MARQUIS GEL FORMULA- marquis gel formula 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 0n 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

acrylate copolymer, aloe, alpha-tocopheral acetate, denatonium benzoate, fragrance, glycerin, purified water USP

Package Label - Principal Display Panel

Gel 007



HAND SANITIZER

70% Alcohol
GEL Antiseptic

MARQUISXT.COM

Net Contents 16 fl oz (473 mL)

Drug Facts

Active ingredient[s]
Alcohol 70% v/v.....

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

Inactive ingredients acrylate copolymer, aloe, alpha-tocopherol acetate, denatonium benzoate, fragrance, glycerin, water

Questions? call 888-925-7311

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



MARQUIS GEL FORMULA

marquis gel formula gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76585-007

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredient/active morety				
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		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.05 mL in 100 mL		
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF1O)	0.00035 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	0.75 mL in 100 mL		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.05 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	1.1 mL in 100 mL		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:76585-007- 17	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			
2	NDC:76585-007-11	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			
3	NDC:76585-007- 13	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			
4	NDC:76585-007- 14	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			
5	NDC:76585-007- 15	12113 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			
6	NDC:76585-007- 12	1040875 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			
7	NDC:76585-007- 18	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			
8	NDC:76585-007- 16	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			
9	NDC:76585-007- 20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	07/01/2020			

Labeler - Marquis Extraction Technology LLC (117496233)

Establishment				
Name	Address	ID/FEI	Business Operations	
Marquis Extraction Technology LLC		117496233	manufacture(76585-007)	

Revised: 7/2020 Marquis Extraction Technology LLC