

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

Purpose

Antiseptic

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 benzoate

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: <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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, aminomethyl propanol, denatonium benzoate



SANI HEALTH LABS

Hand Sanitizer
Désinfectant pour les mains

135 fl. oz. **GEL** 4 litres

With jojoba, glycerine and vitamin E
avec jojoba, glycérine et vitamine E

70% Ethyl Alcohol v/v | Alcool éthylique à 70 % v/v

NPN 80100613



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, aminomethyl propanol, denatonium benzoate

Sanihealth Labs Hand Sanitizer 18 oz 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: <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Place enough product on both hands to ensure they are covered. Rub together for 30 sw 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, carbopol, glycerin, hydrolyzed jojoba esters, fragrance, aminomethyl propanol, denatonium benzoate

SANIHEALTH LABS HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79861-000
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Route of Administration	TOPICAL
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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)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	

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.