

HYGIENIUM HAND SANITIZER WIPES- alcohol cloth

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 wipes

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

D-gluconic acid 0.2%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



Made in EU by:
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Importer:
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Hygienium®

15
buc/pcs

ANTIBACTERIAL
HAND SANITIZING WIPES
ALCOHOL ANTISEPTIC 70%
KILLS 99.99% OF GERMS



Active ingredients:
Alcohol 70% v/v
Chlorhexidine digluconate 0,2% v/v



Drug Facts

Active ingredient(s) Purpose
Alcohol 70% v/v.....Antiseptic
D-gluconic acid, compound with
N,N'-bis
(4-chlorophenyl)-3,12-diimi-
no-2,4,11,13-tetraazatetradecane-
amide (2:1) 0,2% v/v.....Antiseptic

Uses
Hand Sanitizer Wipes 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 at 1-800-222-1222.

Directions
• Rub your hands with a wet wipe
and let them 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,
tocopheryl acetate,
cocamidopropyl betaine, purified
water USP

15pc NDC:81592-1939-9

HYGIENIUM HAND SANITIZER WIPES

alcohol cloth

Product Information

Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:81592-1939	
Route of Administration		TOPICAL				
Active Ingredient/Active Moiety						
Ingredient Name				Basis of Strength		Strength
.BETA.-D-GLUCOURONIC ACID (UNII: 00A9JB14O6) (.BETA.-D-GLUCOURONIC ACID - UNII:00A9JB14O6)				.BETA.-D-GLUCOURONIC ACID		0.36 g in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHOL		70 mL in 100 mL
Inactive Ingredients						
Ingredient Name				Strength		
GLYCERIN (UNII: PDC6A3C0OX)				1.45 mL in 100 mL		
COCO-BETAINE (UNII: 03DH2IZ3FY)						
WATER (UNII: 059QF0KO0R)						
Packaging						
#	Item Code	Package Description		Marketing Start Date		Marketing End Date
1	NDC:81592-1939-9	15 in 1 PACKET		03/30/2020		
1		28 mL in 1 PACKET; Type 0: Not a Combination Product				
2	NDC:81592-1939-1	40 in 1 PACKET		03/30/2020		
2		86 mL in 1 PACKET; Type 0: Not a Combination Product				
3	NDC:81592-1939-3	24 in 1 PACKET		03/30/2020		
3		52 mL in 1 PACKET; Type 0: Not a Combination Product				
4	NDC:81592-1939-5	100 in 1 PACKET		03/30/2020		
4		230 mL in 1 PACKET; Type 0: Not a Combination Product				
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(81592-1939)

Revised: 7/2021

Grande Gloria Production S.A.