

ENVIRO E3 RATED SANITIZER- ethanol alcohol liquid
IMPERIAL VALLEY DISTRIBUTING, 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.

ENVIRO E3 RATED sanitizer

Active ingredient

Ethanol Alcohol 70% v/v

Purpose

Antimicrobial

Uses

- Hand sanitizer to help reduce bacteria on the skin that could cause disease.
- Recommended for repeat use.

Warnings

Flammable. Keep away from fire or flame

For external use only.

When using this product

- Do not use in or near the eyes.
- In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

- If irritation or rash appears and lasts.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product in your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- No rinsing required.
- No towels needed

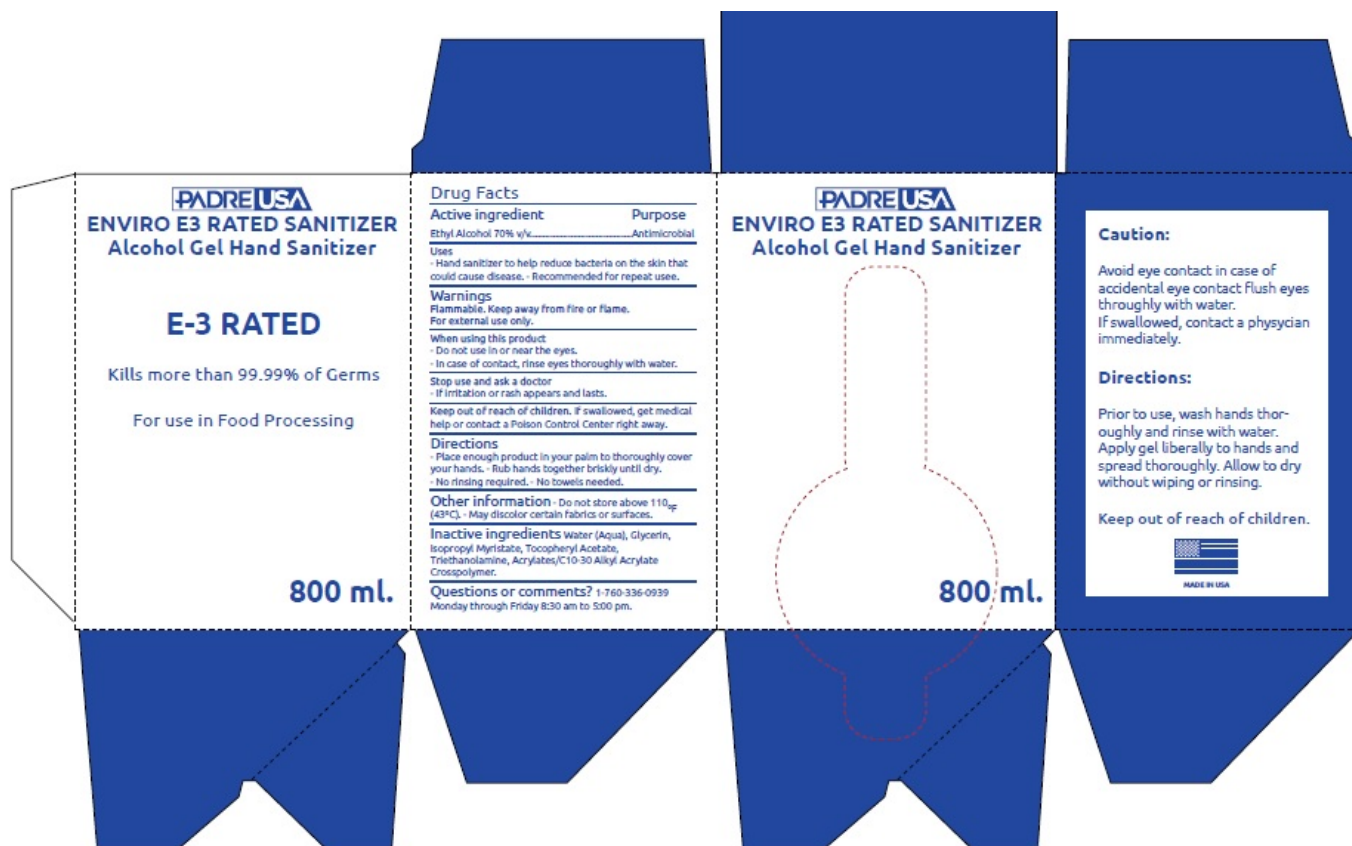
Other information

- Do not store above 110°F(43°C).
- May discolor certain fabrics or surfaces.

Inactive ingredients

Water, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Triethanolamine, Acrylates/C10-C30 Alkyl Akrylate, Crosspolymer

Product Label



ENVIRO E3 RATED SANITIZER

ethanol alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74693-001 |
| 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 |
|---|----------|
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| WATER (UNII: 059QF0K00R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:74693-001-01 | 800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/07/2020 | |
| 2 | NDC:74693-001-02 | 1000000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/07/2020 | |
| 3 | NDC:74693-001-03 | 37854 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/07/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 04/07/2020 | |

Labeler - IMPERIAL VALLEY DISTRIBUTING, INC (062212557)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| MCHEM S.A DE C.V. | | 951576034 | manufacture(74693-001) |

Revised: 4/2020

IMPERIAL VALLEY DISTRIBUTING, INC