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.

Judge 60 ML

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

060 mL NDC: 77357-100-03

Alcohol Antiseptic Topical Solution Non-sterile Solution 2.02 FL OZ (60ml)

Hand Sanitizer



/keepjudgebandin

Drug Facts

Active ingredient Ethyl Alcohol, 70% v/v.....

Purpose .Antiseptic

- Hand sanitizer, alcohol-based, used to kill bacteria in order to prevent diseases
- Ready to be used, as often as needed.

Warnings

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 Distributed by S.A. de C.V. 410 Nafta, Laredo, TX. 78045.

Desmoldantes y Aditivos,

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



Manufactured by:

HAND SANITIZER

alcohol gel

Prod	uct	Info	rma	tion
FIUU			HIIIA	LIVII

HUMAN OTC DRUG NDC:77357-150 Product Type Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 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)	24.3 mL in 100 mL			

Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:77357-150-03	60 mL in 1 BOTTLE; Type 0: Not a Combination 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.		8 1236 46 28	manufacture(77357-150)	

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