ISOPROPYL ALCOHOL- isopropyl alcohol gel
Marine Essence Biosciences Corporation of USA

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.

Isopropyl Alcohol Hand Sanitizer

Active Ingredient[s]

Isopropyl alcohol 75% v/v ……..
……...Antiseptic

Hand sanitizer to help reduce bacteria that potentially can cause disease.

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.

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.

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

glycerin, hydrogen peroxide, carbomer 940, triethanolamine, purified water USP

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

Topical - Administration to a particular spot on the outer surface of the body.

Gel form

To help reduce bacteria on the hands that can potentially cause disease.

ISOPROPYL ALCOHOL

isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73764-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -	ISOPROPYL	75.8 mL

UNII:ND2M416302)	ALCOHOL	in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TROLAMINE (UNII: 9O3K93S3TK)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73764-001-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/23/2020	
2	NDC:73764-001-02	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/23/2020	
3	NDC:73764-001-03	177 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/23/2020	
4	NDC:73764-001-04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/23/2020	
5	NDC:73764-001-05	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/23/2020	

Labeler - Marine Essence Biosciences Corporation of USA (116587566)

Establishment

Name	Address	ID/FEI	Business Operations
Marine Essence Biosciences Corporation of USA		116587566	manufacture(73764-001) , pack(73764-001) , label(73764-001)

Revised: 6/2020 Marine Essence Biosciences Corporation of USA