

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

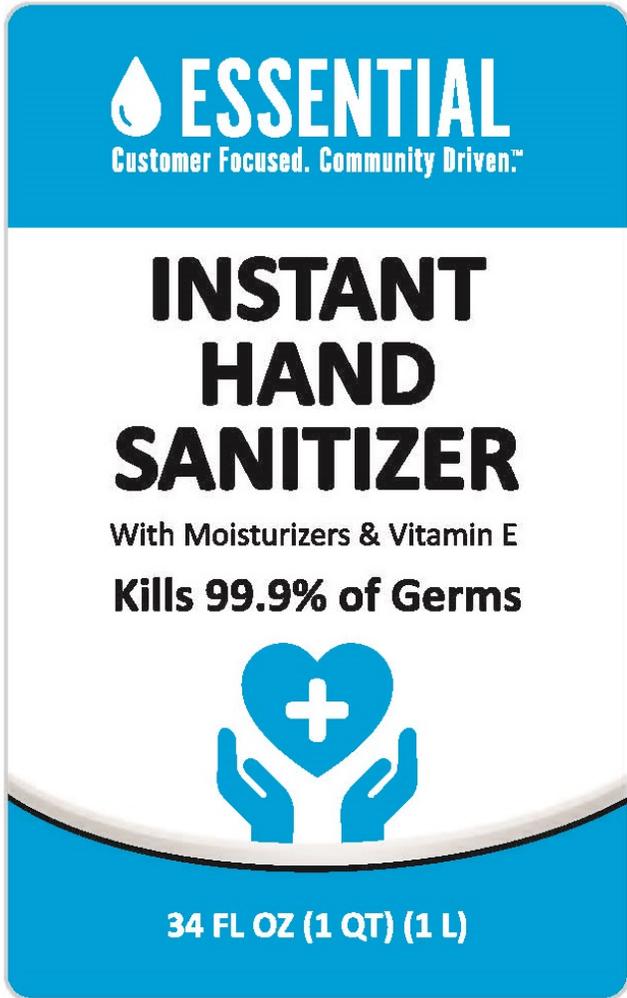
Not recommended for infants. Wet hands thoroughly with product and allow to dry without wiping. Children under 6 years of age should be supervised when using this product.

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 Barbadosis Leaf Juice, Maltodextrin.



Drug Facts	
Active Ingredient[s]	Purpose
Ethyl Alcohol 62%.....	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.	

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: 130244 Made in China NDC:



HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74242-134
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	62 mL in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength
	MALTODEXTRIN (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)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74242-134-01	1000 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