

SIMPA- isopropyl alcohol liquid
Kettenbach GmbH & Co. KG

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.

Hand Sanitizer

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

5L NDC: 77141-001-01

SIMPA®

Isopropyl Alcohol Antiseptic 75% Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

NDC 77141-001-01

Usage

For external use only!

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Application and Dosage

Place 3 ml of solution on hands to cover all surfaces. Keep hands moist for 30 seconds and rub hands together until dry.

Composition

2-propanol 99.8 %	59.03 g
Hydrogen peroxide 3 %	4.22 g
Glycerol 98 %	1.83 g
Purified water	to 87.08 g

Contains 2-propanol 75 % (V/V).
UN 1987



REF 13300US

51



Danger!

Hazard Statements

- H225 Highly flammable liquid and vapour.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.

Precautionary Statements

- P102 Keep out of reach of children.
Do not use in children less than 2 months of age. Supervise children under 6 years of age when using this product to avoid swallowing.
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P233 Keep container tightly closed.

Do not use on open skin wounds. When using this product keep out of eyes, ears, and mouth. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Disposal

- P501 Recycle or dispose of in accordance with current legislation, preferably by a collector or an approved company.

Storage

Keep container tightly closed and in a cool (between 15–30°C/59–86°F), well-ventilated place. Avoid freezing and excessive heat above 40°C/104°F. Protect from sunlight.

Use

Do not use past the specified date. Use within 6 months after opening.

State of Information

04/2020

 Kettenbach GmbH & Co. KG
Im Heerfeld 7
35713 Eschenburg
Germany
25211/1920

Distributed in the U.S. by:
Kettenbach LP
62-64 Enter Lane
Islandia, NY 11749, USA
www.kettenbach.com

Made
in
Germany 



1L NDC: 77141-001-02



SIMPA®

Isopropyl Alcohol Antiseptic 75 % Topical Solution

Antiseptic Hand Rub
Non-sterile Solution



NDC 77141-001-02

Usage

For external use only!
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Application and Dosage

Place 3 ml of solution on hands to cover all surfaces. Keep hands moist for 30 seconds and rub hands together until dry.

Composition

2-propanol 99.8 %	59.03 g
Hydrogen peroxide 3 %	4.22 g
Glycerol 98 %	1.83 g
Purified water	to 87.08 g

Contains 2-propanol
75 % (V/V).
UN 1987

REF 13302US

1000 ml

Hazard Statements

H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.



Precautionary Statements

P102 Keep out of reach of children.
Do not use in children less than 2 months of age. Supervise children under 6 years of age when using this product to avoid swallowing.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.

Do not use on open skin wounds. When using this product keep out of eyes, ears, and mouth. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER / doctor.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Disposal

P501 Recycle or dispose of in accordance with current legislation, preferably by a collector or an approved company.

Storage

Keep container tightly closed and in a cool (between 15 – 30°C/59 – 86°F), well-ventilated place. Avoid freezing and excessive heat above 40°C/104°F. Protect from sunlight.

Use

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State of Information

04/2020

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25212/1920

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5L NDC: 77141-001-03



SIMPA®

Isopropyl Alcohol Antiseptic 75% Topical Solution

Antiseptic Hand Rub Non-sterile Solution

NDC 77141-001-03

Usage

For external use only!
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Application and Dosage

Place 3 ml of solution on hands to cover all surfaces. Keep hands moist for 30 seconds and rub hands together until dry.

Composition

2-propanol 99.8 %	59.03 g
Hydrogen peroxide 3 %	4.22 g
Glycerol 98 %	1.83 g
Purified water	to 87.08 g

**Contains 2-propanol
75% (V/V).**
UN 1987

REF 13301US

500 ml



Hazard Statements: **H225** Highly flammable liquid and vapour. **H319** Causes serious eye irritation. **H336** May cause drowsiness or dizziness.

Precautionary Statements: **P102** Keep out of reach of children. Do not use in children less than 2 months of age. Supervise children under 6 years of age when using this product to avoid swallowing **P210** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **P233** Keep container tightly closed.

Do not use on open skin wounds. When using this product keep out of eyes, ears, and mouth. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. **P301 + P310** IF SWALLOWED: Immediately call a POISON CENTER/doctor **P305 + P351 + P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Disposal: **P501** Recycle or dispose of in accordance with current legislation, preferably by a collector or an approved company.

Storage: Keep container tightly closed and in a cool (between 15–30°C/59–86°F), well-ventilated place. Avoid freezing and excessive heat above 40°C/104°F. Protect from sunlight.

Use: Do not use past the specified date. Use within 6 months after opening.

State of Information: 04/2020

 Kettenbach GmbH & Co. KG 25213/1920
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www.kettenbach.com

Made
in
Germany 

SIMPA

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77141-001
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 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77141-001-01	5000 mL in 1 CANISTER; Type 0: Not a Combination Product	05/17/2020	
2	NDC:77141-001-02	1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/24/2020	
3	NDC:77141-001-03	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/10/2020	

Labeler - Kettenbach GmbH & Co. KG (316803246)

Establishment

Name	Address	ID/FEI	Business Operations
KETTENBACH GMBH & CO KG		316803246	manufacture(77141-001)

Revised: 5/2020

Kettenbach GmbH & Co. KG