

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 ORANGE ESSENCE DESMOLDANTES

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

Deionized water

Glycerin
 Polyethylene glycol
 Isopropyl myristate
 Fragrance

Package Label - Principal Display Panel

125 mL NDC: 77357-154-01

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	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, Fragrance.

Questions or Comments?
 ■ MixOfEssences@gmail.com ■ (956)627-3119

HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77357-154
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	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: 059QF0KO0R)	28.24 mL in 100 mL
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77357-154-01	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

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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(77357-154)

Revised: 7/2020

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