

HAND SANITIZER- alcohol liquid
COSMETIC 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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% 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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away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

60 mL NDC: 76569-110-03



KEVIN.MURPHY

**Alcohol Antiseptic 80%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

60 mL / 2 fl oz

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic

Use[s]
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Distr:
KEVIN MURPHY USA
47 Discovery Ste. 230, Irvine, CA 92618
NOT FOR RESALE

NASSIFMD
DERMACEUTICALS™

Hand Sanitizer
Non-Sterile Solution

Alcohol Antiseptic 80%
Topical Solution

2 oz / 60 ml

DRUG FACTS

ACTIVE INGREDIENTS: PURPOSE

ALCOHOL 80% V/V..... ANTISEPTIC

USES:

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.

DIRECTIONS:

- PLACE ENOUGH PRODUCT ON HANDS TO COVER ALL SURFACES. RUB HANDS TOGETHER UNTIL DRY.
- SUPERVISE CHILDREN UNDER 6 YEARS OF AGE WHEN USING THIS PRODUCT TO AVOID SWALLOWING.

OTHER INFO:

- STORE BETWEEN 15-30C (59-86F)
- AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40C (104F)

INACTIVE INGREDIENTS:

GLYCERIN, HYDROGEN PEROXIDE, PURIFIED WATER USP.

SDS-CA-15047

Distributed by/par: ECC Aesthetics, Beverly Hills, CA | EU: KINESIS MEDICAL B.V. 5144 NV 13, The Netherlands
Made in USA | Fabricat/par: Frats-Unis | NASSIFMDKONCARE.COM

SDS-CA-15224

terrasiL[®]

HAND SANITIZER

Alcohol Antiseptic
80% Topical Solution

**Hand Sanitizer
Non-sterile Solution**

www.safehandsanitizer.us

59.2 mL (2 fl oz)

Distributed by Aidance
Scientific, Inc., Woonsocket, RI.

Terrasil[®] is a registered trademark of Aidance Scientific, Inc.

Drug Facts

Active ingredient	Purpose
Alcohol USP 80% v/v.....	Antiseptic

Uses 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
■ on 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.

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

Directions ■ Place enough product on hands to cover all surfaces. ■ Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing.

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions or comments? 401-432-7750





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Hand Sanitizer



SeneGence[®]

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

60 mL / 2 fl oz. U.S.

Drug Facts

Active Ingredient(s)	Purpose
Alcohol 80% V/V	Antiseptic

Use(s)

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- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Glycerin, Hydrogen Peroxide, Purified Water USP.

Dist. By/For SeneGence[®] Essential Brands, CA 92610
Made in the USA w/ Global Ingredients. US#1313/A. Rev B. 909-CA-1524



HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76569-110
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: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76569-110-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76569-110-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76569-110-05	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76569-110-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - COSMETIC LAB INC (196409143)

Registrant - COSMETIC LAB INC (196409143)

Establishment

Name	Address	ID/FEI	Business Operations
COSMETIC LAB INC		196409143	manufacture(76569-110)