

PANACHE ANTIBACTERIAL BODY WASH - triclosan liquid
Deb USA, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Triclosan 0.5%

Antibacterial

Uses

For washing to decrease bacteria on the skin

Warnings

For external use only

Avoid contact with the eyes

Keep out of reach of children

Consult with a physician if ingested

Directions

Dispense product onto washcloth or directly onto skin

Lather and wash for 15-20 seconds

Rinse thoroughly

Water, Sodium Laureth Sulfate, Propylene Glycol, Disodium Laureth Sulfosuccinate, Sodium Chloride, Cocamide DEA, Cocamidopropyl Betaine, Fragrance, Tetrasodium EDTA, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, FDC Red No. 40, FDC Yellow No. 5.

Drug Facts

Active Ingredient

Triclosan 0.5%

Purpose

Antibacterial

Uses For washing to reduce bacteria on the skin

Warnings

■ Keep out of the reach of children ■ For external use only ■ Avoid contact with the eyes ■ Consult with a physician if ingested

Directions

■ Dispense product onto washcloth or directly onto skin ■ Lather and wash for 15-20 seconds ■ Rinse thoroughly

Inactive Ingredients

Water, Sodium Laureth Sulfate, Propylene Glycol, Disodium Laureth Sulfosuccinate, Sodium Chloride, Cocamide DEA, Cocamidopropyl Betaine, Fragrance, Tetrasodium EDTA, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, FD&C Red No. 40, FD&C Yellow No. 5.



Proudly made in the USA by
Deb

Stanley, NC 28164

1-800-248-7190

cser@debsbs.com • www.debgroup.com

triclosan liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11084-115 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| Triclosan (UNII: 4NM5039Y5X) (Triclosan - UNII:4NM5039Y5X) | Triclosan | .55 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Water (UNII: 059QF0K00R) | |
| Sodium Laureth Sulfate (UNII: BPV390UAP0) | |
| Propylene Glycol (UNII: 6DC9Q167V3) | |
| Disodium Laureth Sulfosuccinate (UNII: D6DHIDTN7E) | |
| Sodium Chloride (UNII: 451W47IQ8X) | |
| COCO DIETHANOLAMIDE (UNII: 92005F972D) | |
| Cocamidopropyl Betaine (UNII: 5OCF3O11KX) | |
| Edetate Sodium (UNII: MP1J8420LU) | |
| Anhydrous Citric Acid (UNII: XF417D3PSL) | |
| FD&C Red No. 40 (UNII: WZB9127XOA) | |
| FD&C Yellow No. 5 (UNII: I753WB2F1M) | |
| Methylchloroisothiazolinone (UNII: DEL7T5QRPN) | |
| Methylisothiazolinone (UNII: 229D0E1QFA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:11084-115-34 | 118 mL in 1 BOTTLE, PLASTIC | | |
| 2 | NDC:11084-115-27 | 1000 mL in 1 CARTRIDGE | | |
| 3 | NDC:11084-115-07 | 2000 mL in 1 CARTRIDGE | | |
| 4 | NDC:11084-115-05 | 3780 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 01/01/2010 | |

Labeler - Deb USA, Inc. (607378015)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

Deb USA, Inc.

607378015

manufacture

Revised: 2/2011

Deb USA, Inc.