

SP HAND SANITIZER 99- alcohol solution
Solutions Plus, 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.

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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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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

0.9464 L (946.4 mL) NDC: 77096-002-01

SP HAND SANITIZER 99

ISOPROPYL ALCOHOL ANTISEPTIC
75% TOPICAL SOLUTION
HAND SANITIZER
NON-STERILE SOLUTION

D.O.T. and Hazard Information:

UN 1219

Isopropyl Alcohol, 3, III

KEEP OUT OF THE REACH OF CHILDREN.
FOR INDUSTRIAL OR FOOD PLANT USE ONLY

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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HMIS RATINGS:

HEALTH	2
FLAMMABILITY	2
REACTIVITY	0
PERSONAL PROTECTION	A

WARNING



HAZARD STATEMENTS:

CAUSES SERIOUS EYE IRRITATION.
FLAMMABLE LIQUID AND VAPOR.

PRECAUTIONARY STATEMENTS:

Keep away from heat/sparks/open flames/hot surfaces - No smoking.
Keep container tightly closed.
Ground/bond container and receiving equipment
Use explosion-proof electrical/ventilating/light/equipment
Use only non-sparking tools
Take precautionary measures against static discharge

IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses if present and easy to do. Continue rinsing.
IF EYE IRRITATION PERSISTS: Get medical advice/attention.

Solutions Plus, Inc.
INDUSTRIAL CLEANING PRODUCTS
"Turning Problems into Solutions"
3907 Bach Buxton Road
Amelia, OH 45102-1013
(888)943-1100

24 Hour Emergency Transportation
Number: 1-800-255-3924

Product Code: SP 1769

Labeler Code: NDC 77096-002-01

Batch Number: S043020-20

1 Quart (946.4 mL) Bottle

3.78 L (3780 mL) NDC: 77096-002-02

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Product Code: SP 1769

Labeler Code: NDC 77096-002-02

Batch Number: S043020-20

1 Gallon (3.78L) Bottle

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HEALTH	2
FLAMMABILITY	2
REACTIVITY	0
PERSONAL PROTECTION	A

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18.92 L (18920 mL) NDC: 77096-002-03

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Product Code: SP 1769

Labeler Code: NDC 77096-002-03

Batch Number: S043020-20

5 Gallon (18.92L) Pail

HMIS RATINGS:

HEALTH	2
FLAMMABILITY	2
REACTIVITY	0
PERSONAL PROTECTION	A

WARNING



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208.2 L (208200 mL) NDC: 77096-002-04

SP HAND SANITIZER 99

ISOPROPYL ALCOHOL ANTISEPTIC
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Product Code: SP 1769

Labeler Code: NDC 77096-002-04

Batch Number: S043020-20

55 Gallon (208.2L) Drum

SP HAND SANITIZER 99

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77096-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L

HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0KO0R)	18.425 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77096-002-01	0.9464 L in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
2	NDC:77096-002-02	3.78 L in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
3	NDC:77096-002-03	18.92 L in 1 PAIL; Type 0: Not a Combination Product	05/11/2020	
4	NDC:77096-002-04	208.2 L in 1 DRUM; Type 0: Not a Combination Product	05/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/11/2020	

Labeler - Solutions Plus, Inc. (965638760)

Establishment

Name	Address	ID/FEI	Business Operations
Solutions Plus, Inc.		965638760	manufacture(77096-002)

Revised: 5/2020

Solutions Plus, Inc.