

A2A ELITE 8OZ GEL HAND SANITIZER- a2a elite 8oz gel hand sanitizer gel
SunBeam Laboratories 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.

A2A Elite 64 Oz Gel Hand Sanitizer

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. Water (26.28% v/v),
- c. Alkyl Acrylate (3.00% v/v).
- d. , Isopropyl Alcohol (0.4% v/v),
- e. Glycerin (0.18% v/v),
- f. Aminomethyl Propanol (0.01% v/v),
- g. Glycol (0.10% v/v),
- h. Isopropyl Miristrate (0.01% v/v),
- i. Aloe (0.01% v/v),
- j. Vitamin E (0.01% v/v).

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

Water, Alkyl Acrylate, Isopropyl Alcohol, Glycerin, Aminomethyl Propanol, Glycol, Isopropyl Miristrate, Aloe, Vitamin E

Package Label - Principal Display Panel

**Kills 99%
Bacteria**



**A2A Elite
Hand Sanitizer**

**70% Alcohol
with Refreshing
Aloe Vera +
Moisturizers
Vitamin E**



Net Contents
64 oz (1892 ml)

FOR FREQUENT USE • MADE IN THE USA BY VETERANS

Drug Facts

Active Ingredient	Purpose
Ethanol 70%.....	Hand Sanitizer
Uses	
<ul style="list-style-type: none">■ An antiseptic hand sanitizer for topical application.■ Helps prevent infection and cross-contamination.■ Reduces transient microorganisms on intact skin.■ Recommended for repeated use.	
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 for 15 minutes.	
Discontinue use and see a doctor if irritation occurs.	
Avoid contact with broken skin.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions Wet hands thoroughly with product. Allow to dry without wiping. Use no water or towels.	
Inactive Ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Caprylyl Glycol, Glycerin, Isopropyl Alcohol, Isopropyl Miristrate, Vitamin E, Water (Aqua)	
Questions? Call 1-800-493-3736 Distributor Address: 1830 Owen Dr. Ste 10-2 Fayetteville, NC 28301	



A2A ELITE 8OZ GEL HAND SANITIZER

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75321-1364
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1324.89 mL in 1892.7 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	56.78 mL in 1892.7 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	7.57 mL in 1892.7 mL
WATER (UNII: 059QF0KO0R)	497.4 mL in 1892.7 mL
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.19 mL in 1892.7 mL
GLYCERIN (UNII: PDC6A3C0OX)	3.41 mL in 1892.7 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.19 mL in 1892.7 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	1.89 mL in 1892.7 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.19 mL in 1892.7 mL
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	0.19 mL in 1892.7 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75321-1364-5	1892.7 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 - SunBeam Laboratories LLC (105139335)

Establishment

Name	Address	ID/FEI	Business Operations
SunBeam Laboratories LLC		105139335	manufacture(75321-1364)