KERMA HAND SANITIZER- ethyl alcohol gel MCCORD RESEARCH

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.

KERMA HAND SANITIZER

Active Ingredient

Ethyl Alcohol

Purpose

Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water 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
- 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 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

Other information

Store between 15-30°C (59-86F)

Avoid freezing and excessive heat above 40°C (104F)

Inactive Ingredients

Water, Fragrance, Carbomer, PEG-40 Hydrogenated Castor Oil, chlorphenesin, Aminomethyl Propanol

product Label



KERMA HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71358-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
CHLORPHENESIN (UNII: 1670DAL4SZ)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/03/2020		

Labeler - MCCORD RESEARCH (010011284)

Establishment				
Name	Address	ID/FEI	Business Operations	
Wasatch Product Development, LLC		962452533	manufacture(71358-018)	

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