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.

ESSENCE DESMOLDANTES Y ADITIVOS 60 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.

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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, POLUETHYLENE GLYCOL, ISOPROPYL MYRISTATE,

Package Label - Principal Display Panel

60 mL NDC: 77357-136-01



HAND SANITIZER

Draduct Information

alcohol spray

Froduct fillor mation			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77357-136

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		
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.21 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	0.68 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	28.5 mL in 100 mL		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	0.49 mL in 100 mL		

POLYETHYLENE GLYCOI	UNSPECIFIED	(UNII: 3WIC	00SDW1A)

0.37 mL in 100 mL

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	DC · 77357-136-01	60 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.		8 1236 46 28	manufacture(77357-136)	

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