

HAND SANITIZER- alcohol gel
ESKBIOCHEM 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.

Active Ingredient(s)

Alcohol 80% v/v.

Purpose

Antimicrobial, 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
- do not use in or near eyes

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

Carbomer, Tricolamine, water

safe&cclean nogerm label NDC 74589-003-01

NDJCN

NMNDC



80% ALCOHOL CONTENT

CleanCare
no+germ

ADVANCED HAND SANITIZER
KILLS 99.9% OF GERMS

33.8 FL OZ (1L)

Drug Facts:

Active Ingredient	Purpose
Ethyl Alcohol 80.00%.....	Antimicrobial


Uses: Helps reduce bacteria on the skin that could cause diseases.

WARNINGS:
Flammable. Keep away from fire or flame. For external use only. Non potable.
 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 or contact a Poison Control Center right away.

Directions: Place enough product in the palm of your hands to thoroughly cover your hands. Rub hands together briskly until product is completely absorbed and hands are dry.

Inactive Ingredients: Deionized Water, Salt of acrylate C12 C30, Dimethyl lauramine oxide, Methyl paraben, L-lactic acid, Limonene, Sodium propionate.
Denaturing compound: Denoatonium benzoate.
 Ethanol 80% as determined by brix degrees

Distributed By:
ESPMEX, LLC



Made in Mexico

DUNS number: 951570433
Manufactured on April/1/20

Produced By:
Eskbiochem SA de CV
Av. México Japón 50
Celaya, Gto, Mexico 38010
+52 1 33 3190 5592



HAND SANITIZER		
alcohol gel		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:74589-003
Route of Administration	TOPICAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)				
TROLAMINE (UNII: 9O3K93S3TK)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74589-003-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/15/2020		

Labeler - ESKBIOCHEM S.A. DE C.V. (951570433)

Registrant - ESKBIOCHEM S.A. DE C.V. (951570433)

Establishment

Name	Address	ID/FEI	Business Operations
ESKBIOCHEM S.A. DE C.V.		951570433	manufacture(74589-003)

Revised: 4/2020

ESKBIOCHEM S.A. DE C.V.