

BROOKSTONE CLEAR FRESH ADVANCED FOAMING HAND SANITIZER- benzalkonium chloride solution

Argento sc by sicura 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.

77731-088/AB0054CL-BLA foaming

Active Ingredient(s)

Benzalkonium Chloride 0.13%

Purpose:

Antibacterial

Use

Decreases bacteria on skin that could cause diseases

Recommended for repeated use

Warnings

For external use on hands only.

When using this product

When using this product, keep out of eyes. In case of contact with eyes, flush thoroughly with water

Do not ingest or inhale

Avoid contact with broken skin

Stop use and ask a doctor

if irritation and redness develop or if condition persists for more than 72 hours

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- Spread product on hands thoroughly and allow to dry, do not wipe off
- For children under 6, use only under adult supervision
- Not recommended for use with infants

Other information

Do not store above 105F (40.6C)

May discolor some fabrics

Harmful to plastics and wood finished

Inactive ingredients

Water, Sodium lauroamphoacetate, Cocamidopropylamine oxide, Cocamidopropyl betaine, Glycerin, Olea europaea (olive) leaf extract, Polyminopropyl biguanide, Citric acid, Disodium EDTA, Benzophenone-3, Methylchloroisothiazolinone, Methylisothiazolinone, Fragrance, Cetylpyridinium chloride



The image shows the front of a Brookstone hand sanitizer bottle. The label features the Brookstone logo at the top, followed by 'DERMATOLOGICALLY TESTED' and 'ADVANCED FOAMING HAND SANITIZER'. Below this, it states 'KILLS 99.99% OF GERMS*' and 'CLEAR FRESH'. The volume is listed as '16.9 FLOZ (500 ml)'. On the right side of the label, there is a 'Drug Facts' panel with sections for Active Ingredient, Uses, Warnings, Directions, and Inactive Ingredients. A barcode is located at the bottom right of the label.

BROOKSTONE CLEAR FRESH ADVANCED FOAMING HAND SANITIZER

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77731-088
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
WATER (UNII: 059QF0K00R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DISODIUM HEDTA (UNII: KME849MC7A)	
BENZOPHENONE (UNII: 701M4TTV9O)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77731-088-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/17/2020	

Labeler - Argento sc by sicura inc. (168718778)

Revised: 9/2020

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