

**HAND WASH- benzalkonium chloride liquid
Old East Main CO.**

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.

Studio Selection Foaming Hand Wash 340 340.000-340AA

Active ingredient

Benzalkonium chloride 0.13%

Purpose

Antibacterial

Use

for handwashing to decrease bacteria on the skin

Warnings

For external use only: hands only

When using this product

- avoid contact with eyes. If contact occurs, rinse eyes with water.

Stop use and ask a doctor if

- irritation or redness develops
- condition persists for more than 72 hours

Keep out of reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands
- apply to hands
- scrub thoroughly
- rinse thoroughly

Inactive ingredients

water, cocamidopropyl betaine, lauramidopropylamine oxide, lauramine oxide, myristamidopropylamine oxide, glycerin, fragrance, citric acid, tetrasodium EDTA, benzophenone-4, sodium benzoate, red 4, yellow 6

Questions?

1-888-287-1915

DISTRIBUTED BY Old East Main CO

100 MISSION RIDGE, GOODLETTSVILLE, TN 37072

STUDIO

SELECTION

antibacterial

FOAMING

HAND SOAP

Helps kill

harmful germs

citriburst

7.5 FL OZ (221 mL)



HAND WASH

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-658
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)
LAURAMINE OXIDE (UNII: 4F6FC4M18W)
MYRISTAMIDOPROPYLAMINE OXIDE (UNII: 3HSF539C9T)
GLYCERIN (UNII: PDC6A3C0OX)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
EDETATE SODIUM (UNII: MP1J8420LU)
sulisobenzone (UNII: 1W6L629B4K)
SODIUM BENZOATE (UNII: OJ245FE5EU)
FD&C RED NO. 4 (UNII: X3W0AM1JLX)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-658-96	221 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/05/2020	

Labeler - Old East Main CO. (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-658)

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Vi-Jon, LLC		790752542	manufacture(55910-658)