

**SUNKURE- alcohol liquid**

**SUNKURE- alcohol gel**

**CRC GROUP LLC**

*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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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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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.

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 80% 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

### Package Label - Principal Display Panel

**70% ALCOHOL**

**GEL FORMULA**

**SUNKURE**  
FRESH & PURE

**HAND SANITIZER**

SUNKURE.COM  
1 gal (3,785ml)

**GEL HAND SANITIZER** **SUNKURE**  
FRESH & PURE  
WWW.SUNKURE.COM

Non-Sterile Solution Alcohol Antiseptic  
1 Gal (3,785ml) 70% Topical Solution

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 70% v/v.....	Antiseptic
<b>Use</b>	
•Hand sanitizer to help reduce bacteria on the skin that potentially can cause disease.	
•For use when soap and water are unavailable	
<b>Warnings</b>	
•For external use only.	• Flammable.
•Keep away from heat or flame	
<b>Do not use</b>	
•in children less than 2 months of age	•in eyes
•on open skin wounds	
<b>When using this product</b>	
•keep out of eyes, ears, and mouth.	
•In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b>	
•irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
•Place enough product on hands to cover all surfaces. Rub hands together until dry.	
•Supervise children under age 6 when using this product to avoid swallowing.	
<b>Other information</b>	
•Store between 59-86°F (15-30°C)	
•Avoid freezing and excessive heat above 104°F (40°C)	
<b>Inactive Ingredients</b> acrylate copolymer, aloe, denatonium benzoate, fragrance, glycerin, water	
<b>Questions</b> call 800.450.6295	

Manufactured for:  
CRC GROUP LLC  
12527 Central Ave NE, Suite 232  
Minneapolis, MN 55434

NDC: 80386-006-17

7 07245 90069 8

**80% ALCOHOL**

**WHO FORMULA**

**SUNKURE**  
FRESH & PURE

**HAND SANITIZER**

SUNKURE.COM  
1 gal (3,785ml)

**WHO HAND SANITIZER** **SUNKURE**  
FRESH & PURE  
Non-Sterile Solution Alcohol Antiseptic  
1 Gal (3,785ml) 80% Topical Solution  
WWW.SUNKURE.COM

**Drug Facts**

**Active ingredient[s]** **Purpose**  
Antiseptic  
Alcohol 80% v/v

**Use**  
• Hand sanitizer to help reduce bacteria on the skin that potentially can cause disease.  
• For use when soap and water are unavailable

**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 • in eyes

**When using this product** • keep out of eyes, ears, and mouth.  
• In case of contact with eyes, rinse eyes thoroughly with water.

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• 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.  
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**Other information** • Store between 59-86°F (15-30°C)  
• Avoid freezing and excessive heat above 104°F (40°C)

**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

**Questions** call 800.450.8295

Manufactured for:  
CFC GROUP LLC  
12527 Central Ave NE, Suite 232  
Minneapolis, MN 55434

NDC: 80386-001-07  
7 07245 90078 1

## SUNKURE

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80386-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80386-001-07	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/31/2020	

# SUNKURE

alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80386-006
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
2-PHENYLPROPANAL PROPYLENE GLYCOL ACETAL (UNII: 1ZRR9A405A)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
TRISOPROPANOLAMINE (UNII: W9EN9DLM98)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80386-006-17	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	08/31/2020	

**Labeler** - CRC GROUP LLC (112006124)

Revised: 8/2020

CRC GROUP LLC