EPI-CLENZ INSTANT HAND ANTISEPTIC- ethyl alcohol gel
Medline Industries, 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.

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212 Epi-Clenz Instant Hand Antiseptic

Active ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Uses

- for handwashing to decrease bacteria on skin.
- recommended for repeated use.

Warnings

For external use only.

Flammable, keep away from fire or flame.

Do Not Use

- in the eyes. In case of eye contact, immediately flush with water.

Stop use and ask a doctor if

- irritation or redness develop
- Condition persist for more than 72 hours

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product
- rub hands together covering all surfaces until hands are dry.

Inactive Ingredients

Aloe barbadensis leaf juice, Aminomethyl Propanol, carbomer, glycerin, isopropyl alcohol, isopropyl myristate, propylene glycol, purified water, Tocopheryl Acetate.

Package/Label Principal Display Panel

EPI-CLENZ INSTANT HAND ANTISEPTIC

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53329-212
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	

WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-212-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2013	
2	NDC:53329-212-06	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/30/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/30/2013	

Labeler - Medline Industries, Inc. (025460908)

Establishment

Name	Address	ID/FEI	Business Operations
Hydrox Laboratories		025164302	manufacture(53329-212)

Revised: 12/2019 Medline Industries, Inc.