

GEL HAND SANITIZER- gel hand sanitizer 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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 0% 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 not available.

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, dentaonium benzoate, glycerin, isopropyl myristate, Propylene glycol, Tert-butyl alcohol, triisopropylamine

Package Label - Principal Display Panel

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



MARQUIS XT
HAND SANITIZER
NON-STERILE SOLUTION

70% Alcohol
GEL Antiseptic

2 fl oz (59 ml)
MARQUISXT.COM

Batch#: 20002 • expires: Jun-2022 • 76585-003-20

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 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	

Questions? call: 888-925-7311

59 mL NDC: 76585-003-20

GEL HAND SANITIZER		
gel hand sanitizer gel		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:76585-003
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
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Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 mL in 100 mL
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	4 mL in 100 mL
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TRISOPROPYLAMINE (UNII: Y67CF9Z56L)	0.7 mL in 100 mL
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	0.005 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76585-003-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
2	NDC:76585-003-16	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
3	NDC:76585-003-18	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
4	NDC:76585-003-12	1040875 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
5	NDC:76585-003-15	12113 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
6	NDC:76585-003-14	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
7	NDC:76585-003-13	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
8	NDC:76585-003-11	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
9	NDC:76585-003-17	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/04/2020	

Labeler - Marquis Extraction Technology LLC (117496233)

Establishment

Name	Address	ID/FEI	Business Operations
Marquis Extraction Technology LLC		117496233	manufacture(76585-003)