

ANTISEPTIC HAND RUB- isopropyl alcohol liquid ND Industries, 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 sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

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) 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 Sanitizer

Use

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.

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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

1893 ml NDC: 75154-604-00



Drug Facts
Active Ingredient Isopropyl alcohol 75% w/v.....
Claim Hand sanitizer to help reduce germs
Warnings For external use only. Flammable. Do not use on children less than 6 years of age. When using this product keep it away from eyes, rinse eyes thoroughly if contact occurs. Stop use and ask a doctor if irritation or rash occurs.
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
Questions? Call 1-800-621-2863

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Made in U.S.A. and
Distributed by: Vibe



17.03 L NDC: 75154-604-05

Vibra-TIME 604 ANTISEPTIC HAND RUB

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Non-sterile Solution

4.5 Gal (17.03 L)

Drug Facts

Active Ingredient

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

Uses Hand sanitizer to help red.

Warnings

For external use only. Flammab

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with eyes, rinse eyes thoroughl

Stop use and ask a doctor if irr
serious condition.

Keep out of reach of children. I
Poison Control Center right away.

Directions

Place enough product on hands to

Supervise children under 6 years c

Other information

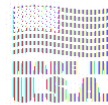
Store between 15-30C (59-86F

Avoid freezing and excessive h

Inactive Ingredients glycerin

Questions? 1-800-521-2863

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Distributed by: Vibe



18.93 L NDC: 75154-604-06

Vibra-TIME 604 ANTISEPTIC HAND RUB

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Non-sterile Solution

5.0 Gal (18.93 L)

Drug Facts

Active Ingredient

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

Uses Hand sanitizer to help red.

Warnings

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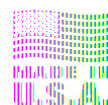
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ANTISEPTIC HAND RUB

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75154-604
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75154-604-00	1893 mL in 1 JUG; Type 0: Not a Combination Product	04/22/2020	
2	NDC:75154-604-05	17030 mL in 1 PAIL; Type 0: Not a Combination Product	04/22/2020	
3	NDC:75154-604-06	18930 mL in 1 PAIL; Type 0: Not a Combination Product	04/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

Labeler - ND Industries, Inc. (078395803)

Establishment

Name	Address	ID/FEI	Business Operations
ND Industries, Inc.		933092207	manufacture(75154-604)