INCH-POUND

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28 March 1998

COMMERCIAL ITEM DESCRIPTION

CONTAINER, THERMAL, SHIPPING, FOR MEDICAL MATERIEL REQUIRING CONTROLLED TEMPERATURE RANGES

The General Services Administration has authorized the use of this interim Commercial Item Description by all Federal Agencies. This document was developed by DLA Troop Support, Medical Supply Chain, and is based upon currently available technical information.

1. SCOPE

1.1 This Commercial Item Description covers the requirements and test procedures for various types and sizes of fully-assembled thermal shipping containers.

1.2 Intended use. Containers shall be suitable for the shipment and storage of medical materiel, pharmaceuticals, biologicals and specimens requiring constant chill or freeze environment. Containers shall meet all requirements of the DLA Packaging Protocols for Medical Temperature Sensitive Products.

2. CLASSIFICATION

2.1 Containers covered by this document shall be suitable for use for freeze or chill shipments and shall be the following sizes:

Beneficial comments, recommendations, additions, deletions, clarifications, etc. and any other data which may be used to improve this document should be sent to: DLA Troop Support, Medical Supply Chain, ATTN: FS, 700 Robbins Avenue, Philadelphia, PA 19111-5092, by letter or using the self-addressed Standardization Document Improvement Proposal, (DD Form 1426) appearing at the end of this document.

AMSC N/A FSC 8115
DISTRIBUTION STATEMENT A: Approved for public release; distribution is unlimited.

Size 1 - Small
Size 2 - Medium
Size 3 - Large
Size 4 - XLarge

2.1.1 Required size(s) shall be specified in the contract or purchase order (see 7.2).

3. SALIENT CHARACTERISTICS

3.1 Material.

3.1.1 Insulation material. Insulation material shall be polyurethane, shall be chlorofluorocarbon-free (CFC), and shall provide required thermal and structural characteristics as specified herein.

3.1.1.2 Container bottom and 4 side walls. Polyurethane foam used to construct the container bottom and sides shall be CFC-free rigid high strength polyurethane foam conforming to MIL-PRF-83671B, class 1, category 2. To insure optimum thermal efficiency, construction of the insulation component of the container shall be a single construction with no seams or bonds. The bottom and 4 side walls of the polyurethane insulation shall be formed in one single operation. There shall be no seams or points in the insulation side wall and base material. A full bond shall exist between the insulation material and the contact surfaces of the inner liner and the outer container. Panel construction or the use of successive steps in the formation of the side walls and base **shall not be acceptable**.

3.1.1.3 Insulation closure (plug). Polyurethane foam used to construct the separate insulation closure (plug) shall be CFC-free flexible polyurethane foam conforming to MIL-PRF-83671B, class 2, grade B. Dimensions shall be as specified in 7.2, Table II. Closure of the insulated container shall maintain integrity of the seal for the life of the container.

3.1.1.4 Insulation wall thickness. Insulation wall thickness shall be as specified in 7.2, table III.

3.1.2 Inner liner and outer container. Inner liner and outer container shall be furnished in the sizes indicated herein and as specified in the contract or order.

3.1.2.1 Inner liner. Inner liner shall be constructed of C flute, corrugated fiberboard conforming to ASTM D 4727, class domestic, having a minimum bursting strength of 200 pounds. Liner shall be style RSC, shall have a half-slotted center body. The liner flutes shall be perpendicular to the top of the box. The liner joint shall be butted and shall be located in one of the corners of the liner, in accordance with figure 1. The liner joint shall be taped with suitable pressure-sensitive tape.

3.1.2.2 Outer container. Outer container shall be constructed of C flute, corrugated fiberboard conforming to ASTM D 4727, class domestic, having a minimum bursting strength of 200 pounds. Outer container shall be in accordance with ASTM D 5118, style RSC.

