

ARROPURE 80- alcohol liquid
ARROPOL Chemicals, 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.

ArroPure 80

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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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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Image for all packaging

<h1>ArroPure 80</h1>  <h2>WARNING</h2>		WEIGHT : . BATCH NO : .
<p>GHS CLASSIFICATIONS Specific Target Organ Toxicity--Single Exposure, Respiratory Irritation, Category 3 Flammable Liquids, Category 3</p> <p>HAZARD STATEMENTS H226 : Flammable liquid and vapour. H319 : Causes serious eye irritation. H336 : May cause drowsiness or dizziness.</p> <p>PRECAUTIONARY STATEMENTS P261 : Avoid breathing dust/fume/gas/mist/vapours/spray. P240 : Ground and bond container and receiving equipment. P210 : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P235 : Keep cool. P243 : Take action to prevent static discharges. P241 : Use explosion-proof [electrical/ventilating/lighting/...] equipment. P242 : Use non-sparking tools. P271 : Use only outdoors or in a well-ventilated area. P264 : Wash hands thoroughly after handling. P280 : Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304+P312 : IF INHALED: Call a POISON CENTER/doctor/...if you feel unwell. P303+P361+P353 : IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P337+P313 : If eye irritation persists: Get medical advice/attention. P370+P378 : In case of fire: Use ... to extinguish. P340 : Remove person to fresh air and keep comfortable for breathing. P403+P233 : Store in a well-ventilated place. Keep container tightly closed. P405 : Store locked up. P501 : Dispose of contents/container in accordance with local/regional/national/international regulations.</p>	<p>FIRST AID EYES: Flush eyes immediately with plenty of water for at least 15 minutes holding eyelids apart to ensure flushing of the entire surface. Contact a physician.</p> <p>SKIN: Remove contaminated clothing, wash contaminated area thoroughly with soap and water. If redness or irritation occurs, seek medical attention.</p> <p>INGESTION: Rinse mouth with water. DO NOT induce vomiting. Call a physician or poison control center immediately.</p> <p>INHALATION: Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.</p> <p>NOTES TO PHYSICIAN: Treat symptomatically. Symptoms of poisoning may occur even after several hours; therefore provide medical observation for at least 48 hours after the accident.</p>	<p>SHIPPING DESCRIPTION UN/NA NUMBER: UN1987 ,Alcohols, n.o.s. ,3 ,II</p> <p>FIRE RESPONSE Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Firefighters should be equipped with self-contained breathing apparatus and full protective fire fighting gear. Dilution of burning liquid with water will affect extinguishment.</p>  <p>SPILL RESPONSE Stop leak if without risk. Move containers from spill area. Use spark proof tools and explosion proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible absorbent material, e.g. sand, earth, vermiculite or diatomaceous earth and place in a container for disposal according local regulations (See Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as spilled product. Note see Section 1 for emergency contact information and Section 1 for waste disposal.</p> <p>STORAGE AND HANDLING Store cool and dry, under well-ventilated conditions. Keep away from heat, sparks and open flames. Store this material away from incompatible substances (see section 10). Do not store in open, unlabeled or mislabeled containers. Keep container closed when not in use. Empty container contains residual product which may exhibit hazards of product. Do not reuse empty container without commercial cleaning or reconditioning. Eliminate all possible ignition sources. Containers must not be cut, welded, or exposed to ignition sources even if empty, as they may explode.</p>
<p>Consult SDS for Full Statements of Health, Safety, and Environmental Information.</p>		<p>ARROPOL 16 G. S. E. Blvd. St. P. O. Box 2686 Dalton, GA 30720</p> <p>Transportation/Spill 24-Hour Emergency Phone Number 800-424-9300 (emergencies only)</p> <p>Date: 04/29/2020</p>

18,927 mL NDC: 77040-266-05

ArroPure 80
Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

18.927 L (18,927 mL)

NDC: 77040-266-05

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none">• 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.	
Directions	
<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.	
Other information	
<ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

208,198 mL NDC: 77040-266-55

ArroPure 80
Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

208.198 L (208,198 mL)

NDC: 77040-266-55

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none">• 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.	
Directions	
<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.	
Other information	
<ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

1,040,990 mL NDC: 77040-266-00

ArroPure 80
Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

1,040.99 L (1,040,990 mL)

NDC: 77040-266-00

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none">• 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.	
Directions	
<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.	
Other information	
<ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

3,785 mL NDC: 77040-266-01

ARROPURE 80

Hand Sanitizer

Alcohol Antiseptic 80%
Topical Non-sterile Solution

3.7854 L (3,785.4 mL)
NDC: 77040-266-01

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none"> 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.	
Directions	
<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. 	
Other information	
<ul style="list-style-type: none"> 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	

Manufactured by: ARROPOL Chemicals, Inc. Dalton, GA 30720
Questions? 706-277-2981

ARROPURE 80

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77040-266
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:77040-266			

1	NDC:77040-266-05	18925 mL in 1 PAIL; Type 0: Not a Combination Product	04/29/2020	
2	NDC:77040-266-55	208175 mL in 1 DRUM; Type 0: Not a Combination Product	04/29/2020	
3	NDC:77040-266-00	1040875 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/29/2020	
4	NDC:77040-266-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/29/2020	

Labeler - ARROPOL Chemicals, Inc. (007806457)

Establishment

Name	Address	ID/FEI	Business Operations
ARROPOL Chemicals, Inc.		007806457	manufacture(77040-266)

Revised: 5/2020

ARROPOL Chemicals, Inc.