# FREDS ANTIBACTERIAL FRESH PEAR- triclos an liquid FREDS 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.

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#### **DRUG FACTS**

#### ACTIVE INGREDIENT

TRICLOSAN 0.46%

#### **PURPOSE**

**ANTIBACTERIAL** 

#### **USES**

HELPS REDUCE BACTERIA ON THE SKIN.

#### WARNINGS

FOR EXTERNAL USE ONLY.

#### WHEN USING THIS PRODUCT

STOP USING THIS PRODUCT AND ASK DOCTOR IF

KEEP OUT OF REACH OF CHILDREN

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

#### **DIRECTIONS**

APPLY ONTO DRY HANDS. WORK INTO A RICH FOAMY LATHER, RINSE AND DRY THOROUGHLY.

#### **OTHER INFORMATION**

STORE AT ROOM TEMPERATURE.

#### **INACTIVE INGREDIENTS:**

WATER (AQUA), SODIUM XYLENESULFONATE, DIPROPYLENE GLYCOL, GLYCERIN, SODIUM PCA, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-10, FRAGRANCE (PARFUM), DISODIUM PHOSPHATE, CETYL ALCOHOL, ALOE BARBADENSIS LEAF JUICE, CITRIC ACID, METHYLPARABEN, PROPYLPARABEN, GREEN 3 (CI 42053), YELLOW (CI 47005).



#### **Drug Facts**

Active ingredient

Purpose Antibacterial

Uses Helps reduce bacteria on the skin.

#### Warnings

For external use only.

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop using this product and ask doctor it irritation or redness develops and lasts more Ihan 7 days.

KEEP OUT OF REACH OF CHILDREN. ■ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions Apply onto dry hands. Work into a rich loamy father, rinse and dry thoroughly.

Other Information ■ Slore at room temperature

Inactive Ingredients: Water (Aqua), Sodium Xylenesulionate, Dipropylene Glycol, Glycenn, Sodium PCA, Ammonium Lauryl Sulfate, Cocarnidopropyl Betaine, Polyqualernium-10, Fragrance (Parlum), Disodium Phosphate, Cetyl Alcohol, Aloe Berbadensis Leaf Juice, Chric Acid, Methylparaben, Propylparaben, Green 3 (Cl 42053), Yelkiw 10 (Cl 47005).

Made in Canada

DISTRIBUTED BY: And'S, Inc.
4300 HERV GETWIEL RD, MERLANDS, TN 1811.5
Werelfredsing.com

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#### FREDS ANTIBACTERIAL FRESH PEAR

triclosan liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55315-185

TOPICAL **Route of Administration** 

### Active Ingredient/Active Moiety

Active ingredient/Active wrotery			
Ingredient Name	Basis of Strength	Strength	
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.46 mg in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBO XYLATE (UNII: 469 OTG57A2)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SODIUM PHO SPHATE, DIBASIC ANHYDRO US (UNII: 22ADO53M6F)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Packaging			
# Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>
1 NDC:55315-185-08	222 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	09/25/2012	

## Labeler - FREDS INC. (005866116)

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

Establishment			
Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		20 19 0 12 0 9	manufacture(55315-185)

Revised: 9/2012 FREDS INC.