

HAND SANITIZER- 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.

Jack Wylde Hand sanitizer

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

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

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

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Directions

- For occasional and personal domestic use, spray on the palm of hands and rub together for 30 seconds. Allow to dry. Supervise children when they use this product.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, glycerol, hydrolyzed jojoba esters, fragrance, tocopheryl acetate, denatonium benzoate

Package Label - Principal Display Panel

DIRECTIONS:

For occasional and personal domestic use. Spray on the palm of hands and rub together for 30 seconds. Allow to dry. Supervise children when they use this product.

MEDICINAL INGREDIENTS:

Ethyl Alcohol 70% Purpose Antiseptic

NON MEDICINAL INGREDIENTS:

Water (aqua), Glycerol, Hydrolyzed Jojoba Esters, Fragrance, Tocopheryl Acetate (Vitamin E), Denatonium Benzoate

WARNINGS:

For external use only. Flammable. Keep out of reach of children! If swallowed, get medical help or contact the poison center right away. Do not use near eyes. If contact with eyes, rinse thoroughly with water, stop use and ask a Doctor if skin irritation develops. Do not use on children less than 2 years of age (unless directed by a medical doctor)

MODE D'EMPLOI:

Pour un usage domestique occasionnel et personnel. Vaporisez sur la paume des mains et frottez les mains ensemble pendant 30 secondes. Laissez sécher. Surveillez les enfants lorsqu'ils utilisent ce produit.

INGRÉDIENTS MÉDICINAUX:

Alcool éthylique à 70% (à but antiseptique)

INGRÉDIENTS NON MÉDICINAUX:

Eau (aqua), glycérol, esters de jojoba hydrolysé, parfum, acétate de l'alpha-tocophéryle (vitamine E), benzoate de dénatonium.

MISE EN GARDE:

Pour usage externe seulement! Inflammable. Gardez hors de portée des enfants! En cas d'ingestion, consultez un médecin ou entrez immédiatement en contact avec le centre antipoison. N'utilisez pas près des yeux. En cas de contact avec les yeux, rincez abondamment à l'eau, cessez l'utilisation et consultez un médecin en cas d'irritation cutanée. N'utilisez pas sur les enfants de moins de deux ans (sauf sur indication d'un médecin)

WYLDE SCENT/PARFUM WYLDE

SaniHealth Labs Inc.
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HAND SANITIZER
DÉSINFECTANT POUR LES MAINS

1.3 FL OZ / 38 mL

NPN 80100609

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79861-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79861-003-38	38 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/13/2021	

Labeler - Sanihealth Labs Inc. (204172811)

Registrant - Sanihealth Labs Inc. (204172811)

Establishment

Name	Address	ID/FEI	Business Operations
Sanihealth Labs Inc.		204172811	manufacture(79861-003)

Revised: 9/2021

Sanihealth Labs Inc.