

**HANDRUB HAND SANITIZER- alcohol solution**  
**LABORATORIO MAGNACHEM INTERNATIONAL SRL**

*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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**Hand Rub**

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) (80%, 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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

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

**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

**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.

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.

## 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, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

NDC 65131-102-23

**HAND RUB®**

Alcohol Antiseptic  
80% Topical Solution

Hand Sanitizer  
Non-Sterile Solution

(1.6 fl oz) e 47.0 mL

The hand is the tool of tools. —Aristotle

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v	
<b>Use[s]</b>	Hand Sanitizer to help reduce bacteria that soap and water are not available.
<b>Warnings</b>	<b>For external use only. Flammable. Keep out of reach of children.</b>
<b>Do not use</b>	■ in children less than 2 months of age
<b>When using this product</b> keep out of eyes, ears, and mouth. Wash thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. This product may contain irritants.	
<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 surfaces. 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 15–30°C (59–86°F). Avoid excessive heat above 40°C (104°F).
<b>Inactive ingredients</b>	Glycerin, Hydrogen Peroxide

<b>Información del Medicamento</b>	
<b>Ingrediente[s] activo[s]</b> Alcohol 80% v/v	
<b>Uso[s]</b>	Antiséptico de manos para ayudar a reducir la propagación de bacterias que el jabón y el agua no eliminan.
<b>Advertencias</b>	<b>Para uso Externo únicamente. Inflamable. Mantenga fuera del alcance de los niños.</b>
<b>No usar</b>	■ con los niños de 2 años o menos
<b>Cuando use este producto,</b> mantener fuera de sus ojos, nariz y boca. Lavar con agua suficiente.	
<b>Detenga el uso y llame a su médico</b> si alguna irritación, erupción o sarpullido persiste.	
<b>Mantenga lejos del alcance de los niños.</b> Si se traga, busque ayuda médica inmediatamente.	
<b>Direcciones</b>	
■ Use la cantidad suficiente para cubrir con el producto toda la superficie de las manos.	
■ Supervisar niños de 6 años de edad al usar este producto.	
<b>Otra Información</b>	■ Guardar entre 15–30°C (59–86°F). Evitar el calor excesivo por encima de los 40°C (104°F).
<b>Ingredientes inactivos</b>	Glicerina, Peróxido de Hidrógeno

Manufactured in Dominican Republic by  
Fabricado en República Dominicana por  
**Magnachem Laboratory International**

**Exclusively for Global Corporation, Inc.**  
globalcorporation.com

# HANDRUB HAND SANITIZER

alcohol solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65131-102
<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	80 L in 1000 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 1000 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 1000 mL
WATER (UNII: 059QF0KO0R)	18.425 L in 1000 mL

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:65131-102-28	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	06/01/2020	

**Labeler** - LABORATORIO MAGNACHEM INTERNATIONAL SRL (871446100)

**Registrant** - LABORATORIO MAGNACHEM INTERNATIONAL SRL (871446100)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LABORATORIO MAGNACHEM INTERNATIONAL SRL		871446100	manufacture(65131-102)

Revised: 5/2020

LABORATORIO MAGNACHEM INTERNATIONAL SRL