

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.

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

GRUPO DYASA

HAND SANITIZER
with Moisturizers

KILLS 99.99% OF GERMS

33.81 FL OZ
(1 L)

Drug Facts

| Active ingredient | Purpose |
|------------------------|------------|
| Ethyl Alcohol, 70% v/v | 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, 2-Propanoic acid, 2-methyl-polymer with 2-propeonate, Glycerin, Fragrance, Triethanolamine.

Questions or comments?
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Manufactured by:
Desmoldantes y Aditivos, S.A. de C.V.
Humberto Lobo 8010, Ciudad Industrial Mitras,
García, NL, Mexico 66023

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

PRODUCT OF MEXICO

1000 mL NDC: 77357-100-01

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:77357-100-01 | 1000 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: 5/2020

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