

HAND SANITIZER- alcohol liquid Forms Plus Inc

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)

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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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, Peppermint Oil

Package Label - Principal Display Panel

3785 mL NDC: 77242-100-01

SHARK ARMOR

Hand Sanitizer



Drug Facts

Can be used on hands and surfaces.

Active Ingredients	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Inactive Ingredients	
Glycerine	Water
Hydrogen Peroxide	Peppermint Oil

Questions/Comments
Call 1-844-866-9381
Monday-Friday 8:00am - 5:00pm

Warnings
Flammable. Keep away from heat or flame.
Store between 59-86° F.
For external use only.

When using this product
Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if
Irritation and redness persist

Keep out of reach of children
If swallowed, get medical help promptly

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SHARK ARMOR

Hand Sanitizer



Re-Orders:
www.PrintShark.co

1010700 mL NDC: 77242-100-02

SHARK ARMOR

Hand Sanitizer

Drug Facts

Can be used on hands and surfaces.

Active Ingredients	Purpose
Ethyl Alcohol 80% v/v	Antiseptic

Inactive Ingredients	
Glycerine	Water
Hydrogen Peroxide	Peppermint Oil

Questions/Comments
Call 1-844-866-9381
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UN 1987, ALCOHOLS, nos HAZ 3, PG III

267 GALLON/TOTES

LOT#

WARNING



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3435 Breckinridge Blvd., Suite 130
Duluth GA, 30096

P: 1-844-866-9381
E: sales@printshark.co
W: www.printshark.co



Re-Orders:
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18927 mL NDC: 77242-100-03

SHARK ARMOR

Hand Sanitizer

Drug Facts	
Can be used on hands and surfaces.	
Active Ingredients	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic
Inactive Ingredients	
Glycerine	Water
Hydrogen Peroxide	Peppermint Oil
Questions/Comments	
Call 1-844-866-9381	
Monday-Friday 8:00am - 5:00pm	
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If swallowed, get medical help promptly	
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UN 1987, ALCOHOLS, nos HAZ 3, PG III

5 GALLON/PAIL

LOT#

WARNING



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HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77242-100(NDC:75569-100)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	77.7 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	2 mL in 100 mL
WATER (UNII: 059QF0KO0R)	17.25 mL in 100 mL
PEPPERMINT OIL (UNII: AV092KU4JH)	0.05 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77242-100-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/17/2020	
2	NDC:77242-100-02	1010700 mL in 1 TANK; Type 0: Not a Combination Product	04/17/2020	
3	NDC:77242-100-03	18927 mL in 1 PAIL; Type 0: Not a Combination Product	04/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/17/2020	

Labeler - Forms Plus Inc (131325953)

Registrant - Forms Plus Inc (131325953)

Establishment

Name	Address	ID/FEI	Business Operations
Forms Plus Inc		131325953	relabel(77242-100)

Revised: 5/2020

Forms Plus Inc