# HAND SANITIZER- is opropyl alcohol liquid RealChem Manufacturing Inc

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.

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#### 99% IPA Antiseptic

This is a first aid antiseptic manufactured according to FDA Guidance.

# **Active Ingredient(s)**

Isopropyl Alcohol 99% v/v. Purpose: Antiseptic

# Purpose

Antiseptic, Hand Sanitizer

#### Use

Antiseptic to decrease germs in minor cuts and scrapes and for preparation of skin prior to an injection; 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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- Clean the affected area; apply small amount of product on the area 1 to 3 times daily.
- Supervise children under 6 years of age when using this product to avoid swallowing.

#### Other information

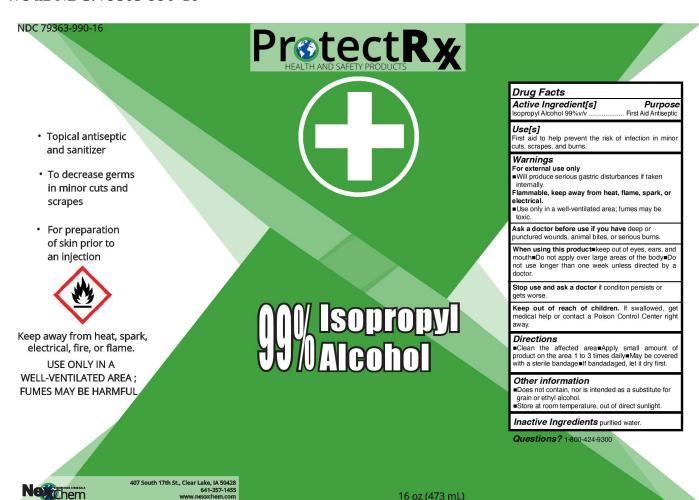
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

purified water USP

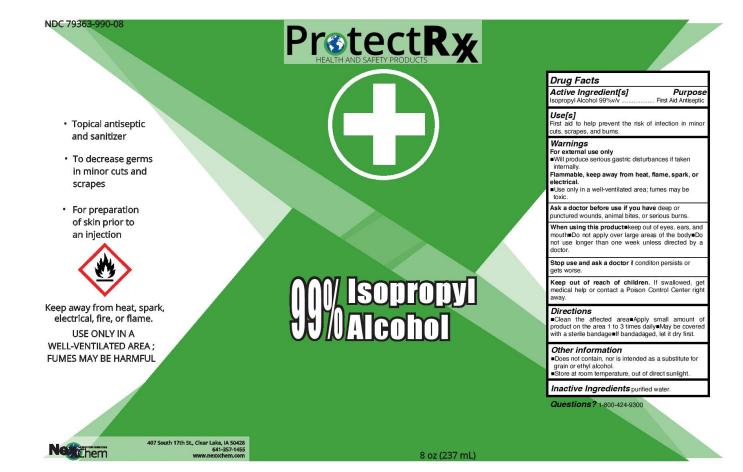
# **Package Label - Principal Display Panel**

473 ml NDC: 79363-990-16



16 oz (473 mL)

237ml NDC: 79393-990-08



3785ml NDC: 79363-990-28



946ml NDC: 79363-990-32



Keep away from heat, spark,

USE ONLY IN A

WELL-VENTILATED AREA; FUMES MAY BE HARMFUL





Drug Facts
Active Ingredient[s]

Stop use and ask a doctor if conditon persists or

Directions
■Clean the affected area∎Apply small amount product on the area 1 to 3 times daily∎May be cover with a sterile bandage ■if bandadaged, let it dry first.

Other information

Does not contain, nor is intended as a substitute for grain or ethyl alcohol.

Store at room temperature, out of direct sunlight.

Inactive Ingredients purified water.

gg// Isopropyl 99// Alcohol

Newhem

407 South 17th St., Clear Lake, IA 50428 641-357-1455

32 oz (946.4 mL)

# HAND SANITIZER

isopropyl alcohol liquid

#### **Product Information**

HUMAN OTC DRUG NDC:79363-990 Product Type Item Code (Source)

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

**Basis of Strength Ingredient Name** Strength ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -ISOPROPYL 99 mL ALCOHOL in 100 mL UNII:ND2M416302)

#### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059OF0KO0R)	

#### **Packaging**

П	0 0			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:79363-990-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2020	
	2 NDC:79363-990- 08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2020	
l	3 NDC:79363-990-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2020	
l	4 NDC:79363-990-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2020	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/30/2020	

# Labeler - RealChem Manufacturing Inc (120491681)

Establishment			
Name	Address	ID/FEI	Business Operations
RealChem Manufacturing Inc		117584702	manufacture(79363-990), pack(79363-990), repack(79363-990)

Establishment			
Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		117742005	manufacture(79363-990), pack(79363-990), repack(79363-990)

Establishment			
Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		117828480	manufacture(79363-990), pack(79363-990), repack(79363-990)

Establishment				
Name	Address	ID/FEI	Business Operations	
RealChem Manufacturing Inc		120491681	pack(79363-990), repack(79363-990), manufacture(79363-990)	

Revised: 2/2021 RealChem Manufacturing Inc