FOAMING NON ALCOHOL HAND SANITIZER- foaming non alcohol hand sanitizer 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.

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. Benzalkonium Chloride (0.13% w/v).
- b. Coco-Glucoside (1.5% v/v).
- c. Laurtrimonium Chloride (0.3% v/v).
- d. Cocamidopropylamine Oxide (0.3% v/v).
- e. Citric Acid (0.02% v/v).
- 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)

Benzalkonium Chloride 0.13% w/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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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

Coco-Glucoside, Laurtrimonium Chloride, Cocamidopropylamine Oxide, Citric Acid, purified water USP

Package Label - Principal Display Panel



Amano Pioneer Eclipse Corp. 3080L4-10/2 Eclipse Road.P0 Box 909 Sparta .NC 28675-USA

Drug Facts

Active Ingredient

Purpose

Benzalkonium Chloride 0.13%

..... Antibacterial

Uses ■ For handwashing to decrease bacteria on the skin. Recommended for repeat use.

Warnings

For external use only.

Avoid contact with eyes. In case of eye contact, flush with water.

Keep out of reach of children. If swallowed, get immediate medical attention. Stop use and ask doctor if irritation or redness develops and persists.

Directions Apply foam sanitizer to hands. Rub over surfaces of both hands for 15 seconds. No rinsing required.

Inactive ingredients Water, Coco-Glucoside, Laurtrimonium Chloride, Cocamidopropylamine Oxide, Citric Acid, Fragrance.





-800-367-3550·1-336-372-8080 www.pioneereclipse.com

Amano Pioneer Eclipse@Corp.

NON-ALCOHOL HAND SANITIZER

CONTENTS: 1 Liter (33.8 fl. oz.)







1000 ml NDC: 80401-102-10

FOAMING NON ALCOHOL HAND SANITIZER

foaming non alcohol hand sanitizer liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80401-111

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strenath

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM	0.13 g
UNII:7N6JUD5X6Y)	CHLORIDE	in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	0.3 mL in 100 mL		
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	0.3 mL in 100 mL		
COCO GLUCOSIDE (UNII: ICS790225B)	1.5 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			
CHLOROCITRIC ACID (UNII: 0W1BY8O77G)	0.02 mL in 100 mL		

l	Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date		
	1	NDC:80401- 111-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

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)

Registrant - Uweport Ilc (081252924)

Establishment				
Name	Address	ID/FEI	Business Operations	
Uweport		081252924	label(80401-111)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Guangdong Bolicen Bio-Technology Co Ltd		554525110	manufacture(80401-111)	

Revised: 12/2021 Uweport LLC