PROCLEAN HAND SANITIZER- is opropyl alcohol gel Biominerales 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 Achohol 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

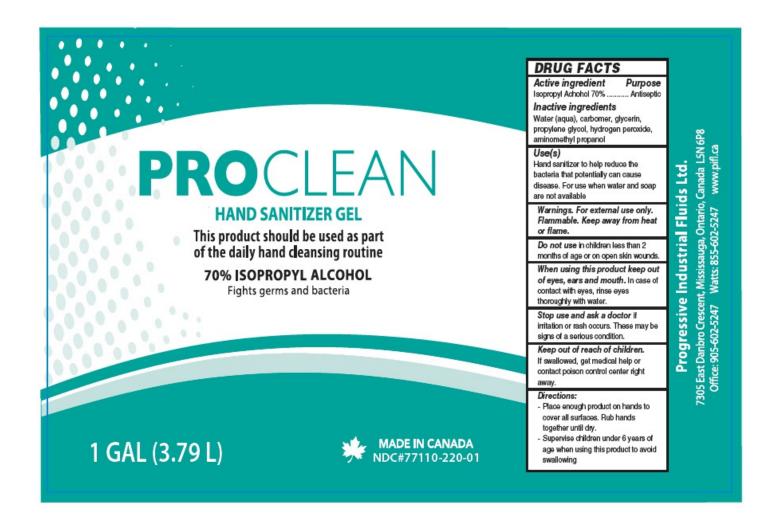
PROCLEAN

HAND SANITIZER GEL

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

70% ISOPROPYL ALCOHOL

NDC#77110-220-01



PROCLEAN HAND SANITIZER

isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77110-220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDRO GEN PERO XIDE (UNII: BBX060 AN9 V)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

	Packaging				
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:77110-220-01	$3785\ mL$ in $1\ BOTTLE;$ Type $0:$ Not a Combination Product	09/15/2020		
	NDC:77110-220-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2020		
	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