

**HAND SANITIZER- ethyl alcohol gel**  
**CUSTOM RESEARCH LABS 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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**CRL (as CMO) - STND. ISSUE HAND SANITIZER (50518-303)**

**ACTIVE INGREDIENT**

ETHYL ALCOHOL 70%

**PURPOSE**

ANTISEPTIC

**USES**

- TO DECREASE BACTERIA ON THE SKIN THAT COULD CAUSE DISEASE
- RECOMMENDED FOR REPEATED USE

**WARNINGS**

FOR EXTERNAL USE ONLY.

FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

WHEN USING THIS PRODUCT

- KEEP OUT OF EYES. IN CASE OF CONTACT WITH EYES, FLUSH THOROUGHLY WITH WATER.
- AVOID CONTACT WITH BROKEN SKIN
- DO NOT INHALE OR INGEST

STOP USE AND ASK A DOCTOR IF

- IRRITATION AND REDNESS DEVELOP
- CONDITION PERSISTS FOR MORE THAN 72 HOURS

KEEP OUT OF REACH OF CHILDREN.

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

**DIRECTIONS**

WET HANDS THOROUGHLY WITH PRODUCT AND ALLOW TO DRY WITHOUT WIPING

- FOR CHILDREN UNDER 6, USE ONLY UNDER ADULT SUPERVISION
- NOT RECOMMENDED FOR INFANTS

## OTHER INFORMATION

DO NOT STORE ABOVE 105°F

- MAY DISCOLOR SOME FABRICS
- HARMFUL TO WOOD FINISHES AND PLASTICS

## INACTIVE INGREDIENTS

WATER, GLYCERIN, ISOPROPYL MYRISTATE, CARBOMER, TOCOPHERYL ACETATE, AMINOMETHYL PROPANOL

# STND. ISSUE

## HAND SANITIZER

Kills 99.9% of germs and bacteria\*

1 FL OZ (30 mL)

### Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 70% .....	Antiseptic

**Uses** ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use

### Warnings

For external use only.

Flammable, keep away from fire or flame.

When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin ■ do not ingest

Stop use and ask a doctor if ■ irritation and redness develop ■ condition persists for more than 72 hours

Keep out of reach of children.

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

### Directions

Wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants

### Other information

Do not store above 105°F ■ may discolor some fabrics ■ harmful to wood finishes and plastics

### Inactive Ingredients

Water, Glycerin, Isopropyl Myristate, Carbomer, Tocopheryl Acetate, Aminomethyl Propanol

\*Effective at eliminating more than 99.99% of many common harmful germs and bacteria.

Standard Issue Tees - Vernon, CA 90058  
standardisuetees.com

# HAND SANITIZER

ethyl alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50518-303
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C00X)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50518-303-11	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
2	NDC:50518-303-12	30 mL in 1 TUBE; Type 0: Not a Combination Product	05/25/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/25/2020	

**Labeler** - CUSTOM RESEARCH LABS INC (028611598)

**Registrant** - CUSTOM RESEARCH LABS INC (028611598)

## Establishment

Name	Address	ID/FEI	Business Operations
CUSTOM RESEARCH LABS INC		028611598	manufacture(50518-303)

