HAND SANITIZER- is opropyl alcohol liquid TATA'S NATURAL ALCHEMY, LLC

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.

Hand Sanitizer

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. 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.

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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

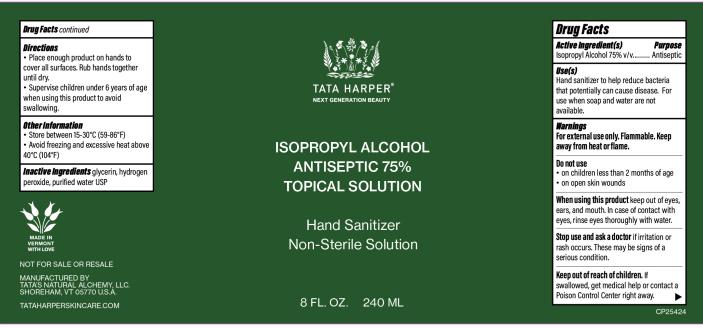
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

240ml - NDC: 74516-102-24



15 ml NDC: 74516-102-15

Drug Facts continued

Directions

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Other Information - Store between 15-30°C (59-86°F) · Avoid freezing and excessive heat ab 40°C (104°F)

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NOT FOR SALE OR RESALE

TATAHARPERSKINCARE.COM



TATA HARPER[®] NEXT GENERATION BEAUTY

ISOPROPYL ALCOHOL **ANTISEPTIC 75% TOPICAL SOLUTION**

Hand Sanitizer Non-Sterile Solution

Drug Facts

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15 ML

CP25421

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74516-102

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredient/Active wrotery					
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 PERO XIDE (UNII: BBX060AN9V) 0.125 mL in 100 mL WATER (UNII: 059QF0KO0R)

Packaging Marketing Start Marketing End Package Description Item Code Date Date 1 NDC:74516-102-15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination 04/03/2020 15 NDC:74516-102-240 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination 04/08/2020

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

Labeler - TATA'S NATURAL ALCHEMY, LLC (022018710)

Registrant - TATA'S NATURAL ALCHEMY, LLC (022018710)

Establishment						
Name	Address	ID/FEI	Business Operations			
TATA'S NATURAL ALCHEMY, LLC		022018710	manufacture (74516-102)			

Revised: 4/2020 TATA'S NATURAL ALCHEMY, LLC