

Abbott Laboratories

Packaging Material Specification

Tracking Number Status PK-00892-11 Approved **Document Number Commodity Type/Description** GM0333 Overcap **Approved Date Commodity Style** 12/13/2011 N/A **Superceded Document Number** Finished Container Size/Type GM0333 502 Diameter Composite Powder Cans **Approved Date** 08/03/2011 **Drawing Number/Revision Acceptance Program** DPK113391 С Q-004 **Drawing New or Revised? Environmental Material Category** LDPE - RS No **Commodity Weight in grams** 10.4 **Owner** Fred A Buck

Author

Fred A Buck

Description of Change

Added White Colorant in General Properties. Added statement in Additional Requirements to be able to run 502 Diameter White Overcaps with and without High Density Polyethylene (HDPE) additive. Adjusted Minimum/Lower Specification Limit (LSL) for Inside Diameter (ID) from 5.114 to 5.112 inches. Adjusted LSL for Weight from 9.7 to 9.2 grams. Adjusted LSL for Height (of skirt) from 0.263 to 0.260 inches. All three adjustments are to incorporate the White Overcap and its resulting dimensions into the existing specification for Natural Overcaps. Updated Drawing from Revision B to Revision C to reflect dimensional changes.

Material Inner to Outer	Material Designation Name / Supplier / Code	Alternate Materials
Product Contact	Linear Low Density Polyethylene (Natural) / Dow / DNDA 1081 Natural 7 with 5% High Density Polyethylene / LyondellBasell / Alathon H5057	N/A

Dimensional Properties	Target	Minimum	Maximum	Units
Inside Diameter	5.128	5.112	5.142	Inches
Inside Diameter - after 7 days	5.121	5.107	5.135	inches
Weight	10.4	9.2	11.1	Grams
Outside Diameter	5.184	5.170	5.198	Inches
Outside Diameter - after 7 days	5.181	5.167	5.195	inches
Height	0.270	0.260	0.277	Inches
Density	N/A	N/A	N/A	g/cc

GENERAL PROPERTIES

Approved Colorants	Per Specific Commodity Number
White	White / Ferro / CL95024FDA
-	Inside and Outside Diameter dimensions listed above are after 24 hours shrink to allow the supplier to produce and ship parts to Abbott. The parts continue to shrink after 24 hours up to 7 days, and Inside and Outside Diameter dimensions are also provided above.

ADDITIONAL REQUIREMENTS

- 1.0 General
- In-house storage should be with a minimum overhang pallet pattern to avoid distortion.
- Ideal storage room temperature 60 90 degrees Fahrenheit.
- 2.0 502 dia White Overcaps may be run without the addition of the 5% HPDE addtiive, which is used maintain overcaps in register (an accordian style stack of overcaps) for ease of packing into cases at the supplier and for unpacking out of cases at the Abbott manufacturing plant. These overcaps can be made without HDPE until we receive the Lettter of Non Objection (LONO) from Health Canada. Overcaps have been made without HDPE at the supplier, and all dimensions on this specification have been achieved.

CONTINUING GUARANTEE

The supplier agrees not to make any changes to materials, formulations, components, process changes, processing aids or adjuvants which impact their ability to meet this Abbott commodity specification or regulatory compliance without prior written approval from Abbott Laboratories.

COMPLIANCE REQUIREMENTS

21 CFR 177.1520(c) 3.1a.

INCOMING REQUIREMENTS

- 1.0 Packaging
- 1,000 per corrugated box in corrugated trays.
- Corrugated trays packed in layers.
- A plastic liner to be used in each corrugated box.
- 2.0 Markings

Mark each shipping container with the following minimum information:

INCOMING REQUIREMENTS

Supplier

Abbott Laboratories

- Name and Address

- Commodity Number

- Quantity

- Product Name

- Manufacturing Date and Shift for Molding and Printing (if applicable)

- Order Number

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