

HAND SANITIZER- ethyl alcohol spray

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 74% 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.

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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, Citrus Paradisi (Grapefruit) Peel Oil, Citrus Limon (Lemon) Peel Oil, Tocopheryl

Acetate, Aloe Barbadensis Leaf Juice, Aloe Barbadensis Leaf Extract, Althaea Officinalis Root Extract, Centella Asiatica Extract, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Citrus Grandis (Grapefruit) Fruit Extract, Citrus Limon (Lemon) Peel Extract, Cymbopogon Schoenanthus Leaf/Stem Extract, Equisetum Arvense Extract, Humulus Lupulus (Hops) Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Salvia Sclarea (Clary) Extract, Vaccinium Myrtillus Fruit/Leaf Extract, Yucca Schidigera Leaf/Root/Stem Extract.

Package Label - Principal Display Panel

Spenser & Jensen
HAND SANITIZER SPRAY
 KILLS 99.99% OF GERMS
 NO WATER OR TOWEL NEEDED
 CITRUS SCENTED
 MADE WITH ALOE & VITAMIN E
 8 FL. OZ. (236 ML)

Drug Facts
Active ingredient Ethyl alcohol 75%
Purpose Antiseptic
Uses • for hand washing to decrease germs on the skin
 • accidental or repeated use throughout the day
Warnings
For external use only
Precautions Keep away from flames.
 When using this product avoid contact with the eyes. In case of contact, flush eyes thoroughly with water.
 Stop use and contact a doctor if irritation or redness develops or lasts for more than 72 hours.
 Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.
Directions • wet hands thoroughly with product
 • rub hands dry with air drying • supervise children under 6 years old
 • not recommended for infants
Other information • may discolor certain fabrics
 • store at room temperature 20°-25° C (68°-77° F)
Inactive ingredients Water, Glycerin, Citrus Paradisi (Grapefruit) Peel Oil, Citrus Limon (Lemon) Peel Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice, Acetylglucosyl N-Amino L-Ala, Barbadensis Leaf Extract, Althaea Officinalis Root Extract, Centella Asiatica Extract, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Citrus Grandis (Grapefruit) Fruit Extract, Citrus Limon (Lemon) Peel Extract, Cymbopogon Schoenanthus Leaf/Stem Extract, Equisetum Arvense Extract, Humulus Lupulus (Hops) Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Salvia Sclarea (Clary) Extract, Vaccinium Myrtillus Fruit/Leaf Extract, Yucca Schidigera Leaf/Root/Stem Extract
Questions? 1-888-942-2230 Mon-Fri 9 AM - 5 PM PST

MADE IN THE USA
 6-192592-052894

236 ml NDC: 43269-932-08

HAND SANITIZER			
ethyl alcohol spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43269-932
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	74 mL in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
LEMON OIL (UNII: I9GRO824LL)			
WATER (UNII: 059QF0K00R)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)			
CENTELLA ASIATICA (UNII: 7M867G6T1U)			
CHAMOMILE (UNII: FGL3685T2X)			

ORANGE PEEL (UNII: T19T76XD44)	
LEMON PEEL (UNII: 72O054U628)	
HUMULUS LUPULUS WHOLE (UNII: 912A6Q1N4A)	
ROSMARINUS OFFICINALIS WHOLE (UNII: EA3289138M)	
VACCINIUM MYRTILLUS WHOLE (UNII: EE76EZ4QNZ)	
YUCCA SCHIDIGERA (UNII: 08A0YG3VIC)	
CYMBOPOGON SCHOENANTHUS WHOLE (UNII: RJJ0F54DE8)	
EQUISETUM ARVENSE WHOLE (UNII: 73DM367W4P)	
SALVIA SCLAREA WHOLE (UNII: I0440F92M2)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43269-932-08	236 mL in 1 BOTTLE, SPRAY; 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
McKenna Labs, Inc.		090631412	manufacture(43269-932)

Revised: 4/2020

SJ Creations, Inc.