

SWIRLING LOLLIPOP- antibacterial hand sanitizer gel
Brands International Corp

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.

PACKAGE LABEL

SWIRLING LOLLIPOP

ANTIBACTERIAL

Hand Sanitizer Gel

Kills 99.99% of Germs

1 FL OZ (29ml)



ACTIVE INGREDIENTS: Ethyl Alcohol 62%

Antiseptic

Use

- To decrease bacteria on the skin and clean hands.
- Recommended for repeated use.

Warnings

For external use only.

Flammable, keep away from fire or flame.

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

Do not get into eyes. If contact occurs, rinse thoroughly with water.

Discontinue use if irritation or redness develop. If irritation persists for more than 72 hours, consult a doctor.

Directions

- apply to hands until thoroughly wet
- rub vigorously until dry
- supervise children in the use of this product

- may discolor certain fabrics or surfaces
- do not store above 110°F (43°C)

Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl (Vitamin E) Acetate, Sunflower (Helianthus Annuus) Seed Extract, Yellow 5 (CI 19140), Blue 1 (CI 42090)

SWIRLING LOLLIPOP

antibacterial hand sanitizer gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 157-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 mL in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 157-114-01	29 mL in 1 BOTTLE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	11/02/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/02/2015	

Labeler - Brands International Corp (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corp		243748238	manufacture(50157-114)

Revised: 11/2015

Brands International Corp