

HAND SANITIZER- alcohol gel
Markwins Beauty Products, 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.

Smackers Purifying Pals Hand Sanitizer Cotton Candy Clouds

Active Ingredient

Ethyl alcohol 63%

Purpose

Antimicrobial

Use

Hand sanitizer to help reduce bacteria on the skin that could cause disease.

Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame.

For external use only - do not use on damaged or broken skin

When using this product

keep out of eyes, ears, and mouth. in case of contact, rinse eyes thoroughly with water. avoid contact with broken skin. do not inhale or ingest

Stop use and ask a doctor

if irritation or rash occurs and lasts.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Other information

Store below 86F (30C). avoid freezing and excessive heat 104F (40C). may discolor certain fabrics or surfaces.

Inactive ingredients

water/eau, glycerin, acrylates/c10-30 alkyl acrylate crosspolymer, sodium hyaluronate, aminomethyl propanol, trehalose, biosaccharide gum-1, glycereth-26, tocopheryl acetate, flavor/aroma, red 40 (ci 16035), yellow 5 (ci 19140).

正面
Top of front panel (NDC 12027-300-01) - address and
 contact information
 WARNING: This drug product contains alcohol. Strengths of
 63 mL and 100 mL are available. Do not use if you are
 pregnant, or if you are breastfeeding.

二层反面
Drug Facts (continued)
OTHER INFORMATION - see back of box - address and
 contact information
 Contains Drug Facts
 See back of box for complete list of ingredients, including
 inactive ingredients, and for full prescribing information.
 See important information about this drug on page 2 of this
 Drug Facts panel.
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三层正面

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12027-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
BIO SACCCHARIDE GUM-1 (UNII: BB4PU4V09H)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
TREHALOSE (UNII: B8WCK70T7I)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
GLYCERETH-26 (UNII: NNE56F2N14)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12027-300-01	25 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final

part333A

06/01/2020

Labeler - Markwins Beauty Products, Inc. (135407760)

Revised: 6/2020

Markwins Beauty Products, Inc.