MERTHIOLATE- benzalkonium chloride cream
Caribe Natural, 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.

Active Ingredients	Purpose
Benzalkonium Chloride 0.13%	First Aid Antiseptic

Use first aid to help prevent skin infection in

- minor cuts
- scrapes
- burns

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Merthiolate Tincture

Mercury Free

First Aid Antiseptic

For External Use Only

Directions

- clean the affected area
- apply a small amount on the area 1 to 3 times daily
- may be covered by a sterile bandage
- if bandaged, let dry first

Warnings

- For external use only
- Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns.
- When using this product
- do not use in eyes or apply over large areas of the body
- do not use longer than 1 week unless directed by a doctor
- Stop use and ask a doctor if condition persists or gets worse

Inactive Ingredients alcohol, acetone, purified water, FD&C red #22

MERTHIOLATE

benzalkonium chloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59561-709
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
ACETONE (UNII: 1364PS73AF)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59561-709-01	30 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/05/2015	

Labeler - Caribe Natural, Inc (624210480)

Establishment

Name	Address	ID/FEI	Business Operations
World Perfumes, Inc		101312044	manufacture(59561-709)

Revised: 5/2015 Caribe Natural, Inc