GENERIC -HAND SANITIZER- generic specialties gel
Generic Specialties, 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:

Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
Triethanolamine
Vitamin E
Aloevera extract
Acrylate crosspolymer
Fragrance
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 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, anti-microbial, Hand Sanitizer

See details in the labels attached below....

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

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

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222

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.
- As referenced on the product labels.

Other information

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

Inactive ingredients

Acrylate Crosspolymer, Triethanolamine, Vitamin E, Alovera extract, Ethyl Alcohol, Fragrance, Water

Package Label - Principal Display Panel

1.69 FL OZ (50 ml)

2X SANITIZING STRENGTH

Generic®

MOISTURIZING

HAND SANITIZER

NON-STERILE SOLUTION

KILLS 99.9% OF ILLNESS CAUSING GERMS†

WITH VITAMIN E

REFRESHING GEL

Leaves Hands Feeling Soft

1.69 FL OZ (50 ml)

Kills 99.9% of most common, germs that may cause illness

Drug Facts

Active ingredient	*Purpose*
Ethyl alcohol 70% v/v.....	Antimicrobial

Uses

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

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Directions

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Other information

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

Inactive ingredients Water (Aqua), Aloevera Extract, Vitamin E, Fragrance, Triethanolamine, Acrylate crosspolymer

visit www.genericspecialties.com for more information

8 09332 31000 5

NDC # 78985-001-01

Distributed by: Generic Specialties, Inc.-USA

Questions: Email: service@genericspecialties.com

EXP 01/2022

TRAVEL SIZE

3 FL OZ (89 ml)

2X SANITIZING STRENGTH

Generic®

MOISTURIZING

HAND SANITIZER

NON-STERILE SOLUTION

TRAVEL SIZE

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Directions

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Other information

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Inactive ingredients Water (Aqua), Aloevera Extract, Vitamin E, Fragrance, Triethanolamine, Acrylate crosspolymer

visit www.genericspecialties.com for more information

8 09332 31010 4

NDC # 78985-001-02

Distributed by: Generic Specialties, Inc.-USA

Questions: Email: service@genericspecialties.com

EXP 01/2022

3.38 FL OZ (100 ml)

2X SANITIZING STRENGTH

Generic®

MOISTURIZING
HAND SANITIZER

NON-STERILE SOLUTION

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WITH VITAMIN E

REFRESHING GEL

Leaves Hands Feeling Soft

3.38 FL OZ (100 ml)

Kills 99.9% of most common, germs that may cause illness

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70% v/v.....	Antimicrobial

Uses

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 at 1-800-222-1222

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 Water (Aqua), Aloevera Extract, Vitamin E, Fragrance, Triethanolamine, Acrylate crosspolymer

visit www.genericspecialties.com for more information

8 09332 31020 3

NDC # 78985-001-03

Distributed by: Generic Specialties, Inc.-USA
Questions: Email: service@genericspecialties.com

EXP 01/2022

6.76 FL OZ (200 ml)

2X SANITIZING STRENGTH

Generic®

MOISTURIZING
HAND SANITIZER

NON-STERILE SOLUTION

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REFRESHING GEL

Leaves Hands Feeling Soft

6.76 FL OZ (200 ml)

Kills 99.9% of most common, germs that may cause illness

Drug Facts

Active ingredient	*Purpose*
Ethyl alcohol 70% v/v.....	Antimicrobial

Uses

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Warnings

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Directions

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- 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 Water (Aqua), Aloevera Extract, Vitamin E, Fragrance, Triethanolamine, Acrylate crosspolymer

visit www.genericspecialties.com for more information

8 09332 31030 2

NDC # 78985-001-04

Distributed by: Generic Specialties, Inc.-USA
Questions: Email: service@genericspecialties.com

EXP 01/2022

11.83 FL OZ (350 ml)

2X SANITIZING STRENGTH

Generic®

MOISTURIZING
HAND SANITIZER

NON-STERILE SOLUTION

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11.83 FL OZ (350 ml)

Kills 99.9% of most common, germs that may cause illness

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70% v/v.....	Antimicrobial

Uses

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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 Water (Aqua), Aloevera Extract, Vitamin E, Fragrance, Triethanolamine, Acrylate crosspolymer

visit www.genericspecialties.com for more information

8 09332 31070 8

NDC # 78985-001-08

Distributed by: Generic Specialties, Inc.-USA
Questions: Email: service@genericspecialties.com

EXP 01/2022

16.9 FL OZ (500 ml)

2X SANITIZING STRENGTH

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NON-STERILE SOLUTION

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16.9 FL OZ (500 ml)

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Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70% v/v.....	Antimicrobial

Uses

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Warnings

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222

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 Water (Aqua), Aloevera Extract, Vitamin E, Fragrance, Triethanolamine, Acrylate crosspolymer

visit www.genericspecialties.com for more information

8 09332 31040 1

NDC # 78985-001-05

Distributed by: Generic Specialties, Inc.-USA
Questions: Email: service@genericspecialties.com

EXP 01/2022

33.8 FL OZ (1000 ml)

2X SANITIZING STRENGTH

Generic®

MOISTURIZING
HAND SANITIZER

NON-STERILE SOLUTION

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33.8 FL OZ (1000 ml)

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Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70% v/v.....	Antimicrobial

Uses

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
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Other information

