

GELMEX BLACK- alcohol gel

Grupo Siller Ingeniería Construcción y Materiales, S.A. de C.V

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.

GelMex Black

Active Ingredient

Alcohol 80%v/v

Purposes

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 mix use with other household chemicals.

Do not use

- In children less than two 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 throughly with water.

Stop use and ask a doctor if irritation or rash occurs. These maybe sings of serious condition.

Keep out of reach of children

If swallowed, get medical help or contact a poison control center right away.

- Place enough product on hands to cover all surfaces. Rub hands together untill dry.
- Supervise children under 6 years age when using this product to avoid swallowing.

undefined

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 400°C (104°F)

Inactive ingredients

Glycerin, carbomer 940, aloe vera extract, purified water.

Image

GelMex.

B L A C K

80% ALCOHOL ANTISEPTIC

ADVANCED

HAND SANITIZER



ALOE VERA

**KILLS 99.99% OF GERMS
AND BACTERIA**

DRUG FACTS

Active Ingredient Purpose
Alcohol 80% 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: For external use only. Flammable. Keep away from heat or flame. Do not mix use with other household chemicals.

Do not use: -In children less than two 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 serious condition. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

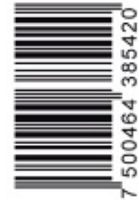
DIRECTIONS: Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years age when using this product to avoid swallowing.

INACTIVE INGREDIENTS: glycerin, carbomer 940, aloe vera extract, purified water.

OTHER INFORMATION:

Store between 15-30°C (59-85°F)
Avoid freezing and excessive heat above 40°C (104°F)

Made in Mexico by/ Hecho en México por
Grupo Siller Ingeniería y Construcción en
Materiales S.A de C.V
Parque Industrial Finsa, 75246
RFC: GSH1711017G2



It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

8.5 fl oz (251 ml)

GELMEX BLACK

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80308-001
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
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80308-001-01	5 mL in 1 POUCH; Type 0: Not a Combination Product	08/31/2020	

2	NDC:80308-001-02	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2020	
3	NDC:80308-001-03	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/31/2020	

Labeler - Grupo Siller Ingeniería Construcción y Materiales, S.A. de C.V (951577512)

Establishment

Name	Address	ID/FEI	Business Operations
Grupo Siller Ingeniería Construcción y Materiales, S.A. de C.V		951577512	manufacture(80308-001)

Revised: 9/2020

Grupo Siller Ingeniería Construcción y Materiales, S.A. de C.V