

ASSURED SHIELD HAND SANITIZER- isopropyl alcohol gel

Direct Sales Unlimited

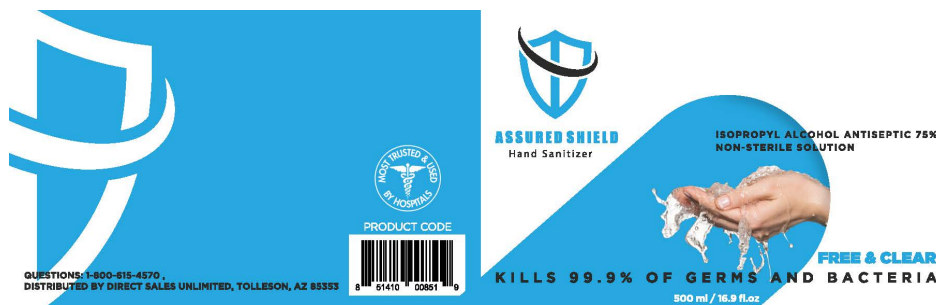
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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.

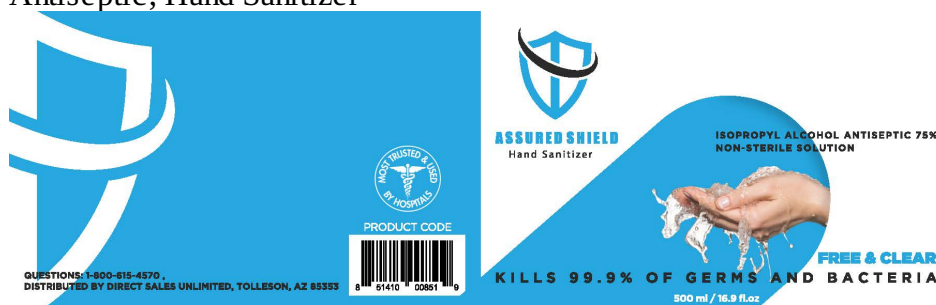


DRUG FACTS LABEL

Drug Facts	Active Ingredient(s)	Purpose
<p>Use(s)</p> <p>Use after each time you wash your hands that potentially can cause disease. For use when soap and water are not available.</p>		
<p>Warnings</p> <p>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 or open skin wounds <p>When using this product</p> <p>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</p> <p>if condition or rash occurs. Throw away package if a rash occurs.</p> <p>Keep out of reach of children</p> <p>if necessary, 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. Remove the residue with a towel or paper towel. <p>Other Information</p> <ul style="list-style-type: none"> Shelf life: 12-24 months (see USP) Keep from freezing and avoid heat above 100°C (212°F) <p>Inactive Ingredients</p> <p>Hydrogen peroxide, purified water, USP</p>		

Purpose

Antiseptic; Hand Sanitizer



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Use

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



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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 • Rub hands thoroughly until hands are completely dry. • Rub hands together until dry. • Rub into creases of wrists. • Rub into palms of hands. • Rub into backs of hands. • Rub into fingers and thumbs. • Rub into wrists. • Rub into forearms. • Rub into elbows. • Rub into forearms. • Rub into wrists. • Rub into palms of hands. • Rub into backs of hands. • Rub into fingers and thumbs. • Rub into wrists.	
Other Information • Store between 15-30°C (59-86°F). • Avoid freezing and excessive heat above 40°C (104°F).	
Inactive ingredients Hydroxyethyl piperazine, Purified water USP	

Warnings

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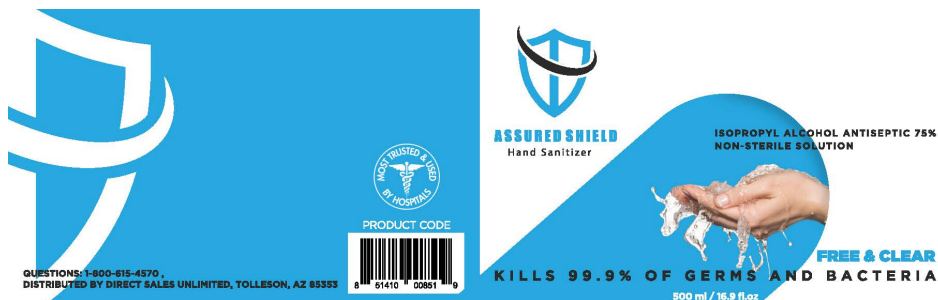


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QUESTIONS: 1-800-615-4570, DISTRIBUTED BY DIRECT SALES UNLIMITED, TOLLESON, AZ 85353

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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- 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.

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Other Information • Data between 12-30°C (50-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive Ingredients Glycerin, 1,3-butylene glycol, Purified water USP	

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:77895-007-00	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

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Isopropyl Alcohol 75%	Antiseptic
Uses(s)	
Kills germs 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 under 2 months of age	
• In heat-stable areas	
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. Stop use at 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.	
• Rub for at least 20 seconds.	
• Avoid flames and sensitive heat (stove, OHP).	
Other information	
• Store between 59°F and 86°F.	
• Avoid flames and sensitive heat (stove, OHP).	
Inactive Ingredients	
Glycerin, Hydroxyacetone, Purified water, USP	

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: 12/2020

Direct Sales Unlimited