

HAND SANITIZER- isopropyl 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.

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

Warnings

For external use only. Flammable. Keep away from heat of flame

Inactive ingredients

Water (aqua), glycerin, triethanolamine, carbomer, fragrance.

Use(s)

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.
If swallowed, get medical help or contact a Poison Control Center right away

Purpose

Hand sanitizer. Antiseptic

Active ingredient

Isopropyl alcohol 75% v/v

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
60 mL NDC: 77271-001-01

HAND+ SANITIZER

Isopropyl Alcohol
Antiseptic 75%

Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

INOVAKER
LAB

2.02 FL OZ (60 ml)



250 mL NDC: 77271-001-02

Drug Facts

Active ingredient	Purpose
Isopropyl 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

Water (aqua), Glycerin, Triethanolamine, Carbomer, Fragrance.

Manufactured by:
INOVAKER LAB SA DE CV
Monterrey, Mexico 64410

Questions? +52177225427
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HAND+ SANITIZER

Isopropyl Alcohol
Antiseptic 75%

Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

INOVAKER
LAB

8.45 FL OZ (250 ml)



500 mL NDC: 77271-001-03

Drug Facts

Active ingredient	Purpose
Isopropyl 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

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Other information

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- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

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HAND+ SANITIZER

Isopropyl Alcohol
Antiseptic 75%

Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

INOVAKER
LAB

16.9 FL OZ (500 ml)



750 mL 77271-001-04

Drug Facts

Active ingredient

Isopropyl alcohol 75% v/v.....Antiseptic

Purpose

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

Water (aqua), Glycerin, Triethanolamine, Carbomer, Fragrance.

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HAND+ SANITIZER

Isopropyl Alcohol
Antiseptic 75%

Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

INOVAKER
LAB

25.3 FL OZ (750 ml)



1000 mL NDC: 77271-001-05

Drug Facts

Active ingredient	Purpose
Isopropyl 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

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HAND+ SANITIZER

Isopropyl Alcohol
Antiseptic 75%

Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

INOVAKER
LAB

33.8 FL OZ (1 L)



Drug Facts

Active ingredient	Purpose
Isopropyl 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

Water (aqua), Glycerin, Triethanolamine, Carbomer, Fragrance.

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4000 mL NDC: 77271-001-06

HAND+ SANITIZER

Isopropyl Alcohol
Antiseptic 75%

Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

INOVAKER
LAB

135.2 FL OZ (4 L)



Drug Facts

Active ingredient	Purpose
Isopropyl 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

Water (aqua), Glycerin, Triethanolamine, Carbomer, Fragrance.

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HAND+ SANITIZER

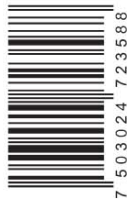
Isopropyl Alcohol
Antiseptic 75%

Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

INOVAKER
LAB

4.04 FL OZ (120 ml)



Drug Facts	
Active ingredient	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Uses]	
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	
<ul style="list-style-type: none"> 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	
<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. 	
Other information	
<ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients	
Water (aqua), Glycerin, Triethanolamine, Carbomer, Fragrance.	

Manufactured by:
INOVAKER LAB SA DE CV
Monterrey Mexico
64410
Imported by:
L'IZZO USA INC.
Laredo Texas USA
78041

Questions? 956 726 6527
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120ml NDC: 77271-001-01

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77271-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	21.5 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
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.4 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77271-001-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
2	NDC:77271-001-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
3	NDC:77271-001-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
4	NDC:77271-001-04	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
5	NDC:77271-001-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
6	NDC:77271-001-06	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
7	NDC:77271-001-07	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/08/2020	

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(77271-001)

Revised: 5/2020

INOVAKER LAB S.A. DE C.V.