# 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.

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# Spray 125 ML Spray DESMOLDANTES LIMON ESSENCE

## **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 77357-153-01



# 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, Glycerin, Polyethylene Glycol, Isopropyl Myristate, Fragance.

## Questions or Comments?

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

#### HAND SANITIZER

alcohol spray

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77357-153

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)

ALCOHOL (UNII: 3K9958 V90M) To 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: PDC6 A3C0 OX)	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

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	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	1	NDC •77357-153-01	125 mL in 1 BOTTLE: Type 0: Not a Combination Product	03/30/2020	

NDC://357-153-01 | 125 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/202

# **Marketing Information**

1,111 He ting 1,11101 Matter			
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(77357-153)	

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