HAND SANITIZER- is opropyl alcohol spray Superior Solutions

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.

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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Isopropyl Alcohol Antiseptic 75%

Topical Solution

Hand Santitizer Non-sterile Solution

(1892 mls)

Drug Facts	
Active ingredient[s]	Purpose
tsopropyl alcohol 75% v/v	Antheptic
Use[s]	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and wi	rter are not available.
Warnings	175-175-10-175-2
For external use only. Flammable. Keep away from heat or flame	
Do not use	
D in children less than 2 months of age	
D 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 rigit	t away.
Directions	
Mace 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 giverin, hydrogen percoide, purified water USP	

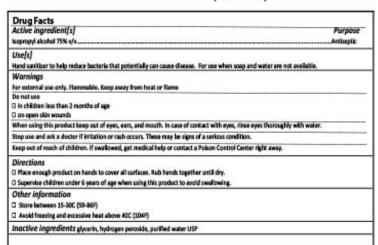
1892 ml NDC: 74101-099-02

Isopropyl Alcohol Antiseptic 75%

Topical Solution

Hand Santitizer Non-sterile Solution

(3785 mls)



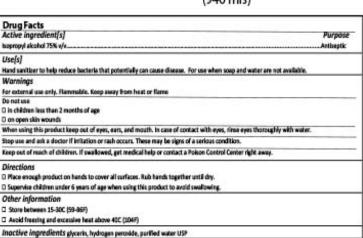
3785 ml NDC: 74101-099-01

Isopropyl Alcohol Antiseptic 75%

Topical Solution

Hand Santitizer Non-sterile Solution

(946 mls)



946 ml NDC:74101-099-16

Isopropyl Alcohol Antiseptic 75%

Topical Solution

Hand Santitizer Non-sterile Solution

(236 mls)



Drug Facts Active ingredient(s)	Purpose
	THE PERSON AND THE PERSON AND ADDRESS OF THE PERSON ADDRESS OF THE PERSON AND ADDRESS OF THE PERSON ADDRESS OF THE P
hopropyl alcohol 75% v/s	Artiseptic
Use[s]	
Hand sanitizer to help reduce bacteris that potentially can cause disease. For use when soap and water a	re not available.
Warnings	1251111115
for external use only. Flammable. Keep away from heat or flame	
Do not use	
🛘 in children less than 2 months of age	
D on open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoro	ughly 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 awa	ış.
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	

236 ml NDC:74101-099-08

Isopropyl Alcohol Antiseptic 75%

Topical Solution

Hand Santitizer Non-sterile Solution

(118 mls)



Drug Facts	
Active ingredient[s]	Purpose
sopropyl alcohol 75% v/e	Antiseptic
Use[s]	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not av	allable.
Warnings	
for external use only. Flammable. Keep away from heat or flame	
Do not use	
I 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 wi	h water.
Stop use and ask a doctor if initation 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	
Mace 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 giycerin, hydrogen percoide, purified water USP	

118 ml NDC:74101-099-04

Active Ingredient/Active Moiety

HAND SANITIZER

isopropyl alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74101-099
Route of Administration	TOPICAL		

Ingredient Name	Basis of Strength	Strength
	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74101-099- 02	1892 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74101-099- 01	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74101-099- 16	946 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74101-099- 08	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74101-099- 04	118 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 not final	part333A	03/30/2020	

Labeler - Superior Solutions (010105055)

Registrant - Superior Solutions (010105055)

Establishment				
Name	Address	ID/FEI	Business Operations	
Superior Solutions		0 10 10 50 55	manufacture(74101-099)	

Revised: 3/2020 Superior Solutions