## ANTIBACTERIAL - triclos an liquid AMERICAN SALES COMPANY

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.

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### **DRUG FACTS**

### **ACTIVE INGREDIENT**

TRICLOSAN 0.15%

### **PURPOSE**

ANTIBACTERIAL

#### **USES**

FOR WASHING TO DECREASE BACTERIA ON THE SKIN.

### **WARNINGS**

FOR EXTERNAL USE ONLY.

### WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER.

### STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS.

### KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

### **DIRECTIONS**

PUMP ONTO WET HANDS, WORK INTO A LATHER, RINSE THROUGHLY.

WATER, SODIUM LAURETH SULFATE, SODIUM COCOYL SARCOSINATE, COCAMIDOPROPYL BETAINE, FRAGRANCE, PYRUS MALUS (APPLE) FRUIT EXTRACT, SODIUM PCA, BETAINE, SORBITOL, GLYCINE, ALANINE, PROLINE, SERINE, THREONINE, ARGININE, LYSINE, GLUTAMIC ACID, ALOE BARBADENSIS LEAF JUICE, PEG-120 METHYL GLUCOSE DIOLEATE, PEG-7 GLYCERYL COCOATE, TETRASODIUM EDTA, CITRIC ACID, SODIUM CHLORIDE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE.





# warm apple

ANTIBACTERIAL HAND SOAP

8 FL OZ (236 mL)

6-15622

### **Drug Facts**

Active ingredient Triclosan 0.15 %.....

Purpose Antibacterial

Uses ■ For washing to decrease bacteria on the skin.

### Warnings

For external use only

# When using this product

■ avoid contact with eyes. ■ If contact occurs, rinse with water.

Stop using this product and ask doctor if irritation or redness develops and lasts

### Keep out of reach of children

■ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions ■Pump onto wet hands, work into a lather, Rinse thoroughly

Inactive ingredients: Water (Aqua), Sodium Laureth Sulfate, Sodium Cocoyl Sarcosinate, Cocamidopropyl Betaine, Fragrance (Parfum), Pyrus Malus (Apple) Fruit, Sodium PCA, Betaine, Sorbitol, Glycine, Alanine, Proline, Serine, Threonine, Arginine, Lysine, Glutamic Acid, Aloe Barbadensis Leaf Juice, PEG-120 Methyl Glucose Dioleate, PEG-7 Glyceryl Cocoate, Tetrasodium EDTA, Citric Acid, Sodium Chloride, Methylchloroisothiazolinone, Methylisothiazolinone,

DISTRIBUTED BY: AMERICAN SALES COMPANY 4201 WALDEN AVENUE LANCASTER, NY 14086

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Product of Canada

06-15623



### ANTIBACTERIAL

triclosan liquid

### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41520-282

**Route of Administration** 

TOPICAL

## **Active Ingredient/Active Moiety**

|                 | 11011 0 1119101111111111111111111111111                    |                   |                   |
|-----------------|--|-------------------|-------------------|
| Ingredient Name |  | Basis of Strength | Strength          |
|                 | TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X) | TRICLOSAN         | 0.15 mL in 100 mL |

| Inactive Ingredients                                   |          |
|--|----------|
| Ingredient Name  | Strength |
| WATER (UNII: 059QF0KO0R)                               |          |
| SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)            |          |
| CO CAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)          |          |
| APPLE (UNII: B423VGH5S9)                               |          |
| SO DIUM PYRRO LIDO NE CARBO XYLATE (UNII: 469 OTG57A2) |          |
| BETAINE (UNII: 3SCV180C9W)                             |          |
| SORBITOL (UNII: 506T60A25R)                            |          |
| GLYCINE (UNII: TE7660 XO1C)                            |          |
| ALANINE (UNII: OF5P57N2ZX)                             |          |
| PROLINE (UNII: 9 DLQ4CIU6 V)                           |          |
| SERINE (UNII: 452VLY9402)                              |          |
| THREO NINE (UNII: 2ZD004190S)                          |          |
| ARGININE (UNII: 94ZLA3W45F)                            |          |
| LYSINE (UNII: K3Z4F929H6)                              |          |
| GLUTAMIC ACID (UNII: 3KX376GY7L)                       |          |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)                   |          |
| PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)     |          |
| PEG-7 GLYCERYL CO CO ATE (UNII: VNX7251543)            |          |
| EDETATE SO DIUM (UNII: MP1J8420 LU)                    |          |
| CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)         |          |
| SO DIUM CHLO RIDE (UNII: 451W47IQ8X)                   |          |
| METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)     |          |
| METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)             |          |

| Packaging          |                          |                      |                    |  |  |
|--------------------|--------------------------|----------------------|--------------------|--|--|
| # Item Code        | Package Description      | Marketing Start Date | Marketing End Date |  |  |
| 1 NDC:41520-282-08 | 236 mL in 1 BOTTLE, PUMP |                      |                    |  |  |

| Marketing Information   |  |                      |                    |  |  |
|-------------------------|--|----------------------|--------------------|--|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |
| OTC monograph not final | part333E                                 | 06/22/2011           |                    |  |  |
|                         |  |                      |                    |  |  |

# Labeler - AMERICAN SALES COMPANY (809183973)

# **Registrant -** APOLLO HEALTH AND BEAUTY CARE (201901209)

| Establishment                 |         |           |                     |  |
|-------------------------------|---------|-----------|---------------------|--|
| Name                          | Address | ID/FEI    | Business Operations |  |
| APOLLO HEALTH AND BEAUTY CARE |         | 201901209 | manufacture         |  |