

**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.*

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**Hand Sanitizer 500 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

Water  
Glycerin  
Fragrance  
TRIETHANOLAMINE

## Package Label - Principal Display Panel

|  |  |   |   |
|--|--|---|---|
|  | <p>Manufactured by:<br/>Desmoldantes y Aditivos, S.A.<br/>de C.V. Humberto Lobo 8010,<br/>Ciudad Industrial Mitras,<br/>Garcia, NL, Mexico 66023</p> | <p><b>Drug Facts</b></p> <p><b>Active ingredient</b>      <b>Purpose</b><br/>Ethyl Alcohol, 70% v/v.....Antiseptic</p> <p><b>Uses</b><br/> <ul style="list-style-type: none"> <li>Surface cleaner and disinfectant, alcohol based, used to kill bacteria in order to prevent diseases.</li> <li>Ready to be used, as often as needed.</li> </ul> </p> <p><b>Warnings</b><br/> <b>For external use only</b><br/>           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.</p> | <p><b>Drug facts</b> (continued)</p> <p><b>Directions</b><br/> <ul style="list-style-type: none"> <li>Apply directly on the area to be disinfected, or on a clean cloth.</li> <li>No rinsing required.</li> <li>Does not require dilution in water.</li> </ul> </p> <p><b>Other information</b><br/> <ul style="list-style-type: none"> <li>Do not store above 104°F (40°C)</li> <li>Careful, may discolor certain surfaces or textiles.</li> </ul> </p> <p><b>Inactive ingredients</b><br/>Deionized Water</p> <p><b>Questions or comments?</b><br/>+52 1 81 8685 5372<br/>feedback@grupodyasa.com</p> |
|  | <p>Distributed by:<br/>Desmoldantes y Aditivos, S.A. de C.V.<br/>410 Nafta, Laredo, TX 78045</p>   |   | <p style="text-align: right;"><b>PRODUCT OF MEXICO</b></p>  |

500 mL NDC: 77357-500-01

| <b>HAND SANITIZER</b>                  |  |   |                      |                    |
|--|--|---|----------------------|--------------------|
| alcohol gel                            |  |   |                      |                    |
| <b>Product Information</b>             |  |   |                      |                    |
| <b>Product Type</b>                    | HUMAN OTC DRUG   | <b>Item Code (Source)</b>   | NDC:77357-500        |                    |
| <b>Route of Administration</b>         | TOPICAL  |   |                      |                    |
| <b>Active Ingredient/Active Moiety</b> |  |   |                      |                    |
|  | Ingredient Name  | Basis of Strength   | Strength             |                    |
|  | ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL   | 71 mL in 100 mL      |                    |
| <b>Inactive Ingredients</b>            |  |   |                      |                    |
|  | Ingredient Name  | Strength  |                      |                    |
|  | TROLAMINE (UNII: 9O3K93S3TK)                           | 0.1 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   |                      |                    |
|  | FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)  | 0.4 mL in 100 mL  |                      |                    |
| <b>Packaging</b>                       |  |   |                      |                    |
| #                                      | Item Code  | Package Description   | Marketing Start Date | Marketing End Date |
| 1                                      | NDC:77357-500-01                                       | 500 mL in 1 BOTTLE, DISPENSING; 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(77357-500) |

Revised: 5/2020

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