

SANITIZER SOLUTION, FORMULATION ONE- alcohol liquid Volu-Sol

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 80% 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.

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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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



Sanitizer Solution, Alcohol Antiseptic 80%
Formulation One, Topical Solution

ID: WHOM016P NDC:74401-700-47
473 mL / 16 fl oz

LOT WHO110
6/2022



Antiseptic, Hand Sanitizer

See SDS for further information

Volu-Sol
5065 W 2100 S
Salt Lake City, UT 84120
Phone: 1-800-821-3495
www.volusol.com
customerservice@volusol.com



Drug Facts

Active Ingredient:
Ethyl Alcohol, 80% v/v.....Antiseptic

Uses
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 or 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.

Directions
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Other Information
Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients
Glycerin, Hydrogen Peroxide, Purified Water USP

120 mL NDC: 74401-700-04



Sanitizer Solution, Alcohol Antiseptic 80%

Formulation One, Topical Solution
Non-sterile Solution

ID: WHO-004 NDC:74401-700-04

120 mL / 4 fl oz

LOT WHO107

5/2022

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

Volu-Sol
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Salt Lake City, UT 84120
Phone: 1-800-821-2495
www.volusol.com
customerservice@volusol.com



Drug Facts

Active Ingredient
Ethyl Alcohol, 80% 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, Purified Water USP

60 mL NDC: 74401-700-02



Sanitizer Solution Alcohol Antiseptic 80%

Formulation One, Topical Solution
Non-sterile Solution

ID: WHO-002 NDC:74401-700-02

60 mL / 2 fl oz

LOT 082720

08/2022

Antiseptic Hand Rub

Flammable, keep away from fire or flame, heat, sparks and sources of static discharge

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15 C (59 F) 30 C (86 F)

Drug Facts

Active Ingredient
Ethyl Alcohol, 80% 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, Purified Water USP

946 mL NDC: 74401-700-32



Sanitizer Solution, Alcohol Antiseptic 80%

Formulation One, Topical Solution, Non-sterile Solution

ID: WHO-270 NDC: 74401-700-27
1022 L / 270 gal

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
5095 W 2100 S
Salt Lake City, UT 84120
Phone: 1-888-621-3495
www.volasol.com
customerservice@volasol.com



Drug Facts

Active ingredient
(Ethyl Alcohol, 80% v/v).....Antiseptic

Uses
Healthcare 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, Purified Water USP



Sanitizer Solution, Alcohol Antiseptic 80%

Formulation One, Topical Solution, Non-sterile Solution

ID: WHO-032PE NDC: 74401-700-32

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

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Drug Facts

Active ingredient
(Ethyl Alcohol, 80% w/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.

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Other information
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Inactive Ingredients
Glycerin, Hydrogen Peroxide, Purified Water USP

1022 L NDC: 74401-700-27

473 mL NDC: 74401-700-16



Sanitizer Solution, Alcohol Antiseptic 80%

Formulation One, Topical Solution
Non-sterile Solution
ID: WHO-016P NDC:74401-700-16

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

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Drug Facts

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Uses
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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
Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients
Glycerin, Hydrogen Peroxide, Purified Water USP

208 L NDC: 74401-700-55



Sanitizer Solution, Alcohol Antiseptic 80%
 Formulation One, Topical Solution, Non-sterile Solution

ID: WHO-055 NDC: 74401-700-55
 208 L / 55 gal

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

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 Salt Lake City, UT 84120
 Phone: 1-888-821-2495
 www.volasol.com
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Drug Facts

Active ingredient
 (Ethyl Alcohol, 80% w/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
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Other information
 Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients
 Glycerin, Hydrogen Peroxide, Purified Water USP

SANITIZER SOLUTION, FORMULATION ONE

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74401-700
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74401-700-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74401-700-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74401-700-55	208000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74401-700-27	1022000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74401-700-47	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:74401-700-04	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
7	NDC:74401-700-02	60 mL in 1 BOTTLE, SPRAY; 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 Drug	505G(a)(3)	03/30/2020	09/30/2023

Labeler - Volu-Sol (050173424)

Registrant - Volu-Sol (050173424)

Establishment

Name	Address	ID/FEI	Business Operations
Volu-Sol		050173424	manufacture(74401-700)

Revised: 1/2025

Volu-Sol