

HANDRUB SANITIZER- alcohol liquid

Volu-Sol

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 69% v/v. Purpose: Antiseptic

Isopropyl Alcohol 7.2% 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

glycerin, hydrogen peroxide, methanol, methyl isobutyl ketone, purified water USP

Package Label - Principal Display Panel

946 mL NDC: 77401-800-32

VOLU-SOL Handrub Sanitizing Solution
Topical Solution, Non-sterile Solution
ID: WHO32PE NDC: 74401-800-32
946 mL / 32 fl oz
LOT 03172020
03/2022
15°C (59°F) - 30°C (86°F)
Antiseptic Hand Rub
Flammable, keep away from fire or flame, heat, sparks and sources of static discharge
See SDS for further information
VOLU-SOL
5005 W 2100 S
Salt Lake City, UT 84120
Phone: 1-800-821-2495
www.volsol.com
customerservice@volsol.com

Drug Facts
Active Ingredients
Ethyl Alcohol, 69% w/v.....Antiseptic
Isopropyl Alcohol, 7.2% w/v.....Antiseptic
Uses
Health care personnel handrub to help reduce bacteria that potentially can cause disease.
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. If contact with eyes occurs, rinse promptly and thoroughly with water. Stop use and ask a doctor if significant irritation or sensitization develops. 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
Avoid freezing and excessive heat above 40C (104F)
Inactive Ingredients
Glycerin, Hydrogen Peroxide, Methanol, Methyl Isobutyl Ketone, Purified Water USP

473 mL NDC: 77401-800-16



Handrub Sanitizing Solution

Topical Solution
Non-sterile Solution
ID: WHO16 NDC:74401-800-16
473 mL / 16 fl oz

LOT 03172020
03/2022

Antiseptic Hand Rub
Flammable, keep away from fire or flame, heat, sparks and sources of static discharge
See SDS for further information

Volu-Sol
5095 W 2100 S
Salt Lake City, UT 84120
Phone: 1-888-611-3495
www.volasol.com
customerservice@volasol.com




Drug Facts

Active Ingredients
Ethyl Alcohol, 60% v/v.....Antiseptic
Isopropyl Alcohol, 7.2% v/v.....Antiseptic

Uses
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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. If contact with eyes occurs, rinse promptly and thoroughly with water. Stop use and ask a doctor if significant irritation or sensitization develops. 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
Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients
Glycerin, Hydrogen Peroxide, Methanol, Methyl Isobutyl Ketone, Purified Water USP

HANDRUB SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74401-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	7.2 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	69 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

WATER (UNII: 059QF0KO0R)				
METHYL ALCOHOL (UNII: Y4S76JWI15)			3.43 mL in 100 mL	
METHYL ISOBUTYL KETONE (UNII: U5T7B88CNP)			0.72 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74401-800-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74401-800-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/30/2020	

Labeler - Volu-Sol (050173424)

Registrant - Volu-Sol (050173424)

Establishment			
Name	Address	ID/FEI	Business Operations
Volu-Sol		050173424	manufacture(74401-800)