SANI-X HAND SANITIZER- 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.

SANI-X HAND SANITIZER

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.

QUESTIONS?

CALL TOLL-FREE 1-866-942-9598 OR VISIT WWW.SANI-EX.COM

SANI-X HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72580-302
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
LEMON OIL (UNII: I9GRO824LL)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72580-302-12	45 mL in 1 TUBE; Type 0: Not a Combination Product	03/31/2020	
2	NDC:72580-302-51	500 mL in 1 POUCH; Type 0: Not a Combination Product	03/31/2020	
3	NDC:72580-302-05	1.5 mL in 1 POUCH; Type 0: Not a Combination Product	03/31/2020	
4	NDC:72580-302-11	30 mL in 1 TUBE; Type 0: Not a Combination Product	03/31/2020	
5	NDC:72580-302-13	100 mL in 1 TUBE; Type 0: Not a Combination Product	03/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/31/2020	

Labeler - Formology Lab Inc. (081102403)

Establishment

Name	Address	ID/FEI	Business Operations
Formology Lab Inc.		081102403	manufacture(72580-302)

Establishment

Name	Address	ID/FEI	Business Operations
Expackusa, Inc.		079234982	pack(72580-302)

Revised: 5/2020 Formology Lab Inc.