TN DICKINSONS ANTISEPTIC HAND SANITIZER- alcohol solution Dickinson Brands Inc.

Reference Label Set Id: f60e4f72-f9bd-4639-bb1c-3a631cff7a30

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.





Magenta = Rotary White



Keep away from heat or flame.

Do not use

- in children less than 2 months of age
- on open skin or 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 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 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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

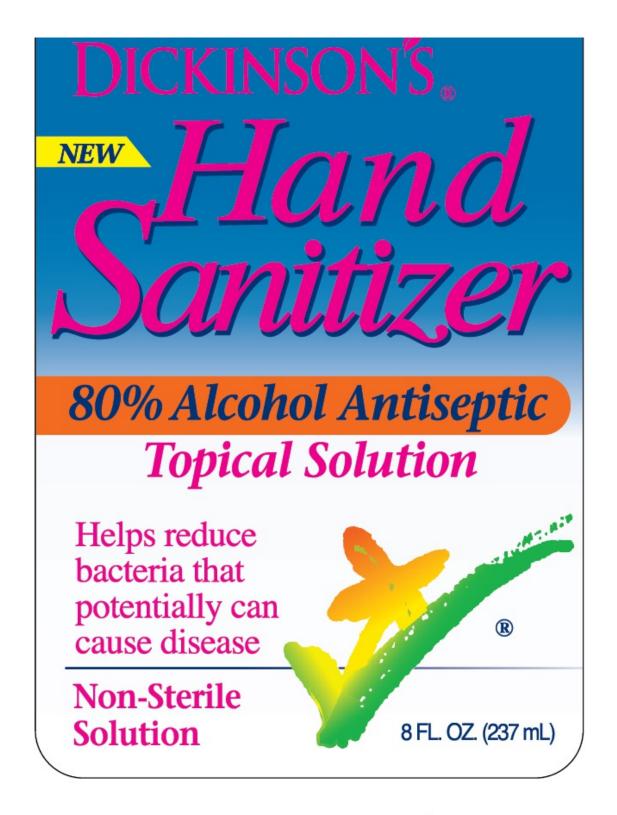
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tndickinsons.com

1-888-860-2279







Magenta = Rotary White



Drug Facts

Active ingredient

Purpose

Alcohol 80% v/v

. Antiseptic

Use 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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Antiseptic, Hand Sanitizer

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Package Label - Principal Display Panel

T.N. Dickinsons Hand Sanitizer

80% Alcohol Antiseptic Topical Solution

Helps reduce bacteria that potentially can cause disease

Non-Sterile Solution

8 FL. OZ. (237 mL)









TN DICKINSONS ANTISEPTIC HAND SANITIZER

alcohol solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52651-007	
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)	18.425 mL in 100 mL	

l	Packaging			
	# Item Cod	e Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:52651	237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/31/2020	
	2 NDC:52651	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/15/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/31/2020		

Labeler - Dickinson Brands Inc. (124620340)

Establishment				
Name	Address	ID/FEI	Business Operations	
American Distilling Inc.		065524738	manufacture(52651-007)	

Revised: 1/2022 Dickinson Brands Inc.