HAND SANITIZER- alcohol solution 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.

HAND SANITIZER

DRUG FACTS

Active ingredient

Ethyl alcohol (70% v/v)

Purpose

Antiseptic

Inactive ingredients

Carbomer, Glycerin, Propylene Glycol, Aminomethyl Propanol, Isopropyl Myristate, Tocopheryl Acetate, Purified Water, Fragrance.

Use (s)

Hand sanitizer to help reduce bacteria that potentiallycan 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 our 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.

Distributed by MPP Dist. LLC.

PRINCIPAL DISPLAY PANEL - 2 FL Oz. Bottle Label

Alcohol Antiseptic 70% Topical Solution

INSTANT HAND SANITIZER

Hand Sanitizer Non-Sterile Solution 2 FL Oz.

Kills 99.9% of Germs



HAND SANITIZER				
alcohol solution				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77110-210	
Route of Administration	TOPICAL			
Active Ingredient/Active	Moiety			
Ingredient Name		Basis of Strengt	h Strength	
Alcohol (UNII: 3K9958V90M) (Al	cohol - UNII:3K9958V90M)	Alcohol	70 mL in 100 mL	
Inactive Ingredients				
	Ingredient Name		Strength	
Carbomer Homopolymer, unspe	cified type (UNII: 0A5MM307FC)			
Glycerin (UNII: PDC6A3C0OX)				
Propylene Glycol (UNII: 6DC9Q1	67V3)			
Aminomethylpropanol (UNII: LU	J49E6626Q)			
	ZALNIC)			
Isopropyl Myristate (UNII: 0 RE8)	(4LINJ5)			

Water	(UNII:	059QF0KO0R)
	(01,111,	000 q10100010

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77110-210- 06	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
2	NDC:77110-210-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
3	NDC:77110-210- 02	944 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
4	NDC:77110-210- 03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
5	NDC:77110-210- 04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/15/2020		

Labeler - Biominerales Pharma (117489663)

Establishment				
Name	Address	ID/FEI	Business Operations	
Biominerales Pharma		117489663	MANUFACTURE(77110-210)	

Revised: 7/2020

Biominerales Pharma