

**HAND SANITIZER- alcohol gel**  
**Distribuidora Dimex,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.*

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**Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

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) (70%, 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. Water (28.7% v/v).
- c. Glycerin (0.5% v/v).
- d. Trolamine(0.5% v/v).
- e. Carbomer 940(0.5% v/v).

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

**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.

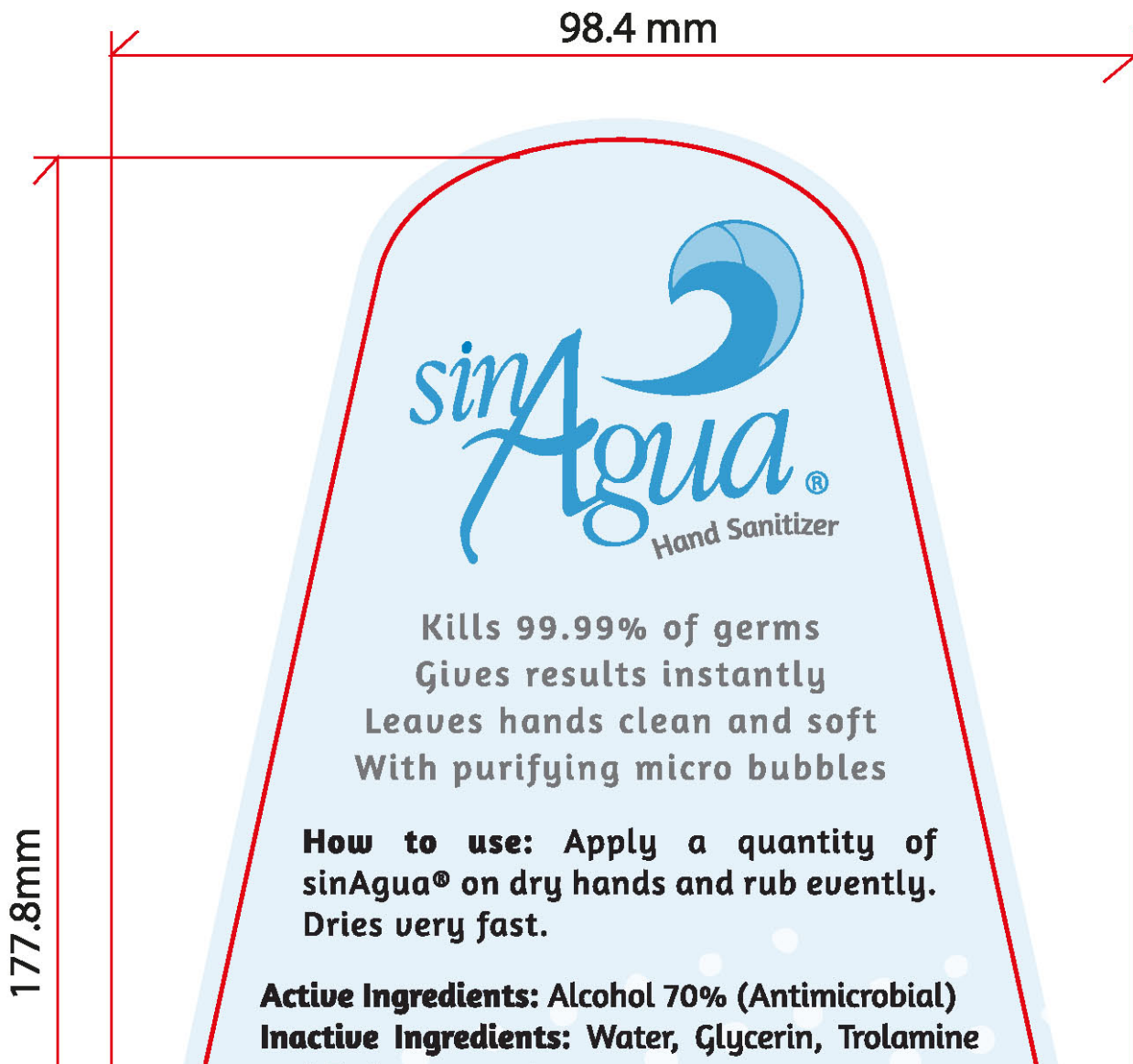
#### Other information

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

#### Inactive ingredients

glycerin,carbomer 940,trolamine,water

#### Package Label - Principal Display Panel



and Carbomero 940.

**Warning:** Flammable. For external use only.

Can be flammable. Keep it away from eyes. Young children should use it under adult supervision. If swallowed, seek medical advice immediately.

**Water is life... take care of it**

Made in Mexico for  
Distribuidora Dimex S.A. de C.V.  
Av. Año de Juárez No. 214,  
Col. Granjas San Antonio, C.P. 09070,  
Iztapalapa, Mexico City, Mexico

Questions?, Call  
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+52 55 5582-6246  
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**Back**

98.4 mm

**Hand  
sanitizer**

177.8mm

• With glycerin •  
Disinfects instantly  
It is not sticky  
**70% alcohol**



*sin Agua*<sup>®</sup>

**67.6 fl oz**

**Front**

2000 mL NDC: 79159-101-03

**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79 159-101
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.5 g in 100 mL
WATER (UNII: 059QF0K00R)	28.7 g in 100 mL

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 159-101-03	2000 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** - Distribuidora Dimex,S.A. de C.V. (588444281)**Registrant** - Distribuidora Dimex,S.A. de C.V. (588444281)**Establishment**

Name	Address	ID/FEI	Business Operations
Distribuidora Dimex,S.A. de C.V.		588444281	manufacture(79 159-101)