
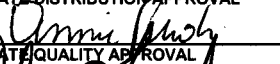



<b>AMGEN®</b>		<b>THERMAL QUALIFICATION REPORT</b>		NUMBER 1116-TQ(R)	
TITLE Thermal Qualification of EVC C-167IL Polyurethane Shipper Finished Goods, (2-8°C) One Amgen Center Drive			INITIATOR Ray Cowland SUPERSEDES New		PAGE 1 of 6 EFFECTIVE DATE
OWNER APPROVAL 		DATE 12   6   05	OTHER APPROVAL		DATE
CORPORATE DISTRIBUTION APPROVAL 		DATE 12   7   05	OTHER APPROVAL		DATE
CORPORATE QUALITY APPROVAL 		DATE 12   07   05	OTHER APPROVAL		DATE

## INTRODUCTION

Amgen has a business requirement to have a packaging configuration available to maintain internal temperature of 2°-8°C with cumulative excursions between 8°-15°C for no more than 24 hours. This report summarizes the testing performed. The total combined time for adherence to this is 55.3 hours. Criteria of a successful packaging configuration shall meet the requirements described in P0430-67, **Thermal Qualification of Packaging Configurations**. The shipper EVC C-167IL is a polyurethane shipper to be used for transporting finished goods.

## METHODS AND MATERIALS

Refer to, 1116-TQ(P), *Thermal Qualification of EVC C-167IL Polyurethane Shipper Finished Goods, (2-8°C)*

## EXCEPTIONAL CONDITIONS

- I. Product data failed to record using thermocouples for both the maximum and minimum loads during exposure to the Amgen heat profile from 11/11/05, 14:00:17 until 11/11/05, 17:32:47. The Temptale data loggers continued to record throughout this period indicating that the product temperature was between 8°-15°C for this time.
- II. A Temptale in the minimum load # 3 of the cold profile failed to record data. This will have no impact on the qualification since a secondary Temptale within the sample recorded the air temperatures.



# THERMAL QUALIFICATION REPORT

NUMBER

1116-TQ(R)

TITLE

Thermal Qualification of EVC C-1671L Polyurethane Shipper Finished Goods, (2-8°C)  
One Amgen Center Drive

INITIATOR

Ray Cowland

SUPERSEDES

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## RESULTS

**Table 1: Product Fill Volumes and Temperature Durations**

<u>Profile</u>	<u>Product Load</u>	<u>Volume</u>	<u>Test</u>	<u>2-8°</u>	<u>9-15°</u>
<b>Amgen Heat</b>	Minimum	100 mls	1	46.3	24
			2	47.2	24
			3	44.8	24
	Maximum	900 mls	1	44.7	24
			2	45.5	24
			3	44.3	24
<b>Amgen Cold</b>	Minimum	100 mls	1	55.3	0
			2	60.3	0
			3	58.3	1.0
	Maximum	900 mls	1	60.0	0
			2	58.8	0
			3	60.0	0


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**Table 2: Air Temperature Ranges While Product Maintains 2°-8°C with cumulative excursions between 8°-15°C for no more than 24 hours.**

<u>Profile</u>	<u>Product Load</u>	<u>Volume</u>	<u>Test</u>	<u>Duration (Hours)</u>		
				<u>0-1°</u>	<u>2-8°</u>	<u>9-10°</u>
<b>Amgen Heat</b>	Minimum	100 mls	1	-	45.0	1.0
			2	-	46.5	0.5
			3	-	44.0	0.5
	Maximum	900 mls	1	-	43.5	0.5
			2	-	43.5	1.0
			3	-	42.5	1.0
<b>Amgen Cold</b>	Minimum	100 mls	1	-	54.0	-
			2	3.5	56.0	-
			3	0.5	57.5	-
	Maximum	900 mls	1	-	59.0	-
			2	-	58.5	-
			3	-	59.0	-

**Table 3: Maximum Cumulative Durations of Air Temperatures while Product Remains Within Specification**

<u>Temperature °C</u>	<u>Duration (Hours)</u>
0-1	3.5
9-10	1.0

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DISCUSSION

The C-167IL Polyurethane Shipper was tested in accordance to 1116-TQ(P), Thermal Qualification of EVC C-167IL Polyurethane Shipper Finished Goods, (2-8°C). The results of the thermal qualification are summarized in Table 1, *Product Fill Volumes and Temperature Durations*. Table 1 indicates that the maximum duration that product maintains temperatures of 2°-8°C with cumulative excursions between 8°-15°C for no more than 24 hours is 55.3 hours.

Table 2, *Air Temperature Ranges While Product Maintains 2°-8°C With Cumulative Excursions Between 8°-15°C For No More Than 24 Hours*, indicates the thermal performance of the air within the C-167IL shipper itself. This is important because product temperature itself cannot be monitored during actual shipment without penetrating the primary container. The data indicates that air temperatures and product temperatures are not always equivalent. The air temperatures may be either higher or lower than the products temperature and yet the product remains within the specification of 2°-8°C with cumulative excursions between 8°-15°C for no more than 24 hours. The actual temperature and duration variation between the air and product temperatures are in Table 3.

Table 3, *Maximum Cumulative Durations of Air Temperatures while Product Remains Within Specification*, represents the qualified air temperature excursions that are acceptable during transportation of shipper while product remains within specification.

CONCLUSION

The acceptance criteria of maintaining the refrigerated product temperatures for a minimum of 48 hours were met. The C-167IL Polyurethane Shipper maintains product temperatures of 2 –8 °C for a maximum of 55.3 hours. During the execution of the study the product temperature did not exceeding 8°C for a maximum 24 cumulative hours. The time that C-167IL is qualified for within the required temperature range is between 0 to 55.3 hours.

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**Attachment 1: C167IL Packaging Instructions**

<b>Drawing <sup>(1)</sup> Reference</b>	<b>Packaging Instructions</b>
1	Open the flaps to the C-167 Corrugated RSC.
2, 10	Open the C-167 Shipper Base by removing the C-167 Lid.
2,3	Place 6 gel ice into the sides of the shipper base
2,4,5	Place simulated product into the product cavity of the C-167 Shipper Base.
6	Activate and attach two TempTale <sup>®</sup> 4's probe tips to the top corner of the product load
2, 7	Fill any extra space in the C-167 Shipper Base with Paper Dunnage.
3, 9	Place C-167 ice tray and one gel ice onto product load
2, 10	Securely place the C-167 Lid onto the C-167 Shipper Base.
1	Close the flaps to the C-167 Corrugated RSC.
1	Seal the C-167 Corrugated RSC with Tape.

<sup>(1)</sup> Refer to Drawing 1116-D01, *Exploded View of the C167IL Finished Goods Pack-out*

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**Drawing 1116-D01, Exploded View of the C167IL Finished Goods Pack-out**

TRANSPORTATION CONTAINER C-167	TRANSPORTATION METHOD Internal Temperature Control System	SHIPPING PARAMETERS 2°C to 8°C Not to Exceed 8°C for more than 24 Hours
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Notes:  
1) TempTale placement location is on the Top corner of the product load.

ITEM	QTY.	SPEC. NO.	PART NAME.
1	1	4156567	Corrugated RSC
2	1	4156567	C-167 Base
3	7	AR	32 oz Gel Ice
4	1	4156567	Corrugate Liner Base
5	AR	N/A	Product
6	2	4156468	TempTale 4
7	AR	4156397	Paper Dunnage
8	1	4156567	Corrugate Liner Lid
9	1	4156567	C-167 Ice Tray
10	1	4156567	C-167 Lid