

HAND SANITIZER- instant hand sanitizer gel
IGEL BEAUTY LLC

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.

Instant Hand Sanitizer

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 (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.99% v/v).
- c. Carbomer (0.55% 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 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.

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 information

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

Inactive ingredients

water, glycerin, triethanolamine, carbomer, isopropyl myristate, tocopheryl acetate

Package Label - Principal Display Panel

500 ml NDC: 77059-888-01



The image shows the principal display panel of a hand sanitizer package. On the left, there is a stylized graphic of a person's hands being washed, with the text 'iGel Beauty' at the top and 'HAND SANITIZER' in large, bold letters. Below this, it says 'THICK SOLUTION ALCOHOL ANTISEPTIC 70%' and 'KILLS UP TO 99.9% GERMS THAT MAY CAUSE ILLNESS'. At the bottom left, it indicates '16.9 oz (500mL) e'. On the right side, there is a 'DRUG FACTS' box containing the following information:

DRUG FACTS

USE(S) Hand sanitizer to decrease bacteria on the skin that could cause disease. For use when soap and water are not available.

ACTIVE INGREDIENTS Alcohol 70%v/v **PURPOSE** Antiseptic

WARNINGS
For external use only. Flammable. Keep away from heat and 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 thoroughly with water. Do not inhale or ingest.
Stop use and ask a doctor if irritation or redness occurs. Condition persists for more than 72 hours. 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.
■ For children under 6, use only under adult supervision to avoid swallowing.
■ Not recommended for infants.

OTHER INFORMATION
■ Store between 59-86°F (15-30°C)
■ Avoid freezing and excessive heat above 104°F (40°C)
■ May discolor some fabrics and surfaces

INACTIVE INGREDIENTS Water, glycerin, triethanolamine, carbomer, isopropyl myristate, tocopheryl acetate

Distributed by: **iGel Beauty**
Toms River, NJ USA
www.iGelBeauty.com

At the bottom of the drug facts box, there is a barcode with the number 7 55874 98102 6, and icons for CE, a recycling symbol, and a trash can.

HAND SANITIZER

instant hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77059-888
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.99 mL in 100 mL	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			0.55 mL in 100 mL	
WATER (UNII: 059QF0K00R)			22.4592 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77059-888-01	500 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 - IGEL BEAUTY LLC (096688295)

Registrant - IGEL BEAUTY LLC (096688295)

Establishment			
Name	Address	ID/FEI	Business Operations
IGEL BEAUTY LLC		096688295	manufacture(77059-888)