### 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.

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#### 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

KILLS 99.9% OF BACTERIA. LEAVES HANDS SOFT AND HYDRATED CONTAINS ORGANIC ESSENTIAL OILS

CONTAINS 70% ALCOHOL PROUDLY MADE IN THE USA

45 mL / 1.5 fl oz

## Drug Facts

Use To decrease bacteria on the skin that potentially can

For external use only

Planemable, keep ewey from heet or flame

Do not use in the eyes

Step use and ask a elector M initation or pain occurs

Keep out of reach of children

If swellowed, get medical help or contact a Poisson Control

Center right away.

Directions - Apply a sufficient amount of product to your pain to cover both hands. - Rub until dry.

Other informetion Store below 110F (430)

Inactive Ingredients Agus, Aloe Barbadensis Luef Juice, Blycerin, Hydrocysthylcelulose, Cltrus Limon Peel Oil.

Questiona? Call toll-free 1-866-842-9598 WWW.sani-ex.com

### Manufactured by:

Formology Lab. Inc. Los Angeles, CA 91342



#### 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 Ingradient/Active Mojety

Active ingredictionative violety			
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: ZY8 1Z8 3H0 X)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)			
LEMON OIL (UNII: 19 GRO 8 2 4 L L)			
WATER (UNII: 059QF0KO0R)			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	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.