

HAND SANITIZER- alcohol gel

Ignacio Reyes González

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.

HAND SANITIZER GEL 250 mL

DIRECTIONS OF DOSAGE AND ADMINISTRATION

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.

INACTIVE INGREDIENTS

Water, Glycerin, Carbomer, Triethanolamine

INDICATIONS AND USAGE

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.

ANTIMICROBIAL

Antimicrobial

WARNINGS

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.

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

ACTIVE INGREDIENT

Active ingredient.

Ethyl Alcohol 70%

HAND SANITIZER GEL PRINCIPAL DISPLAY LABEL

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer Gel Non-sterile Solution
250 mL (8.45 fl. oz.)

<p>Drug Facts</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Active ingredient.</td> <td style="width: 50%;">Purpose</td> </tr> <tr> <td>Ethyl Alcohol 70% v/v.....</td> <td>Antimicrobial</td> </tr> </table> <p>Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame</p> <p>Do not use</p> <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds <p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> • 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. <p>Other information</p> <ul style="list-style-type: none"> • Store below 110°F (43°C) • Avoid freezing and excessive heat above 40°C (104°F) <p>Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine</p>	Active ingredient.	Purpose	Ethyl Alcohol 70% v/v.....	Antimicrobial	<p>Datos del Producto</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Ingrediente Activo</td> <td style="width: 50%;">Propósito</td> </tr> <tr> <td>Alcohol etílico 70% v/v.....</td> <td>Antimicrobiano</td> </tr> </table> <p>Usos Desinfectante para manos empleado para reducir la cantidad de bacterias en la piel que pueden causar enfermedades. Utilice este producto cuando no haya jabón y agua disponibles.</p> <p>Advertencias Sólo para uso externo. Inflamable. Mantenga este producto alejado del fuego o calor.</p> <p>No Usar</p> <ul style="list-style-type: none"> • en niños menores a 2 meses de edad • en heridas expuestas <p>Al utilizar este producto, evitar el contacto con los ojos, oídos y boca. En caso de caso de contacto con los ojos, enjuagar completamente con agua.</p> <p>Dejar de usar el producto y consultar a un médico si aparece y persiste una irritación o erupción cutánea. Estas pueden ser señales de una condición médica seria.</p> <p>Mantener fuera del alcance de los niños. En caso de ingestión, acudir de inmediato a un médico o ponerse en contacto con un Centro de Control de Sustancias Tóxicas</p> <p>Modo de Uso</p> <ul style="list-style-type: none"> • Poner suficiente cantidad de producto en la palma de la mano para cubrir las manos completamente. Frotarse las manos vigorosamente hasta que se sequen. • El empleo de este producto por niños menores a 6 años deberá ser supervisado. <p>Información Adicional</p> <ul style="list-style-type: none"> • Almacenar a temperaturas inferiores a 110°F (43°C) • Evitar congelar el producto o exponerlo a temperaturas superiores a 40°C (104°F) <p>Ingredientes Inactivos Agua, Glicerina, carbomero, trietanolamina.</p>	Ingrediente Activo	Propósito	Alcohol etílico 70% v/v.....	Antimicrobiano
Active ingredient.	Purpose								
Ethyl Alcohol 70% v/v.....	Antimicrobial								
Ingrediente Activo	Propósito								
Alcohol etílico 70% v/v.....	Antimicrobiano								

Distributed by
SBL Brands, LLC
MedicallyMinded.us
MADE IN MEXICO

NET CONTENTS
250 mL
(8.45 fl. oz.)

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77196-003
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
TRIETHANOLAMINE CAPROYL GLUTAMATE (UNII: 0F2FO57253)	0.002 mL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.0375 mL in 1 mL
WATER (UNII: 059QF0K00R)	0.2585 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:77196-003-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2020	

Labeler - Ignacio Reyes González (951577216)

Registrant - Ignacio Reyes González (951577216)

Establishment

Name	Address	ID/FEI	Business Operations
Ignacio Reyes González		951577216	manufacture(77196-003)

Revised: 5/2020

Ignacio Reyes González