

HAND SANITIZER- alcohol spray
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.

Spray 1000 ML Spray

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

Deionized water

Glycerin
 Polyethylene glycol
 Isopropyl myristate
 Fragrance

Package Label - Principal Display Panel

1000 mL NDC: 77357-370-11

GRUPO DYASA

**HAND
 SANITIZER
 SPRAY**

KILLS 99.99% OF GERMS

33.81 FL OZ
 (1L)

| 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. | |
| 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, Glycerin, Polyethylene Glycol, Isopropyl Myristate, Fragrance. | |
| Questions or comments? | |
| +52 1 81 8685 5372 • feedback@grupodyasa.com | |

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

PRODUCT OF MEXICO

HAND SANITIZER

alcohol spray

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77357-470 |
|---------------------|----------------|---------------------------|---------------|

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 |
|---|--------------------|
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | 0.5 mL in 100 mL |
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) | 0.39 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.68 mL in 100 mL |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | 0.38 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | 27.05 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:77357-470-11 | 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(77357-470) |

Revised: 5/2020

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