

## **HAND SANITIZER- alcohol liquid**

### **Uweport llc**

*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.*

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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) (70%, 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. Propylene Glycol (0.55% v/v).
- c. Isopropyl Alcohol (0.5% v/v)
- d. BIS-PEG-12 Dimethicone (1.5%)
- e. PEG-12 Dimethicone Crosspolymer (1%)
- f. 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 70% 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**

Propylene Glycol, PEG-12 Dimethicone Crosspolymer, BIS-PEG-12 Dimethicone, purified water USP

**Package Label - Principal Display Panel**



**Pioneer  
Eclipse**  
An AMANO Company

KILLS 99% OF GERMS INSTANTLY

**Touché™** FOAMING  
HAND SANITIZER

ITEM #3079L4 · HAND SANITIZER

1 Eclipse Road, PO Box 909  
Sparta, NC 28675 • USA  
Fax: 1-336-372-2895

Amano Pioneer Eclipse® Corp.  
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### Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%.....	Antibacterial

**Uses** ■ For sanitizing to reduce bacteria on the skin.

**Warnings**  
**For external use only.**

**Flammable:** Keep away from fire or flame.

**When using this product**, avoid contact with eyes. In case of eye contact, flush with water.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply one pump of foaming cleanser to dry hands.      ■ Rub into skin.
- No rinsing required.

**Inactive ingredients** Water, Isopropyl Alcohol, Propylene Glycol, PEG-12 Dimethicone Crosspolymer, Bis-PEG-12 Dimethicone.



7 64320 01060 5

**CONTENTS:**  
**1 Liter (33.8 fl. oz.)**

HAND SANITIZER



CONTAINER  
2  
HDPE

1000 mL NDC:80401-101-11

## HAND SANITIZER

alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80401-101
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name		Strength		
2-PHENYLPROPANAL PROPYLENE GLYCOL ACETAL (UNII: 1ZRR9A405A)		0.5 mL in 100 mL		
BIS-PEG-12 DIMETHICONE (500 MPA.S) (UNII: 2CNS542YRT)		1.5 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)		1 mL in 100 mL		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		0.5 mL in 100 mL		
Product Characteristics				
Color		Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80401-101-11	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Uweport llc (081252924)

Revised: 10/2020

Uweport llc