

B-PROTEK- isopropyl alcohol gel**Grupo Siller Ingeniería Construcción y Materiales, 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

Isopropyl Alcohol 80% v/v.

Purpose

Antiseptic

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 mix use with other household chemicals.

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.

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

Glycerin, carbomer 940, aloe vera extract, vitamin E, purified water.

Package Label - Principal Display Panel



HAND SANITIZER

KILLS GERMS & BACTERIA



16.9 oz (500ml)

| DRUG FACTS | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Active Ingredient Isopropyl Alcohol 80% v/v | Purpose Antiseptic |
| 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 mix use with other household chemicals. | |
| Do not use: -In children less than two 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 serious condition. 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 age when using this product to avoid swallowing. | |
| INACTIVE INGREDIENTS: glycerin, carbomer 940, aloe vera extract, vitamin e, purified water. | |
| OTHER INFORMATION: Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 400°C (104°F) | |

Made in Mexico by/ Hecho en México por
Grupo Siller Ingeniería y Construcción en
Materiales S.A de C.V
Parque Industrial Finsa,76246
RFC: GSH171101702
DUNS NUMBER: 95-157-7512



It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

B-PROTEK

isopropyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80308-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------|-------------------|-----------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 80 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------------------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| WATER (UNII: 059QF0KO0R) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

| | | | | |
|---|------------------|-----------------------------------------------------------------|------------|--|
| 1 | NDC:80308-002-01 | 3 mL in 1 POUCH; Type 0: Not a Combination Product | 09/24/2020 | |
| 2 | NDC:80308-002-02 | 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/24/2020 | |
| 3 | NDC:80308-002-03 | 60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/24/2020 | |
| 4 | NDC:80308-002-04 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/24/2020 | |
| 5 | NDC:80308-002-05 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/24/2020 | |
| 6 | NDC:80308-002-06 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/24/2020 | |
| 7 | NDC:80308-002-07 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/24/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part333A | 09/24/2020 | |

Labeler - Grupo Siller Ingeniería Construcción y Materiales, S.A. de C.V (951577512)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------------------------------------------|---------|-----------|------------------------|
| Grupo Siller Ingeniería Construcción y Materiales, S.A. de C.V | | 951577512 | manufacture(80308-002) |

Revised: 9/2020

Grupo Siller Ingeniería Construcción y Materiales, S.A. de C.V