

HAND SANITIZER- alcohol gel
Combustibles del Noreste DG 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.

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

236.56 mL NDC: 78477-001-01

Conoso

HAND SANITIZER
Non Sterile Solution

Alcohol Antiseptic 80%

8 fl oz (236.56 mL)

Active ingredient(s)	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
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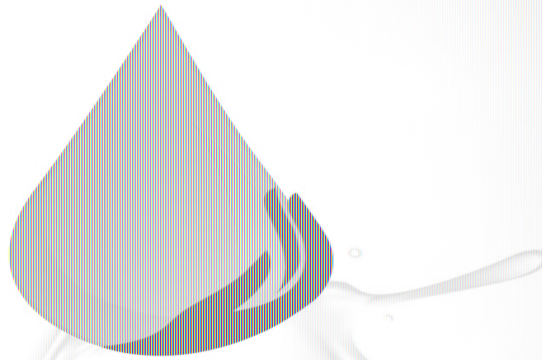
Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients: Glycerin, triethanolamine (Trolamine), polyacrylic acid (Carbomer), water.

LOT No. :
BEST BEFORE:

Package label- Principal Display Panel

473.12 mL NDC: 78477-001-02



HAND SANITIZER Non Sterile Solution

Alcohol Antiseptic 80%

16 fl oz (473.12 mL)

Drug Facts

Active ingredient(s)

Alcohol 80% v/v.....

Use(s)

Hand sanitizer to help reduce bacteria.
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 reach of children.
If contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritated skin or other signs of a serious condition.

Keep out of reach of children. If swallowed, call 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 to avoid swallowing.

Other information

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

Inactive ingredients: Glycerin, triethylamine, Carbomer, water.

Manufactured by:

COMBUSTIBLES DEL NORE

Av. Batallón de San Patricio #111

66269, San Pedro Garza García, N.L.

Ph.: (52) 81 199 99714.

E-mail: adelgado@conosa.com.mx

PRODUCT OF MEXICO

LOT No. :

BEST BEFORE:

Package Label- Principal Display Panel

946.24 mL NDC: 78477-001-03



HAND SANITIZER Non Sterile Solution

Alcohol Antiseptic 80%

32 fl oz (946.24 mL)

Drug Facts

Active ingredient(s)

Alcohol 80% v/v.....

Use(s)

Hand sanitizer to help reduce bacte
For use when soap and water are n

Warnings

**For external use only. Flammable
Keep away from heat or flame**

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Directions

- Place enough product on hands to Rub hands together until dry.
- Supervise children under 6 years o avoid swallowing

Other information

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

Inactive ingredients: Glycerin, trieti acid (Carbomer), water.

Manufactured by:

COMBUSTIBLES DEL NORESTE

Av. Batallón de San Patricio #111 Piso

66269, San Pedro Garza García, Nuev

Ph.: (52) 81199 99714.

E-mail: adelgado@conosa.com.mx

PRODUCT OF MEXICO

LOT No. :

BEST BEFORE:

Package Label- Principal Display Panel

3780 mL NDC: 78477-001-04



HAND SANITIZER Non Sterile Solution

Alcohol Antiseptic 80%

128 fl oz (3.78 L)

Drug Facts

Active ingredient(s)

Alcohol 80% v/v.....

Use(s)

Hand sanitizer to help reduce bacte
For use when soap and water are n

Warnings

**For external use only. Flammable
Keep away from heat or flame**

Do not use

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When using this product keep out
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Directions

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Other information

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- Avoid freezing and excessive heat

Inactive ingredients: Glycerin, trieti
acid (Carbomer), water.

Manufactured by:

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66269, San Pedro Garza García, Nuev

Ph.: (52) 81 199 99714.

E-mail: adelgado@conosa.com.mx

PRODUCT OF MEXICO

LOT No. :

BEST BEFORE:

Package Label- Principal Display Panel

20000 mL NDC: 78477-001-05



HAND SANITIZER Non Sterile Solution

Alcohol Antiseptic 80%

676.36 fl oz (20 L)

Drug Facts

Active ingredient(s)

Alcohol 80% v/v.....

Use(s)Hand sanitizer to help reduce bacteria
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 contact with eyes, rinse eyes thoroughly if contact occurs**Stop use and ask a doctor** if irritated skin or other signs of a serious condition.**Keep out of reach of children.** If swallowed, call 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 to avoid swallowing.

Other information

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

Inactive ingredients: Glycerin, triethylamine, Carbomer, water.

Manufactured by:

COMBUSTIBLES DEL NORESTE

Av. Batallón de San Patricio #111 Piso

66269, San Pedro Garza García, Nuevo

Léon, Coahuila de Zaragoza, México

Ph.: (52) 81 199 99714.

E-mail: adelgado@conosa.com.mx

PRODUCT OF MEXICO

LOT No. :

BEST BEFORE:

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78477-001
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)	0.3 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL

WATER (UNII: 059QF0KO0R)	14.6 mL in 100 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78477-001-01	236.56 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
2	NDC:78477-001-02	473.12 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
3	NDC:78477-001-03	946.24 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
4	NDC:78477-001-04	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
5	NDC:78477-001-05	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	06/08/2020	

Labeler - Combustibles del Noreste DG S de RL de CV (951576921)

Registrant - Combustibles del Noreste DG S de RL de CV (951576921)

Establishment

Name	Address	ID/FEI	Business Operations
Combustibles del Noreste DG S de RL de CV		951576921	manufacture(78477-001)

Revised: 12/2020

Combustibles del Noreste DG S de RL de CV