

## COMPANY ANNOUNCEMENT

# Incredible Products Sa De Cv Issues Voluntary Nationwide Recall of Gelbac T Antibacterial Handgel

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

August 06, 2020

**FDA Publish Date:**

August 07, 2020

**Product Type:**

Drugs

**Reason for Announcement:**

Methanol Contamination

**Company Name:**

Incredible Products Sa de Cv

**Brand Name:**

Gelbac T

**Product Description:**

Antibacterial Handgel

## Company Announcement

INCREDIBLE PRODUCTS SA DE CV is voluntarily recalling 1 lot of GELBAC T ANTIBACTERIAL HANDGEL, packaged in 1 liter /33.8 oz plastic bottles and 125ml/4.2 oz plastic bottles of to the consumer level. The products are being recalled due to the potential presence of methanol (wood alcohol). FDA sampling of product at the port of entry to contain undeclared methanol.

**Risk Statement:** Substantial methanol exposure could result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, and permanent damage to the nervous system or death. Although all persons using these products on their hands are at risk, young children who accidentally ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute are most at risk for methanol poisoning. To date, INCREDIBLE PRODUCTS SA DE CV has not received reports of adverse events related to this recall.

These products are used as hand sanitizers and marketed to help decrease bacteria on the skin when soap and water are not available. The affected Hand Sanitizers are packaged in clear plastic bottles. The recalled products are as follows:

**Product, Sizes and LOT:**

GELBAC T ANTIBACTERIAL HANDGEL

Sizes 33.8 oz, 4.2 oz

LOT CODE 001

**INCREDIBLE PRODUCTS SA DE CV** is notifying its distributors and customers by recall letter and consumers via this press release and is arranging for refund of all recalled products.

Consumers with questions regarding this recall can contact INCREDIBLE PRODUCTS SA DE CV by sending an email to [gcigdl@yahoo.com.mx](mailto:gcigdl@yahoo.com.mx) (<mailto:gcigdl@yahoo.com.mx>) and [dalp\\_07@hotmail.com](mailto:dalp_07@hotmail.com) ([mailto:dalp\\_07@hotmail.com](mailto:dalp_07@hotmail.com)) during business hours.

### **Contact**

Jesus Guillermo Vazquez Ramirez (<https://www.prlog.org/email-contact.html#12833117>)   
(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)


FDA updates on hand sanitizers consumers should not use. (</drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use>)

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## **Company Contact Information**

### **Consumers:**

INCREDIBLE PRODUCTS SA DE CV

 [gcigdl@yahoo.com.mx](mailto:gcigdl@yahoo.com.mx) (<mailto:gcigdl@yahoo.com.mx>)

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## **Product Photos**



**ANTIBACTERIAL  
HAND GEL**

**GEL PARA MANOS  
ANTIBACTERIAL**

**NDC: 71761-000-00**

**Net. Cont. 4.2 Oz**

**125 ml**



## Drug Facts

**ACTIVE INGREDIENTS:** Ethyl alcohol 80%

**PURPOSE:** Antiseptic

**USES:** Hand sanitizer to help decrease bacteria on the skin. When water, soap & towel are not available. Recommended for repeated use.

**WARNINGS:** For external use only.

**Flammable.** Keep away from fire or flame.

Do not apply around eyes. Do not use in ears & mouth.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

**DIRECTIONS:** Apply the gel on the hands, rub and distribute evenly. Let dry at room temperature.

**OTHER INFORMATION:** Store at 20°C (68° to 77° F). May discolor fabrics.

**INACTIVE INGREDIENTS:** water, carbomer, glycerin, triethanolamine, tocopheryl acetate, emulsifiers.

**Distributed by Pacific Coast Global Inc.**

Chula Vista, CA 91911 [pcgiwholesale.com](http://pcgiwholesale.com)

[pacific\\_coastgbl@hotmail.com](mailto:pacific_coastgbl@hotmail.com)

**MADE IN MEXICO**

**Lote: 001 CAD.: Abril 2023 EXP. DATE: April 2023**

**CLASSIFIED AND LABELED / CLASIFICADO Y ETIQUETADO**



**Drug Facts**

**ACTIVE INGREDIENTS:** Ethylalcohol. **PURPOSE:** Antiseptic.  
**INGREDIENTS ACTIVOS:** Alcohol etílico. **PROPOSITO:** Antiséptico.

**USES:** Hand sanitizer to help decrease bacteria on the skin. When water, soap & towel are not available. Recommended for repeated use.  
**USOS:** Ayuda a reducir las bacterias en la piel. Cuando no haya disponible agua, jabón y toalla. Recomendado para uso reiterado.

**WARNINGS:** For external use only.  
**ADVERTENCIAS:** Para uso externo solamente.  
**Inflammable. Keep away from fire or flame.**  
**Inflamable. Mantener alejado del fuego.**

Do not apply around eyes. Do not use in ears or mouth.  
 No aplicar alrededor de los ojos. No utilizar en oídos o boca.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.  
 Cuando se utiliza este producto, evitar el contacto con los ojos. En caso de contacto enjuagar con agua.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.  
 Dejen de usar y consultar a un doctor si aparece irritación o enrojecimiento y persiste por más de 72 horas.

Keep out of reach of children. Children must be supervised in use of this product.  
 Mantener lejos del alcance de los niños. Deben ser supervisados en el uso de este producto.

**DIRECTIONS:** Apply the gel on the hands, rub and distribute evenly. Let dry at room temperature.  
**INSTRUCCIONES:** Aplique el gel en las manos, frote y distribuya uniformemente. Deje secar a temperatura ambiente.

**OTHER INFORMATION:** Store at 20°C (68° to 77° F). May discolor fabric.

**INACTIVE INGREDIENTS:** water, carbomer, glycerin, methacrylamide, isopropylalcohol, emulsifiers.  
**INGREDIENTES INACTIVOS:** agua, carbomero, glicerina, metacrilamida, acetato de tocoferilo, emulsificantes.

**MADE IN MEXICO BY / HECHO EN MÉXICO POR:**  
 Incredible Products S.A. de C.V.  
 Calle Castellanos y Tapia 921, Obispatos,  
 44350 Guadalajara, Jal. MX.  
 Clave SCIAN COFEPRIS 325620  
 CLASSIFIED AND LABELED / CLASIFICADO Y ETIQUETADO

**GELBAC<sup>T</sup>**  
**ANTIBACTERIAL HAND GEL**  
**GEL PARA MANOS ANTIBACTERIAL**

**KILLS 99.9% BACTERIA & GERMS**

**Net. Cont. 33.8 Oz / 1 L**

Lote: 001  
 CAD.: Abril 2023 EXP. DATE: April 2023

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