

HAND SANITIZER GEL- alcohol gel
Califormulations 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

Active Ingredient

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings

For external use only. Flammable. Keep away from heat or flame

When using this product

- Keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water
- Avoid contact with broken skin
- Do not inhale or ingest

Stop use and ask a doctor if

- irritation and redness develop
- condition persist for more than 72 hours

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

Directions

- Wet hands thoroughly with product to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product.
- Not recommended for infants.

Other information

- Avoid freezing and excessive heat above 40C (104F)
- May discolor certain fabrics or surfaces

Inactive ingredients

Water, Acrylates Copolymer, Aloe Barbadensis Leaf Juice, Triethanolamine, Fragrance (Parfum)

Package Label - Principal Display Panel



HAND SANITIZER

MADE IN USA

70% ALCOHOL ANTISEPTIC

HAND SANITIZER

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	Antimicrobial

Use(s)

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Inactive ingredients

Water, Acrylates Copolymer, Aloe Barbadosis Leaf Juice, Thimerosal, Fragrance (Parfum).

Aloe Vera Leaf Juice

Kills 99.9% of harmful germs and bacteria

128 FL OZ (3.785L)

Manufactured by:
califormulations
6000 Technology Parkway,
Midland, GA 31820
1-833-287-1915

8 60003 58535 8

3785 mL NDC: 74391-003-01



**HAND
SANITIZER**

**MADE
IN USA**

Aloe Vera Leaf Juice

**Kills 99.9% of harmful
germs and bacteria**

8 FL OZ (237 mL)

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	Antimicrobial

Use(s)

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**70% ALCOHOL
ANTISEPTIC**

**HAND
SANITIZER**



8 60003 68531 0

Manufactured by:



**6000 Technology Parkway,
Midland, GA 31820
1-833-287-1915**

237 mL NDC: 74391-003-08

HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74391-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHYLAMINE (UNII: VOU728 O6AY)	
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	

WATER (UNII: 059QF0KO0R)

METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74391-003-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:74391-003-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

Labeler - Califormulations LLC (945269491)

Establishment

Name	Address	ID/FEI	Business Operations
Califormulations LLC		945269491	manufacture(74391-003)

Revised: 8/2020

Califormulations LLC