

ETHANOL HAND SANITIZER GEL- ethanol hand sanitizer gel gel 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. 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


DESCRIPTION

Drug Facts
Active ingredient[s] Purpose
Ethyl Alcohol 80% 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 4x1 GAL (3785 mL)



SOLIDS, INC.

HAND SANITIZER

Ethyl Alcohol Antiseptic 80% Topical Gel Solution
Hand Sanitizer Non-sterile Solution

WARNING
KEEP OUT OF REACH OF CHILDREN

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

WARNING

For external use
Flammable
Keep away
Do not use
• in children
• on open skin
When using this product:
Stop use and avoid contact with eyes if contact occurs.
Keep out of reach of children.
If swallowed, get medical attention.
Center right
Store between 15-30°C (59-86°F).
Avoid freezing and excessive heat above 40°C (104°F).
Inactive ingredients: glycerin, hydrogen peroxide, purified water USP.
Store locked up.
Dispose of contents according to federal regulations.

NDC79133-003


DESCRIPTION

Drug Facts
Active ingredient[s] Purpose
Ethyl Alcohol 80% 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 GAL (3785 mL)



SOLIDS, INC.

HAND SANITIZER

Ethyl Alcohol Antiseptic 80% Topical Gel Solution
Hand Sanitizer Non-sterile Solution

WARNING
KEEP OUT OF REACH OF CHILDREN

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

HAZARD WARNING

For external use
Do not use
• in children
• on open skin
When using this product:
Stop use and avoid contact with eyes if contact occurs.
If swallowed, get medical attention.
Store between 15-30°C (59-86°F).
Avoid freezing and excessive heat above 40°C (104°F).
Inactive ingredients: glycerin, hydrogen peroxide, purified water USP.
Store locked up.
Dispose of contents according to local, state, and federal regulations.

000 mL NDC: 00000-000-00

ETHANOL HAND SANITIZER GEL			
ethanol hand sanitizer gel gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79133-003

Route of Administration	TOPICAL
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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
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 133-003-41	1 in 1 BOX	03/30/2020	
1		3785 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(79 133-003)

Revised: 8/2020

Solids, Inc.