# HAND SANITIZER- is opropyl alcohol gel 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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## 70% IPA Scented Gel Hand Sanitizer

This is a scented hand sanitizer gel manufactured with denatured isopropyl alcohol (70% v/v).

# 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.

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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**

# **Package Label - Principal Display Panel**

237 ml NDC: 79363-721-08

NDC # 79363-721-08

WARRANTY DISCLAIMER
Because of conditions of use which may be beyond our control, NewChem, LLC shall not be held responsible in any manner for any personal injury or pracyr loss resulting to the buyer or any other person from handling, storage, or use of this material not in accordance with directions.

The buyer andors use acassures all risk and labelity resulting from improper handling or usage.

There is no warranty expressed or implied of any kind, except as supplied in writing.

### **KEEP OUT OF REACH OF CHILDREN**



For external use only! Flammable Keep away from heat or flame.

Do not use on children less than 2 months of age. Do not use 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.

> IF SWALLOWED: Immediately call a POISON CONTROL CENTER or a doctor/physician. Rinse mouth.

See Safety Data Sheet for further details regarding safe use of this product. NexxChem LLC, 407 South 17th St., Clear Lake IA 50428, 641-357-1455.

For a copy of the NexxChem Product Warranty, contact your local NexxChem distributor or NexxChem's Technical Department at info@nexxchem.com or call 641-357-1455.



407 South 17th St., Clear Lake, IA 50428 www.nexxchem.com



# Drug Facts

Active Ingredient[s] Isopropyl Alcohol 70% v/v ...

Purpos .. First Aid Antisept

Use[s]
First aid to help prevent the risk of infection in mind cuts, scrapes, and burns.

### Warnings

or external use only

Will produce serious gastric disturbances if taken

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

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 declar.

Stop use and ask a doctor if conditon persists or

Geep out of reach of children. If swallowed, get nedical help or contact a Poison Control Center right

### Directions

Eclean the affected area■Apply small amount o product on the area 1 to 3 times daily■May be covered 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, PEG-6 (and) AMP-Acrylates / Vinyl Isodecanoate osspolymer, Fragrance (Parfum)

Questions? 1-800-424-9300

### **PACKAGING**

ProtectRxx Hand Sanitizer - Non Sterile Solution is available in these sizes:

16 oz bottle w/ flip top 32 oz bottle w/flip top 128 oz (gallon) bottle



(473 ml)

(946 ml)

(3785 ml)

### NDC # 79363-721-08

WARRANTY DISCLAIMER

Because of conditions of use which may be beyond our control. NexcChem, LLC shall not be held responsible in any manner for any personal injury or prepry loss resulting to the buyer or any other person from handling storage, or use of this material not in accordance with directions. The buyer andoor user assures all it is don libability resulting from improper handling or usage. There is no warranty expressed or implied of any kind, except as supplied in writing.

### WARNINGS

### **KEEP OUT OF REACH OF CHILDREN**



For external use only! Flammable Keep away from heat or flame.

Do not use on children less than 2 months of age. Do not use 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.

> IF SWALLOWED: Immediately call a POISON CONTROL CENTER or a doctor/physician. Rinse mouth.

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### WARRANTY

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407 South 17th St., Clear Lake, IA 50428 www.nexxchem.com



Drug Facts

Active Ingredient[s] Isopropyl Alcohol 70% v/v ....

Purpo .. First Aid Antise

Use[s]
First aid to help prevent the risk of infection in mind cuts, scrapes, and burns.

Warnings
For external use only

■Will produce serious gastric disturbances if taken internally

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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

Briections

■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 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, PEG-6 (and) AMP-Acrylates / Vinyl Isodecanoate Crosspolymer, Fragrance (Parlum)

Questions? 1-800-424-9300

### PACKAGING

ProtectRxx Hand Sanitizer - Non Sterile Solution is available in these sizes:

16 oz bottle w/ flip top 32 oz bottle w/flip top 128 oz (gallon) bottle

(3785 ml)



473ml NDC: 79363-721-16

WARRANTY DISCLAIMER

### WARNINGS

### **KEEP OUT OF REACH OF CHILDREN**



For external use only! Flammable Keep away from heat or flame.

Do not use on children less than 2 months of age.

Do not use 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.

IF SWALLOWED: Immediately call a POISON CONTROL CENTER or a doctor/physician. Rinse mouth

See Safety Data Sheet for further details regarding safe use of this product. NexxChem LLC, 407 South 17th St., Clear Lake IA 50428.

WARRANTY
For a copy of the NexxChem Product Warranty, contact your local NexxChem
distributor or NexxChem's Technical Department at info@nexxchem.com or call
641-357-1455.



407 South 17th St. www.nexxchem.com



## Drug Facts

Active Ingredient[s] Isopropyl Alcohol 70% v/v ....

Purpose First Aid Antiseption

Use[s]
First aid to help prevent the risk of infection in minor

Warnings

For external use only

Will produce serious gastric disturbances if taken

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

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

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

Stop use and ask a doctor if conditon persists of

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

©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 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, PEG-6 (and) AMP-Acrylates / Vinyl Isodecanoate Crosspolymer, Fragrance (Parfum)

Questions? 1-800-424-9300

### **PACKAGING**

ProtectRxx Hand Sanitizer - Non Sterile Solution is available in these sizes:

8 oz bottle w/ flip top 32 oz bottle w/flip top 128 oz (gallon) bottle

(237 ml) (946 ml) (3785 ml)



# 3785ml NDC: 79363-721-28



For external use only! Flammable Keep away from heat or flame

Do not use on children less than 2 months of age. Do not use 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.

