HAND SANITIZER- alcohol spray 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.

Spray 125 ML Spray ESSENCE DESMOLDANTES JAZMIN

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

Deionized water

Glycerin Polyethylene glycol Isopropyl myristate Fragrance

Package Label - Principal Display Panel

125 mL NDC: 77357-151-01



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

Uses ■ Hand sanitizer, alcohol-based, used to kill bacteria in order to prevent diseases.

Ready to be

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, Glycerin, Polyethylene Glycol, Isopropyl Myristate, Fragance.

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

HAND SANITIZER

alcohol spray

Product Information

HUMAN OTC DRUG NDC:77357-152 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	0.49 mL in 100 mL		
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.21 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	0.68 mL in 100 mL		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	0.37 mL in 100 mL		

WATER	(UNII:	059Q	F0KO0R)
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28.24 mL in 100 mL

Packaging	
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	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	1 NDC · 77357_152_01	125 mL in 1 BOTTLE: Type 0: Not a Combination Product	03/30/2020	

1 NDC:77357-152-01 | 125 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/202

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(77357-152)

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