

**ACTION HAND SANITIZER- isopropyl alcohol gel**  
**Sky Systems Co. 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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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 75% 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, purified water USP

## Package Label - Principal Display Panel



For Professional Use Only  
Protect from freezing. Avoid excessive heat.

Tear off and pull out tube.



Do Not Open Box  
From Top Or Bottom



Manufactured by  
Sky Systems Co., Inc.  
Ontario, CA 91761  
USA

[www.skysystemscoinc.com](http://www.skysystemscoinc.com)



### Drug Facts

#### Active ingredients

Ethyl Alcohol @ 75% . . . . . Antiseptic

#### Purpose

#### Uses

- To decrease bacteria on the skin that could cause disease.
- To help preventing cross contamination thru hand contact.
- Recommended for repeated use.

#### Warnings

- For external use only.
- Flammable, keep away from fire, heat or flame.

#### When using this product

- Avoid contact with eyes. In case of contact with eyes, flush thoroughly with water.
- Avoid contact with broken skin.

#### Stop use this product and ask a doctor if

- Irritation or redness develops and persisted for more than 72 hours.

#### Keep out of reach of children

- If swallowed, get medical help or contact Poison Control Center right away.

#### Directions

- Apply appropriate amount of product to palm of hand.
- Rub until hands are completely wet.
- Let air dry for 15 seconds.
- Supervise children when using this product.
- Not recommended for infants.

#### Other information

- Store at 20-25°C (60 to 77°F)
- May discolor some fabrics

#### Inactive Ingredients

Water, Carbomer, Triethanolamine.

1000 ml - NET 33 FL.OZ.

Questions?  
Call 909-923-7040  
Manufactured by SKY SYSTEMS Co., Inc., CA  
www.skysystemscoinc.com

Printed on 100% Recycled Paper  
Made in U.S.A.

1000 ml NDC: 67106-7242-1

## ACTION HAND SANITIZER

isopropyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67106-7719
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67106-7719-1	1000 mL in 1 BOX; Type 0: Not a Combination Product	01/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2021	

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**Labeler** - Sky Systems Co. Inc. (621886548)

**Registrant** - Sky Systems Co. Inc. (621886548)

**Establishment**

Name	Address	ID/FEI	Business Operations
Sky Systems Co. Inc.		621886548	manufacture(67106-7719)

Revised: 12/2020

Sky Systems Co. Inc.