HAND SANITIZER- alcohol gel 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.

FDA BADIN DESMOLDANTES Y ADITIVOS 60 ML

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

Polyacrylic acid

Glycerin

TRIETHANOLAMINE

Package Label - Principal Display Panel

60 mL NDC: 77357-102-01

Hand Sanitizer

Alcohol Antiseptic Topical Solution Non-sterile Solution Hand sanitizer 2.02 FL OZ (60ml)



Drug Facts Purpose Active ingredient Ethyl Alcohol, 70% v/v Antiseptic Use[s] Hand sanitizer to help reduce bacteria that potencially can cause disease. For use when soap and water are not available Warnings
For external use only. Flammable. Keep away from heat or flame. ■ 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. 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) Deionized water, Polyacrylic acid, Glycerin, Triethanolamine. Questions or comments? +1-518-444-4118 ■ info@cyagerms.com

Distributed by:
Data Logisticas, LLC
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#418

FDA labeler code 77357 Batch # 20150701 Best if used by M07/D15/Y2021

PRODUCT OF MEXICO

HAND SANITIZER

alcohol gel

Product Informa	ation
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:77357-102

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			
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	0.8 mL in 100 mL			

POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.6 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.5 mL in 100 mL

ı	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC:77357-102-01	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(77357-102)	

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