

AG ALCOHOL ANTISEPTIC- alcohol gel

Nivek Distribution, LLC.

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.

AG Alcohol Antiseptic

Drug Facts

Active ingredient[s]

Alcohol 72% v/v

Purpose

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 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 Labeling



**Alcohol Antiseptic 72%
Topical Solution**

Hand Sanitizer
Non-sterile Solution

Eliminates
99.9%
of Germs and
Bacteria



8.45 FL OZ (250 ml) 7 502281 190119

Drug Facts	
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Made in Mexico by: Comercial de Mercancias Selectas de Guadalajara S.A. de C.V.
Calz. Lázaro Cárdenas 2920, Col. Álamo Industrial, C.P. 45593 San Pedro, Tlaquepaque, Jalisco.
Distributed by: Nivek Distribution LLC

Package Labeling: 8ml



Hand Sanitizer

Alcohol Antiseptic 72%

Eliminates
99.9%
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Topical Solution
Non-sterile Solution

0.27 FL OZ (8 ml)

MADE IN NORTH AMERICA

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MADE IN NORTH AMERICA

Distributed by:
Nivek Distribution LLC

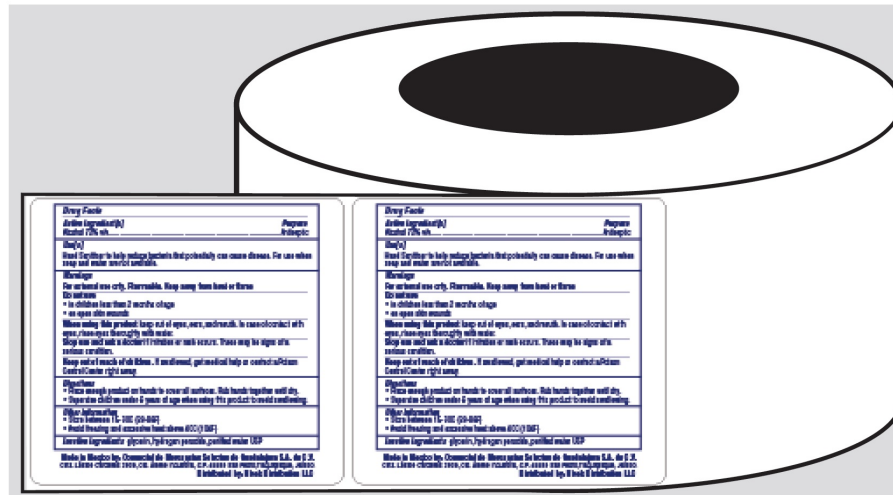
Made by:
Comercial de Mercancias Selectas
de Guadalajara S.A. de C.V.

Package Labeling: 500ml

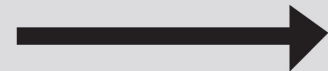


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Distributed by: Nivek Distribution LLC
 Made by: Comercial de Mercancias Selectas de Guadalajara S.A. de C.V.



Salida de etiquetas
 al sentido del
 EMOBINADO



Package Labeling: 1000ml



AG
Hand Sanitizer
Alcohol Antiseptic 72%

Eliminates **99.9%** of Germs and Bacteria

Topical Solution
Non-sterile Solution

33.8 FL OZ (1000 ml)

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MADE IN NORTH AMERICA
Distributed by: Nivek Distribution LLC

Package Labeling: 3.785ml



AG
Hand Sanitizer
Alcohol Antiseptic 72%

Eliminates **99.9%** of Germs and Bacteria

Topical Solution
Non-sterile Solution

128 FL OZ (3.785 L)

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Distributed by: Nivek Distribution LLC
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Eliminates **99.9%** of Germs and Bacteria

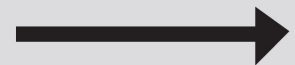
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3.785 L

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Distributed by: Nivek Distribution LLC

Salida de etiquetas al sentido del EMBOBINADO



AG ALCOHOL ANTISEPTIC

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77523-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.72 mL in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77523-000-00	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	
2	NDC:77523-000-02	8 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:77523-000-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
4	NDC:77523-000-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
5	NDC:77523-000-37	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/29/2020	

Labeler - Nivek Distribution, LLC. (117511434)

Revised: 6/2020

Nivek Distribution, LLC.