HAND SANITIZER- alcohol gel Todd's BBI International 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 70% 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, isopropyl alcohol, PEG-6 (and) AMP-acrylates/vinyl isodecanoate crosspolymer, purified water

Package Label - Principal Display Panel



InspireMarketingServices.com 888.914.1400

Gel **Hand Sanitizer**

For Refill Purpose Only

Sparkling Citrus

Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution

DISTRIBUTED BY: TODD'S BBI MADISON, NE 68748 1 (800) 247- 5363

125.1 FL OZ (3.7L)

Drug Facts

Active ingredient

Purpose

Ethyl alcohol 70% v/vAntiseptic

Use

Hand sanitizer to decrease bacteria on the skin that could cause disease. For use when soap and water are not available.

Warnings

For external use only: hands

Flammable. Keep away from heat or flame.

Do not use

 on 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 and lasts.

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.
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- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Do not store above 115°F · May discolor some fabrics.
- . May damage wood finishes or plastics.

Inactive ingredients

Fragrance, glycerin, isopropyl alcohol, PEG-6 (and) AMP-acrylates/vinyl isodecanoate crosspolymer, purified water

> Manufactured for: Inspire Marketing Services *For industrial use only

74616-101-01



HAND SANITIZER Alcohol Gel Antiseptic 70% Topical Solution Non-Sterile Solution

GEL **Hand Sanitizer**

FOR REFILL PURPOSE ONLY

GSR-0520-5GAL



642.4 FL OZ (19L)

Drug Facts

Active ingredient

Purpose

Ethyl alcohol 70% v/vAntiseptic

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Inactive ingredients

Fragrance, glycerin, isopropyl alcohol, PEG-6 (and) AMP-acrylates/vinyl isodecanoate crosspolymer, purified water

74616-102-02

MANUFACTURED FOR fastbeds-na | 877.422.7878

DISTRIBUTED BY TODD'S BBI MADISON, NE 68748 | 800.247.5363

*For industrial use only



Gel **Hand Sanitizer**

For Refill Purpose Only

Sparkling Citrus

Alcohol Antiseptic 70% Topical Solution Hand Sanitizer Non-sterile Solution

DISTRIBUTED BY:

FIRST CHOICE DISTRIBUTION **DES MOINES, IA 50313**

1-800-369-8733

125.1 FL OZ (3.7L)

Drug Facts

Active ingredient

Ethyl alcohol 70% v/vAntiseptic

Purpose

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Warnings

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FOR REFILL PURPOSE ONLY



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74616-102-01

MANUFACTURED FOR fastbeds-na | 877.422.7878

DISTRIBUTED BY TODD'S BBI

*For industrial use only

MADISON, NE 68748 | 800.247.5363

Gel Instant Hand Sanitizer

with Moisturizers

A waterless formula that decreases bacteria on the skin that can cause illness. Leaves hands smooth and refreshed

Drug Facts

Active ingredient

Purpose

Ethyl alcohol 70% v/vAntiseptic

Use

Hand sanitizer to decrease bacteria on the skin that could cause disease. For use when soap and water are not available.

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Inactive ingredients

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888.323.CLEA | www.cleacare.com Made in the USA Stock # CL11504-A 1125 ml (38 fl. oz)



EST. 1926

Gel **Hand Sanitizer**

For Refill Purpose Only

Sparkling Citrus

Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution

DISTRIBUTED BY: TODD'S BBI MADISON, NE 68748 1 (800) 247- 5363

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Drug Facts

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TOMORROW'S HYGIENE TODAY®

888.323.CLEA | www.cleacare.com Made in the USA Stock # CL11514 1000 ml (33.8 fl. oz.)

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74616-103

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74616-103-03	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74616-103-06	1125 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74616-103-04	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74616-103-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74616-103-02	19000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
6	NDC:74616-103-01	3700 mL in 1 JUG; 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 - Todd's BBI International Inc (080157389)

Registrant - Todd's BBI International Inc (080157389)

Establishment					
Name	Address	ID/FEI	Business Operations		
Todd's BBI International Inc		080157389	manufacture(74616-103)		

Revised: 7/2020 Todd's BBI International Inc