

**HAND SANITIZER- isopropyl 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.

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.

**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

NDC 79363-990-16

**ProtectRx**  
HEALTH AND SAFETY PRODUCTS



- Topical antiseptic and sanitizer
- To decrease germs in minor cuts and scrapes
- For preparation of skin prior to an injection



Keep away from heat, spark, electrical, fire, or flame.

USE ONLY IN A  
WELL-VENTILATED AREA ;  
FUMES MAY BE HARMFUL

**99% Isopropyl  
Alcohol**

### Drug Facts

Active Ingredient[s]	Purpose
Isopropyl Alcohol 99%v/v	First Aid Antiseptic

### Use[s]

First aid to help prevent the risk of infection in minor cuts, scrapes, and burns.

### Warnings

#### For external use only

■ Will produce serious gastric disturbances if taken internally.

**Flammable, keep away from heat, flame, spark, or electrical.**

■ Use only in a well-ventilated area; fumes may be toxic.

**Ask a doctor before use if you have deep or punctured wounds, animal bites, or serious burns.**

**When using this product** ■ keep out of eyes, ears, and mouth ■ Do not apply over large areas of the body ■ Do not use longer than one week unless directed by a doctor.

**Stop use and ask a doctor** if condition persists or gets worse.

**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 ■ May be covered with a sterile bandage ■ If bandaged, 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.

**Questions?** 1-800-424-9300

**NexChem**

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

16 oz (473 mL)

237ml NDC: 79393-990-08

NDC 79363-990-08

# ProtectRx<sub>®</sub>

HEALTH AND SAFETY PRODUCTS



- Topical antiseptic and sanitizer
- To decrease germs in minor cuts and scrapes
- For preparation of skin prior to an injection



Keep away from heat, spark, electrical, fire, or flame.

USE ONLY IN A WELL-VENTILATED AREA ; FUMES MAY BE HARMFUL

## 99% Isopropyl Alcohol

### Drug Facts

Active Ingredient[s]	Purpose
Isopropyl Alcohol 99%v/v	First Aid Antiseptic

### Use[s]

First aid to help prevent the risk of infection in minor cuts, scrapes, and burns.

### Warnings

For external use only

Will produce serious gastric disturbances if taken internally.

Flammable, keep away from heat, flame, spark, or electrical.

Use only in a well-ventilated area; fumes may be toxic.

Ask a doctor before use if you have deep or punctured wounds, animal bites, or serious burns.

When using this product keep out of eyes, ears, and mouth. Do not apply over large areas of the body. Do not use longer than one week unless directed by a doctor.

Stop use and ask a doctor if condition persists or gets worse.

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. May be covered with a sterile bandage. If bandaged, 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.

Questions? 1-800-424-9300



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

8 oz (237 mL)

3785ml NDC: 79363-990-28

NDC 79363-990-28

# ProtectRx<sub>®</sub>

HEALTH AND SAFETY PRODUCTS



- Topical antiseptic and sanitizer
- To decrease germs in minor cuts and scrapes
- For preparation of skin prior to an injection



Keep away from heat, spark, electrical, fire, or flame.

USE ONLY IN A WELL-VENTILATED AREA ; FUMES MAY BE HARMFUL

## 99% Isopropyl Alcohol

### Drug Facts

Active Ingredient[s]	Purpose
Isopropyl Alcohol 99%v/v	First Aid Antiseptic

### Use[s]

First aid to help prevent the risk of infection in minor cuts, scrapes, and burns.

### Warnings

For external use only

Will produce serious gastric disturbances if taken internally.

Flammable, keep away from heat, flame, spark, or electrical.

Use only in a well-ventilated area; fumes may be toxic.

Ask a doctor before use if you have deep or punctured wounds, animal bites, or serious burns.

When using this product keep out of eyes, ears, and mouth. Do not apply over large areas of the body. Do not use longer than one week unless directed by a doctor.

Stop use and ask a doctor if condition persists or gets worse.

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. May be covered with a sterile bandage. If bandaged, 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.

Questions? 1-800-424-9300



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

1 Gallon (3785 mL)

946ml NDC: 79363-990-32

NDC 79363-990-32

**ProtectRx**  
HEALTH AND SAFETY PRODUCTS



- Topical antiseptic and sanitizer
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USE ONLY IN A WELL-VENTILATED AREA; FUMES MAY BE HARMFUL

**99% Isopropyl Alcohol**

Drug Facts	
Active Ingredient[s]	Purpose
Isopropyl Alcohol 99%w/v	First Aid Antiseptic
Use[s]	
First aid to help prevent the risk of infection in minor cuts, scrapes, and burns.	
Warnings	
For external use only	
<ul style="list-style-type: none"> <li>Will produce serious gastric disturbances if taken internally.</li> <li>Flammable, keep away from heat, flame, spark, or electrical.</li> <li>Use only in a well-ventilated area; fumes may be toxic.</li> </ul>	
<p>Ask a doctor before use if you have deep or punctured wounds, animal bites, or serious burns.</p>	
<p>When using this product: keep out of eyes, ears, and mouth. Do not apply over large areas of the body. Do not use longer than one week unless directed by a doctor.</p>	
<p>Stop use and ask a doctor if condition persists or gets worse.</p>	
<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<p>Clean the affected area. Apply small amount of product on the area 1 to 3 times daily. May be covered with a sterile bandage. If bandaged, let it dry first.</p>	
Other information	
<ul style="list-style-type: none"> <li>Does not contain, nor is intended as a substitute for grain or ethyl alcohol.</li> <li>Store at room temperature, out of direct sunlight.</li> </ul>	
<p>Inactive Ingredients: purified water.</p>	
<p>Questions? 1-800-424-9300</p>	



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

32 oz (946.4 mL)

## HAND SANITIZER

isopropyl alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79363-990
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	
3	NDC:79363-990-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2020	
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