3.2 Cavity, cargo box insert, and fiberboard barrier dimensions.

3.2.1 Cavity. Cavity dimensions shall be as specified in the contract or purchase order (see 7.2).

3.2.2 Cargo box insert. Cargo box insert dimensions shall be as specified in 7.2, table I. The cargo box insert shall be designed for a type 2 load and shall conform to ASTM D 5118, style RSC, class domestic. The box shall be constructed of C-flute, corrugated fiberboard in accordance with ASTM D 4727, having a minimum bursting strength of 200 pounds. The corrugate direction shall be vertical and the manufacturer's joint shall be inside.

3.2.3 Fiberboard Barrier. Fiberboard barrier dimensions shall be as specified in 7.2, Table IV. The fiberboard barrier shall be constructed of 275# B/C-flute, corrugated fiberboard in accordance with ASTM D 4727. The corrugate direction shall be vertical.

3.3 Design. The design of the fabricated container shall be in accordance with figure 1, except a fiberboard barrier, as indicated on the DLA Packaging Protocols for Medical Temperature Sensitive Products, and as specified in 3.2.3 and 7.2, Table IV, shall also be included in each container.

3.4 Thermal requirements. The container shall support the DLA "Packaging Protocols for Medical Temperature Sensitive Products Requiring Storage Temperatures between 2°C – 8°C (36°F – 46°F)" without change or exception so as to maintain the temperature range of 2°C – 8°C for a minimum of 72 hrs in accordance with stated ambient requirements of Cold Weather (below 55°F), Moderate Weather (between 55°F and 77°F), and Warm Weather (above 77°F).

3.4.1 Design criteria. The design criteria required are as follows:

3.4.1.1 Profiles:

Warm: + 18°C for 18 hrs, + 30°C for 6 hours
Moderate: +14°C for 72 hrs
Cold: +13°C for 18hrs, – 10°C for 6 hrs

3.4.1.2 Probe Locations. Top center (inside) of the cargo space box.

3.4.1.3 Cargo loads. All refrigerated materiel placed into the cargo area, to include the cargo load, must be preconditioned to 4°C prior to use. Refrigerated gel packs and test cargo should be preconditioned in a single layer, inside a refrigerator maintaining 4°C for a minimum of 24 hrs. Any frozen gel packs should be preconditioned in a single layer, inside a freezer maintaining –17° C for a minimum of 24 hrs. Cargo loads shall be as follows:

Small	14 x Cartons*	(28 x 5 mL Vials, each with 5 mL water fill)
Medium	32 x Cartons*	(64 x 5 mL Vials, each with 5 mL water fill)
Large	88 x Cartons*	(176 x 5 mL Vials, each with 5 mL water fill)
XLarge	198 x Cartons*	(396 x 5 mL Vials, each with 5 mL water fill)

* 1 x Carton is made of chipboard or paperboard, and contains 2 x 5 mL plastic vials, each vial contains 5 mL liquid fill.

3.5 Workmanship. Workmanship shall be first class throughout. The thermal shipping container, including all components, shall be free from defects which detract from its appearance or impair its serviceability.

4. REGULATORY REQUIREMENTS

4.1 Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder. If the product covered by this document has been determined by the U.S. Food and Drug Administration to be under its jurisdiction, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/ suppliers, with the requirements of the Federal Food, Drug and Cosmetic requirements of all other applicable Federal, State, and local statutes, ordinances, and regulations.

4.2 Recovered materials. The offeror/contractor is encouraged to use recovered materials in accordance with the Federal Acquisition Regulation (FAR) Subpart 23.403 to the maximum extent practical.

5. QUALITY ASSURANCE PROVISIONS

5.1 Product conformance. The products provided shall meet the salient characteristics of this commercial item description, conform to the producer's own drawings, specifications, standards, and quality assurance practices, and be the same product offered for sale in the commercial market. The government reserves the right to require proof of such conformance.

5.2 Metric products. Products manufactured to metric dimensions will be considered on an equal basis with those manufactured using standard inch/pound measurements.

5.3 Bid sample. The company producing the item shall provide a sample of the item it is bidding on for evaluation to the contracting officer. The contracting officer shall take appropriate action to determine if the sample provided meets the requirements of this specification. Pending approval of the bid sample, acquisition of materials, components, or commencement of production is at the sole risk of the contractor.

