

**TRICLOSAN- antibacterial liquid soap refill soap**  
**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.*

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**Antibacterial Liquid Soap Refill**

**Drug Facts**

Active Ingredients

Triclosan 0.115%

**Purpose**

Antibacterial

**Uses**

for handwashing or decrease bacteria to the skin

For external use only

**Stop use and ask a doctor if**

irritation or redness develops

**When using this product**

- do not get it 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

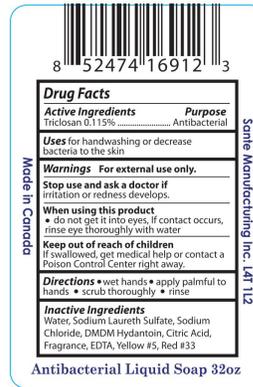
**Package Label**

Spa Soap

Antibacterial

Liquid Soap

# Refill



## TRICLOSAN

antibacterial liquid soap refill soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50 157-119
<b>Route of Administration</b>	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: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

EDETIC ACID (UNII: 9G34HU7RV0)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-119-32	947 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/03/2016	

**Labeler** - Brands International (243748238)

**Registrant** - Sante Manufacturing Inc (252365486)

Establishment			
Name	Address	ID/FEI	Business Operations
Brands International		243748238	manufacture(50157-119)