

HEALTH-STAT FOAM - triclosan soap

Triad Group

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.

Health-Stat Foam 6576 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Triclosan 0.3%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin

Drug Facts Box OTC-Warnings Section

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

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

Drug Facts Box OTC-Dosage & Administration Section

wet hands and forearms

apply 5 milliliters (teaspoonful) or palmful to hands and forearms

scrub thoroughly for 1 minute and rinse

Drug Facts Box OTC-Inactive Ingredient Section

water, sodium laureth sulfate, sodium lauryl sulfate, cocamidopropyl betaine, alcohol denat., propylene glycol, tetrasodium EDTA, PEG-75 lanolin, boric acid, lauramine oxide, chloroxylenol, methylparaben, propylparaben, fragrance, aloe barbadensis, acid red 1, reactive green 12

Health-Stat Foam 6576 1000ml bag

6576M3P5122A.jpg Health-Stat Foam 1000ml bag

HEALTH-STAT FOAM



**High Foaming
Antiseptic Hand Wash**

**Health-Care
Personnel Handwash**

Drug Facts

Active Ingredient

Triclosan 0.3%.....Antiseptic

Purpose

Use for hand-washing to decrease bacteria on the skin

Warnings

For external use only

When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop

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

Directions ■ wet hands and forearms ■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms
■ scrub thoroughly for 1 minute and rinse

Inactive Ingredients water, sodium laureth sulfate, sodium lauryl sulfate, cocamidopropyl betaine, alcohol denat., propylene glycol, tetrasodium EDTA, PEG-75 lanolin, boric acid, lauramine oxide, chloroxylenol, methylparaben, propylparaben, fragrance, aloe barbadensis, acid red 1, reactive green 12

1000 ML 33.8 FL. OZ.

NDC 63551-576-12
Item #: 11105R-FM1000

6576M3P5122A.1010
Batch No:3010

Manufactured for: Triad Group, Inc.



700 West North Shore Dr. • Hartland, WI 53029
Made In the USA • www.triadmedical.net
Emergency/Medical Phone: (800) 535-5053
For information call: (800) 288-1288

HEALTH-STAT FOAM

triclosan soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63551-576 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X) | TRICLOSAN | 0.003 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| |
|--|
| WATER (UNII: 059QF0KO0R) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) |
| BORIC ACID (UNII: R57ZHV85D4) |
| ALCOHOL (UNII: 3K9958V90M) |
| CHLOROXYLENOL (UNII: 0F32U78V2Q) |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) |
| METHYLPARABEN (UNII: A2I8C7HI9T) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:63551-576-06 | 1 in 1 BOX | | |
| 1 | | 800 mL in 1 BAG | | |
| 2 | NDC:63551-576-17 | 532 mL in 1 BOTTLE, PLASTIC | | |
| 3 | NDC:63551-576-24 | 118 mL in 1 BOTTLE, PLASTIC | | |
| 4 | NDC:63551-576-01 | 1200 mL in 1 CARTRIDGE | | |
| 5 | NDC:63551-576-03 | 350 mL in 1 CARTRIDGE | | |
| 6 | NDC:63551-576-05 | 540 mL in 1 BOTTLE, PLASTIC | | |
| 7 | NDC:63551-576-07 | 700 mL in 1 BAG | | |
| 8 | NDC:63551-576-09 | 2000 mL in 1 CARTRIDGE | | |
| 9 | NDC:63551-576-10 | 1000 mL in 1 CARTRIDGE | | |
| 10 | NDC:63551-576-11 | 1000 mL in 1 BOTTLE, PLASTIC | | |
| 11 | NDC:63551-576-12 | 1000 mL in 1 BAG | | |
| 12 | NDC:63551-576-13 | 800 mL in 1 BAG | | |
| 13 | NDC:63551-576-14 | 3785 mL in 1 BOTTLE, PLASTIC | | |
| 14 | NDC:63551-576-15 | 946 mL in 1 BOTTLE, PLASTIC | | |
| 15 | NDC:63551-576-28 | 149 mL in 1 BOTTLE, PLASTIC | | |
| 16 | NDC:63551-576-27 | 800 mL in 1 CARTRIDGE | | |
| 17 | NDC:63551-576-55 | 208200 mL in 1 DRUM | | |
| 18 | NDC:63551-576-08 | 1 in 1 BOX | | |
| 18 | | 1000 mL in 1 BAG | | |
| 19 | NDC:63551-576-16 | 236 mL in 1 BOTTLE, PLASTIC | | |
| 20 | NDC:63551-576-18 | 50 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 01/01/2007 | |

Labeler - Triad Group (050259597)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|---------------------|
| ABC Compounding Co., Inc. | | 003284353 | manufacture |

Revised: 11/2010

Triad Group