

HAND SANITIZER- ethyl alcohol gel NPW-USA, Inc.

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:
Ethyl alcohol, 62%

Purpose Antiseptic

Warnings:

For external use only.

FLAMMBLE. Keep away from fire or flame.

Stop use and ask a doctor if irritation and redness persists for more than 72 hours.

Keep out of reach of children. In case of accidental ingestion, seek medical attention or contact a Poison Control Center right away.

Directions:

- Apply a small amount into palm of hand
- Rub thoroughly over both hands until dry
- Not to be rinsed off with water
- Children must be supervised when using this product
- For personal / domestic use
- Do not dilute product

Inactive ingredients: water, glycerin, propylene glycol, fragrance, carbomer, triethanolamine, acrylates copolymer, polyethylene terephthalate, red 33, diatomaceous earth.

Other Information:

Do not store in temperatures above 118 F

Uses:

- Hand sanitizer to help reduce bacteria on the skin.
- Recommended for repeated use.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

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| <p>Faits relatifs aux médicaments</p> <p>Principes actifs : Ethanol</p> <p>Force : 62% (v/v)</p> <p>Indications : Pour l'usage externe.</p> <p>Contre-indications : Aucune.</p> <p>Précautions : Éviter le contact avec les yeux.</p> <p>Autres informations : À conserver à l'écart des enfants.</p> | <p>Angaben zu dem Arzneimittel</p> <p>Wirkstoff : Ethanol</p> <p>Wirkstärke : 62%</p> <p>Wirkstoffklasse : Antiseptikum</p> <p>Indikation : Für den externen Gebrauch.</p> <p>Contraindikation : Keine.</p> <p>Vorsicht : Vermeiden Sie den Kontakt mit den Augen.</p> <p>Weitere Informationen : Für Kinder unzugänglich halten.</p> | <p>Información sobre el producto</p> <p>Ingredientes activos : Etanol</p> <p>Concentración : 62%</p> <p>Indicaciones : Para uso externo.</p> <p>Contraindicaciones : Ninguna.</p> <p>Precauciones : Evitar el contacto con los ojos.</p> <p>Otros datos : Mantener fuera del alcance de los niños.</p> |
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HAND SANITIZER

ethyl alcohol gel

Product Information

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|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49435-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 62 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| POLYETHYLENE TEREPHTHALATE (INTRINSIC VISCOSITY 0.70-1.00) (UNII: 645M2T7FHZ) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C) | |
| DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:49435-001-01 | 30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 01/11/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 01/11/2016 | |

Labeler - NPW-USA, Inc. (079831598)