

PROCLEAN HAND SANITIZER- isopropyl alcohol gel

Biominales Pharma

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.

PROCLEAN HAND SANITIZER

DRUG FACTS

Active ingredient

Isopropyl Alcohol 70%

Purpose

Antiseptic

Inactive ingredients

Water (aqua), carbomer, glycerin, propylene glycol, hydrogen peroxide, aminomethyl propanol

Use(s)

Hand sanitizer to help reduce the bacteria that potentially can cause disease. For use when water and soap 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 or 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 a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact 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

PRINCIPAL DISPLAY PANEL - 3.79 L Bottle Label

PROCLEAN

HAND SANITIZER GEL

This product should be used as part
of the daily hand cleansing routine

70% ISOPROPYL ALCOHOL

WATER (UNII: 059QF0KO0R)					
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)					
GLYCERIN (UNII: PDC6A3C0OX)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
HYDROGEN PEROXIDE (UNII: BBX060AN9V)					
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77110-220-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2020		
2	NDC:77110-220-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2020		
3	NDC:77110-220-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2020		
Marketing Information					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL		part333E	09/15/2020		

Labeler - Biominerales Pharma (117489663)

Establishment			
Name	Address	ID/FEI	Business Operations
Biominerales Pharma		117489663	MANUFACTURE(77110-220)

Revised: 9/2020

Biominerales Pharma