5.4 First article. Prior to the start of the contract, samples of the completed item shall be tested by the contractor. The samples shall be submitted, together with the contractor's inspection and test reports, to the procuring contracting officer for examination and testing to determine compliance with the requirements of the specification. Written approval of the materials, construction, and performance of the sample shall be obtained from the procuring contracting officer, or his authorized representative, prior to the manufacture and assembly of the remaining quality to be manufactured. Pending approval of the first articles, acquisition of materials, components or commencement of production is at the sole risk of the contractor. Accepted sample shall become the property of the procuring activity and shall be included in the quantity called for in the contract or order. In the event that the sample is not approved, the contractor shall submit a new sample for approval or modify the existing sample to remove the deficiencies cited.

5.4.1 Thermal insulation quality. Testing of thermal insulation quality shall be conducted in accordance with ASTM D 3103.

5.4.2 Thermal conductivity. Determination of thermal conductivity shall be conducted in accordance with ASTM C 177.

5.4.3 Drop test. Drop test shall be conducted in accordance with ASTM D 5276, using a fully packed and sealed thermal shipping container. There shall be three successive drops (one on a face, one on an edge and one on a top corner) from a height of 40 inches onto a concrete surface. The container shall be examined after the third drop. There shall be no visible cracks in the insulation, and there shall be no damage to the product.

5.4.3.1 Drop test packing requirement. Drop test packing requirements shall be as follows:

Small	14 x Cartons*	(28 x 5 mL Vials, each with 5 mL water fill)
Medium	32 x Cartons*	(64 x 5 mL Vials, each with 5 mL water fill)
Large	88 x Cartons*	(176 x 5 mL Vials, each with 5 mL water fill)
XLarge	198 x Cartons*	(396 x 5 mL Vials, each with 5 mL water fill)

* 1 x Carton is made of chipboard or paperboard, and contains 2 x 5 mL plastic vials, each vial contains 5 mL liquid fill.

5.5 Other quality assurance provisions. Shall meet all quality assurance provisions of the contract and/or purchase order.

6. PACKAGING

6.1 Preservation. Preservation shall be commercial.

6.1.1 Unit. Each (EA). One fully-assembled thermal shipping container, as specified, constitutes one unit. A fully assembled unit shall consist of the following parts:

a. Insulated shipping container inner liner and outer container

b. Cargo box insert

c. Fiberboard barrier

d. Insulation closure plug

6.1.2 Packing. Each fully-assembled thermal shipping container shall require no overpacking.

6.2 Unitization. Fully-assembled thermal shipping containers shall be uniformly unitized in accordance with commercial practice.

6.3 Marking.

6.3.1 Unit. Each fully-assembled thermal shipping container shall be marked in accordance with commercial practice. Marking shall include the boxmaker's certificate and any additional markings specified in the contract or order.

6.3.2 Unitized load. Each unitized load shall be marked with the National Stock Number (NSN) or commercial part number (P/N) and container size, the quantity and unit of issue, contract/order number, manufacturer's name and date of manufacture, and any additional markings specified in the contract or purchase order.

7. NOTES

7.1 Ordering data. Acquisition documents shall specify the following:

a. Title, number and date of this document.

b. NSN (when applicable).

c. Container type, size and dimension requirements. Dimension requirements shall include cavity size, insulation wall thickness, insulation closure (plug) thickness, inside cargo box insert dimensions, fiberboard barrier dimensions, and outer container dimensions.

7.2 Dimension requirements. The following tables are provided for information. The required type and dimensions (cavity dimensions, insulation wall thickness, insulation closure (plug) thickness, fiberboard barrier dimensions, inside cargo box insert dimensions, and outer dimensions) for the thermal shipping container shall be as specified in the contract or purchase order.

