

**SANIKEM GEL PLUS- isopropyl alcohol gel**  
**Italkem Srl**

*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. Hydrogen peroxide (0.125% v/v).
- d. 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

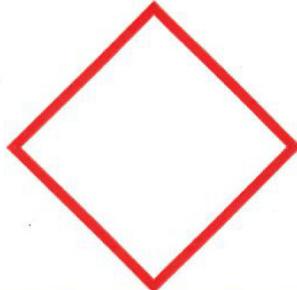
## Package Label - Principal Display Panel

4500 ml NDC: 74948-001-45

9000 ml NDC: 74948-001-90

29000 ml NDC: 74948-001-29

58000 ml NDC: 74948-001-58



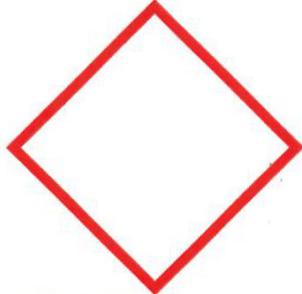
# SANIKEM<sup>®</sup> Gel Plus UN 1993

Isopropyl Alcohol Antiseptic 75% Topical Solution. Antiseptic Hand Rub/Hand Sanitiser Non-sterile Solution  
PURPOSE: Antiseptic - USES: Health care personnel hand rub to help reduce bacteria that potentially can cause disease - 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 - DILUTION: Ready to use  
ACTIVE INGREDIENTS: Isopropyl alcohol 75% v/v - N°CAS: 67-63-0. NET CONTENT: 4500/9000/29000/58000 mL  
WARNING: 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 - EXPIRY DATE: 6 months after opening the package.  
HAZARD STATEMENTS: H225 Highly flammable liquid and vapour. PRECAUTIONARY STATEMENTS: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/ protective clothing/ eye protection / face protection. P370+P378 In case of fire: use powder, foam, water spray, carbon dioxide to extinguish. P233 Keep container tightly closed. P102 Keep out of reach of children.  
FIRST AID MEASURES: Eye contact: Wash immediately with running water for at least 15 minutes. If irritation persists, consult a doctor. Ingestion: Drink plenty of water immediately, do not induce vomiting, call a doctor immediately. Inhalation: Move the person outdoor to a well-ventilated place. If irritation persists consult a doctor.  
CONSERVATION METHOD: Keep in a cool and dry place. Validity of the solution: 36 months. The expiration date indicated refers to the product in its intact and correctly stored container - OTHER INFORMATION: Store between 15-30°C (59-86F); Avoid freezing and excessive heat above 40°C (104F) - INACTIVE INGREDIENTS: Glycerin, Hydrogen Peroxide, Purified water USP - DISPOSAL: Non-hazardous waste. Dispose of in accordance with local regulations, with reference to the levels for Active Chlorine, Chlorides, COD and BOD. Do not dispose polyethylene containers into the environment after use. Read the label before use. Keep out of reach of children.

## 9000mL

**italkem**  
srl

Via A. Einstein, 5 - 15053 Castelnuovo Scrivia (AL)  
Tel. 0131.823851 - Fax 0131.825764 [www.italkem.it](http://www.italkem.it)



# SANIKEM<sup>®</sup> Gel Plus UN 1993

Isopropyl Alcohol Antiseptic 75% Topical Solution. Antiseptic Hand Rub/Hand Sanitiser Non-sterile Solution

PURPOSE: Antiseptic - USES: Health care personnel hand rub to help reduce bacteria that potentially can cause disease - 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 - DILUTION: Ready to use - ACTIVE INGREDIENTS: Isopropyl alcohol 75% v/v - N°CAS: 67-63-0. NET CONTENT: 4500/9000/29000/58000 mL

WARNING: 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 - EXPIRY DATE: 6 months after opening the package.

HAZARD STATEMENTS: H225 Highly flammable liquid and vapour. PRECAUTIONARY STATEMENTS: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/ protective clothing/ eye protection / face protection. P370+P378 In case of fire: use powder, foam, water spray, carbon dioxide to extinguish. P233 Keep container tightly closed. P102 Keep out of reach of children.

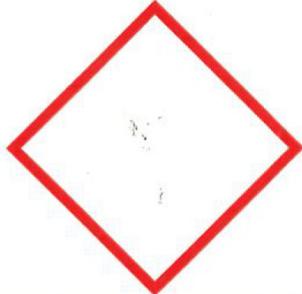
FIRST AID MEASURES: Eye contact: Wash immediately with running water for at least 15 minutes. If irritation persists, con-sult a doctor. Ingestion: Drink plenty of water immediately, do not induce vomiting, call a doctor immediately. Inhalation: Move the person outdoor to a well-ventilated place. If irritation persists consult a doctor.

CONSERVATION METHOD: Keep in a cool and dry place. Validity of the solution: 36 months. The expira-tion date indicated refers to the product in its intact and correctly stored container - OTHER INFORMATION: Store between 15-30°C (59-86F); Avoid freezing and excessive heat above 40°C (104F) - INACTIVE INGREDIENTS: Glycerin, Hydrogen Peroxide, Purified water USP - DISPOSAL: Non-hazardous waste. Dispose of in accordance with local regulations, with reference to the levels for Active Chlorine, Chlorides, COD and BOD. Do not dispose polyethylene containers into the environment after use. Read the label before use. Keep out of reach of children.

