

NAKED X RESTORE HAND SANITIZER- alcohol gel
Essations 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.

Naked X Restore Hand Sanitizer

Drug Facts

Active ingredient

Ethyl Alcohol 70.0% v/v

Purpose

Antimicrobial

Uses

- For handwashing to decrease bacteria on the skin.
- Moisturizing, cleansing solution.
- Repeated use encouraged.

Warnings

For external use only.

Flammable; keep away from heat, fire, and flame.

Avoid contact with eyes, ears, and mouth. In case of eye contact, flush thoroughly with water for 10 minutes.

Stop use and ask a doctor if

irritation and redness develop and persist for more than 72 hours.

Keep out of reach of children.

If swallowed, immediately seek medical attention or contact poison control.

Directions

- Apply a generous amount to one palm.
- Rub to saturate both palms.
- Rub across back of hands, between fingers, & around thumbs covering all surfaces until they feel dry.

Other information

- Store at 20°C to 25°C (68°F to 77°F)
- May discolor certain surfaces and fabrics.

Inactive ingredients

D.I. Water (Aqua), Polysorbate-20, Fragrance, Carbomer, Triethanolamine.

Children under the age of 6 years old should be supervised when using this product. Do not use on children under 2 months of age, or on open skin wounds.

Package Labeling:64ml

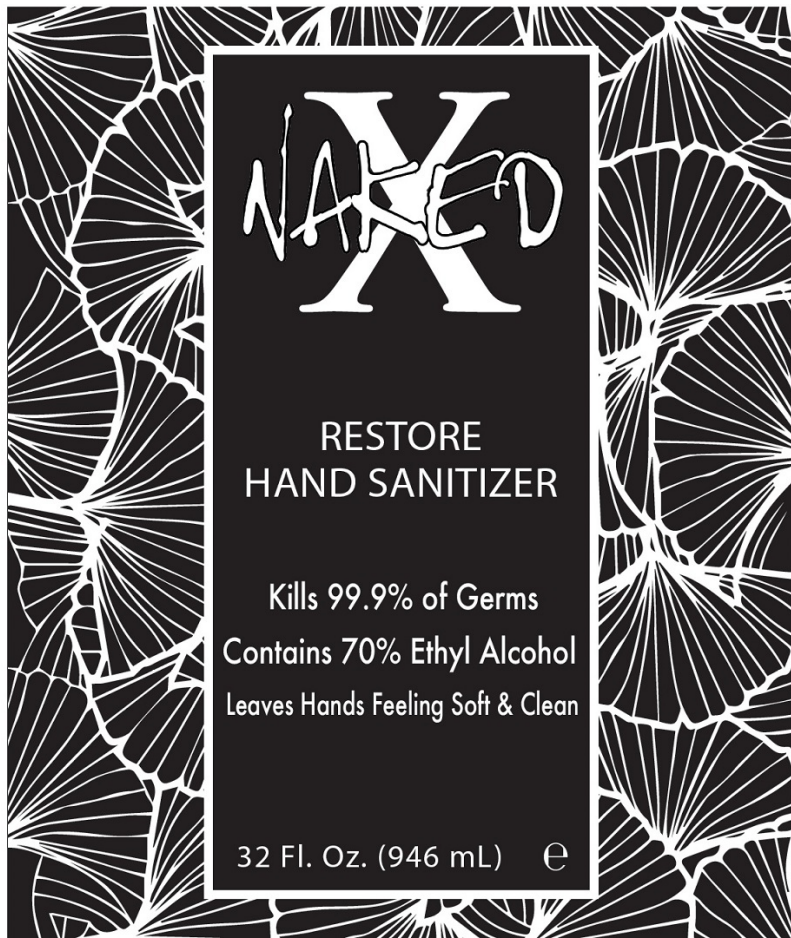


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|--|----------------|
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Essations Incorporated
 Park Forest, IL 60466
 www.essations.com
 1-800-248-3858
 Made in USA



Package Labeling:946ml



Drug Facts

| Active ingredient | Purpose |
|------------------------------|---------------|
| Ethyl Alcohol 70.0% v/v..... | Antimicrobial |

Uses • For handwashing to decrease bacteria on the skin.
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Naked X Restore Hand Sanitizer was formulated using CDC guidelines (recommended that hand sanitizers contain at least 60% alcohol to be **effective in killing germs**) as well as tested and approved by a licensed medical practitioner. The moisturizing formula conditions the hands, leaving them feeling soft and clean.



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Made in USA

NAKED X RESTORE HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79116-000 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.7 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| TROLAMINE (UNII: 903K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:79116-000-01 | 64 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:79116-000-02 | 946 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 | part333E | 03/30/2020 | |

Labeler - Essations Inc. (084183600)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|---|
| Essations Inc. | | 084183600 | manufacture(79116-000) , label(79116-000) , pack(79116-000) |

Revised: 1/2023

Essations Inc.