

SPASOAP LIQUID ANTIBACTERIAL - triclosan solution

Brands International

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.

SpaSoap Liquid Antibacterial

Drug Facts

Active Ingredients

Triclosan 0.115%

Purpose

Antibacterial

Uses

for handwashing to decrease bacteria on the skin

Warnings

For external use only.

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

When using this product do not get into eyes. If contact occurs, rinse eye 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
- apply palmful to hands
- scrub thoroughly
- rinse

Inactive ingredients

Water, Sodium Laureth Sulfate, Sodium Chloride, DMDM Hydantoin, Citric Acid, Fragrance, EDTA, Yellow # 5, Red # 33

Package Label

SpaSoap

Liquid Soap
Antibacterial
Refill
64 oz / 1.9L
Hand Soap



8 52474 16872 0

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Antibacterial Liquid Soap

Made In Canada

Sante Manufacturing Inc. LAT 112

SPASOAP LIQUID ANTIBACTERIAL

triclosan solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 157-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	1.15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETIC ACID (UNII: 9G34HU7RV0)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 157-10 1-64	1900 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/24/20 15	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/24/20 15	

Labeler - Brands International (243748238)**Registrant** - Sante Manufacturing Inc (252365486)**Establishment**

Name	Address	ID/FEI	Business Operations
Brands International		243748 238	manufacture(50 157-10 1)

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Brands International