

HAND SANITIZER GEL- alcohol liquid

Nine Mile Health, 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.

Hand Sanitizer Gel

Drug Facts

Active Ingredient(s)

Alcohol 80% 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 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 Information

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

Inactive Ingredients

glycerin, hydrogen peroxide, purified water USP

Questions?

www.ninemilehealth.com

Manufactured by Economy Polymers and Chemicals
435 E Anderson Road, Houston, TX 77047

Distributed by **Nine Mile Health, LLC**
5500 Greenwood Plaza Blvd., Suite 130, Greenwood Village, CO 80111

PRINCIPAL DISPLAY PANEL - 3785 mL Bottle Label

NINE MILE
HEALTH

GEL

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION

1
GALLON
(3785 mL)
| NON-STERILE SOLUTION

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HAND SANITIZER GEL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78697-128
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)	
Hydrogen Peroxide (UNII: BBX060AN9V)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78697-128-01	3785 mL in 1 BOTTLE, DISPENSING; 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 - Nine Mile Health, LLC (131106596)

Establishment

Name	Address	ID/FEI	Business Operations
Economy Polymers		008087603	MANUFACTURE(78697-128)

Revised: 7/2020

Nine Mile Health, LLC