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 Berry Sweet Mermaid

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).

Directions

place enough product on hands to cover hands thoroughly. rub hands together until dry. for children under 6 years of age, use only under adult supervision. not recommended for infants.



LMK_Purifying Pals- Hand Sanitizer 20200427



APPROVED 5/4/2020

HAND SANITIZER

alcohol gel

Product Information	Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12027-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	63 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
BIOSACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
TREHALOSE (UNII: B8WCK70T7I)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
GLYCERETH-26 (UNII: NNE56F2N14)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:12027-301- 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
OTC monograph not final	part333A	06/01/2020	

Labeler - Markwins Beauty Products, Inc. (135407760)

Revised: 6/2020 Markwins Beauty Products, Inc.