HAND SANITIZER- ethyl alcohol gel Kem Krest LLC

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[s]

Ethyl Alcohol 62%

Purpose

Antiseptic

Use[s]

For hand washing to decrease bacteria on the skin. Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame. For external use only. Avoid contact with broken skin.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children.

If swallowed get medical help.

Directions

Not recommended for infants. Wet hands thoroughly with product and allow to dry without wiping. Children under 6 years of age should be supervised when using this product.

Other information

Do not store above 110 F (43°C). May discolor some fabrics.

Inactive ingredients

Water(Aqua), Glycerin, propylene Glycol, Acrylates/C10-30Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, fragrance(Parfum), Denatonium Benzoate, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice, Maltodextrin.



Drug Facts

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Imported for/Distributed by: Kem Krest, 12785 Emerson Drive, Brighton, MI 48116 (248) 486-3800 www.kemkrest.com In case of medical emergency using this product, call (800) 704-1559.

KK PN: 130242 Made in China NDC:



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74242-110

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
WATER (UNII: 059QF0KO0R)		

GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:74242-110-	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/20/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	07/20/2020			

Labeler - Kem Krest LLC (933954179)

Revised: 7/2020 Kem Krest LLC