CLEAN ALL- calcium oxide liquid Durapim Co., Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer 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:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

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)

Calcium Oxide 0.01% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

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 on hands to cover all surfaces. Rub hands together until dry.
- 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

Package Label - Principal Display Panel

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calcium-based antise

Drug Facts

Active ingredient

Purpose

Calcium oxide 0.01% Antiseptic

Uses

Disinfectants reduce the bacteria that can cause disease. It can also be used as a spray method.

Do not use

- (1) Keep out of reach of children
- (2) If it gets into your eyes, rinse it under running water
- (3) Do not use it for any other purpose.

How to use

- (1) Can be used immediately in a spray-type container
- (2) The object is sprayed more than twice depending on the degree of contamination

First Aid

- (1)When spraying on the wound, wash it with water as it is a product without skin trouble
- (2) In the event of an allergy, consult with a related doctor

Inactive ingredients

water





Made in Korea by; Manufacturer : DURAPIM Address : 5th Fl, 213Beun-gil, Buyoung-ro, Eujeongbu-si, Kyunggi-do, ROK Contat : +82-70-7769-8999



Durcipim Co., Ltd.

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2 Oz/60ml

0 mL NDC: 79898-0020-1

calcium oxide liquid

P	ro	du	ct	Inf	or	ma	tio	n

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79898-0020

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIME (CALCIUM O XIDE) (UNII: C7X2M0 VVNH) (LIME (CALCIUM O XIDE) - UNII:C7X2M0 VVNH)	LIME (CALCIUM OXIDE)	1 mg in 100 mL

Inactive Ingredients

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Ingredient Name	Strength	
WATER (UNII, 0500 E0 VOOD)	00 ml in 100 ml	

WATER (UNII: 059QF0KO0R) 99 mL in 100 mL

Packaging

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:79898-0020-	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/31/2020	

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		07/31/2020		

Labeler - Durapim Co., Ltd (557837712)

Registrant - Durapim Co., Ltd (557837712)

Establishment				
Name	Address	ID/FEI	Business Operations	
Durapim Co., Ltd		557837712	manufacture(79898-0020)	

Revised: 8/2020 Durapim Co., Ltd