

ALL HANDS CO. HAND SANITIZER- alcohol liquid
Specified Coating Technologies 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. 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

Flammable. Keep away from heat or flame. For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product

Do not use in eyes. In case of contact with eyes, rinse with water.

Stop use and ask a doctor if

Irritation and redness persist.

Stop use and ask a doctor if

Irritation or redness persist.

Keep out of reach of children

If swallowed, get medical help promptly.

Directions

Place enough product on hands to cover all surfaces. Rub until dry.

Other information

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

Inactive ingredients

Glycerine

Hydrogen Peroxide

Water

Questions/ Comments

Call 616-216-6395

Monday-Friday 8:00am-5:00pm EST

Package Label - Principal Display Panel

4oz 119mL NDC: 77163-616-04 Small Packaging



Instant Hand Sanitizer



All Hands Co.

4oz/ 119ml

6oz 179mL NDC: 77163-616-06 Small Packaging

Drug Facts	
Can be used on hands and surfaces.	
Active Ingredients	Purpose
80% Ethyl Alcohol.....	Antibacterial
Inactive Ingredients	
Kosher Natural Glycerine Hydrogen Peroxide Water	
Directions	
Place enough product on hands or surfaces to cover all areas. Rub until dry.	
Questions/Comments	
Call 616-216-6395 Monday-Friday 8:00am-5:00pm EST	
Warnings	
Flammable. Keep away from fire or flame. For external use only.	
When using this product	
Do not use in eyes. In case of contact with eyes, rinse 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.	
Packaged and distributed by	
All Hands Company Grand Rapids, MI www.allhandscompany.com	  All Hands Co. <small>by SPECIFIED</small>

Advanced Liquid Formula



Instant Hand Sanitizer



All Hands Co.

6oz/ 179ml

1/2 Gallon 1.89L NDC: 77163-616-64 Small Packaging

Drug Facts	
Can be used on hands and surfaces.	
Active Ingredients	Purpose
80% Ethyl Alcohol.....	Antibacterial
Inactive Ingredients	
Kosher Natural Glycerine Hydrogen Peroxide Water	
Directions	
Place enough product on hands or surfaces to cover all areas. Rub until dry.	
Questions/Comments	
Call 616-216-6395 Monday-Friday 8:00am-5:00pm EST	
Warnings	
Flammable. Keep away from fire or flame. For external use only.	
When using this product	
Do not use in eyes. In case of contact with eyes, rinse 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.	
Packaged and distributed by	
All Hands Company Grand Rapids, MI www.allhandscompany.com	  All Hands Co. <small>by SPECIFIED</small>

Advanced Liquid Formula



All Hands Co.

Instant
Hand Sanitizer

Advanced Liquid
Refill

½ Gallon (64oz)/ 1.89 L

Drug Facts

Can be used on hands and surfaces.

Active Ingredients

Purpose

80% Ethyl Alcohol.....Antibacterial

Inactive Ingredients

Kosher Natural Glycerine
Hydrogen Peroxide
Water

Directions

Place enough product on hands or surfaces to cover all areas.
Rub until dry.

Questions/Comments

Call 616-216-6395
Monday-Friday 8:00am-5:00pm EST

Warnings

Flammable. Keep away from fire or flame.
For external use only.

When using this product

Do not use in eyes. In case of contact with eyes,
rinse 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.

Packaged and distributed by

All Hands Company
Grand Rapids, MI
www.allhandscompany.com



All Hands Co.
by SPECIFIED

1 Gallon 3.78L NDC: 77163-616-01 Small Packaging



All Hands Co.

Instant
Hand Sanitizer

Advanced Liquid
Refill

1 Gallon (128oz) / 3.78L

Drug Facts

Can be used on hands and surfaces.

Active Ingredients	Purpose
80% Ethyl Alcohol.....	Antibacterial

Inactive Ingredients
 Kosher Natural Glycerine
 Hydrogen Peroxide
 Water

Directions
 Place enough product on hands or surfaces to cover all areas.
 Rub until dry.

Questions/Comments
 Call 616-216-6395
 Monday-Friday 8:00am-5:00pm EST

Warnings
 Flammable. Keep away from fire or flame.
 For external use only.

When using this product
 Do not use in eyes. In case of contact with eyes,
 rinse 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.

Packaged and distributed by

All Hands Company
 Grand Rapids, MI
 www.allhandscompany.com



All Hands Co.
 by SPECIFIED

ALL HANDS CO. HAND SANITIZER

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77163-616

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77163-616-04	119 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/24/2020	
2	NDC:77163-616-06	179 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/24/2020	
3	NDC:77163-616-64	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	
4	NDC:77163-616-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

Labeler - Specified Coating Technologies LLC (034901858)

Establishment

Name	Address	ID/FEI	Business Operations
Specified Coating Technologies LLC		034901858	pack(77163-616) , label(77163-616) , repack(77163-616) , relabel(77163-616) , manufacture(77163-616)

Revised: 5/2020

Specified Coating Technologies LLC