

ADVANCED HAND SANITIZER- alcohol gel
Biominaerales Pharma, 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.

ADVANCED HAND SANITIZER

Drug facts

Active Ingredient (s)

Ethyl alcohol 80% v/v

Purpose

Antiseptic

Use(s)

Hand Sanitizer to help reduce bacteria on the skin when water and soap are not available.

WARNINGS

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

Do not use

- Children under 6 years of age should be supervised when using this product
- 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 for more than 72 hours, consult a doctor.

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 or misuse.

OTHER INFORMATION

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

Inactive Ingredients

glycerin, hydrogen, peroxide, purified water USP

PRINCIPAL DISPLAY PANEL - 3785 ML Bottle Label

BIOMINERALES
PHARMA

ADVANCED
HAND SANITIZER

Kills more than 99.99% of germs

Prevention:

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Keep container tightly closed.

Response:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/ attention. In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

Store in a well-ventilated place. Keep cool.

Disposal:

Dispose of contents/ container to an approved waste disposal plant.

Active ingredients

Ethyl Alcohol 80%

Glycerin 1.45%

Hydrogen Peroxide .125%

Sterilized water 18.425%

Net Contents 3785 ML

Made in the USA

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ADVANCED HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77110-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.8 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.0145 mL in 1 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.00125 mL in 1 mL
WATER (UNII: 059QF0K00R)	0.18425 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77110-100-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	05/10/2020	

Labeler - Biominerales Pharma, LLC (117489663)

Establishment

Name	Address	ID/FEI	Business Operations
Biominerales Pharma, LLC		117489663	MANUFACTURE(77110-100)

Revised: 5/2020

Biominerales Pharma, LLC