HAND SANITIZER- alcohol gel
Valley of the Sun Cosmetics 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.

Hand Sanitizer (no fragrance)

Active Ingredients

Ethyl Alcohol 80% v/v

Purpose

Antimicrobial

Uses

Hand Sanitizer is to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product

keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask doctor

Stop use and ask doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients

Water (aqua), glycerin, carbomer, acrylates/C10 30 alkyl acrylate crosspolymer, aminomethyl propanol, hydrogen peroxide, retinyl palmitate (vitamin A), tocopheryl acetate (vitamin E), cannabis sativa (hemp) seed oil

Package Label

Hand Sanitizer 80% Alcohol (no fragrance), 8oz/236ml, NDC: 76523-080-08

Hand Sanitizer-Drs Formula - 8oz Bottle 80% Alcohol - 10-30-2020 (No Fragrance)

Label Specs: 4 color
Coating: Laminate (Flat)
Material: White BOPP Adhesive
Die: 6.1713" x 4.75"

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76523-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.05 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06 mL in 100 mL
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	0.2 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	0.03 mL in 100 mL
CARBOMER 934 (UNII: Z135WT9208)	0.01 mL in 100 mL
WATER (UNII: 059QF0KO0R)	18.05 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	0.02 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76523-080-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/16/2020	

Labeler - Valley of the Sun Cosmetics LLC (176470664)

Registrant - Valley of the Sun Cosmetics LLC (176470664)

Establishment

Name	Address	ID/FEI	Business Operations
Valley of the Sun Cosmetics LLC		176470664	manufacture(76523-080)

Revised: 11/2020 Valley of the Sun Cosmetics LLC