XTRACARE FOAMING HAND SANITIZER- benzalkonium chloride gel
China Ningbo Shangge Cosmetic Technology Corp

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.

XtraCare Foaming Hand Sanitizer

Active Ingredient ***Purpose***

Benzalkonium Chloride 0.13% ..... Antimicrobial

Use:

to help reduce bacteria on the skin

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

XtraCare® Foaming Hand Sanitizer

Superior Protection

Alcohol Free

Kills 99.9% of germs

Clean Fresh Scent

7 FL OZ (207 mL)

Warnings: for external use only.

When using this product Avoid contact with eyes. In case of eye contact, flush with plenty of water. Avoid contact with broken skin.

Stop use and ask a doctor if skin iffitation develops.

Directions

wet hands thoroughly with product and rub into skin until dry.

For children under 6, use only under adult supervision.

Not recommended for infancts.

Inactive Ingredients: water, cetrimonium chloride, disodium cocoamphodiacetate, fragrance, glycerin, citric acid, dimethicone, tetrasodium EDTA, methylchloroisothiazolinone, methylisothiazolinone.

Questions/Comments? 1-855-345-5575

DISTRIBUTED BY:

REJOICE INTERNATIONAL INC

NORTHVILLE, MI 48168 USA

MADE IN CHINA

XTRACARE FOAMING HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58503-057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	3 g in 207 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	

GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-057-01	207 g in 1 PACKAGE; Type 0: Not a Combination Product	02/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/18/2014	

Labeler - China Ningbo Shangge Cosmetic Technology Corp (529287434)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp		529287434	manufacture(58503-057)

Revised: 9/2019 China Ningbo Shangge Cosmetic Technology Corp