

# ASSURED SHIELD HAND SANITIZER- isopropyl alcohol gel

## Direct Sales Unlimited

*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:

- Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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.

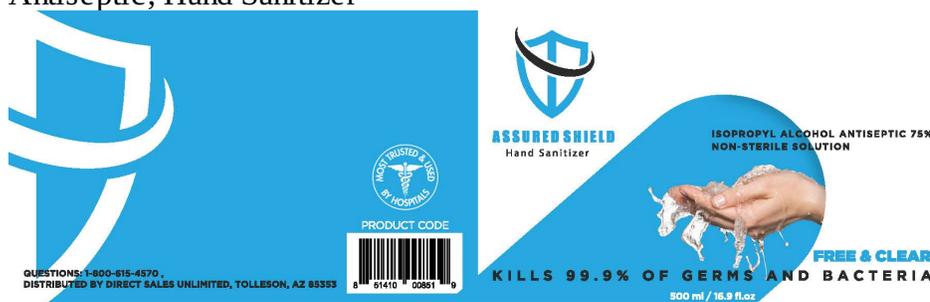


**DRUG FACTS LABEL**

Drug Facts	Active Ingredient(s)	Purpose
<p><b>Use(s)</b></p> <p>Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p>		
<p><b>Warnings</b></p> <p>For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>or open skin wounds</li> </ul> <p><b>When using this product</b></p> <p>Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b></p> <p>if condition or rash occurs. Throw away package if a rash occurs.</p> <p><b>Keep out of reach of children</b></p> <p>if necessary, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Remove residue with a towel or paper napkin.</li> </ul> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>Shelf life: 12-24 months (see USP)</li> <li>Keep from freezing and avoid heat above 100°C (212°F)</li> </ul> <p><b>Inactive Ingredients</b></p> <p>Hydrogen peroxide, purified water, USP</p>		

## Purpose

Antiseptic; Hand Sanitizer



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



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<b>Directions</b> • Rub hands together until hands are completely dry. • Rub hands together until dry. • Rub hands together until dry.	
<b>Other Information</b> • Store between 15-30°C (59-86°F). • Avoid freezing and excessive heat above 40°C (104°F).	
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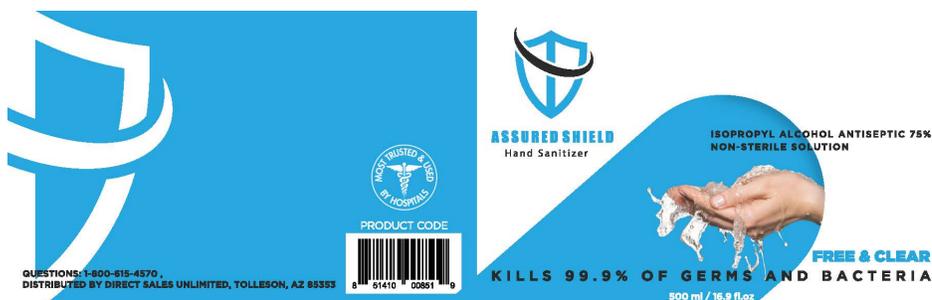


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QUESTIONS: 1-800-615-4570, DISTRIBUTED BY DIRECT SALES UNLIMITED, TOLLESON, AZ 85353

ASSURED SHIELD Hand Sanitizer

ISOPROPYL ALCOHOL ANTISEPTIC 75% NON-STERILE SOLUTION

KILLS 99.9% OF GERMS AND BACTERIA

FREE & CLEAR

500 ml / 16.9 fl.oz

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## Active Ingredient(s)

Isopropyl Alcohol 75% v/v



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500 ml NDC: 77895-007-01



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## ASSURED SHIELD HAND SANITIZER

isopropyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77895-007
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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)

**Product Characteristics**

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77895-007-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

**Labeler** - Direct Sales Unlimited (117466051)

**Establishment**

Name	Address	ID/FEI	Business Operations
Direct Sales Unlimited		117466051	manufacture(77895-007)

Revised: 5/2020

Direct Sales Unlimited