SUEZ GEL FORMULA- suez gel formula gel SUEZ Water Technologies & Solutions

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 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.

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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 104 F (40C)

Inactive ingredients

acrylate copolymer, aloe, denatonium benzoate, fragrance, glycerin, water

Package Label - Principal Display Panel







80896-010 Gel 10

SUEZ GEL FORMULA

suez gel formula gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80896-010	
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

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL		
LINALOOL, (+)- (UNII: F4VNO44C09)	0.3 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	1.1 mL in 100 mL		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.01 mL in 100 mL		
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF1O)	0.00035 mL in 100 mL		
CUMINYL ACETALDEHYDE (UNII: WSW8QXE6HG)	0.3 mL in 100 mL		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:80896-010- 17	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/23/2020		
2	NDC:80896-010- 12	1040875 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/23/2020		
2	NDC:80896-010-	255 ml in 1 ROTTI F. Type O. Not a Combination Droduct	10 /23 /20 20		

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Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not fina	l part333A	10/23/2020		

Labeler - SUEZ Water Technologies & Solutions (009722265)

Registrant - Marquis Extraction Technology LLC (117496233)

Establishment				
Name	Address	ID/FEI	Business Operations	
Marquis Extraction Technology LLC		117496233	manufacture(80896-010)	

Revised: 10/2020 SUEZ Water Technologies & Solutions