

BERNAL HAND SANITIZER- alcohol gel
Inflatables LLC

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.

Inflatables LLC-bernal-PLD 70% Hand Sanitizer

Drug Facts

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

Carbomer, Triethanolamine, Water

Package Label - Principal Display Panel

bernal.

PREMIUM
HAND SANITIZER

70% ALCOHOL ANTISEPTIC
TOPICAL SOLUTION

3785 ML | 1 GALLON

Drug Facts

Active ingredient(s) Alcohol 70% v/v..... **Purpose** Antiseptic

Use[s]
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 and lasts. 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 Carbomer, Triethanolamine, Water

MFG for Inflatables LLC.
Garden Grove, CA 92843 USA
follow @bernal.brand

NEVER TESTED ON ANIMALS

NDC: 74541-270-37

| BERNAL HAND SANITIZER | | | | |
|--|------------------|---|----------------------|--------------------|
| alcohol gel | | | | |
| Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74541-270 | |
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | | ALCOHOL | 70 mL in 100 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | | | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:74541-270-02 | 60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:74541-270-04 | 130 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:74541-270-06 | 200 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:74541-270-08 | 220 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |

| | | | | |
|---|------------------|--|------------|--|
| 5 | NDC:74541-270-17 | 500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 6 | NDC:74541-270-34 | 1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 7 | NDC:74541-270-01 | 30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 | |
| 8 | NDC:74541-270-37 | 3785 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 - Inflatables LLC (108619168)

Registrant - Quimica Magna de Mexico, S.A. de C.V. (951576195)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------------|---------|-----------|------------------------|
| Quimica Magna de Mexico, S.A. de C.V. | | 951576195 | manufacture(74541-270) |

Revised: 5/2020

Inflatables LLC