

# Hand sanitizer 250 ml Gel antibacterial



**Alcohol Antiseptic**  
**75 %**  
*Topical Solution*

**Hand Sanitizer**

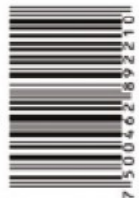
**8.45 FL OZ (250mL)**

<b>Drugs Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl alcohol 75% v/v.....	Antiseptic
<b>Uses</b> ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable, Keep away from heat or flame	
<b>Do not use</b> ■ In children less than 2 months of age ■ On open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children</b> if swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ Place enough product on hands to cover all surface. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing	
<b>Other Information</b> ■ Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Glycerin, Carbomer 940, Trolamine, Purified water.	

**PRODUCT OF MEXICO**

**Imported by:**  
Dist. de Prod. Alim. el Paisita  
4712 N 12Th St Suite 47  
McAllen TX. 78504  
Phone 956-438-5436

**Manufactured by:**  
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Nuevo Leon, Sep 19, 2020 ([Issuewire.com](http://Issuewire.com)) - Harmonic Nature Issues Voluntary Nationwide Recall of Alcohol Antiseptic 75% Topical Solution Hand Sanitizer 8.45 Fl Oz (250 mL) Due to the Presence of 1-Propanol

**Company Contact:** HARMONIC NATURE S. DE R.L. MI

**Name:** Miguel Isaac Martinez Marina

**Phone Number:** +956 438 5436 **Name on the label:** Alcohol Antiseptic 75% Topical Solution Hand Sanitizer 8.45 Fl Oz (250 mL)

Harmonic Nature is voluntarily recalling all lots of Alcohol Antiseptic 75% Topical Solution Hand

Sanitizer 8.45 Fl Oz (250 mL), product shipped to the US (6/02/2020) due to the potential presence of 1-propanol. The products have been tested and found to contain 1 propanol.

**Risk Statement:** Any amount of 1-propanol with a concentration greater than or equal to 1% by volume that is unlisted in a product labeled as an ethanol-based hand sanitizer has a reasonable probability of acute toxicity from ingestion which can cause central nervous system depression, which could result in death, permanent impairment, or necessitate medical or surgical intervention. Populations most at risk include an individual with alcohol addiction and adolescents, who have been known to ingest ethanol-based antiseptic rubs intentionally to become intoxicated, as well as infants and children who may unintentionally ingest the defective product. Harmonic Nature has not received any reports of adverse events related to this recall.

The product is used as a hand sanitizer and is packaged in 250 mL plastic bottles, with UPC Code **7500462892210**. The product can be identified by Harmonic Nature as a **hand sanitizer** Topical Solution distributed only to and currently on hold the 2400 bottles at the US custom broker, Aquiles INC.

**Harmonic Nature** is notifying Aquiles INC. Currently, Aquiles INC has the 2400 bottles of Alcohol Antiseptic 75% Topical Solution Hand Sanitizer 8.45 Fl Oz (250 mL), in his warehouse and is arranging for the **return** of all recalled product. Consumers with questions regarding this recall can contact **Harmonic Nature** by **+956 438 5436** or [miguel\\_martinez2000@yahoo.com](mailto:miguel_martinez2000@yahoo.com) **Monday to Friday from 8:00 am to 6:00 pm central time**. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** [fda.gov/medwatch/report.htm](https://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download form [fda.gov/MedWatch/getforms.htm](https://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

## Media Contact

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Source : Harmonic Nature S de RL MI

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