

**BAK-OFF HAND SANITIZER 70 PERCENT- 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) - BAK-OFF HAND SANITIZER - 70% ETHYL ALCOHOL (50518-305)**

**ACTIVE INGREDIENT**

ETHYL ALCOHOL 70%

**PURPOSE**

ANTISEPTIC

**USES**

TO DECREASE BACTERIA ON THE SKIN

RECOMMENDED FOR REPEATED USE

**WARNINGS**

FOR EXTERNAL USE ONLY (HANDS).

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, ALOE BARBADENSIS LEAF JUICE, GLYCERIN, ISOPROPYL MYRISTATE, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL, PELARGONIUM GRAVEOLENS (GERANIUM) FLOWER OIL, CARBOMER, TOCOPHERYL ACETATE, AMINOMETHYL PROPANOL

Made in California

**Instant Hand Sanitizer w/ Aloe & Vitamin E**

Alcohol 70% v/v  
Lavender Oil  
Rosemary Leaf Oil  
Geranium Flower Oil  
Antimicrobial Properties  
Kills 99.99% of Germs

3.38 FL. OZ. / 100 ML

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Distributed by: Creatures Beauty LLC, Gardena, CA 90248

**Drug Facts**

Active Ingredients	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

**Uses** To decrease bacteria on the skin  
 ■ Recommended for repeated use

**Warnings** For external use only (hands)  
 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 broke skin  
 ■ Do not inhale or ingest

**Stop use and ask a doctor if**  
 irritation and redness develop. Conditions 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. Supervise children under 6. Not for infants.

**Inactive Ingredients**  
 Water, Aloe Barbadensis Leaf Juice, Glycerin, Isopropyl Myristate, Lavandula Angustifolia (Lavender) Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Pelargonium graveolens (Geranium) Flower Oil, Carbomer, Tocopheryl Acetate, Aminomethyl Propanol

**Other Information** Do not store above 105°F. May discolor some fabrics. Harmful to wood finishes and plastics.

## BAK-OFF HAND SANITIZER 70 PERCENT

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50518-305
<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
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>GERANIUM OIL, ALGERIAN TYPE</b> (UNII: 5Q1I94P4WG)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50518-305-11	100 mL in 1 BOTTLE; 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(50518-305)

Revised: 3/2022

CUSTOM RESEARCH LABS INC