IF SWALLOWED: Immediately call a POISON CONTROL CENTER or a

See Safety Data Sheet for further details regarding safe use of this product. NexxChem LLC, 407 South 17th St., Clear Lake IA 50428. 641-357-1455.

WARRANTY
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Technical Department at info@nexxchem.com or call 641-357-1455.

**New** hem







NDC: 79363-721-28

LIFESGUARD HAND SANITIZER - NON-STERILE SOLUTION

IS AN FDA ACCEPTED FORMULA OF HAND SANITIZER THAT HELPS REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.

## PACKAGING LIFESGUARD HAND SANITIZER - NON STERILE SOLUTION

| IS AVAILA | BLE IN THESE | SIZES:              |    |
|-----------|--------------|---------------------|----|
| 8 0       | DZ BOTT      | LE W/ FLIP TOP (237 | ML |
| 16 0      | DZ BOTT      | LE W/ FLIP TOP (473 | ML |
| 32 0      | DZ BOTT      | LE W/FLIP TOP (946  | ML |
| 128       | DZ (GALI     | LON) BOTTLE (3785   | ML |

SEE SAFETY DATA SHEET FOR FURTHER DETAILS REGARDING SAFE USE OF THIS PRODUCT.

Guardian Sales & Supply Inc. 401 Washington Blvd. Unit 2, Mundelein IL, 60060 847-306-9922

LIFESC TARD DISTRUIBUTED BY





| Drug Facts   |
|--|
| Active ingredient[s] Purpose<br>Isopropyl Alcohol 70% viv 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 gastrio disturbances if taken internally. Flammable, keep away from head, flame, spark, or electrical. Ulse only in a well-versibled area; furnes may be toolic. |
| Ask a doctor before use if you have deep or<br>punctured wounds, animal bites, or serious burns.   |
| When using this productakeep out of eyes, ears, and<br>mouthabo not apply over large areas of the bodyabo<br>not use longer than one week unless directed by a<br>doctor.  |
| Stop use and sak a doctor if conditon persists or<br>gets worse.   |
| Keep out of reach of children. If swallowed, get<br>medical help or contact a Poison Control Center right<br>away.   |
| Directions  Clean the affected areamApply small amount of product on the area 1 to 3 times dailymMay be covered with a sterile bandagemIt bandadaged, let it dry first.  |
| Other Information  Does not contain, nor is intended as a substitute for grain or ethyl alcohol.  Store at noom temperature, cut of direct sunlight.   |
| Inactive Ingredients purited water, PEG-6<br>(and) AMP-Acrylates / Vinyl Isodecancate<br>Crosspolymer, Fragrance (Partum)  |



# HAND SANITIZER

isopropyl alcohol gel

| D 1 .   | T C         |
|---------|-------------|
| Product | Information |

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:79363-721

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

| retive ingredient retive violety   |                      |                    |  |  |  |  |
|--|----------------------|--------------------|--|--|--|--|
| Ingredient Name  | Basis of Strength    | Strength           |  |  |  |  |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL<br>ALCOHOL | 70 mL<br>in 100 mL |  |  |  |  |

# **Inactive Ingredients**

| inactive ingredients            |                |  |  |  |  |
|---------------------------------|----------------|--|--|--|--|
| Ingredient Name                 | Strength       |  |  |  |  |
| WATER (UNII: 059QF0KO0R)        |                |  |  |  |  |
| RAPIDGEL EZ1 (UNII: 33JH4A7R2K) | 1 mL in 100 mL |  |  |  |  |

# **Packaging**

| 1 | # Item Code      | Package Description                                    | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:79363-721-08 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 10/23/2020                  |                           |
| 2 | NDC:79363-721-16 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 10/23/2020                  |                           |
| 3 | NDC:79363-721-28 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/23/2020                  |                           |

# **Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 10/23/2020           |                    |

# Labeler - RealChem Manufacturing Inc (120491681)

# Establishment

| Name                       | Address | ID/FEI    | Business Operations  |
|----------------------------|---------|-----------|--|
| RealChem Manufacturing Inc |         | 117584702 | manufacture(79363-721), pack(79363-721), repack(79363-721) |

# Establishment

| Name                   | Address | ID/FEI    | Business Operations  |
|------------------------|---------|-----------|--|
| REALCHEM MANUFACTURING |         | 117742005 | manufacture(79363-721), pack(79363-721), repack(79363-721) |

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|------------------------|---------|-----------|--|
| Name                   | Address | ID/FEI    | Business Operations  |
| REALCHEM MANUFACTURING |         | 117828480 | manufacture(79363-721), pack(79363-721), repack(79363-721) |

| Establishment              |         |           |  |  |
|----------------------------|---------|-----------|--|--|
| Name                       | Address | ID/FEI    | Business Operations  |  |
| RealChem Manufacturing Inc |         | 120491681 | manufacture(79363-721), pack(79363-721), repack(79363-721) |  |

Revised: 1/2021 RealChem Manufacturing Inc