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.

Mix of Essence 1 Gallon

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

TRIETHANOLAMINE

Package Label - Principal Display Panel

3785 ML NDC 77357-130-01



Manufactured by:

Desmoldantes y Aditivos, S.A. de C. V. Humberto Lobo 8010 Cd. Industrial Mitras, García, N. L., México 66023 NDC 77357 *Distributed by:* Mix of Flavors, LLC 2525 W Military Hwy. Suite 10

Ph. (956) 627-3119 MixOfEssences@gmail.com PRODUCT OF MEXICO

McAllen, TX 78503

ESSENCES

HAND SANITIZER

WITH MOISTURIZERS

Tough on **germs**, Gentle on your **hands**

GEL

1 GALLON (3.785 L)

Drug Facts

Active Ingredient Ethyl Alcohol 70% v/v..... Purpose ...Antiseptic

Uses

- 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 water. If 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, Fragrance, Triethanolamine.

Questions or Comments?

- MixOfEssences@gmail.com
- (956)627-3119

HAND SANITIZER

alcohol gel

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:77357-130

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		
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL		
GLYCERIN (UNII: PDC6 A3C0 OX)	0.8 mL in 100 mL		
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.6 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	28.5 mL in 100 mL		

ı	Pa	ckaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC:77357-130-01	3785 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.		812364628	manufacture(77357-130)

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