- Store between 15-30C (59-86F)
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Inactive ingredients Water (Aqua), Aloevera Extract, Vitamin E, Fragrance, Triethanolamine, Acrylate crosspolymer

visit www.genericspecialties.com for more information

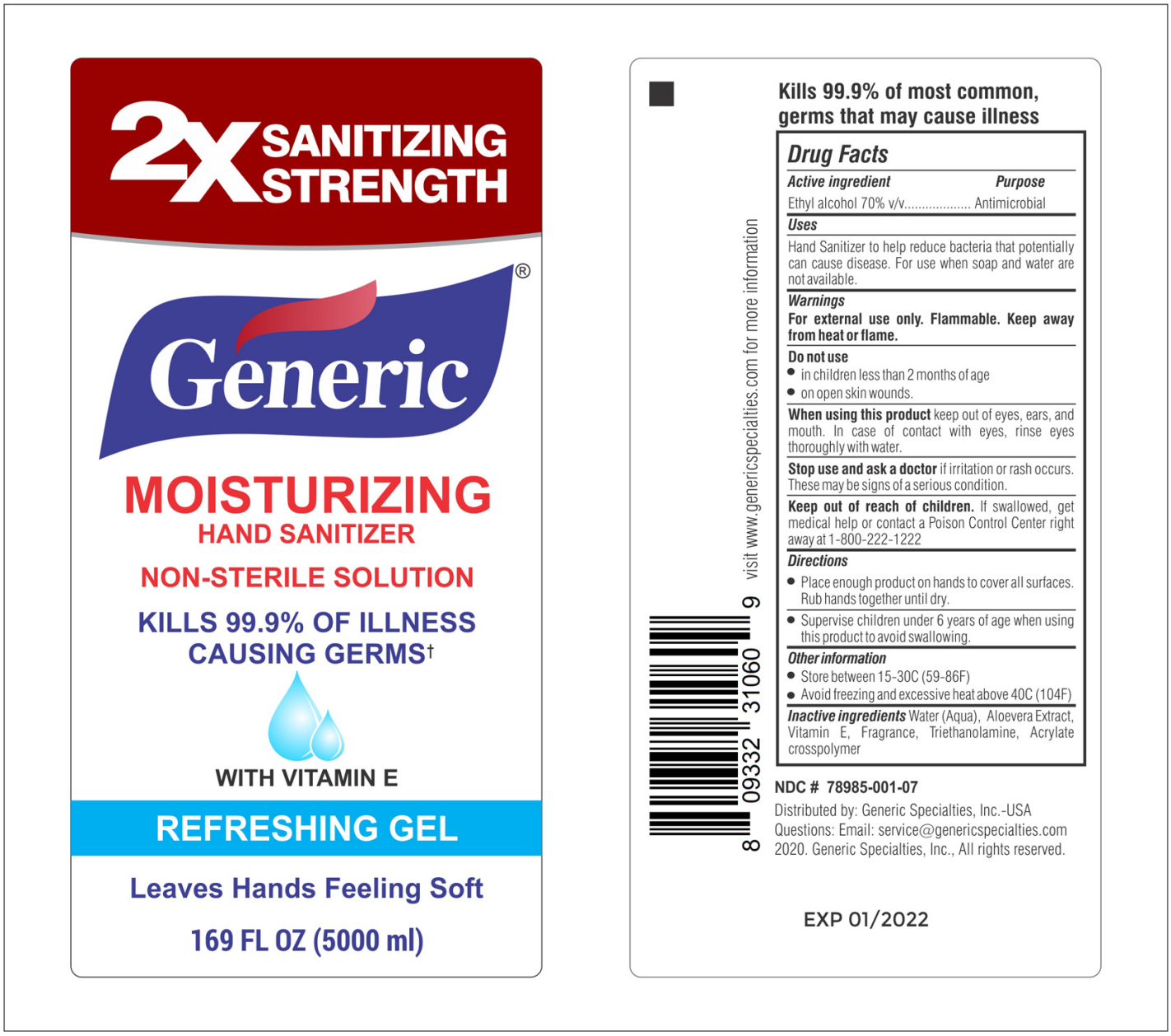
8 09332 31050 0

NDC # 78985-001-06

Distributed by: Generic Specialties, Inc.-USA
Questions: Email: service@genericspecialties.com

EXP 01/2022

169 FL OZ (5000 ml)



package label principal display panel

As mentioned below NDC codes

50 ml - 78985-001-01

89 ml - 78985-001-02

100 ml - 78985-001-03

200 ml - 78985-001-04

350 ml - 78985-001-08

500 ml - 78985-001-05

1000 ml - 78985-001-06

5000 ml - 78985-001-07

GENERIC -HAND SANITIZER

generic specialties gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78985-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.2 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.2 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.2 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.6 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78985-001-03	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
2	NDC:78985-001-04	200 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
3	NDC:78985-001-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
4	NDC:78985-001-06	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
5	NDC:78985-001-02	89 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
6	NDC:78985-001-07	5000 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
7	NDC:78985-001-08	350 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
8	NDC:78985-001-01	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

Labeler - Generic Specialties, Inc. (012830710)

Registrant - Generic Specialties, Inc. (012830710)

Establishment

Name	Address	ID/FEI	Business Operations
Generic Secialties, Inc.		012830710	manufacture(78985-001)