

HAWAIIAN PASSION HAND SANITIZER - alcohol 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.

Hawaiian Passion Hand Sanitizer

Drug Facts

Active Ingredients

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

- 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.

Other information

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

Inactive ingredients

Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl (Vitamin E) Acetate, Sunflower (Helianthus Annus) Seed Extract, Grapefruit (Citrus Grandis) Seed Extract, Red 33 (CI 17200).

Manufactured by:

Brands International Corp.
Markham, ON, L6G 1B9 Canada
www.brandsicorp.com

Package Label

HAWAIIAN PASSION

ANTIBACTERIAL

Hand Sanitizer Gel

Kills 99.99% of Germs

1 FL OZ (29 ml)



HAWAIIAN PASSION HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-106-01	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/20/2015	

Labeler - Brands International (243748238)