

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.

Plus de Sant 250 NDC 77357-100-03

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

Polyacrylic acid

Water
 Glycerin
 Fragrance
 TRIETHANOLAMINE

Package Label - Principal Display Panel



GRUPO DYASA

PLUS DESANTE

HAND SANITIZER

with Moisturizers

70% Alcohol

8.45 FL.OZ (250ML)

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

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	
<ul style="list-style-type: none"> Place a small amount in your hands and rub together until dry. No rinsing required. 	
Other information	
<ul style="list-style-type: none"> Do not store above 104°F (40°C). Careful, may discolor certain surfaces or textiles. 	
Inactive ingredients	
Deionized water, Polyacrylic acid, Glycerin, Fragrance, Triethanolamine.	
Questions or comments?	
+52 1 81 8685 5372 feedback@grupodyasa.com	

Lot number and expiration date on container.

PRODUCT OF MEXICO

250 mL NDC: 7757-100-03

HAND SANITIZER				
alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77357-100	
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			
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL			
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.4 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 100 mL			
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	4.9 mL in 100 mL			
WATER (UNII: 059QF0K00R)	23.3 mL in 100 mL			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:77357-100-03	250 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(77357-100)

Revised: 6/2020

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