ANTISEPTIC DISINFECTANT- ethyl alcohol liquid
Maquiladora La Central, S.A. de C.V.

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.

The antiseptic disinfectant is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

Ethyl Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (96%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Ethyl Alcohol 96% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

Antiseptic Disinfectant to help reduce bacteria that potentially can cause disease.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

in children less than 2 months of age

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.

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Directions

Place enough product to clean the infected area
Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

Store between 15-30C (59-86F)
Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

purified water USP

Maximum 1000000000 mL in 1 CONTAINER (77217-200-05)

1000 mL NDC: 77217-200-05

ANTISEPTIC DISINFECTANT

ethyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77217-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	96 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77217-200-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Maquiladora La Central, S.A. de C.V. (812810862)

Registrant - Maquiladora La Central, S.A. de C.V. (812810862)

Establishment

Name	Address	ID/FEI	Business Operations
Maquiladora La Central, S.A. de C.V.		812810862	manufacture(77217-200)

Revised: 7/2020 Maquiladora La Central, S.A. de C.V.