

PURE AND PROTECTED HAND SANITIZING LIQUID- alcohol solution

UNITERS SPA

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. 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

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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient[s]</td> <td>Purpose</td> </tr> <tr> <td>Alcohol 80% v/v.....</td> <td>Antiseptic</td> </tr> </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 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, hydrogen peroxide, purified water USP</p>	Active ingredient[s]	Purpose	Alcohol 80% v/v.....	Antiseptic	 <div style="font-size: 2em; color: green; margin-left: 10px;">Pure + Protected</div> <hr/> <div style="font-size: 2em; color: blue; margin-bottom: 10px;">Hand Sanitizing Liquid</div>  <div style="font-size: 1.5em; color: blue; margin-top: 20px;">  </div> <p style="color: blue; font-weight: bold;">Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-Sterile</p> <p>2.54OZ /75ML</p>	<p>This hand sanitizing liquid contains CDC-recommended levels of alcohol to effectively kill germs. With a quick-drying formula, your hands will feel smooth with no residue.</p> <hr/> <p>Clean, dry and sanitized in no time at all!</p>
Active ingredient[s]	Purpose					
Alcohol 80% v/v.....	Antiseptic					
<p>28215 (05/20)</p> 		 <p>UNITERS North America, LLC 1700 Palm Beach Lakes Blvd. West Palm Beach, FL 33401 uniters.com (800) 234-8986</p>				

75 mL NDC: 77506-001-11

PURE AND PROTECTED HAND SANITIZING LIQUID alcohol solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77506-001
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:77506-001-11	75 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/15/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/15/2020		

Labeler - UNITER SPA (442983326)

Registrant - Genesis Custom Chemical Blending (080744214)

Establishment

Name	Address	ID/FEI	Business Operations
Genesis Custom Chemical Blending		080744214	manufacture(77506-001)

Revised: 5/2020

UNITERS SPA