

ANTIBACTERIAL- antibacterial liquid

Topco Associates LLC

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

Triclosan 0.14%

Purpose

Antibacterial

Uses

For hand washing to decrease bacteria on the skin.

Warnings

For external use only.

- **When using this product, avoid getting into eyes. If this happens, rinse thoroughly with water.**
- **Keep out of reach of children.**
- **If swallowed, get medical help or contact a Poison Control Center right away.**

Directions

- wet hands
- pump into hands
- lather vigorously
- rinse and dry thoroughly

Inactive Ingredients

Water, Cocoamidopropyl Betaine, Sodium Lauryl Ether Sulphate, Coconut Acid Diethanol Amide, PEG-40 Castor Oil, Sodium Chloride, Phenoxyethanol, Fragrance, Citric Acid, Ethylenediaminetetraacetic Acid Disodium Salt, PEG-600 Stearate, Red 4(C.I. 14700)

DISTRIBUTED BY

TOPCO ASSOCIATES LLC

7711 GROSS POINT RD.

SKOKIE, IL 60077

MADE IN CHINA

© TOPCO JPC1106

Principal Display Panel – Floral Bottle Label

VALU TIME

antibacterial

Hand Soap

FLORAL

11.5 FL OZ (340mL)



Drug Facts	
Active Ingredient	Purpose
Triclosan 0.14%.....	Antibacterial
Uses For hand washing to decrease bacteria on the skin.	
Warnings For external use only. ■ When using this product, avoid getting into eyes. If this happens, rinse thoroughly with water. ■ Keep out of reach of children. ■ If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ wet hands ■ pump into hands ■ lather vigorously ■ rinse and dry thoroughly	
Inactive Ingredients Water, Cocoamidopropyl Betaine, Sodium Lauryl Ether Sulphate, Coconut Acid Diethanol Amide, PEG-40 Castor Oil, Sodium Chloride, Phenoxyethanol, Fragrance, Citric Acid, Ethylenediaminetetraacetic Acid Disodium Salt, PEG-600 Stearate, Red 4(C.I.14700)	
DISTRIBUTED BY TOPCO ASSOCIATES LLC 7711 GROSS POINT RD., SKOKIE, IL 60077 MADE IN CHINA ©TOPCO JPC1106	 0 11225 06044 1

Principal Display Panel – Herbal Bottle Label

VALU TIME
antibacterial
Hand Soap
HERBAL
11.5 FL OZ (340mL)



Drug Facts	
Active Ingredient	Purpose
Triclosan 0.14%.....	Antibacterial
Uses For hand washing to decrease bacteria on the skin.	
Warnings For external use only. ■ When using this product, avoid getting into eyes. If this happens, rinse thoroughly with water. ■ Keep out of reach of children. ■ If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ wet hands ■ pump into hands ■ lather vigorously ■ rinse and dry thoroughly	
Inactive Ingredients Water, Cocoamidopropyl Betaine, Sodium Lauryl Ether Sulphate, Coconut Acid Diethanol Amide, PEG-40 Castor Oil, Sodium Chloride, Phenoxyethanol, Fragrance, Citric Acid, Ethylenediaminetetraacetic Acid Disodium Salt, PEG-600 Stearate, Green 3(C.I.42053)	
DISTRIBUTED BY TOPCO ASSOCIATES LLC 7711 GROSS POINT RD., SKOKIE, IL 60077 MADE IN CHINA ©TOPCO JPC1106	 0 11225 06043 4

Principal Display Panel – Natural Bottle Label

VALU TIME
antibacterial
Hand Soap
NATURAL
11.5 FL OZ (340mL)



Drug Facts	
Active Ingredient	Purpose
Triclosan 0.14%.....	Antibacterial
Uses For hand washing to decrease bacteria on the skin.	
Warnings	
For external use only.	
<ul style="list-style-type: none"> ■ When using this product, avoid getting into eyes. If this happens, rinse thoroughly with water. ■ Keep out of reach of children. ■ If swallowed, get medical help or contact a Poison Control Center right away. 	
Directions	
<ul style="list-style-type: none"> ■ wet hands ■ pump into hands ■ lather vigorously ■ rinse and dry thoroughly 	
Inactive Ingredients Water, Cocoamidopropyl Betaine, Sodium Lauryl Ether Sulphate, Coconut Acid Diethanol Amide, PEG-40 Castor Oil, Sodium Chloride, Phenoxyethanol, Fragrance, Citric Acid, Ethylenediaminetetraacetic Acid Disodium Salt, PEG-600 Stearate, Yellow 5(C.I.19140)	
DISTRIBUTED BY TOPCO ASSOCIATES LLC 7711 GROSS POINT RD., SKOKIE, IL 60077 MADE IN CHINA ©TOPCO JFC1106	
 0 11225 06042 17	

ANTIBACTERIAL

antibacterial liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 162-10 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
triclosan (UNII: 4NM5039 Y5X) (triclosan - UNII:4NM5039 Y5X)	triclosan	0.476 mL in 340 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	
sodium chloride (UNII: 451W47IQ8X)	
phenoxyethanol (UNII: HIE492ZZ3T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76 162-101-01	340 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/01/2006	

ANTIBACTERIAL

antibacterial liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 162-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
triclosan (UNII: 4NM5039 Y5X) (triclosan - UNII:4NM5039 Y5X)	triclosan	0.476 mL in 340 mL

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	
sodium chloride (UNII: 451W47IQ8X)	
phenoxyethanol (UNII: HIE492ZZ3T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76 162-102-01	340 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/01/2006	

ANTIBACTERIAL

antibacterial liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 162-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
triclosan (UNII: 4NM5039 Y5X) (triclosan - UNII:4NM5039 Y5X)	triclosan	0.476 mL in 340 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	
sodium chloride (UNII: 451W47IQ8X)	
phenoxyethanol (UNII: HIE492ZZ3T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76 162-103-01	340 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/01/2006	

Labeler - Topco Associates LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
BBC Group Limited		421270060	MANUFACTURE

