DIGNITY HEALTH MEDSPA ANTIBACTERIAL- triclosan soap Jiangsu Xinheyuan Plastic Daily Chemical Co., Ltd.

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.

Active Ingredient

 $Triclosan\,0.3\%$

Purpose

Antibacterial

Uses for washing to decrease bacteria on the skin.

Warnings

For external use only.

When using this product

Avoid contact with eyes. In case of eye contact, flush with water.

Don't use this product on infants under 6 months of age.

Stop use and ask a doctor

If irritation and redness develops.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet bar with water
- lather vigorously and wash skin
- rinse and dry thoroughly.

Inactive Ingredients

Water, calcium carbonate, fragrance, glycerine, sodium chloride, sodium palmate



| DIGNITY HEA | ALTH ME | DSPA ANTIBACTE | RIAL | | | | |
|--|-----------------|--------------------------------|---------------|-------------------|----------------|---------------|--|
| triclosan soap | | | | | | | |
| | | | | | | | |
| Product Informa | tion | | | | | | |
| Product Type | | HUMAN OTC DRUG | Item Code (Se | tem Code (Source) | | NDC:69688-001 | |
| Route of Administra | ition | TOPICAL | | | | | |
| | | | | | | | |
| | | | | | | | |
| Active Ingredien | t/Active Moi | ety | | | | | |
| Ingredient Name Basis of Stre | | | | | | Strength | |
| TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X) TRICLOSAN | | | | | 0.3 g in 100 g | | |
| | | | | | | | |
| | | | | | | | |
| Inactive Ingredie | ents | | | | | | |
| Ingredient Name | | | | | | Strength | |
| WATER (UNII: 059QF0 | | | | | | | |
| SODIUM PALMATE (| | | | | | | |
| CALCIUM CARBONA | | 379 FGK) | | | | | |
| GLYCERIN (UNII: PDC | | | | | | | |
| SODIUM CHLORIDE | (UNII: 451W47IQ | 8X) | | | | | |
| | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | | Package Description | Mark | eting Start Date | Marke | ting End Date | |
| 1 NDC:69688-001-01 | 200 in 1 BOX | | | | | | |
| 1 | 21 g in 1 PACK | AGE; Type 0: Not a Combination | Product | | | | |
| | | | | | | | |
| | | | | | | | |
| Marketing Inf | ormation | | | | | | |
| Marketing Catego | ry Applicat | ion Number or Monograph (| Citation Mar | keting Start Date | Marke | ting End Date | |
| OTC monograph not final part333E | | | 06/09 | /2015 | | | |
| | | | | | | | |

| Establishment | | | | | | | | |
|--|---------|-----------|----------------------------|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | |
| Jiangsu Xinheyuan Plastic Daily Chemical Co., Ltd. | | 527743312 | manufacture(69688-001) | | | | | |

Revised: 6/2015

Jiangsu Xinheyuan Plastic Daily Chemical Co., Ltd.