

PROPOLIS HAND SANITIZER- ethyl alcohol gel
Iden Cosmetics, 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.

IDEN BEE PROPOLIS - PROPOLIS HAND SANITIZER

ACTIVE INGREDIENT

ALCOHOL 70% V/V

PURPOSE

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 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 INFORMATION

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

INACTIVE INGREDIENTS

WATER (AQUA), METHYL GLUCETH-20, CARBOMER, AMINOMETHYL PROPANOL,

PROPOLIS EXTRACT, ALOE BARBADENSIS LEAF JUICE, CAMELLIA SINENSIS LEAF EXTRACT, GLYCERIN, TOCOPHERYL ACETATE

QUESTIONS?

1-800-935-IDEN * 1-800-935-4336

Drug Facts

Active Ingredient(s) Alcohol 70% v/v	Purpose Antiseptic
Use(s) 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.	
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 Water (Aqua), Methyl Gluceth-20, Carbomer, Antiseptic Preservative, Propolis Extract, Aloe Barbadensis Leaf Juice, Camellia Sinensis Leaf Extract, Glycerin, Tocopheryl Acetate	
Questions? 1-800-935-IDEN • 1-800-935-4336	

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Made in U.S.A. H500204
74048

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PROPOLIS HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74048-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCERIN (UNII: PDC6A3C00X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74048-101-14	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:74048-101-11	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
3	NDC:74048-101-12	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	04/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - Iden Cosmetics, Inc. (067502042)

Revised: 4/2020

Iden Cosmetics, Inc.