

BIOTECH GEL HAND SANITIZER- alcohol gel

BioTech Industries

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.

Active Ingredient

Ethyl Alcohol 80% v/v

Purpose

Antiseptic

Use

For handwashing to decrease bacteria on the skin

Warnings

For external use only.

Flammable. Keep away from heat or flame

When using this product do not use in or near the 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 and persists 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 products and allow to dry without wiping.

For children under six years, use only under adult supervision.

Not recommended for infants.

Inactive ingredients

Glycerol, hydrogen peroxide, sterile distilled water or boiled cold water, scent, rapid gel

Package Label - Principal Display Panel



BIOTECH GEL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:7779 1-00 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:77791-001-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
2	NDC:77791-001-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
3	NDC:77791-001-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
4	NDC:77791-001-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
5	NDC:77791-001-05	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
6	NDC:77791-001-06	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
7	NDC:77791-001-07	208198 mL in 1 DRUM; Type 0: Not a Combination Product	05/03/2020	
8	NDC:77791-001-08	946353 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/03/2020	

Labeler - BioTech Industries (040897538)

Establishment

Name	Address	ID/FEI	Business Operations
BioTech Industries		040897538	manufacture(77791-001)

Revised: 5/2020

BioTech Industries