

HAND SANITIZER- alcohol liquid

Mirus Group

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.

Hand Sanitizer

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.
- e. Carboxymethylcellulose
- f. Fragrance

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 70% 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

250 mL NDC: 80430-333-04

500 mL NDC: 80430-333-03

1000 mL NDC: 80430-333-02

3785.41 mL NDC : 80430-333-01



1484398A
 Smart Plastics
 Advanced Hand Sanitizer
 Tropical Gel
 128 fl oz
 4.00 X 8.875 Label
 Version 7
 09/03/2020



Artwork Approval

Please carefully check this proof. Approval is required before this item will proceed to production. Any corrections or changes after approval will incur additional costs.

Approved for printing as is.
 Approved for printing with changes indicated below.
 Please make changes indicated below and reproof.

Signature _____ Date _____



NDC: 80430-333-01



8 60004 38401 4

DISTRIBUTED BY
 MIRUS GROUP LLC.
 SAN CLEMENTE, CA 92673



**ADVANCED
 HAND SANITIZER**
 TOPICAL GEL

KILLS UP TO
99.9%

OF
 COMMON GERMS

128 FL OZ (3.78 L)

DRUG FACTS
 Active Ingredients
 Ethyl Alcohol 70%

USE
 Hand sanitizer to help reduce bacteria on the skin.

WARNING
 • Flammable. Keep away from fire and flame.
 For external use only.
 • When using this product avoid use in or near the eyes.
 In case of contact rinse eyes thoroughly with water.
 • Stop use and ask a doctor if inflammation or rash occurs.
 • Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center.

DIRECTIONS
 Apply product generously in palm using enough to cover hands. Rub hands together until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION
 • Protect the product in this container from excessive heat and direct sun. Store below 104° F (40° C).
 • May discolor some fabric or surfaces.

INACTIVE INGREDIENTS
 Deionized Water, Glycerin, Plant Based Polymer, Hydrogen Peroxide, Fragrance.

PACKAGED BY TRIMEDA
 1704 S VINEYARD AVE
 ONTARIO, CA 91761



1484397B
 Smart Plastics
 Advanced Hand Sanitizer
 Tropical Gel
 33.8 fl oz
 4.00 x 6.00 Label
 Version 6
 09/03/2020



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1484397A
 Smart Plastics
 Advanced Hand Sanitizer
 Tropical Gel
 16.9 fl oz
 4.00 x 6.00 Label
 Version 6
 09/03/2020



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1484396A
 Smart Plastics
 Advanced Hand Sanitizer
 Tropical Gel
 8.45 fl oz
 1.5 x 5.375 Label
 Version 8
 09/03/2020



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Signature _____ Date _____



HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80430-333
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80430-333-04	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/30/2020	
2	NDC:80430-333-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/30/2020	
3	NDC:80430-333-02	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/30/2020	
4	NDC:80430-333-01	3785.41 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/30/2020	

Labeler - Mirus Group (065028635)

Establishment

Name	Address	ID/FEI	Business Operations
Mirus Group		065028635	label(80430-333)

Establishment

Name	Address	ID/FEI	Business Operations
Trimed Tech, Inc		117658787	manufacture(80430-333)

Revised: 9/2020

Mirus Group