HAND SANITIZER- ethyl alcohol liquid 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.

DESMOLDANTES AP 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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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, Polyarcylic acid, glycerin, fragrance, AMP 95

Package Label - Principal Display Panel

50



16.90 FL OZ (500ml).

Drug Facts

Active ingredient Ethyl Alcohol, 70% v/v ...

Purpose

. Antiseptic

Uses

- 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.

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, Polyacrylic acid, Glycerin, Fragance, AMP 95 (2-Amino-2-methyl-1-propanol).

Questions or comments?

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Lot number and expiration date on container





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

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

PRODUCT OF MEXICO

0 ml NDC: 77357-500-05

HAND SANITIZER

ethyl alcohol liquid

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77357-501 |
|--------------|----------------|--------------------|---------------|
|--------------|----------------|--------------------|---------------|

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| 1100110 111011 | | | | | |
|----------------|--|-------------------|-----------------|--|--|
| | Ingredient Name | Basis of Strength | Strength | | |
| ALCOHOL (UN | III: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 71 mL in 100 mL | | |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-------------------|
| POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F) | 4.9 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.3 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | 23.3 mL in 100 mL |
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) | 0.3 mL in 100 mL |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | 0.2 mL in 100 mL |

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|---|---|---------------------------------|---|-------------------------|-----------------------|--|
| | # | # Item Code Package Description | | Marketing Start Date | Marketing End Date | |
| | | NDC:77357-501- 05 | 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(77357-501) | |

Revised: 6/2020 Desmoldantes y Aditivos, S.A. de C.V.