

HAND SANITIZER- alcohol liquid
Todds 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.

hand sanitizer

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. Hydroxypropyl Cellulose
- 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.

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.

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, Hydroxypropyl Cellulose, purified water USP

label.jpg

<h1>Todd's</h1> <p>EST. 1926</p> <h2>Hand Sanitizer</h2> <p>For Refill Purpose Only</p>	Drug Facts			
	<table border="1"><thead><tr><th>Active ingredient[s]</th><th>Purpose</th></tr></thead><tbody><tr><td>Alcohol 80% v/v.....</td><td>Antiseptic</td></tr></tbody></table> <p>Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame</p> <p>Do not use</p> <ul style="list-style-type: none">• in children less than 2 months of age• on open skin wounds <p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none">• 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. <p>Other information</p> <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F) <p>Inactive ingredients glycerin, hydroxypropyl cellulose, purified water USP</p>	Active ingredient[s]	Purpose	Alcohol 80% v/v.....
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Alcohol 80% v/v.....	Antiseptic			

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

125.1 FL OZ (3.7L) 74616-100-01

*For industrial use only

3700ml ndc 74616-100-01

HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74616-100
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
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74616-100-01	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 - Todds bbi international inc (080157389)**Registrant** - Todds bbi international inc (080157389)**Establishment**

Name	Address	ID/FEI	Business Operations
Todds bbi international inc		080157389	manufacture(74616-100)

Revised: 4/2020

Todds bbi international inc