

TRAVELSHIELD HAND SANITIZER- ethyl alcohol gel

WESSCO International

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.

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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

20 mL in 1 BOTTLE NDC: 42509-006-01

The diagram shows the principal display panel for the TravelShield Hand Sanitizer. The box features the TravelShield logo and 'GEL DISINFECTANTE DE MANOS'. The bottle label includes the product name, volume (20ML/0.7FL.OZ), and '70% ALCOHOL FOR MAXIMUM EFFECTIVENESS'. The Drug Facts label provides detailed information on ingredients, warnings, directions, and other information.

2171C | **2728C** | **285C** | **287C** | **280C** | **2728C** | **311C** | **2728C** | **206C**

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 70%	Antiseptic

Uses: to help reduce germs on the skin.

Warnings:

- **For external use only**
- **Flammable:** Keep away from heat or flame.
- **When using this product:** avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- **Stop using and ask a doctor** for irritation or redness develops and lasts.
- **Keep out of reach of children;** in case of accidental ingestion, get medical help or contact a poison control center immediately.

Directions: Squeeze a significant amount in your palm and rub hands until fully dry. Rinse free.

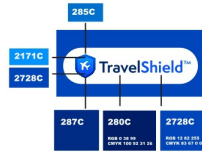
Other information: Store below 100°F (40°C).

Inactive ingredients: Acrylates C10-30 Alkyl Acrylate Copolymer, Aminomethyl propanol, Aloe Barbadensis Leaf Juice, Benethonium benzoate, Fragrance, Glycerin, Mahoelectin, Propylene Glycol, Xanthophyll Xantho, Water.

Exclusively by
WESSCO International
Los Angeles, California
mytravelshield.com

Made in China

29 mL in 1 BOTTLE NDC: 42509-006-02



TRAVELSHIELD HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42509-006
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
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.15 mL in 100 mL
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.2 mL in 100 mL
MALTODEXTRIN (UNII: 7CVR7L4A2D)	0.001 mL in 100 mL
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	0.004 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	0.3 mL in 100 mL
WATER (UNII: 059QF0K00R)	27.834 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.01 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.001 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42509-006-01	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2020	
2	NDC:42509-006-02	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/13/2020	

Labeler - WESSCO International (118553619)

Establishment

Name	Address	ID/FEI	Business Operations
WESSCO International		118553619	relabel(42509-006)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Ouyali Daily Cosmetic Co., Ltd.		542920070	manufacture(42509-006)

Revised: 6/2020

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