

NIVANA HAND SANITIZER- alcohol gel
JINHUA KAZSHOW COSMETICS CO., LTD.

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.

- Store between 15-30°C(59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Purified water USP, Glycerin, Propylene Glycol, Carbomer, Triethanolamine, Fragrance ,Aloe Barbadensis (Aloe Vera) Gel □Tocopheryl Acetate (Vitamin E)

- 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.

Alcohol

keep out of reach of children

Disinfection
 Sterilization
 No Rinseing

For external use only. Flammable.Keep away from heat or flame

| DRUG FACTS | |
|---|------------------------------|
| Active ingredient Ethanol (alcohol) 75%w/v | Purpose Antiseptic |
| Uses/ Health care personnel hand rub to help reduce bacteria that potentially can cause disease | |
| Warning For external use only. Flammable. Keep away from heat or flame | |
| Do not use | |
| <ul style="list-style-type: none"> • 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. | |
| Step 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 | |
| <ul style="list-style-type: none"> • 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 | |
| <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients | |
| purified water USP, Glycerin, Propylene Glycol, Carbomer, Triethanolamine, Fragrance, Aloe Barbadensis (Aloe Vera) Gel, Tocopheryl Acetate (Vitamin E) | |
| <small> Manufacturer: EMANANTE JEAN INC. Address: 926 CROCKER ST LA, CA 90021 USA TEL: 213-553-4553 www.emanantejean.com Dist by: Jinhua Kazshow Cosmetic Co., Ltd No.118, Cheng Gang North Street, Jin Dong Economic Development Area, Jinhua City Zhejiang Province, China ENTERPRISE EMERGENCY PHONE: 0086-579-8992777 </small> | |
| 6 955050 994875 PRO: 06/2020 EXP: 06/2023 | |

NIVANA HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54248-004 |
| Route of Administration | EXTRACORPOREAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | | ALCOHOL | 45 mL in 60 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) | | | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | | | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | | | | |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:54248-004-01 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/11/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333E | 06/11/2020 | | |

Labeler - JINHUA KAZSHOW COSMETICS CO., LTD. (542991908)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|------------------------|
| JINHUA KAZSHOW COSMETICS CO., LTD. | | 542991908 | manufacture(54248-004) |

Revised: 6/2020

JINHUA KAZSHOW COSMETICS CO., LTD.