

HAND SANITIZER- alcohol gel
Portal de Soluciones, 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.

Active Ingredient(s)

Alcohol 70% 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.

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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, polyacrylic acid (Carbomer), triethanolamine (Trolamine), water.

Package Label - Principal Display Panel

500 mL NDC: 79648-002-01

<p>Alcohol Antiseptic 70%</p> <p>Hand Sanitizer Gel</p> <p>Non-sterile Topical Solution</p> <p>16.9 fl. oz. (500 mL)</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Drug Facts</td> </tr> <tr> <td style="width: 60%;">Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Alcohol 70% w/v.....</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Use (s)</td> </tr> <tr> <td colspan="2">Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2">- In children less than 2 months of age - on open skin wounds</td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2">- Place enough product on hands to cover all surfaces. - Rub hands together until dry. - Supervise children under 6 years if age when using this product to avoid swallowing</td> </tr> <tr> <td colspan="2">Other information</td> </tr> <tr> <td colspan="2">Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)</td> </tr> <tr> <td colspan="2">Inactive ingredients</td> </tr> <tr> <td colspan="2">Glycerin, polyacrylic acid (Carbomer), triethanolamine (Trolamine), Water.</td> </tr> <tr> <td colspan="2">Manufactured by:</td> </tr> </table>	Drug Facts		Active Ingredient	Purpose	Alcohol 70% w/v.....	Antiseptic	Use (s)		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		Directions		- Place enough product on hands to cover all surfaces. - Rub hands together until dry. - Supervise children under 6 years if 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, polyacrylic acid (Carbomer), triethanolamine (Trolamine), Water.		Manufactured by:	
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HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79648-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6 A3C0 OX)	1 mL in 100 mL		
WATER (UNII: 059QF0 KO0R)	27 mL in 100 mL		
POLYACRYLIC ACID (8000 MW) (UNII: 7386 1X4K5F)	0.5 mL in 100 mL		
TROLAMINE (UNII: 9O3K93S3TK)	1.5 mL in 100 mL		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79648-002-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/16/2020	

Labeler - Portal de Soluciones, S.A. de C.V. (951580524)

Registrant - Portal de Soluciones, S.A. de C.V. (951580524)

Establishment

Name	Address	ID/FEI	Business Operations
Portal de Soluciones, S.A. de C.V.		951580524	manufacture(79648-002)

Revised: 12/2020

Portal de Soluciones, S.A. de C.V.