HAND SANITIZER- alcohol gel Desmoldantes y Aditivos, S.A. de C.V.

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.

60 ML CYAGERMS

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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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

Polyacrylic acid

Water Glycerin Fragrance TRIETHANOLAMINE

Package Label - Principal Display Panel

60 mL NDC: 77357-160-01



- No sticky residueNo water needed
- Evaporates quickly

Kills more than 99.99% of many common germs and bacteria*

2.02 FL OZ (60ml)

Drug Facts

Active ingredient Ethyl Alcohol, 70% v/v Purpose

.Antiseptic

Hand sanitizer, alcohol-based, used to kill bacteria in order to prevent

■ Ready to be used, as often as needed.

For external use only

Flammable. Keep away from fire or flame. Do not use near the eyes. In case of contact, rinse thoroughly with waterIf irritation develops, discontinue use and ask doctor. Keep out of reach of children. If swallowed, get medical help or call a Poison Control Center immediately.

Directions

- Place a small amount in your hands and rub together until dry.
- No rinsing required

Other information

- Do not store above 104°F (40°C)
- Careful, may discolor certain surfaces or textiles.

Inactive ingredients

Deionized water, Polyacrylic acid, Glycerin, Fragance, Triethanolamine

Questions or comments?

+52 1 81 8685 5372 feedback@grupodyasa.com

S.A. de C.V. 410 Nafta, Laredo, TX. 78045. Desmoldantes y Aditivos,

Mitras, Garcia, NL, Mexico. 66023. Lot number and expiration date on container Humberto Lobo 8010, Ciudad Industrial Desmoldantes y Aditivos, S.A. de C.V.



Manufactured by

HAND SANITIZER

alcohol gel

Product Information

HUMAN OTC DRUG NDC:77357-161 Product Type Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

receive ingredient/receive virtuety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 903K93S3TK)	0.1 mL in 100 mL		
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.4 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 100 mL		
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	4.9 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	23.3 mL in 100 mL		

	Packaging			
ı	# Item Coc	e Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:77357-16	1-01 60 mL in 1 BOTTLE; Type 0: Not a Combination 1	Product 03/30/2020	

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

Labeler - Desmoldantes y Aditivos, S.A. de C.V. (812364628)

Registrant - Desmoldantes y Aditivos, S.A. de C.V. (812364628)

Establishment					
Name	Address	ID/FEI	Business Operations		
Desmoldantes y Aditivos, S.A. de C.V.		812364628	manufacture(77357-161)		

Revised: 7/2020 Desmoldantes y Aditivos, S.A. de C.V.