#### HAND SANITIZER- alcohol gel NATURATLALI S DE RL DE CV

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.

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77143-004 - 70% alcohol

#### **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**

Flammable, keep away from fire or flame.

For external use only.

#### Do not use

• on open 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.

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**

Purified water USP, glycerin, carbomer, triethaanolamine, methylparabene, propylparabene, propylene glycol, DMDM Hydantoin.

### Package Label - Principal Display Panel

946 mL NDC: 77143-004-08



250 mL NDC: 77143-004-01



## HAND SANITIZER

70% ALCOHOL



8.5 fl oz (250 mL)



#### Drug Facts Active Ingredient [s] Purpose Ethyl alcohol 70% v/v . Use [s] Hand sanitizer to help reduce bacteria that potentially can cause diseas For use when soap and water are not available. 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 throughly with water. Stop use and ask a doctor if redness or irritation develop and persist for 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 sufaces. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoic swallowing Other information ■ Store between 15-30°C (59-86 °F) ■ May discolor certain fabrics or sufaces Inactive ingredients: water, carbomer, triethanolamine, glycerine. Questions ?/¿Preguntas? Call: (956) 999-5319 MANUFACTURED BY: NATURATLALIS. DE RL DE C.V. VILLAJUÁREZ 53 COL FRANCISCO SARABIA CP 46226 JALISCO MADE IN MÉXICO, DISTRIBUTED BY: PHI MPORTING COMPANY: 1214 BELTWAY PARKWAY, LAREDO, TX, 78045 USA EXPRATION DATE: 65/23 BATCH NUMBER: CABPT0520

236 mL NDC: 77143-004-02



# INSTANT **HAND SANITIZER**

## REFRESHING GEL







8FLOZ (236 ML)



3785 mL NDC: 77143-004-06

# Drug Facts

## Active Ingredient [s]

Purpose

## 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 throughly with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

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

#### Other information

- Store between 15-30°C (59-86 °F)
- May discolor certain fabrics or sufaces.

**Inactive ingredients:** water, carbomer, triethanolamine, glycerin.

MANUFACTURED FOR: NATURATLALI S DE R.L DE C.V VILLA JUAREZ 53 COL. FRANCISCO SARABIA CP 45236, JALISCO. MADE IN MEXICO FOR QUESTIONS: CALL: +1(778)748-0838



## **INSTANT HAND SANITIZER**

## **REFRESHING GEL**







1GAL(3.785 L)





## **Drug Facts**

Active Ingredient [s]

Purpose

NDC: 77143-004-06

Ethyl alcohol 70% v/v.

Antiseptic

#### Use [s]

Hand sanitizer to help reduce bacteria that potentially can cause disea For use when soap and water are not available.

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 throughly with water

Stop use and ask a doctor if irritation or rash occurs. These may be signs

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.

■ Place enough product on hands to cover all sufaces. Rub hands together

until dry.

Supervise children under 6 years of age when using this product to avoid swallowing

#### Other information

- Store between 15-30°C (59-86 °F)
   Avoid freezing and excessive heat above 40°C (104 °F)

Inactive ingredients: water, carbomer, triethanolamine, glycerin.

MANUFACTURED FOR: NATURATLALI S DE R.L DE C.V VILLA JUAREZ 53 COL. FRANCISCO SARABIA CP 45236, JALISCO. MADE IN MEXICO FOR QUESTIONS: CALL: +1(778)748-0838

500 mL NDC: 77143-004-03



## **Drug Facts**

Active Ingredient [s]

Purpose

Ethyl alcohol 70% v/v . . . . .

. Antiseptic

NDC: 77143-004-03

## 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 throughly with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.

- ■Place enough product on hands to cover all sufaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid

#### Other information

- Store between 15-30°C (59-86 °F)
- May discolor certain fabrics or sufaces.

Inactive ingredients: water, carbomer, triethanolamine, glycerin.

946 mL NDC: 77143-004-05



250mL NDC: 77143-004-10





8.3 FL OZ (250 ML)

3785 mL NDC: 77143-004-11

# **Drug Facts**

## Active Ingredient [s]

Purpose

#### 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 throughly with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

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

#### Other information

- Store between 15-30°C (59-86 °F)
- May discolor certain fabrics or sufaces.

Inactive ingredients: water, carbomer, triethanolamine, glycerin.

MANUFACTURED FOR: VITUS LG. 6101 ROYAL ST. SUITE 106, 77081, HOUSTON, TXMADE IN MEXICO. FOR QUESTIONS CALL: +1 (786) 253-8972



2



60 mL NDC: 77143-004-12

## Drug Facts

#### Active Ingredient [s]

**Purpose** 

... Antiseptic

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 throughly with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

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

swallowing.

#### Other information

Store between 15-30°C (59-86 °F) May discolor certain fabrics or sufaces.

Inactive ingredients: water, carbomer, triethanolamine, glycerin.

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NDC:77143-004-11





2.02 fl oz (60 mL)

Purpose

. . . . Antiseptic

Active Ingredient [s] Drug Facts

Ethyl alcohol 70% v/v . . . .

Hand sanitizer to help reduce bacteria that potentially can cause disease For use when soap and water are not available. Use [s]

# 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 throughly with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

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 sufaces. Rub hands together until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

May discolor certain fabrics or sufaces. Store between 15-30°C (59-86 °F)

Inactive ingredients: water, carbomer, triethanolamine, glycerin.

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125 mL NDC: 77143-004-18





4.2FL OZ(125ML)

# **Drug Facts**

Active Ingredient [s] 

Purpose

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.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, winse throughly with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

AANUFACTURED FOR: VITUS LG. 6101 ROYAL ST. SUITE 106, 77081, HOUSTON XMADE IN MEXICO. FOR QUESTIONS CALL: +1 (844) 848-8754

- Place enough product on hands to cover all sufaces. Rub hands together
- until dry.

  Supervise children under 6 years of age when using this product to avoid swallowing.

#### Other information

- Store between 15-30°C (59-86 °F)
- May discolor certain fabrics or surfaces

Inactive ingredients Water, carbomer, triethanolamine, glycerine

#### HAND SANITIZER

alcohol gel

#### **Product Information**

HUMAN OTC DRUG NDC:77143-004 Product Type Item Code (Source)

Route of Administration **TOPICAL** 

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

#### **Inactive Ingredients**

S .	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 g in 100 mL
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A218 C7HI9 T)	0.025~g in $100~mL$
PROPYLPARABEN (UNII: Z8IX2SC1OH)	$0.025\;g$ in $100\;mL$
DMDM HYDANTO IN (UNII: BYR0546 TOW)	0.025 g in 100 mL
TRIETHANO LAMINE HYDRIO DIDE (UNII: DT98IT03JK)	1 g in 100 mL

#### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77143-004- 01	250 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77143-004- 02	236 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77143-004- 03	473 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77143-004- 05	946 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77143-004- 06	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77143-004- 08	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:77143-004- 10	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
8	NDC:77143-004-11	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:77143-004- 12	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:77143-004- 18	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

## Labeler - NATURATLALIS DE RL DE CV (951577202)

## **Registrant - NATURATLALIS DE RL DE CV (951577202)**

Establishment			
Name	Address	ID/FEI	Business Operations
NATURATLALI S DE RL DE CV		951577202	pack(77143-004), manufacture(77143-004), label(77143-004)

Revised: 11/2020 NATURATLALI S DE RL DE CV