HONEYWELL HAND SANITIZER- alcohol solution Honeywell International Inc.

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

Purpose

Antiseptic, Hand Rub

Use

Health care personnel hand rub 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.

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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

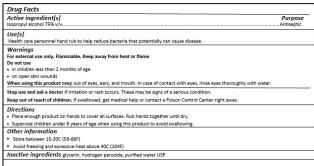
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel







HONEYWELL HAND SANITIZER

alcohol solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12728-543	
Route of Administration	TOPICAL			

ı	Active Ingredient/Active Moiety				
ı	Ingredient Name	Basis of Strength	Strength		
ı	ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 L in 100 L		
ı					

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 L in 100 L			
WATER (UNII: 059QF0KO0R)	18.425 L in 100 L			

ı	Packaging					
ı	# Item C	o de	Package Description	Marketing	Start Date	Marketing End Date
ı	1 NDC:12728	-543-01 3.785 L i	n 1 BOTTLE; Type 0: Not a Combination	Product 04/20/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/20/2020		

Labeler - Honeywell International Inc. (879085116)

Establishment					
Name	Address	ID/FEI	Business Operations		
Honeywell International Inc.		879085116	manufacture(12728-543)		

Revised: 4/2020 Honeywell International Inc.