

DELTA HAND SANITIZER- alcohol gel
Antisépticos de México, 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 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.

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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

125 mL NDC: 76554-004-01

 <p style="font-size: 1.2em; font-weight: bold; margin: 10px 0;">Alcohol Antiseptic 80%</p> <p style="font-size: 1.1em; font-weight: bold; margin: 10px 0;">Topical Solution Hand Sanitizer Gel Non-sterile Solution</p> <p style="font-size: 1.1em; font-weight: bold; margin: 10px 0;">4.22 fl. oz. (125 mL)</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Drug Facts</th> </tr> <tr> <td style="width: 70%; padding: 2px;">Active Ingredient</td> <td style="padding: 2px;">Purpose</td> </tr> <tr> <td style="padding: 2px;">Alcohol 80% v/v.....</td> <td style="padding: 2px;">Antiseptic</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Use (s)</td> </tr> <tr> <td colspan="2" style="padding: 2px;">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" style="padding: 2px;">Warnings</td> </tr> <tr> <td colspan="2" style="padding: 2px;">For external use only. Flammable. Keep away from heat or flame</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Do not use</td> </tr> <tr> <td colspan="2" style="padding: 2px;">- In children less than 2 months of age - on open skin wounds</td> </tr> <tr> <td colspan="2" style="padding: 2px;">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" style="padding: 2px;">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" style="padding: 2px;">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" style="padding: 2px;">Directions</td> </tr> <tr> <td colspan="2" style="padding: 2px;">- 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" style="padding: 2px;">Other information</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Inactive ingredients</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Glycerin, polyacrylic acid (Carbomer), triethanolamine (Trolamine), Water.</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Manufactured by: Antisépticos de México S.A. de C.V. Blvd. Clio #1029, León. Guanajuato, Z.P. 37358. México. atnclientes@antisepticosdemexico.com Ph.: +52 477-842-26-54 PRODUCT OF MEXICO</td> </tr> </table>	Drug Facts		Active Ingredient	Purpose	Alcohol 80% v/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: Antisépticos de México S.A. de C.V. Blvd. Clio #1029, León. Guanajuato, Z.P. 37358. México. atnclientes@antisepticosdemexico.com Ph.: +52 477-842-26-54 PRODUCT OF MEXICO	
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DELTA HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76554-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	1 mL in 100 mL
WATER (UNII: 059QF0K00R)	17 mL in 100 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76554-004-01	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2020	

Marketing Information

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

Labeler - Antisépticos de México, S.A. de C.V. (951576637)

Registrant - Antisépticos de México, S.A. de C.V. (951576637)

Establishment

Name	Address	ID/FEI	Business Operations
Antisépticos de México, S.A. de C.V.		951576637	manufacture(76554-004)

Revised: 6/2020

Antisépticos de México, S.A. de C.V.