

**HAND SANITIZER 70 PERCENT- ethyl alcohol spray
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.

CRL (as CMO) - CSI - HAND SANITIZER SPRAY - 70% ETHYL ALCOHOL (50518-307)

ACTIVE INGREDIENT

ETHYL ALCOHOL 70%

PURPOSE

ANTIMICROBIAL

USES

- FOR HANDWASHING TO DECREASE MICROBIAL CONTAMINATION ON THE SKIN
- MAY BE REAPPLIED DURING THE DAY AS REQUIRED

WARNINGS

FOR EXTERNAL USE ONLY. DO NOT DRINK.

FLAMMABLE, KEEP AWAY FROM FIRE AND FLAME.

DO NOT USE IN THE EYES. IN CASE OF CONTACT, RINSE EYES THOROUGHLY WITH WATER, THEN CONTACT PHYSICIAN.

STOP USE AND ASK A DOCTOR IF IRRITATION AND REDNESS DEVELOP AND 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
- BRISKLY RUB HANDS TOGETHER UNTIL DRY
- SUPERVISE CHILDREN UNDER 6 YEARS IN THE USE OF PRODUCT
- WET THE SURFACE WITH THE SPRAY. ALLOW TO AIR DRY. NO RINSING OR WIPING REQUIRED.

OTHER INFORMATION

- STORE AT 20°C TO 25°C (68°F TO 77°F)

- MAY DISCOLOR SOME FABRICS

INACTIVE INGREDIENTS

PURIFIED WATER/AQUA/EAU PURIFIE, GLYCERIN

Drug Facts

Active ingredients	Purpose
Ethyl Alcohol min. 70%	Antimicrobial

Uses • for handwashing to decrease microbial contamination on the skin • may be reapplied during the day as required

Warnings
For external use only. Do not drink.
Flammable. Keep away from heat and flame.
Do not use in the eyes. In case of contact, rinse eyes thoroughly with water. Then contact physician.
Stop use and ask a doctor if irritation and redness develop and persist 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 • briskly rub hands together until dry • supervise children under 6 years in the use of the product • wet the surface with the spray. Allow to air-dry. No rinsing or wiping required.

Other information • store at 20°C to 25°C (68°F to 77°F) • may discolor certain fabrics

Inactive ingredients Purified Water/Aqua/Eua Purifie, Glycerine.

Dist. by P&P International Inc.
El Monte, CA 91731
Made in USA
www.csihealth.org





HAND SANITIZER

Contains min. 70% Alcohol
KILLS 99% OF GERMS

Easy To Use Spray
+ Surface Disinfectant

8 FL. OZ.



HAND SANITIZER 70 PERCENT

ethyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50518-307
Route of Administration	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: PDC6A3C0OX)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50518-307-11	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2020	
2	NDC:50518-307-12	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/17/2020	

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(50518-307)

Revised: 3/2022

CUSTOM RESEARCH LABS INC