

HAND SANITIZER- alcohol liquid

Smart Plastic

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 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.

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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, plant based polymer, purified water USP, fragrance

Package Label - Principal Display Panel

250 mL NDC: 79192-444-04

500 mL NDC: 79192-444-03

1000 mL NDC: 79192-444-02

3785.41 mL NDC: 79192-444-01



1484396A
Smart Plastics
Advanced Hand Sanitizer
Tropical Gel
16.9 fl oz
6.00 x 4.00 Label
Version 2
08/20/2020



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 _____





1484397B
 Smart Plastics
 Advanced Hand Sanitizer
 Tropical Gel
 33.8 fl oz
 6.00 x 4.00 Label
 Version 2
 08/20/2020



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1484398A
 Smart Plastics
 Advanced Hand Sanitizer
 Tropical Gel
 128 fl oz
 9.00 x 4.00 Label
 Version 2
 08/20/2020



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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



1484396A
 Smart Plastics
 Advanced Hand Sanitizer
 Tropical Gel
 8.45 fl oz
 5.00 x 1.57 Label
 Version 2
 08/20/2020



Artwork Approval

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Signature _____ Date _____



HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79 192-444
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	

CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 192-444-01	3785.41 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2020	
2	NDC:79 192-444-02	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2020	
3	NDC:79 192-444-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2020	
4	NDC:79 192-444-04	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/23/2020	

Labeler - Smart Plastic (117552677)

Establishment

Name	Address	ID/FEI	Business Operations
Smart Plastic		117552677	manufacture(79 192-444)

Revised: 6/2020

Smart Plastic