

HAND SANITIZER- isopropyl alcohol liquid
RACK Furniture Group for Children, 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.

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 70% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial, Hand Sanitizer

Use

For hand washing to decrease bacteria on the skin. Good for repeated use.

Warnings

External use only. Keep out of reach of children. Flammable.

Keep out of reach of children.

Directions

- Briskly rub generous amount on hands and rub together until dry.

Inactive ingredients

Water, distilled

Package Label - Principal Display Panel

59.2mL NDC: 80428-109-01



Truline

Instant Hand Sanitizer

Kills 99% of Germs that cause illness
Made in USA **2 oz. • 59.2mL**

Active Ingredient **Purpose**
70% Isopropyl Alcohol.....Antimicrobial

Uses:
For hand washing to decrease bacteria on the skin. Good for repeated use.

External use only
Keep out of reach of children

Directions: Briskly rub generous amount on hands and rub together until dry.

Inactive ingredients: Water

118.3mL NDC: 80428-209-02



Truline

Instant Hand Sanitizer

Kills 99% of Germs that cause illness
Made in USA **4 oz. • 118.3 mL**

Active Ingredient **Purpose**
70% Isopropyl Alcohol.....Antimicrobial

Uses:
For hand washing to decrease bacteria on the skin. Good for repeated use.

External use only
Keep out of reach of children

Directions: Briskly rub generous amount on hands and rub together until dry.

Inactive Ingredients: Water

HAND SANITIZER			
isopropyl alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80428-109

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 in 100

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	30

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80428-109-01	59.2 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	03/30/2049



Active Ingredient **Purpose**
70% Isopropyl Alcohol.....Antimicrobial

Uses:

For hand washing to decrease bacteria on the skin. Good for repeated use.

External use only

Keep out of reach of children

Directions: Briskly rub generous amount on hands and rub together until dry.

Inactive ingredients: Water

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	03/30/2049

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80428-209
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 in 100

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	30

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80428-209-02	118.3 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	03/30/2049



Truline

Instant Hand Sanitizer

Kills 99% of Germs that cause illness
Made in USA 4 oz. • 118.3 mL

Active Ingredient **Purpose**
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Labeler - RACK Furniture Group for Children, LLC. (080196774)

Registrant - RACK Furniture Group for Children, LLC. (080196774)

Establishment			
Name	Address	ID/FEI	Business Operations
RACK Furniture Group for Children, LLC.		080196774	repack(80428-109)