

HYGIENIUM HAND SANITIZER- ethyl alcohol gel

Grande Gloria Production S.A.

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.

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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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

500ml NDC:81592 -1549 -6

155 x 75 mm

Made in E.U. by:
GRANDE GLORIA PRODUCTION S.A.
 Str. Tuluce, Nr. 1, Hala 68, Biroul 2,
 Sat Costi, Com. Vânători, Jud. Galați, România.
 Tel: +40 236 470 890 Fax: +40 236 449 445
 Email: office@grandegloria.com
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Importer:
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 601 13th Street, NW, Suite 900 South
 90124, Washington, DC 20005
 Tel: (+1) 202 964 7888
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 www.hygienium.com



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HAND SANITIZER
GEL

ALCOHOL ANTISEPTIC 70%
KILLS 99.99% OF GERMS



NON-STERILE SOLUTION
 TOPICAL SOLUTION

16.9
FL. OZ.
500 ml

Drug Facts	
Active ingredient(s)	Purpose
Ethyl alcohol 70%	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 at 1-800-222-1222.	
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 :	
glycerin, carbomer, aloe barbadensis leaf extract, purified water USP	

NDC 81592

HYGIENIUM HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81592-1549
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81592-1549-0	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2021	
2	NDC:81592-1549-2	5000 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2021	
3	NDC:81592-1549-3	85 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2021	
4	NDC:81592-1549-1	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2021	
5	NDC:81592-1549-6	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2021	
6	NDC:81592-1549-4	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2021	

155 x 75 mm

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HAND SANITIZER

GEL

ALCOHOL ANTISEPTIC 70%
KILLS 99.99% OF GERMS





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NON-STERILE SOLUTION
TOPICAL SOLUTION



16.9
FL. OZ.
500 ml

NDC 81592

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Grande Gloria Production S.A. (534041167)

Registrant - Grande Gloria Production S.A. (534041167)

Establishment

Name	Address	ID/FEI	Business Operations
Grande Gloria Production S.A		534041167	manufacture(81592-1549)

Revised: 3/2021

Grande Gloria Production S.A.