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.

(CRL (as CMO) - CSI - HAND SANITIZER - 70% ETHYL ALCOHOL (50518-306)

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

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, CELLULOSE



HAND SANITIZER 70 PERCENT

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50518-306
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: SMD1X3X09M)				

ı	Packaging			
	# Item Cod	Package Description	Marketing Start Date	Marketing End Date

1	NDC:50518-306- 11	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
2	NDC:50518-306- 12	480 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	
final	partoson	03/23/2020	

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(50518-306)	

Revised: 3/2022 CUSTOM RESEARCH LABS INC