

SMPLY ISOPROPYL 50- isopropyl alcohol liquid

Froggy's Fog 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. 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.

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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.

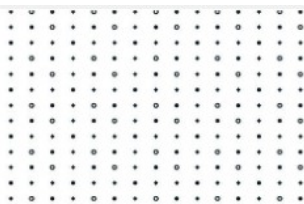
Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

SMPLY ISOPROPYL 50



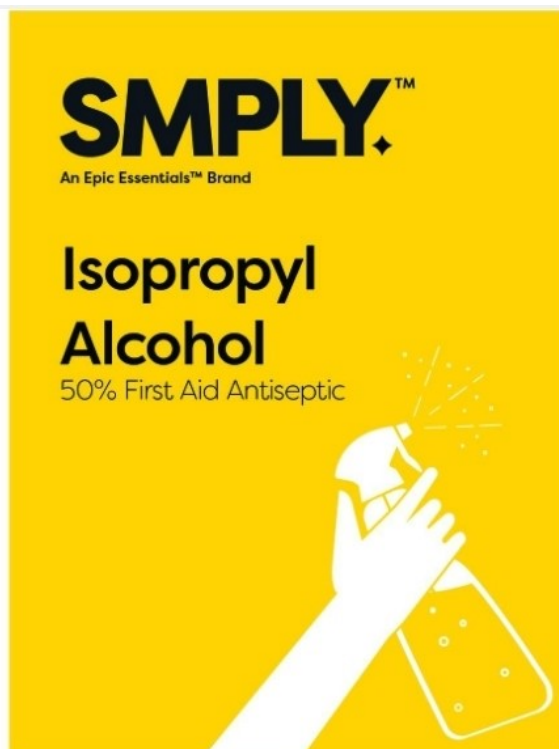
Our Simple Story

SMPLY Isopropyl Alcohol was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 91% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SMPLY.



WWW.SMPLYBRANDS.COM



Drug Facts	
ACTIVE INGREDIENT Isopropyl Alcohol 50% v/v	PURPOSE First aid antiseptic
USES helps prevent the risk of infection in: ■ minor cuts ■ scrapes ■ burns	
WARNINGS For external use only. If taken internally serious gastric disturbances will result. Flammable ■ keep away from fire of flame, heat, spark, electrical Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns When using this product ■ do not get into eyes ■ do not inhale ■ do not apply over large areas of the body ■ do not use longer than 1 week Stop use and ask doctor if the condition persists or gets worse Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
DIRECTIONS First Aid Antiseptic: Clean the affected area - Apply a small amount of product on the affected area 1 to 3 times a day - may be covered with a sterile bandage - if bandaged, let dry first	
Caution - Fumes can be acutely irritating to skin, eyes, and the respiratory system. Do not apply to irritated skin or if excessive irritation develops. Avoid getting into the eyes or mucous membranes. Avoid inhaling this product.	
OTHER INFORMATION ■ does not contain, nor is intended as a substitute for grain or ethyl alcohol	
INACTIVE INGREDIENTS purified water	

Distributed by: SMPLY.
1536 N. Main St.
Mt. Pleasant, TN 38474
615.393.6700 • NDC: 75682-800-12



12 FL OZ (355 mL)

We clean up well
together.

355mL NDC: 75682-800-12

Our Simple Story

SMPLY Isopropyl Alcohol was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 70% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SMPLY.



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SMPLY™

An Epic Essentials™ Brand

Isopropyl Alcohol 50% First Aid Antiseptic



Drug Facts

ACTIVE INGREDIENT	PURPOSE
Isopropyl Alcohol 50% v/v	First aid antiseptic
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INACTIVE INGREDIENTS purified water	

Manufactured by: Froggy's Fog
1536 N. Main St.
Mt. Pleasant, TN 38474
615.393.6700 • NDC: 75682-800-16



16 FL OZ (473 mL)

We clean up well
together.

473mL NDC: 75682-800-16

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SMPLY™

An Epic Essentials™ Brand

Isopropyl Alcohol 50% First Aid Antiseptic



Drug Facts

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Isopropyl Alcohol 50% v/v	First aid antiseptic
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INACTIVE INGREDIENTS purified water	

Distributed by: SMPLY.
1536 N. Main St.
Mt. Pleasant, TN 38474
615.393.6700 • NDC: 75682-800-32



32 FL OZ (946 mL)

We clean up well
together.

946mL NDC: 75682-800-32



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SMPLY™

An Epic Essentials™ Brand

Isopropyl Alcohol

50% First Aid Antiseptic



Drug Facts

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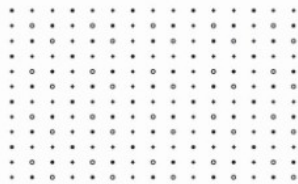
Distributed by: SMPLY
1536 N. Main St.
Mt. Pleasant, TN 38474
615.393.6700 • NDC 75682-800-01



1 US Gallon (3785 mL)

We clean up well together.

3785mL NDC: 75682-800-01



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SMPLY™

An Epic Essentials™ Brand

Isopropyl Alcohol

50% First Aid Antiseptic



Drug Facts

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INACTIVE INGREDIENTS purified water	

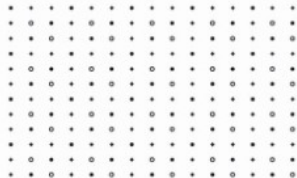
Distributed by: SMPLY.
1536 N. Main St.
Mt. Pleasant, TN 38474
615.393.6700 • NDC 75682-800-55



55 Gallons (208198 mL)

We clean up well together.

209198mL NDC: 75682-800-55



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SMPLY™

An Epic Essentials™ Brand

Isopropyl Alcohol

50% First Aid Antiseptic



Drug Facts

ACTIVE INGREDIENT Isopropyl Alcohol 50% v/v	PURPOSE First aid antiseptic
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OTHER INFORMATION ■ does not contain, nor is intended as a substitute for grain or ethyl alcohol	
INACTIVE INGREDIENTS purified water	

Distributed by: SMPLY.
1536 N. Main St.
Mt. Pleasant, TN 38474
615.393.6700 • NDC: 75682-800-25

8 40472 11984 4

250 Gallons (946353 mL)

We clean up well together.

946353 ml NDC: 75682-800-25

SMPLY ISOPROPYL 50

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75682-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	50 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75682-800-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

2	NDC:75682-800-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-800-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-800-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-800-55	2081989 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-800-25	946353 mL in 1 TANK; 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	

Labeler - Froggy's Fog LLC (144348161)

Registrant - Froggy's Fog LLC (144348161)

Establishment

Name	Address	ID/FEI	Business Operations
Froggy's Fog LLC		144348161	manufacture(75682-800)

Revised: 3/2021

Froggy's Fog LLC