

HAND SANITIZER- ethyl alcohol gel
Hans Manufacturer 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.

Hand Sanitizer Gel 75% Alcohol

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 ingredients in the preparation of the product (percentage in final product formulation):

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, 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 (0.89% v/v).
- c. Triethanolamine (0.39% v/v).
- d. Polyacrylic acid (0.35% v/v).
- e. Tea Tree Oil (0.05% v/v).
- f. Aloe Vera Gel (0.1% v/v).
- g. Phenoxyethanol (0.2% v/v).
- h. 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 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, Triethanolamine, Polyacrylic acid, Tea Tree Oil, Aloe Vera Gel, Phenoxyethanol, purified water USP

Package Label - Principal Display Panel

60 mL NDC: 74496-8751-1

Leaves Hands Feeling
Soft & Refreshed



HAND
SANITIZER
With Moisturizer

kills **99.99%**
of GERMS

2FL OZ(60ML)

Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 75% v/v	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none"> • 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.	
Directions	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients	
Water (Aqua), Triethanolamine, Polyacrylic acid, Glycerine, Tea Tree Oil, Aloe Vera Gel, Phenoxyethanol.	
Questions and comments? Tel: 1-800-654-0957	
HHS22006T1	
EXP : 07/2022	

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74496-8751
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	0.05 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.89 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.39 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.35 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74496-8751-1	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/30/2020	

Labeler - Hans Manufacturer Inc. (787300008)

Registrant - Hans Manufacturer Inc. (787300008)

Establishment

Name	Address	ID/FEI	Business Operations
THRONE COSMETICS CO.		657075412	manufacture(74496-8751)

Establishment

Name	Address	ID/FEI	Business Operations
Hans Manufacturer Inc.		787300008	label(74496-8751)

