

HAND SANITIZER 70 PERCENT- ethyl alcohol gel
Formology Lab 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.

HAND SANITIZER GEL, 72580-309

ACTIVE INGREDIENT

ETHYL ALCOHOL 70% V/V

PURPOSE

ANTISEPTIC

USES

TO DECREASE BACTERIA ON THE SKIN THAT POTENTIALLY CAN CAUSE DISEASE

WARNINGS

FOR EXTERNAL USE ONLY.

FLAMMABLE, KEEP AWAY FROM HEAT OR FLAME.

DO NOT USE IN THE EYES.

STOP USE AND ASK A DOCTOR IF IRRITATION OR PAIN OCCURS.

KEEP OUT OF REACH OF CHILDREN.

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

DIRECTIONS

- APPLY A SUFFICIENT AMOUNT OF PRODUCT TO YOUR PALM TO COVER BOTH HANDS.
- RUB UNTIL DRY.

OTHER INFORMATION

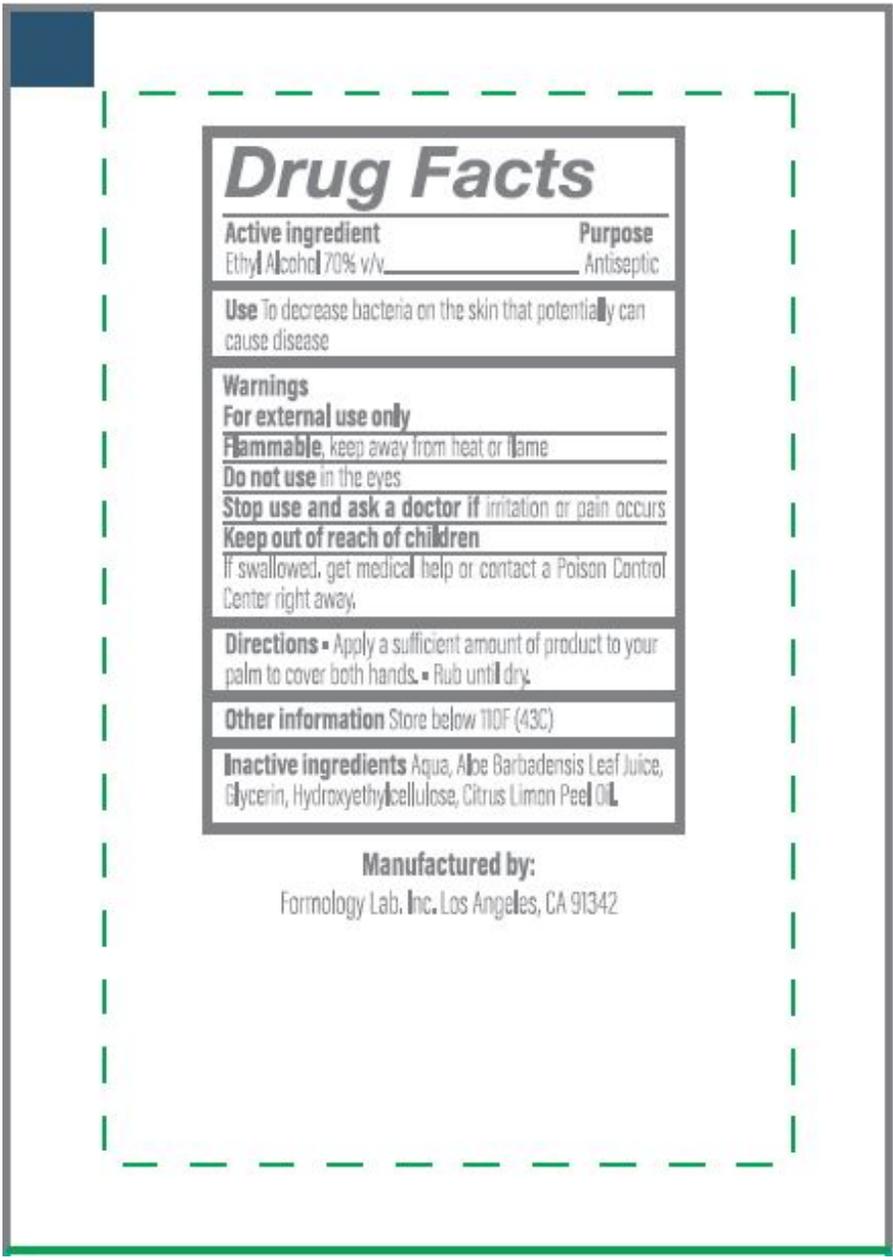
- STORE BELOW 110F (43C)

INACTIVE INGREDIENTS

AQUA, ALOE BARBADENSIS LEAF JUICE, GLYCERIN, HYDROXYETHYLCELLULOSE,

CITRUS LIMON PEEL OIL





HAND SANITIZER 70 PERCENT

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72580-309(NDC:43219-105)
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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
LEMON OIL (UNII: I9GRO824LL)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72580-309-03	3 mL in 1 POUCH; Type 0: Not a Combination Product	08/25/2020	
2	NDC:72580-309-01	1.5 mL in 1 POUCH; Type 0: Not a Combination Product	08/25/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/25/2020	

Labeler - Formology Lab Inc. (081102403)

Establishment			
Name	Address	ID/FEI	Business Operations
Emilia Cosmetics Ltd		600076624	manufacture(72580-309) , relabel(72580-309)

Establishment			
Name	Address	ID/FEI	Business Operations
Agrippas Industries Ltd.		600579170	pack(72580-309)

Revised: 10/2021

Formology Lab Inc.