underscore the environmental significance of CryoVault® container's mono-material HDPE construction.

Conclusion

With maximal load, the single-use shipping system delivers validated cold-chain hold times of at least 96 hours at ≤ -40 °C, tested to ASTM D4169 and ISTA 3E standards. Also, with minimal load the shippers deliver very good cold-chain times at ≤ -40 °C. One additional advantage is the passenger-aircraft approval across all single-use shipper variants.

A comparative CO_2 impact analysis demonstrates that the multi-use shipper generates almost 90% less CO_2 impact compared with the single-use shipper. At the same time, the cost per shipment of a 16 L CryoVault® using the multi-use shipper is more than 2 times more expensive compared with the single-use shipper.

References

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[4] Meissner. “Transport Simulation Test Report”. CryoVault® Single-Use Shipper: 20 x 16 L CryoVault® Containers
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[5] Meissner. "Thermal qualification studies" Please contact Meissner in case you require the entire report

[6] All weight specifications in kilograms that serve as the basis for these calculations regarding the single-use shipper can be found in the CryoVault® packing instruction brochures on the Meissner website, www.meissner.com. The data for the multi-use shipper are representative of a typical multi-use shipper.

[7] UK Government, Department for Environment, Food & Rural Affairs (DEFRA / GLEC); this number can also be found in a lot of other calculations like Eco-transit and IATA.

[8] Franklin Associates. (2018). Life Cycle Impacts For Post Consumer Recycled Resins: PET, HDPE, AND PP. Prepared for the Association of Plastic Recyclers (APR). Eastern Research Group (ERG)
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