

UNICHEM- hand sanitizer refreshing gel gel Universal Chemical Products, Corp.

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 Refreshing Gel

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: 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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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, glutaraldehyde, purified water USP, Thickening Agent

Package Label - Principal Display Panel

3.78 L NDC: 82150-570-01

Hand Sanitizer

DRUG FACTS

ACTIVE INGREDIENT

Isopropyl Alcohol 70%..... Antiseptic

Purpose

USE(S) - Helps prevent the risk of infection in minor cuts, scrapes and burns.
Do not use in children less than 2 months - on open skin wounds.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control.

WARNINGS

For external use only. (Flammable, keep away from heat or flame)

When using this product keep out of eyes, ears and mouth.

In case of contact, rinse with plenty of water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

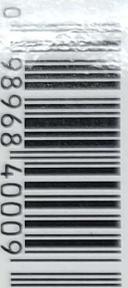
DIRECTIONS - Clean the affected area - Apply 1 to 3 times daily

OTHER INFORMATION - Store between 15-30°C (59-86°F), avoid freezing and excessive heat above 40°C.

INACTIVE INGREDIENTS - Purified Water, Isopropyl Alcohol, Glutaraldehyde, Glycerine, Thickening Agent.

Packed by:

UNIVERSAL CHEMICALS PRODUCTS, CORP.
PO BOX 540 LOUISIANA, MO 65072
787.876.1117



Hand Sanitizer

Antiseptic

Refreshing Gel



Net Content:
128 FL OZ (3.78L)

Safe

UNICHEM

hand sanitizer refreshing gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82150-570
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 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.25 L in 100 L
GLUTARALDEHYDE (UNII: T3C89M417N)	0.03 L in 100 L
WATER (UNII: 059QF0KO0R)	30 L in 100 L
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82150-570-01	3.78 L in 1 BOTTLE; Type 0: Not a Combination Product	12/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/03/2020	

Labeler - Universal Chemical Products, Corp. (963557095)

Registrant - Universal Chemical Products, Corp. (963557095)

Establishment

Name	Address	ID/FEI	Business Operations
Universal Chemical Products, Corp.		963557095	manufacture(82150-570)