

HAND CLEANSE WATER MELON SCENT- triclosan soap
Volume Distributors, 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.

Active Ingredient Purpose

Triclosan 0.2% Antibacterial

☐**Uses**☐ For handwashing to decrease bacteria on the skin.

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

Bebelle For Kids

Gently cleanses & kills germs

Anti-Bacterial Hand Soap

Jabon de Manos Antibacterial para Ninos

Water Melon Scent

☐**Directions**

- Pump into hands
- Lather vigorously for at least 15 seconds
- rinse and dry thoroughly

☐**Warnings**

For external use only

When using this product, avoid contact with eyes. In case of eye contact, flush with water.

Stop use and ask a doctor if irritation and redness develops.

☐**Inactive Ingredients**

water, sodium c14-16 olefin sulfonate, sodium laureth sulfate, cocamide MEA, sodium chloride, PEG-150 distearate, glycerin, fragrance, citric acid, disodium EDTA, methylchloroisothiazolinone, methylisothiazolinone, FD&C yellow no.5, FD&C blue no.1



Anti-Bacterial

Hand Soap

Jabón de Manos
Antibacterial Para Niños



Water Melon Scent

7.5 FL OZ (221ml)

Drug Facts

Active ingredient

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Purpose

Antibacterial

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Warnings For external use only.

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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 • pump into hands • lather vigorously for at least 15 seconds • rinse and dry thoroughly.

Other information • store at room temperature

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HAND CLEANSE WATER MELON SCENT

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50523-085
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50523-085-01	221 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/10/2015	

Labeler - Volume Distributors, Inc. (002029544)

Establishment

Name	Address	ID/FEI	Business Operations
Volume Distributors, Inc.		002029544	manufacture(50523-085)

Revised: 7/2015

Volume Distributors, Inc.