TABLE I. Thermal Shipping Containers. [1/]

SIZE	DIMENSIONS (Length x Width x Height (inches))		
	Outer Container (OD) (+/- 0.375")	Inside Cavity (ID, including Plug) (+/- 0.188")	Inside Cargo Box Insert (OD) (+/- 0.125")
Small	15.50" x 12.50" x 13.75"	11.0" x 8.0" x 7.0"	10.75" x 6.50" x 4.0"
Medium	18.50" x 12.50" x 16.75"	14.0" x 8.0" x 10.0"	12.0" x 6.5" x 6.5"
Large	23.0" x 19.0" x 18.75"	19.0" x 14.50" x 12.625"	16.50" x 12.0" x 7.0"
Extra Large	23.0" x 22.75" x 23.50"	18.25" x 19.0" x 16.75"	18.0" x 14.5" x 12.0"

[1/] These containers are designed for use for "ANY TEMPERATURE-SENSITIVE PRODUCT" and are acceptable for use with packaging protocols (see 3.4). These containers maintain the required temperature as indicated in the applicable protocol for at least 72 hours during shipment.

TABLE II. Insulation Closure (Plug).

SIZE	DIMENSIONS (Length x Width x Height (*inches*))
Small	**11.2” x 8.2” x 4” (+/-0.125”)**
Medium	**14.2” x 8.2” x 4” (+/-0.125”)**
Large	**18.75” x 14.75” x 4” (+/-0.125”)**
XLarge	**18.7” x 18.7” x 4” (+/-0.125”)**

TABLE III. Insulation Wall.

SIZE	THICKNESS (*inches*)
Small	**2” (+/-0.25”)**
Medium	**2” (+/-0.125”)**
Large	**2” (+/-0.25”)**
XLarge	**2” (+/-0.25”)**

TABLE IV. Fiberboard Barrier.

SIZE	DIMENSIONS (Length x Width (*inches*))
Small	**10.75" x 7.75" (+/- 0.125")**
Medium	**13.75" x 7.75" (+/- 0.125")**
Large	**18.25" x 14.25" (+/- 0.125")**
XLarge	**18.25" x 18" (+/- 0.125")**

7.6 Sources of referenced documents.

7.6.1 Government documents.

7.6.1.1 The Federal Food, Drug and Cosmetic Act is available from the Food and Drug Administration, Washington, DC 20204.

7.6.1.2 The following Regulation is available a http://www.dscc.dla.mil/Offices/packaging/medical.asp:

DLAR 4145.21 – Preparation of Medical Temperature-Sensitive Products Requiring Freeze or Refrigerated (Chill) Environments for Shipment
DLAR 4145.21 (Attachment 1) – Packaging Protocols for Medical Temperature Sensitive Products Sensitive Products Requiring Storage Temperatures

7.6.1.2 The following Military Specification is available from the Defense Automation and Production Service, Bldg 4/D, 700 Robbins Avenue, Philadelphia, PA 19111-5094:

MIL-PRF-83671B - Foam-in-Place Packaging Materials, General Specification for

7.6.2 Non-Government documents.

7.6.2.1 The following documents are available for purchase from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959:

C 177 – Standard Test Method for Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus

D 3103 – Standard Test Method for Thermal Insulation Quality of Packages

D 4727 – Standard Specification for Corrugated and Solid Fiberboard Sheet Stock (Container Grade) and Cut Shape

D 5118 – Standard Practice for Fabrication of Fiberboard Shipping Boxes

D 5276 – Standard Test Method for Drop Test of Loaded Containers by Free Fall

MILITARY INTERESTS:

Custodians:
Army - MD
Navy - MS
Air Force – 03

Review activities:
HQ DLA J-3732
DLA Distribution

Preparing Activity:
DoD-MB

Agent:
DLA-DM

CONTAINER, THERMAL SHIPPING FOR MEDICAL MATERIEL REQUIRING FREEZE AND CHILL

FIGURE 1

(REVISED 20 AUGUST 2010)

