

D HAND- alcohol gel
SODI PINTURAS, 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.

D HAND SANITIZER GEL

ACTIVE INGREDIENT

Active ingredient Ethyl Alcohol 70% v/v

PURPOSE

Purpose Antmicrobial

INDICATIONS AND USAGE

Use[s]

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

DOSAGE AND ADMINISTRATION

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

WARNINGS AND PRECAUTIONS

Store below 110°F (43°C)

Children under 6 years of age should be supervised when using.

WARNINGS

Warnings

For external use only. Flammable. Keep away from heat or flame

STOP USE

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

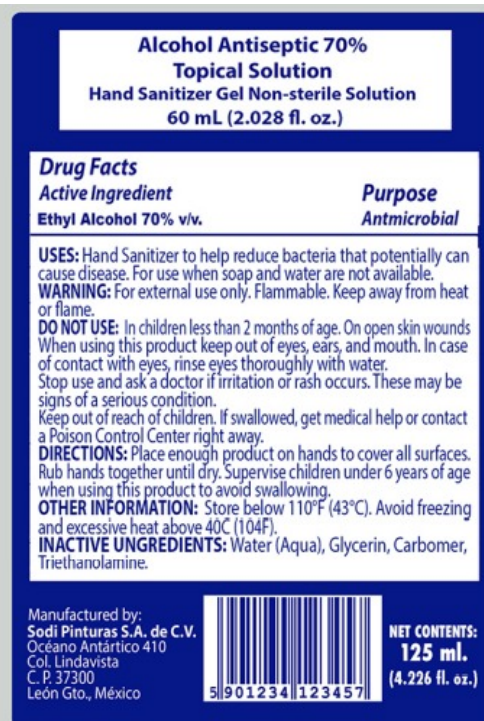
KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

INACTIVE INGREDIENTS

Water (Aqua), Glycerin, Carbomer, Triethanolamine

PACKAGE LABELS



ALCOHOL 70%

d

Hand Sanitizer Gel


ANTIMICROBIAL FORMULA

ANTIBACTERIAL GEL NET CONTENTS: **250 ml.**
(8.453 fl. oz.)

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer Gel Non-sterile Solution
250 mL (8.453 fl. oz.)

| | |
|--|----------------|
| Drug Facts | |
| Active Ingredient | Purpose |
| Ethyl Alcohol 70% v/v. | Antimicrobial |
| Uses(±) | |
| 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: | |
| <ul style="list-style-type: none"> 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. | |
| Directions: | |
| <ul style="list-style-type: none"> 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: | |
| <ul style="list-style-type: none"> Store below 110°F (43°C) Avoid freezing and excessive heat above 40°C (104°F) | |
| Inactive ingredients: Water (Aqua), Glycerin, Carbomer, Triethanolamine | |

Manufactured by:
Sodi Pinturas S.A. de C.V.
Océano Antártico 410
Col. Lindavista
C. P. 37300
León Gto., México



NET CONTENTS: **250 ml.**
(8.453 fl. oz.)

ALCOHOL 70%

d

Hand Sanitizer Gel

ANTIMICROBIAL FORMULA

ANTIBACTERIAL GEL NET CONTENTS: **500 ml.**
(16.907 fl. oz.)

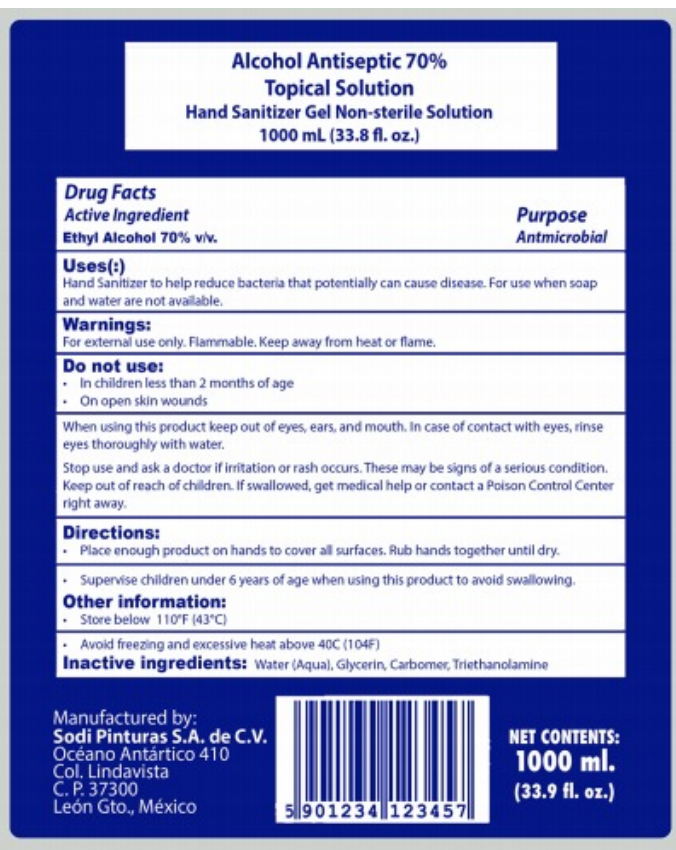
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| Inactive ingredients: Water (Aqua), Glycerin, Carbomer, Triethanolamine | |

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NET CONTENTS: **500 ml.**
(16.907 fl. oz.)



D HAND

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79050-0030 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.7 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|------------------|
| TRIETHANOLAMINE CAPROYL GLUTAMATE (UNII: 0F2FO57253) | 0.002 mL in 1 mL |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 0.003 mL in 1 mL |
| WATER (UNII: 059QF0K00R) | 0.293 mL in 1 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.003 mL in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:79050-0030-1 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/04/2020 | |
| | NDC:79050-0030 | | | |

| | | | | |
|---|------------------|--|------------|--|
| 2 | NDC:79050-0030-2 | 125 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/04/2020 | |
| 3 | NDC:79050-0030-3 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/04/2020 | |
| 4 | NDC:79050-0030-4 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/04/2020 | |
| 5 | NDC:79050-0030-5 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/04/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 08/04/2020 | |

Labeler - SODI PINTURAS, S.A. DE C.V. (951579471)

Registrant - SODI PINTURAS, S.A. DE C.V. (951579471)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|-------------------------|
| SODI PINTURAS, S.A. DE C.V. | | 951579471 | manufacture(79050-0030) |

Revised: 8/2020

SODI PINTURAS, S.A. DE C.V.