SUMMER BREEZE HAND SANITIZER- alcohol gel
Reaction Retail, LLC

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.

Summer Breeze Hand Sanitizer

Drug Facts

Active Ingredients

Ethyl Alcohol 75%

Purpose

Antiseptic

Uses:

Hand sanitizer to help decrease bacteria on the skin.

Warnings:

For external use only. Flammable. Keep away from fire or flame.

Stop use and ask doctor

if irritation or rash appears and lasts.

Keep out of reach of children.

If swallowed, get medical help or contact a doctor right away.

Directions:

Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry.

Other Information:

Store below 118°F.

INACTIVE INGREDIENTS:

Aqua (Water), Propylene Glycol, Glycerin, Aloe Barbadensis Leaf Juice Parfum (Fragrance) Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Citric Acid, Potassium Sorbate, Sodium Benzoate, Sucrose, Zea Mays (Corn) Starch, Hydroxypropyl Methylcellulose, Polyvinyl Alcohol, BHT, Benzyl Salicylate, Linalool, Limonene, CI 77267 (D&C Black No.3), CI 42090 (FD&C Blue No.1).

Package Labeling:

SUMMER BREEZE HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80026-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
CORN (UNII: 0N8672707O)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
D&C BLACK NO. 2 (UNII: 4XYU5U00C4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80026-001-35	35 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/15/2020	

Labeler - Reaction Retail, LLC (968085212)

Revised: 8/2020 Reaction Retail, LLC