

NURINSE 1 GAL- isopropyl alcohol gel

NuGenTec

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.

NuRinse Hand Sanitizer

This is a hand sanitizer manufactured according to the Guidelines established by the CDC.

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) (70%, 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.
- e. Hydroxymethyl cellulose (0.7 g per 100ml)

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 70% 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, hydroxymethyl cellulose

Package Label - Principal Display Panel

Personal Care Hand Sanitizer

Designed in The USA. Made in The USA.™

NuRinse® Hand Sanitizer Gel

World Health Organization
Recommended Hand Rub Formulation
*Ethanol 70%

Advanced Formula
Hand Moisturizing
Hospital & Institutional Grade

1-Gallon (~3.8L)

Product Description:

Personal care product. Use for hand sanitizing. Recommended for repeated use. The formula contains 70% alcohol (ethanol) which meets the CDC, FDA, and WHO guidelines for hand sanitizer. All USP ingredients. Enhanced WHO formula to increase moisturizing effect.

Active Ingredients:

Ethanol Alcohol 70% v/v, Antiseptic Purpose

Inactive Ingredients:

Glycerin (for moisturizing), Hydrogen Peroxide, Water, Hydroxymethyl Cellulose

California Prop 65 Compliant



Directions:

When using NuRinse Hand Sanitizer, apply a palmful of the product to one hand and rub the product all over the surfaces of both hands until your hands are dry. Do not wipe away excess sanitizer. For children under 6, use only with adult supervision. Not recommended for infants.

WARNINGS:

Use: For external use only on hands.

Flammable: Keep away from heat and flame. Keep container closed when not in use.

When using this product: Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a Doctor: If skin irritation develops.

Keep out of reach of children: If ingested, get medical help or call the Poison Control Center immediately.

Other Information:

Do not store above 105°F. May discolor some fabrics. Harmful to wood finishes and plastics.

Manufactured and Distributed By:



1155 Park Avenue, Emeryville, CA 94608
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www.nugentec.com

3785 mL NDC: 77368-071-01

NURINSE 1 GAL

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77368-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	0.7 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (clear)	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77368-071-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
2	NDC:77368-071-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
3	NDC:77368-071-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
4	NDC:77368-071-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

Labeler - NuGenTec (090331927)

Registrant - NuGenTec (090331927)

Establishment

Name	Address	ID/FEI	Business Operations
NuGenTec		090331927	manufacture(77368-071)