

HAND SANITIZER- alcohol gel
Marquis Extraction Technology LLC

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(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin that potentially can cause disease. For use when soap and water are unavailable

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
- in eyes

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.

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)

Inactive ingredients

acrylates copolymer, alpha tocopherol acetate, Denatonium benzoate, glycerin, isopropyl myristate
propylene glycol, triisopropyl amine, fragrance

Package Label - Principal Display Panel



MARQUIS XT

HAND SANITIZER

70% Alcohol
GEL Antiseptic

16 fl oz (473 ml)

| | |
|---|----------------|
| Drug Facts | |
| Active ingredient[s] | Purpose |
| Alcohol 70% v/v..... | Antiseptic |
| Use: •Hand sanitizer to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are unavailable | |
| 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 •in eyes | |
| 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 age 6 when using this product to avoid swallowing. | |
| Other information • Store between 59-86F (15-30C) • Avoid freezing and excessive heat above 104F (40C) | |
| Inactive ingredients acrylates copolymer, alpha-tocopherol acetate, denatonium benzoate, glycerin, isopropyl myristate, propylene glycol, tert-butyl alcohol, triisopropanolamine, fragrance | |

MARQUISXT.COM

Manufactured by:
MARQUIS XT
11953 Prairie Industrial Pkwy
Hennepin, IL 61327

#: 41-1722- 000000001
Expires: Jul - 2022
Questions? call:
888-925-7311

76585-004-11



HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76585-004 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|--------------------|
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C) | 5 mL in 100 mL |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1) | 0.005 mL in 100 mL |
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) | 0.6 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.25 mL in 100 mL |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | 0.2 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | 0.75 mL in 100 mL |
| TRIISOPROPYLAMINE (UNII: Y67CF9Z56L) | 0.875 mL in 100 mL |
| CUMINYL ACETALDEHYDE (UNII: WSW8QXE6HG) | 0.6 mL in 100 mL |
| LINALOOL, (+)- (UNII: F4VNO44C09) | 0.6 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76585-004-17 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |
| 2 | NDC:76585-004-11 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |
| 3 | NDC:76585-004-13 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |
| 4 | NDC:76585-004-14 | 946 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |
| 5 | NDC:76585-004-12 | 1040875 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |
| 6 | NDC:76585-004-18 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |
| 7 | NDC:76585-004-15 | 12113 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |
| 8 | NDC:76585-004-16 | 18927 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |
| 9 | NDC:76585-004-20 | 59 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/27/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 06/27/2020 | |

Labeler - Marquis Extraction Technology LLC (117496233)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Marquis Extraction Technology LLC | | 117496233 | manufacture(76585-004) |

Revised: 6/2020

Marquis Extraction Technology LLC