SANIHEALTH LABS HAND SANITIZER- ethyl alcohol gel Sanihealth 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.

SaniHealth Labs Hand Sanitizer

Active Ingredients

Ethyl Alcohol 70%v/v.

Purpose: Antiseptic

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Safety Instructions

Flammable, Keep away from fire and flame

Ask Doctor

Stop Use and Ask a doctor if irritation or redness develops

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact Poison Control right away

Other Information

Store below 15-30°C

May discolor certain fabrics or surfaces.

Avoid freezing and excessive heat

Inactive Ingredients

water, hydrolyzed jojoba esters, glycerin, carbopol, fragrance, aminomethyl propanol, denatonium benozate

Directions

- Place enough product in your palm to thoroughly cover your hands
- Rub hands together briskly until dry
- Children should be supervised when using this product.
- For personal and occasional domestic use

Warnings

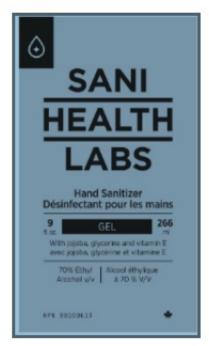
For external use only.

Flammable. Keep away from fire or flame.

Uses

• helps reduce bacteria on the skin that could cause disease

Sanihealth Labs 9 oz Hand Sanitizer gel Front and Back Labels (not to scale)



Drug Facts

Active Ingredient: Ethyl alcohol 70%

Uses:

Hand sanitizer to help reduce bacteria that can potentially cause disease. Use when soap and water is not available.

Warnings:

For external use only. Flammable. Keep away from heat or flame.

Do not use:

- · On children less than 2 years of age
- · On open skin wounds

When using this product keep out of the eyes, ears and mouth. In case of contact with eyes, rinse thoroughly with water.

If an irritation develops, stop use and consult a medical physician

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- Place enough product on both hands to ensure they are covered. Rub together for 30 sec until dry.
- · For personal and occasional domestic use
- · Supervise children when using this product
- Store between 15-30 degrees C
- · Avoid freezing and excessive heat

Inactive ingredients: water, carbomer, glycerin, hydrolyzed jojoba esters, fragrance, <u>aminomethyl</u> propanol, denatonium benzoate



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SANIHEALTH LABS HAND SANITIZER

ethyl alcohol gel

P	ro	du	ct	Inf	or	ma	tion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79861-000

TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
WATER (UNII: 059QF0KO0R)				
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)				
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)				
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)				
GLYCERIN (UNII: PDC6A3C0OX)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:79861-000- 26	266 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2020			
2	NDC:79861-000- 04	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2020			
3	NDC:79861-000-53	532 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2020			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	08/22/2020		

Labeler - Sanihealth Labs Inc. (204172811)

Revised: 8/2020 Sanihealth Labs Inc.