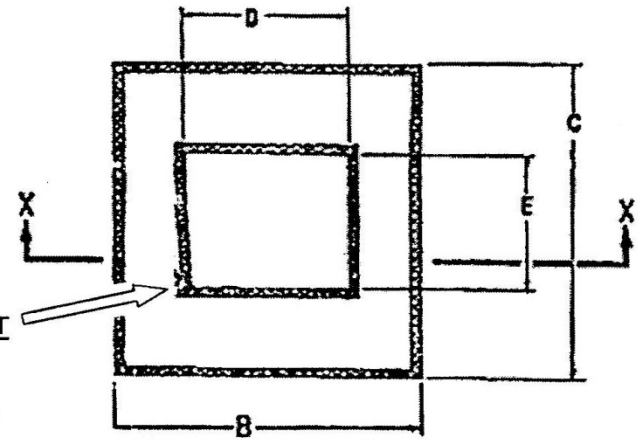
KEY TO DIMENSIONS

A = Height
B = Width
C = Length
} Outer Container

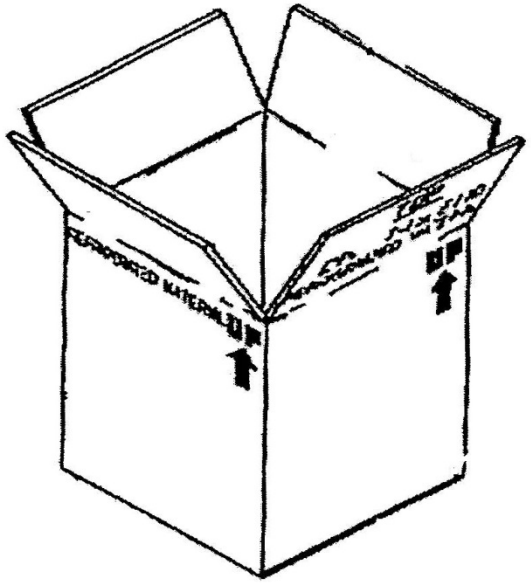
D = Height
E = Width
F = Length
} Cavity

G = Insulation Closure (Plug) Thickness

H = Insulation (Wall) Thickness



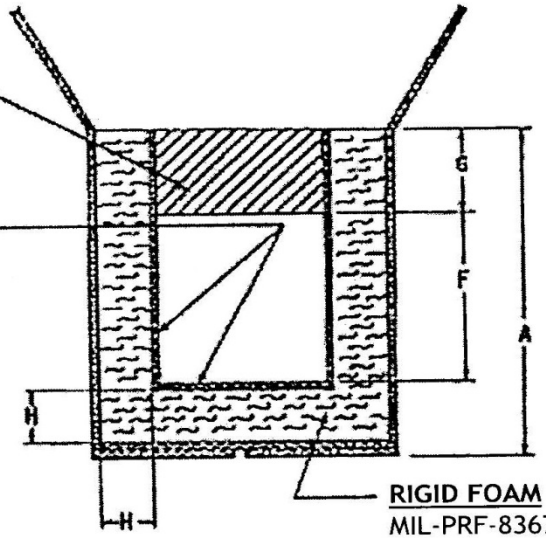
TAPED JOINT



FIBERBOARD CONTAINER
ASTM D 5118, TYPE CF,
CLASS DOMESTIC,
GRADE 200, STYLE RSC

FLEXIBLE FOAM
MIL-PRF-83671B,
CLASS 2, GRADE B
(THICKNESS SHALL
BE AS SPECIFIED
IN THE CONTRACT
OR ORDER.)

FIBERBOARD LINER
ASTM D 4727,
TYPE CF,
CLASS DOMESTIC,
GRADE 200



SECTION X-X
INSULATION LINING

RIGID FOAM
MIL-PRF-83671B,
CLASS 1, CATEGORY 2
THICKNESS SHALL BE
AS SPECIFIED IN THE
CONTRACT OR ORDER).

DIMENSIONS SHALL BE AS SPECIFIED IN THE CONTRACT OR PURCHASE ORDER. DIMENSIONS SHALL INCLUDE CAVITY SIZE, INSULATION WALL THICKNESS, INSULATION CLOSURE (PLUG) THICKNESS, FIBERBOARD BARRIER DIMENSIONS, INSIDE CARGO BOX INSERT, AND OUTER CONTAINER SIZE.

PERMITTED TOLERANCES FOR ALL DIMENSIONS SHALL BE AS INDICATED IN PARA. 7.2, TABLES I-IV.