

IPA HAND SANITIZER- isopropyl alcohol hand sanitizer liquid Solids, 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


DESCRIPTION

Drug Facts
Active ingredient[s] Purpose
Isopropyl Alcohol 75% v/v.....Antiseptic

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

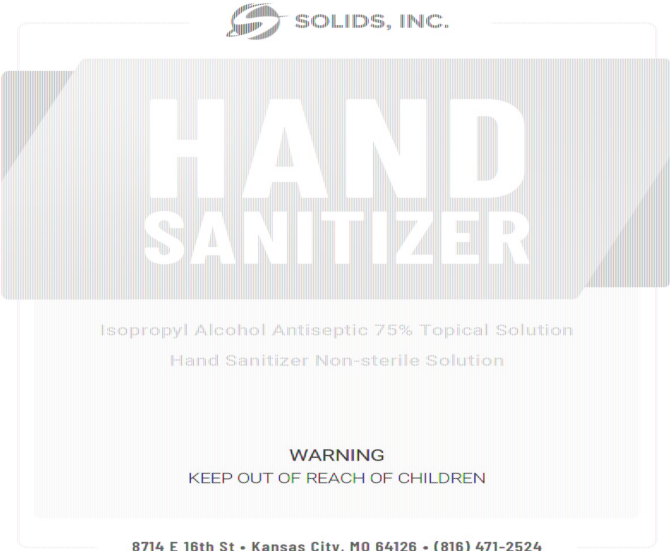
DIRECTIONS FOR USE

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.



09999991230484

To reorder call (913) 713-4120 CONTENTS 12x1 QT (946 mL)



8714 E 16th St • Kansas City, MO 64126 • (816) 471-2524

WARNING

For external use only
Flammable
Keep away
Do not use

- in children less than 6 years of age
- on open skin wounds

When using this product, avoid contact with eyes.
Stop use and avoid contact if a serious contact reaction occurs.
Keep out of reach of children.
If swallowed, get medical help or call a poison control center.
Store between 15°C and 30°C (59°F and 86°F).
Avoid freezing.
Inactive ingredients: Glycerin, Hydrogen Peroxide, Purified Water USP.
Store locked up.
Dispose of contents according to local, state, and federal regulations.

NDC79133-002


DESCRIPTION

Drug Facts
Active ingredient[s] Purpose
Isopropyl Alcohol 75% v/v.....Antiseptic

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.


DIRECTIONS FOR USE

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.



09999991230484

To reorder call (913) 713-4120 CONTENTS 1 QT (946 mL)



8714 E 16th St • Kansas City, MO 64126 • (816) 471-2524

HAZARD WARNING

For external use only
Do not use

- in children less than 6 years of age
- on open skin wounds

When using this product, avoid contact with eyes.
Stop use and avoid contact if a serious contact reaction occurs.
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000 ml NDC: 00000-000-00

IPA HAND SANITIZER			
isopropyl alcohol hand sanitizer liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79133-002
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 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:79 133-002-32	1 in 1 BOX	08/20/2020	
1		946 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Solids, Inc. (079782683)**Establishment**

Name	Address	ID/FEI	Business Operations
Solids, Inc.		079782683	manufacture(79 133-002)

Revised: 8/2020

Solids, Inc.