

BIOZONE- alcohol gel

Biozone Chemical, S. de R.L. 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.

BIOZONE HAND SANITIZER GEL

ACTIVE INGREDIENT SECTION

Active ingredient Ethyl Alcohol 70%

DOSAGE AND ADMINISTRATION SECTION

Place enough product on hands to cover all surfaces. Rub hands together until dry.

INACTIVE INGREDIENT SECTION

Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine

INDICATIONS AND USAGE SECTION

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

PURPOSE

Purpose Antmicrobial

WARNINGS

Warnings

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

WARNINGS AND PRECAUTIONS

Warnings

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

ASK A DOCTOR

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

PACKAGE LABEL SECTION

Manufacture by: Biozone chemical S. de R.L. de C.V. Calle 3 # 1338, Nave 5, Zona Industrial 44940, Guadalaajara, Jalisco Mexico. Tel. (33) 3666 2100 www.biozone.mx

GERM KILLER FORMULA*

Biozone®

+ | Hand Sanitizer Gel

70% Alcohol With Moisturizers

2.028 fl. oz. (60mL)

Alcohol Antiseptic 70% Topical Solution
Hand Sanitizaer Gel Non-sterile Solution

Drug Facts	Active Ingredient	Purpose
	Ethyl Alcohol	Antimicrobial
	70% v/v.	

USES: Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
WARNING: For external use only. Flammable. Keep away from heat or flame.
DO NOT USE: In children less than 2 months of age. Open skin wounds, When using this product keep put of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and consult a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, seek medical help or contact a Poison Control Center right away.
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 below 110°F (43°C). Avoid freezing and excessive heat above 40C (104F).
INACTIVE INGREDIENTS: Water (Aqua), Glycerin, Carbomer, Triethanolamine.

7 502228 648093

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NET CONTENTS 2.028 fl. oz. (60mL)

7 502228 648093

GERM KILLER FORMULA*

Biozone®

+ | Hand
Sanitizer Gel



70% Alcohol
With Moisturizers

8.453 fl. oz. (250mL)

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer Gel Non-sterile Solution

Drug Facts	Active Ingredient	Purpose
	Ethyl Alcohol 70% v/v.	Antimicrobial

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Chemical S. de R.L. de C.V.
Calle 3 #1338,
Nave 5, Zona Industrial 44940,
Quedixtapa, Jalisco, México.
Tel. (33) 3696 2100
www.biozone.mx



NET CONTENTS:
8.453 fl. oz. (250mL)

GERM KILLER FORMULA*

Biozone®

+ | Hand
Sanitizer Gel



70% Alcohol
With Moisturizers

33.814 fl. oz. (1000 mL)

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer Gel Non-sterile Solution

Drug Facts	Active Ingredient	Purpose
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NET CONTENTS:
33.814 fl. oz.
(1000 mL)

GERM KILLER FORMULA*

Biozone®

Hand Sanitizer Gel

**70% Alcohol
With Moisturizers**

127.817 fl. oz. (3.78L)

**Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizaer Gel Non-sterile Solution**

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NET CONTENTS:
127.817 fl. oz. (3.78L)

BIOZONE				
alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78349-0003	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL		
Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)	0.2585 mL in 1 mL			
TRIETHANOLAMINE CAPROYL GLUTAMATE (UNII: 0F2FO57253)	0.002 mL in 1 mL			
GLYCERIN (UNII: PDC6A3C0OX)	0.0375 mL in 1 mL			
CARBOMER 940 (UNII: 4Q93RCW27E)	0.002 mL in 1 mL			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78349-0003-1	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2021	
2	NDC:78349-0003-2	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2021	

3	NDC:78349-0003-3	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2021	
4	NDC:78349-0003-4	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2021	
5	NDC:78349-0003-5	3780 mL in 1 JUG; Type 0: Not a Combination Product	02/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/15/2021	

Labeler - Biozone Chemical, S. de R.L. de C.V. (812910867)

Registrant - Biozone Chemical, S. de R.L. de C.V. (812910867)

Establishment

Name	Address	ID/FEI	Business Operations
Biozone Chemical, S. de R.L. de C.V.		812910867	manufacture(78349-0003)

Revised: 2/2021

Biozone Chemical, S. de R.L. de C.V.