

ANTIBACTERIAL GOLD - triclocarban soap
Kareway Product, 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

Triclocarban 0.10%

Purpose

Antibacterial

Use

For washing to decrease bacteria on the skin

Warnings

For external use only

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

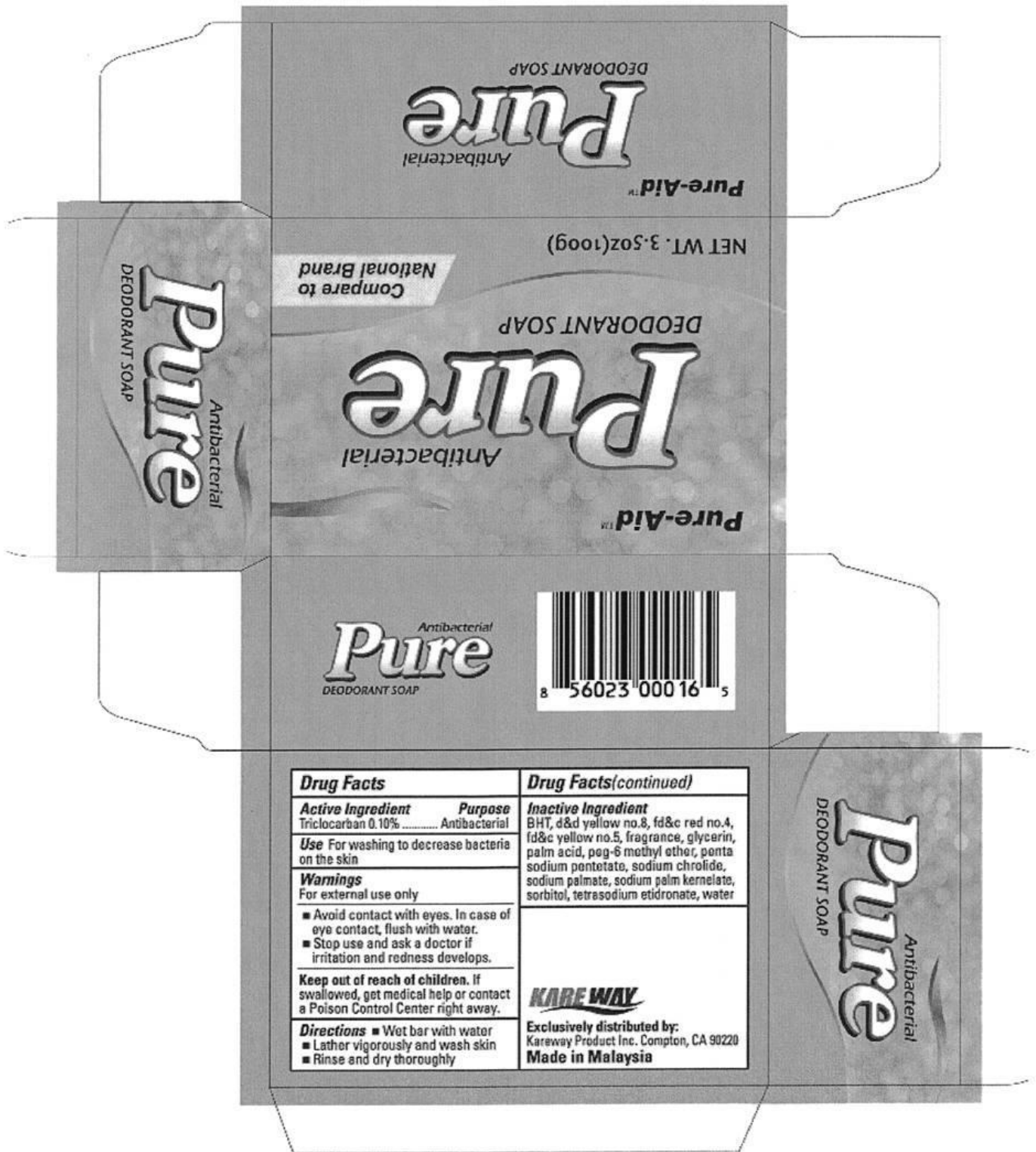
- Wet bar with water
- Lather vigorously and wash skin
- Rinse and dry thoroughly

Inactive Ingredient

BHT, DC yellow no.8, FDC red no.4, FDC yellow no.5, glycerin, palmitic acid, PEG-6 methyl ether, pentasodium pentetate, sodium chloride, sodium palmitate, sodium palm kernelate, sorbitol, tetrasodium etidronate, water

Package label

Pure Antibacterial



Compare to
National Brand

NET WT. 3.5oz(100g)



| Drug Facts | | Drug Facts(continued) |
|---|---------------------------------|---|
| Active Ingredient Triclocarban 0.10% | Purpose Antibacterial | Inactive Ingredient BHT, d&d yellow no.8, fd&c red no.4, fd&c yellow no.5, fragrance, glycerin, palm acid, peg-6 methyl ether, penta sodium pentetate, sodium chloride, sodium palmate, sodium palm kernelate, sorbitol, tetrasodium etidronate, water |
| Use For washing to decrease bacteria on the skin | |  Exclusively distributed by: Kareway Product Inc. Compton, CA 90220 Made in Malaysia |
| Warnings For external use only | | |
| <ul style="list-style-type: none"> ■ Avoid contact with eyes. In case of eye contact, flush with water. ■ 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 | | |

triclocarban soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67510-0016 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| TRICLO CARBAN (UNII: BGG1Y1ED0Y) (TRICLOCARBAN - UNII:BGG1Y1ED0Y) | TRICLOCARBAN | .1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| D&C YELLOW NO. 8 (UNII: 93X55PE38X) | |
| FD&C RED NO. 4 (UNII: X3W0AM1JLX) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PALMITIC ACID (UNII: 2V16EO95H1) | |
| PEG-6 METHYL ETHER (UNII: WXH089JZ5E) | |
| PENTASODIUM PENTETATE (UNII: 961TOZ5L7T) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM PALMITATE (UNII: JQ43KP6296) | |
| SODIUM PALM KERNELATE (UNII: 6H91L1NXTW) | |
| SORBITOL (UNII: 506T60A25R) | |
| ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4) | |
| WATER (UNII: 059QF0KO0R) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:67510-0016-3 | 3 in 1 CELLO PACK | | |
| 1 | | 100 g in 1 BOX | | |
| 2 | NDC:67510-0016-2 | 2 in 1 CELLO PACK | | |
| 2 | | 100 g in 1 BOX | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part333E | 09/07/2011 | |

Labeler - Kareway Product, Inc. (121840057)