

HAND SANITIZER- isopropyl alcohol gel

Andes Ingredients LLC

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v)..
- c. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl 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.

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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3785.42 mL NDC: 77832-100-01

Drug Facts	
Active Ingredient(s)	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	
<ul style="list-style-type: none"> • In children less than 2 months of age 	<ul style="list-style-type: none"> • In open skin wounds
When using this product keep out of eyes, and mouth. In case of contact with eyes, rinse 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 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	
Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).	
Inactive Ingredients	

inactive ingredients

Purified water USP, glycerin, carbomer, aminomethyl propanol

MANUFACTURED BY  ANDES
INGREDIENTS
LLC

SALES@ANDESINGREDIENTS.NET

MADE IN USA



3785.42 mL NDC: 77832-100-01





ISOPROPYL ALCOHOL ANTISEPTIC 75%
NON-STERILE SOLUTION

MADE WITHOUT



KILLS 99.9%
OF GERMS & BACTERIA

1 GALLON (128 FL. OZ. / 3.78 L)

204412 mL NDC: 77832-101-54

Drug Facts	Purpose
Active Ingredient(s) Isopropyl alcohol 70% v/v.....Antiseptic	Purpose 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	
<ul style="list-style-type: none"> In children less than 2 months of age In open skin wounds 	
When using this product keep out of eyes, and mouth. In case of contact with eyes, rinse 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 Poison Control Center right away.	



ISOPROPYL ALCOHOL ANTISEPTIC 70%
NON-STERILE SOLUTION

MADE WITHOUT

- FRAGRANCES
- TRICLOSAN
- PARABENS
- DYES
- BENZALKONIUM CHLORIDE
- METHYLISOTHIAZOLINONE

**KILLS 99.9%
OF GERMS & BACTERIA**

54 GAL

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
Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).
Inactive Ingredients
Purified water USP, glycerin, carbomer, aminomethyl propanol

MANUFACTURED BY



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MADE IN USA



Drug Facts	
Active Ingredient(s) Isopropyl alcohol 70% v/v.....	Purpose 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	
<ul style="list-style-type: none"> In children less than 2 months of age In open skin wounds 	
When using this product keep out of eyes, and mouth. In case of contact with eyes, rinse 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 Poison Control Center right away.	

ADVANCED HAND SANITIZER

KILLS 99.9% OF ALL GERMS

ISOPROPYL ALCOHOL ANTISEPTIC 70%
NON-STERILE GEL SOLUTION

2 FL. OZ.

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
Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).
Inactive Ingredients
Purified water USP, glycerin, carbomer, aminomethyl propanol



MADE IN MIAMI, FL

Drug Facts	Purpose
Active Ingredient(s) Isopropyl alcohol 75%v/v.....Antiseptic	Purpose 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	
<ul style="list-style-type: none"> In children less than 2 months of age In open skin wounds 	
When using this product keep out of eyes, and mouth. In case of contact with eyes, rinse 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 Poison Control Center right away.	



HAND SANITIZER

ISOPROPYL ALCOHOL ANTISEPTIC 75%
NON-STERILE SOLUTION

MADE WITHOUT

- X FRAGRANCES
- X TRICLOSAN
- X PARABENS
- X DYES
- X BENZALKONIUM CHLORIDE
- X METHYLISOTHIAZOLINONE

KILLS 99.9%
OF GERMS & BACTERIA

55 GAL (208.2 L)

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	Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).
Inactive Ingredients	Purified water USP, glycerin, carbomer, aminomethyl propanol

MANUFACTURED BY



SALES@ANDESINGREDIENTS.NET

MADE IN USA



354 ml NDC: 77832-100-12

Drug Facts	Purpose
Active Ingredient(s) Isopropyl alcohol 75%v/v.....Antiseptic	Purpose 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	
<ul style="list-style-type: none"> In children less than 2 months of age In open skin wounds 	
When using this product keep out of eyes, and mouth. In case of contact with eyes, rinse 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 Poison Control Center right away.	



ISOPROPYL ALCOHOL ANTISEPTIC 75%
NON-STERILE SOLUTION

MADE WITHOUT

- X FRAGRANCES
- X TRICLOSAN
- X PARABENS
- X DYES
- X BENZALKONIUM CHLORIDE
- X METHYLISOTHIAZOLINONE

**KILLS 99.9%
OF GERMS & BACTERIA**

250 GALLON TOTE

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	Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).
Inactive Ingredients	Purified water USP, glycerin, carbomer, aminomethyl propanol

MANUFACTURED BY



SALES@ANDESINGREDIENTS.NET

MADE IN USA



Drug Facts	Purpose
Active Ingredient(s) Isopropyl alcohol 75%v/v.....Antiseptic	Purpose 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	
<ul style="list-style-type: none"> In children less than 2 months of age In open skin wounds 	
When using this product keep out of eyes, and mouth. In case of contact with eyes, rinse 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 Poison Control Center right away.	



ISOPROPYL ALCOHOL ANTISEPTIC 75%
NON-STERILE SOLUTION

MADE WITHOUT

- X FRAGRANCES
- X TRICLOSAN
- X PARABENS
- X DYES
- X BENZALKONIUM CHLORIDE
- X METHYLISOTHIAZOLINONE

**KILLS 99.9%
OF GERMS & BACTERIA**

12 FL. OZ. (354 ML)

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
Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).
Inactive Ingredients
Purified water USP, glycerin, carbomer, aminomethyl propanol

MANUFACTURED BY



SALES@ANDESINGREDIENTS.NET

MADE IN USA





MADE WITHOUT

- X FRAGRANCES
- X TRICLOSAN
- X PARABENS
- X DYES
- X BENZALKONIUM CHLORIDE
- X METHYLISOTHIAZOLINONE

KILLS 99.9% OF GERMS & BACTERIA

16 FL. OZ. (473 ML)

Drug Facts	Purpose Antiseptic
Active Ingredient(s) Isopropyl alcohol 75%w/v	
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 <ul style="list-style-type: none"> • In children less than 2 months of age • In open skin wounds 	
When using this product keep out of eyes, and mouth. In case of contact with eyes, rinse 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 to 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 Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, purified water USP	

DISTRIBUTED BY
 ALLERGAN

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77832-100
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77832-100-12	350 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77832-100-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

3	NDC:77832-100-55	208197 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77832-100-25	946352 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77832-100-01	3785.42 mL in 1 BOTTLE, PLASTIC; 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	

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77832-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77832-101-02	59.15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77832-101-54	204412 mL in 1 DRUM; 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	

Registrant - Andes Ingredients LLC (087901876)

Establishment

Name	Address	ID/FEI	Business Operations
Andes Ingredients LLC		087901876	manufacture(77832-100, 77832-101)

Revised: 6/2020

Andes Ingredients LLC