

HAND SANITIZER- ethyl alcohol gel

SJ Creations, 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.

Drug Facts

Active Ingredient(s)

Ethyl Alcohol 65% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer 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 a 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.

Stop use and ask a 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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, Glycerin, Propylene Glycol, Carbomer, Fragrance, Tocopheryl Acetate, Isopropyl Alcohol,

Aminomethyl Propanol, Isopropyl Palmitate.

Package Label - Principal Display Panel



HAND
SANITIZER
GEL

KILLS 99.99% OF GERMS
VITAMIN E & MOISTURIZERS

16 FL.OZ. (473 ML)

Drug Facts

Active ingredient
Ethyl alcohol 65% v/v

Purpose
Antiseptic

Use
• Hand sanitizer to help reduce bacteria on the skin.

Warnings
For external use only.
Flammable. Keep away from fire and flame.
When using this product avoid contact with eyes. In case of contact, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation and redness develop.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions
• Put enough on your palm to cover hands and rub hands together briskly until dry
• Children under 6 years of age should be supervised when using this product

Other information
• Store at 20°C to 25°C (68°F to 77°F).
• May discolor some fabrics or surfaces.

Inactive ingredients
Deionized Aqua (Water), Glycerin, Propylene Glycol, Carbomer, Fragrance (Parfum), Tocopheryl Acetate, Isopropyl Alcohol, Aminomethyl Propanol, Isopropyl Palmitate.

Questions?
1-888-942-2280 Monday – Friday 9 AM – 5 PM PST

201107
DIST. BY SJ CREATIONS, INC.
P.O. BOX 22928
LEUCADIA, CA 92023, U.S.A.
WWW.SJCREATIONSGINC.COM
PRODUCT OF CHINA



0201 1073

473ml NDC: 43269-927-16

HAND SANITIZER						
ethyl alcohol gel						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43269-927			
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Ingredient Name		Basis of Strength	Strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	65 mL in 100 mL			
Inactive Ingredients						
Ingredient Name			Strength			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)						
WATER (UNII: 059QF0KO0R)						
GLYCERIN (UNII: PDC6A3C0OX)						
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
CARBOMER 940 (UNII: 4Q93RCW27E)						
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)						
ISOPROPYL ALCOHOL (UNII: ND2M416302)						
Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		

1	NDC:43269-927-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/07/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/30/2020	

Labeler - SJ Creations, Inc. (146379495)

Establishment			
Name	Address	ID/FEI	Business Operations
Tonic Bath & Body Products Shenzhen Ltd		528197042	manufacture(43269-927)