## 29000mL

**italkem**  
srl

Via A. Einstein, 5 - 15053 Castelnuovo Scrivia (AL)  
Tel. 0131.823851 - Fax 0131.825764 [www.italkem.it](http://www.italkem.it)



# SANIKEM<sup>®</sup> Gel Plus UN 1993

Isopropyl Alcohol Antiseptic 75% Topical Solution. Antiseptic Hand Rub/Hand Sanitiser Non-sterile Solution

PURPOSE: Antiseptic - USES: Health care personnel hand rub to help reduce bacteria that potentially can cause disease - 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 - DILUTION: Ready to use - ACTIVE INGREDIENTS: Isopropyl alcohol 75% v/v - N°CAS: 67-63-0. NET CONTENT: 4500/9000/29000/58000 mL

WARNING: 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 - EXPIRY DATE: 6 months after opening the package.

HAZARD STATEMENTS: H225 Highly flammable liquid and vapour. PRECAUTIONARY STATEMENTS: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/ protective clothing/ eye protection / face protection. P370+P378 In case of fire: use powder, foam, water spray, carbon dioxide to extinguish. P233 Keep container tightly closed. P102 Keep out of reach of children.

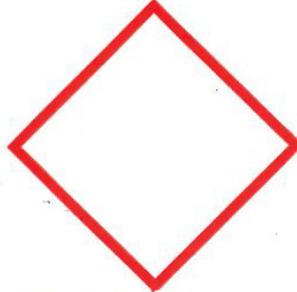
FIRST AID MEASURES: Eye contact: Wash immediately with running water for at least 15 minutes. If irritation persists, con-sult a doctor. Ingestion: Drink plenty of water immediately, do not induce vomiting, call a doctor immediately. Inhalation: Move the person outdoor to a well-ventilated place. If irritation persists consult a doctor.

CONSERVATION METHOD: Keep in a cool and dry place. Validity of the solution: 36 months. The expira-tion date indicated refers to the product in its intact and correctly stored container - OTHER INFORMATION: Store between 15-30°C (59-86F); Avoid freezing and excessive heat above 40°C (104F) - INACTIVE INGREDIENTS: Glycerin, Hydrogen Peroxide, Purified water USP - DISPOSAL: Non-hazardous waste. Dispose of in accordance with local regulations, with reference to the levels for Active Chlorine, Chlorides, COD and BOD. Do not dispose polyethylene containers into the environment after use. Read the label before use. Keep out of reach of children.

## 4500mL

**italkem**  
srl

Via A. Einstein, 5 - 15053 Castelnuovo Scrivia (AL)  
Tel. 0131.823851 - Fax 0131.825764 [www.italkem.it](http://www.italkem.it)



# SANIKEM<sup>®</sup> Gel Plus UN 1993

isopropyl Alcohol Antiseptic 75% Topical Solution. Antiseptic Hand Rub/Hand Sanitiser Non-sterile Solution

PURPOSE: Antiseptic - USES: Health care personnel hand rub to help reduce bacteria that potentially can cause disease - 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 - DILUTION: Ready to use - ACTIVE INGREDIENTS: Isopropyl alcohol 75% v/v - N°CAS: 67-63-0. NET CONTENT: 4500/9000/29000/58000 mL

WARNING: 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 - EXPIRY DATE: 6 months after opening the package.

HAZARD STATEMENTS: H225 Highly flammable liquid and vapour. PRECAUTIONARY STATEMENTS: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/ protective clothing/ eye protection / face protection. P370+P378 In case of fire: use powder, foam, water spray, carbon dioxide to extinguish. P233 Keep container tightly closed. P102 Keep out of reach of children.

FIRST AID MEASURES: Eye contact: Wash immediately with running water for at least 15 minutes. If irritation persists, consult a doctor. Ingestion: Drink plenty of water immediately, do not induce vomiting, call a doctor immediately. Inhalation: Move the person outdoor to a well-ventilated place. If irritation persists consult a doctor.

CONSERVATION METHOD: Keep in a cool and dry place. Validity of the solution: 36 months. The expiration date indicated refers to the product in its intact and correctly stored container - OTHER INFORMATION: Store between 15-30°C (59-86F); Avoid freezing and excessive heat above 40°C (104F) - INACTIVE INGREDIENTS: Glycerin, Hydrogen Peroxide, Purified water USP - DISPOSAL: Non-hazardous waste. Dispose of in accordance with local regulations, with reference to the levels for Active Chlorine, Chlorides, COD and BOD. Do not dispose polyethylene containers into the environment after use. Read the label before use. Keep out of reach of children.

## 58000mL

**italkem**  
srl

Via A. Einstein, 5 - 15053 Castelnuovo Scrivia (AL)  
Tel. 0131.823851 - Fax 0131.825764 [www.italkem.it](http://www.italkem.it)

GEL PLUS version



# SANIKEM<sup>®</sup>

## HIGH-ACTION RAPID SANITIZER



### SANIKEM GEL PLUS

isopropyl alcohol gel

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74948-001
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 75 mL

#### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 75 mL
WATER (UNII: 059QF0KO0R)	21.8 mL in 75 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	1.7 mL in 75 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74948-001-45	4500 mL in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	
2	NDC:74948-001-90	9000 mL in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	
3	NDC:74948-001-29	29000 mL in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	
4	NDC:74948-001-58	58000 mL in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

**Labeler** - Italkem Srl (544450856)

**Registrant** - Italkem Srl (544450856)

## Establishment

Name	Address	ID/FEI	Business Operations
Italkem Srl		544450856	manufacture(74948-001)

Revised: 4/2020

Italkem Srl