

PROTECT ANTIBACTERIAL BAR- triclosan soap
Boya Biotechnology Company Limited

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(s)

Triclosan 0.3%

Purpose

Antiseptic

Use

Decrease bacteria on the skin

Warnings

For external use only.

Stop use and ask a doctor if redness or irritation develops and persist for more than 72 hours

Keep out of reach of children except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to skin while bathing or washing

Rinse and repeat

Inactive ingredients

Sodium Palmate, Sodium Palm Kernelate, Water, Glycerin, Fragrance, Sodium Chloride, Disodium EDTA, CI 19140, CI 42090, CI 14700, CI 17200

Package Label - Principal Display Panel





| PROTECT ANTIBACTERIAL BAR | | | |
|---------------------------------|----------------|--------------------|---------------|
| triclosan soap | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73885-002 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X) | | TRICLOSAN | 0.3 g in 100 g | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| SODIUM PALMATE (UNII: S0A6004K3Z) | | | | |
| SODIUM PALM KERNELATE (UNII: 6H91L1NXTW) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| DISODIUM HEDTA (UNII: KME849MC7A) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:73885-002-01 | 140 g in 1 BOTTLE; Type 0: Not a Combination Product | 04/26/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 04/26/2020 | | |

Labeler - Boya Biotechnology Company Limited (403701144)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|------------------------|
| Boya Biotechnology Company Limited | | 403701144 | manufacture(73885-002) |

Revised: 4/2020

Boya Biotechnology Company Limited