

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 500 ML Spray

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

Distributed by: Desmoldantes y Aditivos, S.A. de C.V.
410 Nafta, Laredo, TX 78045

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol, 70% v/v.....	Antiseptic
Uses	
<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. 	
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.	

Drug facts (continued)

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?
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Manufactured by: Desmoldantes y Aditivos, S.A. de C.V.
 Humberto Lobo 8010, Ciudad Industrial Mitras, Garcia, NL, Mexico 66023
 PRODUCT OF MEXICO

5500 mL NDC: 77357-470-12

HAND SANITIZER				
alcohol spray				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77357-470	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	71 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			0.5 mL in 100 mL	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)			0.39 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)			0.68 mL in 100 mL	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			0.38 mL in 100 mL	
WATER (UNII: 059QF0K00R)			27.05 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77357-470-12	500 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(77357-470)

Revised: 5/2020

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