

HAND WASH- benzalkonium chloride liquid

The Kroger 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.

Kroger 628.002/628AD-AE

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 thoroughly 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

- apply palmful 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, blue 1, red 33

Adverse reactions

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OH 45202

For comments or questions please call

1-800-632-6900

www.kroger.com

628.002/628AD

principal display panel

Kroger

Antibacterial

Foaming

Hand Wash

7.5 FL OZ (221 mL)



HAND WASH

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-628
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 BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-628-96	221 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/26/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/26/2014	

Labeler - The Kroger Co., (006999528)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(30142-628)

