

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.

ESSENCE DESMOLDANTES Y ADITIVOS 250 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.

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

Polyacrylic acid

Water

Glycerin

TRIETHANOLAMINE

Package Label - Principal Display Panel

250 mL NDC: 77357-134-01

Drug Facts		Drug Facts (continued)
Active Ingredient	Purpose	Directions
Ethyl Alcohol 70% v/v.....	Antiseptic	<ul style="list-style-type: none"> Place a small amount in your hands and rub together until dry. No rinsing required.
Uses		Other information
<ul style="list-style-type: none"> Hand sanitizer, alcohol-based, used to kill bacteria in order to prevent diseases. Ready to be used, as often as needed. 		<ul style="list-style-type: none"> Do not store above 104 °F (40 °C). Careful, may discolor certain surfaces or textiles.
Warnings		Inactive ingredients
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.		Deionized water, Polyacrylic acid, Glycerin, Fragrance, Triethanolamine.
		Questions or Comments?
		<ul style="list-style-type: none"> MixOfEssences@gmail.com (956)627-3119

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77357-134
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: PDC6A3C0OX)	0.8 mL in 100 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.6 mL in 100 mL
WATER (UNII: 059QF0K00R)	28.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77357-134-01	250 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(77357-134)

Revised: 7/2020

Desmoldantes y Aditivos, S.A. de C.V.