COROCCLEAN HAND SANITIZER- isopropyl alcohol liquid
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Rhydburg Pharmaceuticals Limited

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.

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)

a. Isopropyl Alcohol (70%, v/v)
b. Glycerol (0.5% v/v).
c. Propylene Glycol (1% v/v).
d. Carbomer 940 (0.20% v/v)
e. SodiumHydroxide (0.015% v/v)
f. Lemongrass Oil (INHS) (0.10% v/v)
g. Purified water q. s. to 1 ml

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)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria 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

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.

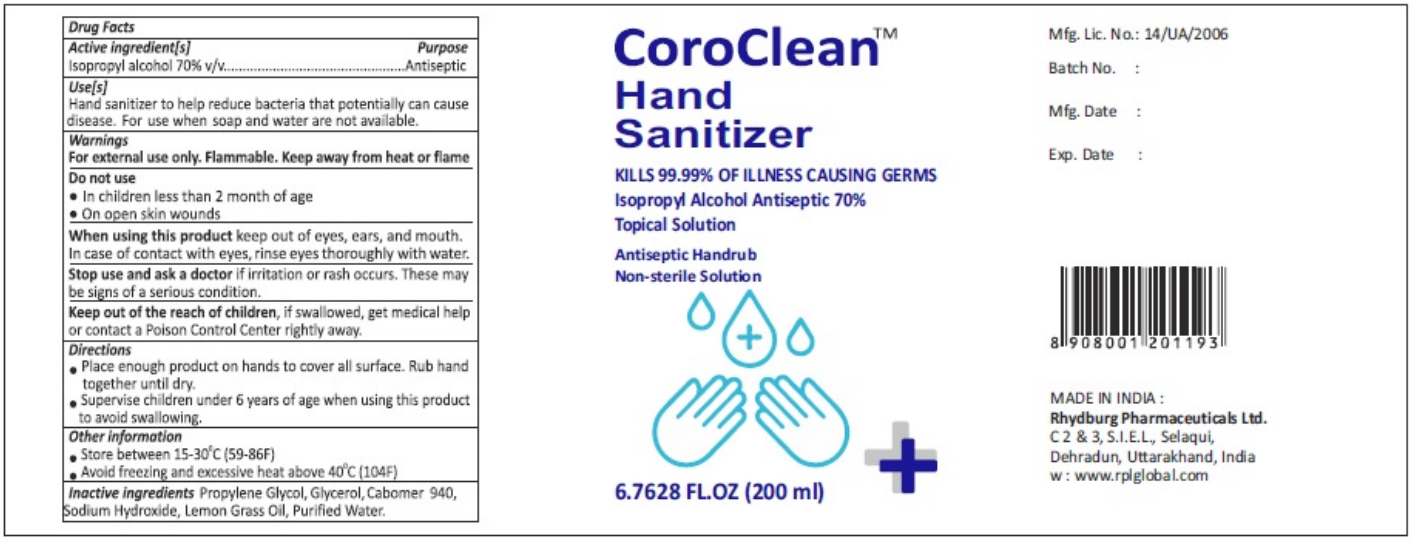
Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, Propylene Glycol, Carbomer 940,Sodium Hydroxide,Lemongrass Oil,purified water USP

Package Label - Principal Display Panel



COROCCLEAN HAND SANITIZER

isopropyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78925-001

Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78925-001-10	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78925-001-20	200 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

COROCLEAN HAND SANITIZER

isopropyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78925-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78925-002-10	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78925-002-20	200 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Rhydburg Pharmaceuticals Limited (650552128)

Establishment

Name	Address	ID/FEI	Business Operations
Rhydburg Pharmaceuticals Limited		650552128	manufacture(78925-001, 78925-002)

Revised: 1/2021 Rhydburg Pharmaceuticals Limited