CLEANOVA GEL HAND SANITIZER- alcohol gel Pantero

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.

Clenova Gel Hand Sanitizer (361)

Active Ingredient(s)

Alcohol 70% v/v

Purpose

Antiseptic

Use

Hand Sanitizer to help reduce bacteria that can potentially 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.

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)
- May discolor some fabrics
- May damage wood finishes or plastics

Inactive ingredients

Fragrance, glycerin, isopropyl alcohol, PER-6 (and) AMP-acrylates/vinyl isodecanoate crosspolmer, purified water USP

Package Label - Principal Display Panel

946 mL NDC:74153-361-32



4730 mL NDC:74153-361-05



| CLEANOVA GEL HAND SANITIZER | | | |
|-----------------------------|----------------|--------------------|---------------|
| alcohol gel | | | |
| | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74153-361 |
| 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 | | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| RAPIDGEL EZ1 (UNII: 33JH4A7R2K) | | | |
| WATER (UNII: 059QF0KO0R) | | | |

| | Packaging | | | |
|---|--------------------|--|-----------------------------|---------------------------|
| ı | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 NDC:74153-361-32 | 946 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/06/2020 | |
| | 2 NDC:74153-361-05 | 4730 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/06/2020 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 07/06/2020 | |
| | | | |

Labeler - Pantero (116669041)

Registrant - Frestedt Incorporated (018853696)

| Establishment | | | |
|---------------|---------|-----------|---------------------------------------|
| Name | Address | ID/FEI | Business Operations |
| Pantero Inc. | | 116669041 | relabel(74153-361), repack(74153-361) |

Revised: 10/2020 Pantero