

HAND SANITIZER- alcohol gel
INOVAKER LAB 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 75% 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 (Aqua)

Package Label - Principal Display Panel



HAND
SANITIZER

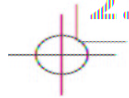
Ethyl Alcohol
Antiseptic 75%

Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

INOVAKER
LAB

2.02 fl oz (60 mL)



Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
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Directions	
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• 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.	



Manufactured by: INOVAKER LAB SA DE CV
Luis Quintanar 1105 , Colonia Bella vista Monterrey
Nuevo León México 64410 Imported by: L'IZZO USA
INC. Laredo Texas 78041 PRODUCT OF MEXICO
OF MEXICO

60 mL NDC: 77271-002-01

Package Label- Principal display panel

120 mL NDC: 77271-002-02



HAND+ SANITIZER

Ethyl Alcohol
Antiseptic 75%
Topical Solution

Antiseptic Hand Rub
Non- sterile Solution

INOVAKER
LAB

4.05 fl oz (120 mL)



Package Label - Principal Display Panel

250 mL NDC: 77271-002-03



HAND+ SANITIZER

Ethyl Alcohol
Antiseptic 75%
Topical Solution

Antiseptic Hand Rub
Non- sterile Solution

INOVAKER
LAB

8.45 fl oz (250 mL)



Package Label - Principal Display Panel

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Use[s] Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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 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, Polyacrylic Acid (Carbomer), Triethanolamine (Trolamine), Water.	

Manufactured by: INOVAKER LAB SA DE CV
Luis Quintanar 1105 , Colonia Bella vista
Monterrey Nuevo León México 64410
Imported by: L'IZZO USA INC. Laredo Texas
78041 PRODUCT OF MEXICO

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Use[s] Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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 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. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get help or contact a Poison Control Center right	
Directions • Place enough product on hands to cover a Rub hands together until dry. • Supervise children under 6 years of age wh this product to avoid swallowing.	
Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 4C	
Inactive ingredients Glycerin, Polyacrylic Acid (Carbomer), Triethan (Trolamine), Water.	

Manufactured by: INOVAKER L
DE CV Luis Quintanar 1105 , Co
Bella vista Monterrey Nuevo Le
México 64410 Imported by: L'IZ
INC. Laredo Texas 78041
PRODUCT OF MEXICO

500 mL NDC: 77271-002-04



HAND+ SANITIZER

Ethyl Alcohol
Antiseptic 75%
Topical Solution

*Antiseptic Hand Rub
Non-sterile Solution*

INOVAKER
LAB

16.9 fl oz (500 mL)



Drug Facts

Active ingredient

Ethyl alcohol 75% v/v.....

Use[s]

Health care personnel hand rub to help re that potentially can cause disease.

Warnings

For external use only. Flammable. Keep heat or flame

Do not use

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Keep out of reach of children. If swallow help or contact a Poison Control Center

Directions

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- Supervise children under 6 years of ag this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat abo

Inactive ingredients

Glycerin, Polyacrylic Acid (Carbomer), Ti (Trolamine), Water.

Manufactured by: INOVAKE
DE CV Luis Quintanar 1105 ,
Bella vista Monterrey Nuevc
México 64410 Imported by: I
INC. Laredo Texas 78041
PRODUCT OF MEXICO

Package Label - Principal Display Panel

1000 mL NDC: 77271-002-05



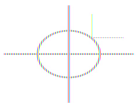
HAND+ SANITIZER

**Ethyl Alcohol
Antiseptic 75%
Topical Solution**

*Antiseptic Hand Rub
Non-sterile Solution*

**INOVAKER
LAB**

33.81 fl oz (1 L)



Package Label - Principal Display Panel

3780 mL NDC: 77271-002-06

Drug Facts

Active ingredient

Ethyl alcohol 75% v/v.....

Use[s]

Health care personnel hand rub to help that potentially can cause disease.

Warnings

For external use only. Flammable. Keep heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out eye mouth. In case of contact with eyes, rinse thoroughly with water.

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

Keep out of reach of children. If swallowed help or contact a Poison Control Center.

Directions

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- Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

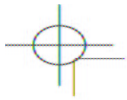
Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 30C (86F)

Inactive ingredients

Glycerin, Polyacrylic Acid (Carbomer), Triethylamine (Trolamine), Water.

Manufactured by: INOVAKER
Luis Quintanar 1105 , Colonia E
Nuevo León México 64410 Im
INC. Laredo Texas 78041
PRODUCT OF MEXICO



HAND SANITIZER

Ethyl Alcohol
Antiseptic 75%

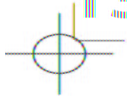
Topical Solution

Antiseptic Hand Rub

Non- sterile Solution

INOVAKER
LAB

135.27 fl oz (4 L)



Drug Facts

Active ingredient

Ethyl alcohol 75% v/v.....Ar

Use[s]

Health care personnel hand rub to help reduce that potentially can cause disease.

Warnings

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Do not use

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Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40

Inactive ingredients

Glycerin, Polyacrylic Acid (Carbomer),Triethanolam (Trolamine), Water.

Manufactured by: INOVAKER LAB SA D Quintanar 1105 , Colonia Bella vista Mor León México 64410 Imported by: L' IZZO Laredo Texas 78041. PRODUCTOFMEX

HAND SANITIZER

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77271-002

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
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.2 mL in 100 mL
WATER (UNII: 059QF0K00R)	21.9 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77271-002-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	
2	NDC:77271-002-02	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	
3	NDC:77271-002-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	
4	NDC:77271-002-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	
5	NDC:77271-002-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	
6	NDC:77271-002-06	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/27/2020	

Labeler - INOVAKER LAB S.A. DE C.V. (951577122)

Registrant - INOVAKER LAB S.A. DE C.V. (951577122)

Establishment

Name	Address	ID/FEI	Business Operations
INOVAKER LAB S.A. DE C.V.		951577122	manufacture(77271-002)

Revised: 12/2020

INOVAKER LAB S.A. DE C.V.