

NANOXEN HAND SANITIZER- alcohol gel

Nano Coating Technologies, 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 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, triethanolamine (Trolamine), water.

Package Label - Principal Display Panel

250 mL NDC: 79473-001-01



Nanoxen
Gel

Hand Sanitizer


Alcohol Antiseptic 80%
Non-sterile topical solution

NET. CONT.
8.45 fl oz (250ml)

DRUG FACTS

Active ingredient(s) Alcohol 80% v/v	Purpose Antiseptic
Uses(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 <ul style="list-style-type: none">• 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 <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 glycerin, polyacrylic acid (carbomer), purified water USP, and triethanolamine (trolamine).	


Manufactured by:
Nano Coating Technologies S.A de C.V
1088 Antea Avenue, Int. 601-A Querétaro México 76100.
Tel: (+52) 442-245-2400 www.nctmexico.com.mx



7 503030 201162

Package Label- Principal Display Panel

500 mL NDC: 79473-001-02



Nanoxen
Gel

Hand Sanitizer


Alcohol Antiseptic 80%
Non-sterile topical solution

NET. CONT.
16.90 fl oz (500ml)

DRUG FACTS

Active ingredient(s) Alcohol 80% v/v	Purpose Antiseptic
Uses(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 <ul style="list-style-type: none">• 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 <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 glycerin, polyacrylic acid (carbomer), purified water USP, and triethanolamine (trolamine).	

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7 503030 201156

Package Label- Principal Display Panel

1000 mL NDC: 79473-001-03



Nanoxen
Gel

Hand Sanitizer

Alcohol Antiseptic 80%
Non-sterile topical solution

NET. CONT.
33.81 fl oz (1L)

DRUG FACTS

Active ingredient(s) Alcohol 80% 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 <ul style="list-style-type: none">• 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 <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 glycerin, polyacrylic acid (carbomer), purified water USP, and triethanolamine (trolamine).	

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NANOXEN HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79473-001
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
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.5 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	1.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	17 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79473-001-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	

2	NDC:79473-001-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
3	NDC:79473-001-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	07/08/2020	

Labeler - Nano Coating Technologies, S.A. de C.V. (812763889)

Registrant - Nano Coating Technologies, S.A. de C.V. (812763889)

Establishment

Name	Address	ID/FEI	Business Operations
Enter Establishment Name		812763889	manufacture(79473-001)

Revised: 1/2021

Nano Coating Technologies, S.A. de C.V.