INSTANT HAND SANITIZER- ethyl alcohol gel Kentron Healthcare, Inc.

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 ingredients

Chloroxylenol 0.52%

Purpose

Antiseptic

Warnings: For external use only.

Do not apply around eyes.

Do not use in ears or mouth.

When using this products, avoid contact with eyes. In case of contact, flush eyes with water.

Keep out of reach of children. Children must be supervised in use of this product.

Directions:

Pump as needed into your palms and thoroughly spread on both hands.

Rub into skin until dry.

Inactive Ingredients:Water, Cetearyl Alcohol, Mineral Oil, Petrolatum, Stearic Acid, DMDM Hydantoin, Ceteareth-20, Triethanolamine, Carbomer, Methyl Pareben, Propyl Paraben, Fragrance, Disodium EDTA, Aloe Barbadensis Leaf Juice

Uses: Hand sanitizer to help decrease bacteria on the skin when water, soap & towel are not available. Recommended for repeated use.

Other information: Do not store in temperature above 118 F.

Stop use or ask for a doctor if redness or irritation develops and persists for more than 72 hours.



KENTEX

Drug Facts
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Manufactured for: Kentron Healthcare, Inc Springfield, TN 37172 Made in China Latex Free



INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69556-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 903K93S3TK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DMDM HYDANTO IN (UNII: BYR0546 TOW)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PETRO LATUM (UNII: 4T6 H12BN9 U)	
PROPYLPARABEN (UNII: Z8 IX2SC1OH)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:69556-002- 01	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2017	

Marketing Inform	Marketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/04/2017	

Labeler - Kentron Healthcare, Inc. (618825723)

Revised: 5/2017 Kentron Healthcare, Inc.