

HAND SANITIZER- alcohol gel
Regis Corporation 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.

Design Line 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.

Active Ingredient(s)

Alcohol 75% 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

- 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, Carbomer, Triethanolamine.

Package Label - Principal Display Panel

60 mL NDC: 78546-001-00

designline[®]

Instant
Hand Sanitizer
Alcohol 75%
Non-Sterile Solution
60 mL / 2 FL. OZ.

Kills 99.9%
of germs and bacteria.

Drug Facts:

Active Ingredients	Purpose
Alcohol 75% 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:

- **Flammable.**
- **Keep away from fire or flame.**
- **For external use only.**
- **Do not use**
 - In children less than 2 months of age.
 - On open skin wounds.
- **When using this product** do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask doctor if

Drug Facts (continued)

irritation or rash appears and lasts.

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

Directions:

- Put enough product in your palm to cover hands and rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other Information:

- Store between 59 - 86°F (15 - 30°C).
- Avoid freezing and excessive heat above 104°F (40°C).
- May discolor certain fabric surfaces.

Inactive Ingredients:
Water, Glycerin, Carbomer, Triethanolamine.

Questions, Comments:

Drug Facts (continued)

YOU MAY REPORT AN ADVERSE REACTION TO: REGIS CORPORATION / GO REPORT REACTION LLC, PO BOX 22, PLAINSBORO, NJ 08536-0222.

DIST. BY REGIS CORPORATION
701 WAYZATA BLVD
SUITE 500
MINNEAPOLIS, MN 55416
USA

8 40797 14161 2

Made in China

PEEL

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78546-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	45 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.15 mL in 60 mL
WATER (UNII: 059QF0K00R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	0.27 mL in 60 mL

GLYCERIN (UNII: PDC6A3C0OX)

0.6 mL in 60 mL

Product Characteristics

Color	white (Transparent)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78546-001-00	60 mL in 1 PACKET; Type 0: Not a Combination Product	05/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2020	

Labeler - Regis Corporation Inc. (046709747)

Revised: 6/2020

Regis Corporation Inc.