

ROYAL HH ALCOHOL HAND SANITIZER- alcohol hand sanitizer solution
Code Red Four 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.

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

The hand rub 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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

ROYAL H&H

Alcohol Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

4 OZ (110 mL)

NDC: 77755-001-01

Drug Facts

Active ingredient[s]

Isopropyl alcohol 75% v/v.....

Purpose

Antiseptic

Use[s]

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

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.

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, hydrogen peroxide, purified water USP

Code Red Four Ltd
#3031, 11816 Inwood Rd
Dallas, TX 75244, USA
+1 (972) 885-6578

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NDC 77755-001-01

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Use

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.

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Package Label - Principal Display Panel

4 fl oz (120 mL) NDC: 77755-001-01

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NDC 77755-001-01

ROYAL HH ALCOHOL HAND SANITIZER

alcohol hand sanitizer solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77755-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL	75 mL in 100 mL
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)			18.425 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77755-001-01	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/18/2020	

Labeler - Code Red Four Limited (663408170)

Establishment			
Name	Address	ID/FEI	Business Operations
Code Red Four Limited		663408170	manufacture(77755-001)