

CKP SAN-4I LIQ- alcohol solution
CK Polymers

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.

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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away.

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

1 L (1000 mL) NDC: 78235-996-41

Product name: **CKP SAN-40 Gel**

MANUFACTURER:

United States
CK Polymers, LLC.
4801 Woodway Drive
Suite 275E
Houston, TX 77056

EMERGENCY PHONE:

United States
CHEMTREC
1-800-424-9300 (24 hours)

BUSINESS PHONE:

United States
1-713-979-3970

LABELING AND CLASSIFICATIONS:

Classification of the substance or mixture according to Hazardous Communication Standard, 29 CFR 1910.1200:

Eye irritation, category 2A
Flammable liquids, category 2
Signal word: Danger

PICTOGRAM:



Hazard-determining components of labeling:

Ethanol

HAZARD STATEMENT(S):

H225 Highly flammable liquid and vapor
H319 Causes serious eye irritation

PRECAUTIONARY STATEMENT(S):

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking
P233 Keep container tightly closed
P240 Ground/bond container and receiving equipment
P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment
P242 Use only non-sparking tools
P243 Take precautionary measures against static discharge
P264 Wash hands thoroughly after handling
P280 Wear protective gloves/protective clothing/eye protection/face protection
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313 If eye irritation persists: Get medical advice/attention
P370+P378 In case of fire: Use agents recommended in section 5 to extinguish
P403+P235 Store in a well-ventilated place. Keep cool
P501 Dispose of contents/container in accordance with local regulations.

CKP

Delivering Reliable Quality

TRANSPORTATION

UN Number:

1170

Proper shipping name: Ethanol Solution

Packing group: II

Hazard class: 3



California Proposition 65: None of the ingredients are listed.

LOT#	
NET#	
ITEM#	
MANUFACTURING DATE	
ADDITIONAL INFO	NDC# 78235-996-41

Refer to the SDS for full guidelines and product information
Generated using Total SDS™ (patent-pending), www.GSMSDS.com

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P501 Dispose of contents/container in accordance with local regulations.

TRANSPORTATION:

UN Number: 1170

Proper shipping name: Ethanol Solution

Packing group: II

Hazard class: 3

California Proposition 65: None of the ingredients are listed.

Refer to the SDS for full guidelines and product information

Generated using Total SDS (patent-pending), www.GSMSDS.com

NDC: 78235-996-51

Product name: **CKP SAN-40 Gel**

MANUFACTURER:

United States
CK Polymers, LLC.
4801 Woodway Drive
Suite 275E
Houston, TX 77056

EMERGENCY PHONE:

United States
CHEMTREC
1-800-424-9300 (24 hours)

BUSINESS PHONE:

United States
1-713-979-3970

LABELING AND CLASSIFICATIONS:

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PICTOGRAM:



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Delivering Reliable Quality

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UN Number:

1170

Proper shipping name: Ethanol Solution

Packing group: II

Hazard class: 3



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ITEM#	
MANUFACTURING DATE	
ADDITIONAL INFO	NDC# 78235-996-51

Refer to the SDS for full guidelines and product information
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NDC: 78235-996-61

Product name: **CKP SAN-40 Gel**

MANUFACTURER:

United States
CK Polymers, LLC.
4801 Woodway Drive
Suite 275E
Houston, TX 77056

EMERGENCY PHONE:

United States
CHEMTREC
1-800-424-9300 (24 hours)

BUSINESS PHONE:

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1-713-979-3970

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TRANSPORTATION

UN Number:

1170

Proper shipping name: Ethanol Solution

Packing group: II

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LOT#	<input type="text"/>
NET#	<input type="text"/>
ITEM#	<input type="text"/>
MANUFACTURING DATE	<input type="text"/>
ADDITIONAL INFO	NDC# 78235-996-61

Refer to the SDS for full guidelines and product information
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NDC: 78235-996-71

Product name: **CKP SAN-40 Gel**

MANUFACTURER:

United States
CK Polymers, LLC.
4801 Woodway Drive
Suite 275E
Houston, TX 77056

EMERGENCY PHONE:

United States
CHEMTREC
1-800-424-9300 (24 hours)

BUSINESS PHONE:

United States
1-713-979-3970

LABELING AND CLASSIFICATIONS:

Classification of the substance or mixture according to Hazardous Communication Standard, 29 CFR 1910.1200:

Eye irritation, category 2A
Flammable liquids, category 2
Signal word: Danger

PICTOGRAM:



Hazard-determining components of labeling:
Ethanol

HAZARD STATEMENT(S):

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Delivering Reliable Quality

TRANSPORTATION

UN Number:

1170

Proper shipping name: Ethanol Solution

Packing group: II

Hazard class: 3



California Proposition 65: None of the ingredients are listed.

LOT#	
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ITEM#	
MANUFACTURING DATE	
ADDITIONAL INFO	NDC# 78235-996-71

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CKP SAN-4I LIQ

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78235-996
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0K00R)	18.425 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78235-996-31	1249.19 L in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	
2	NDC:78235-996-51	3.78541 L in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
3	NDC:78235-996-61	18.9271 L in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
4	NDC:78235-996-71	208.198 L in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/29/2020	

Labeler - CK Polymers (079790285)**Establishment**

Name	Address	ID/FEI	Business Operations
CK Polymers		079790285	manufacture(78235-996)

Revised: 7/2020

CK Polymers