HAND SANITIZER- 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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)

Alcohol 80% 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.

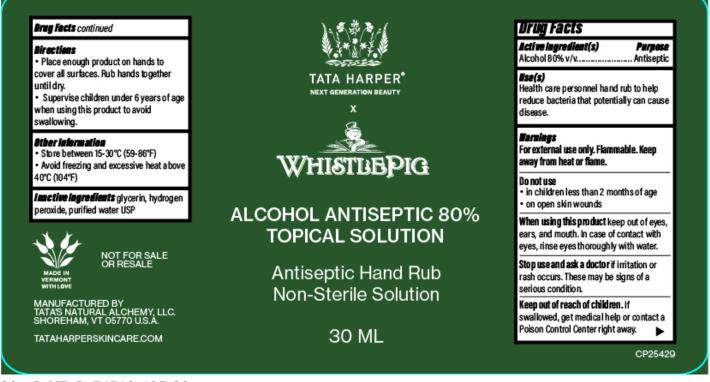
Other information

- 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



30 mL NDC: 74516-105-30

HAND SANITIZER							
alcohol liquid							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74516-105				
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							

Ingredient Name		Basis	of Strength	Strength		
ALCOHOL (UNII: 3	K9958	V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL		80 mL in 100 mL	
Inactive Ingred	lients					
Ingredient Name				Strength		
GLYCERIN (UNII: PDC6A3C0OX)				1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)				0.125 mL in 100 mL		
WATER (UNII: 059C	F0KO)R)				
Packaging						
# Item Code		Package Description	Mar	keting Start Date	Marketing End Date	
	30 mI Produ	. in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	Mar 0 4/17/2	Date	Marketing End Date	
# Item Code NDC:74516-105-	Pro du	, in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct		Date	-	
 <i>Item Code</i> NDC:74516-105- 30 	Produ nfori	, in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	0 4/17/2	Date		

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(74516-105)

Revised: 4/2020

TATA'S NATURAL ALCHEMY, LLC