STUDIO 35 AMBER- benzalkonium chloride liquid
WALGREEN COMPANY

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.

DRUG FACTS

ACTIVE INGREDIENT

BENZALKONIUM CHLORIDE 0.13%

PURPOSE

ANTIBACTERIAL

USES

HELPS ELIMINATE BACTERIA ON HANDS.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IN CASE OF CONTACT, RINSE WITH WATER.

STOP USE AND ASK A DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

APPLY ONTO WET HANDS. LATHER AND RINSE THOROUGHLY.

OTHER INFORMATION

STORE AT ROOM TEMPARATURE.

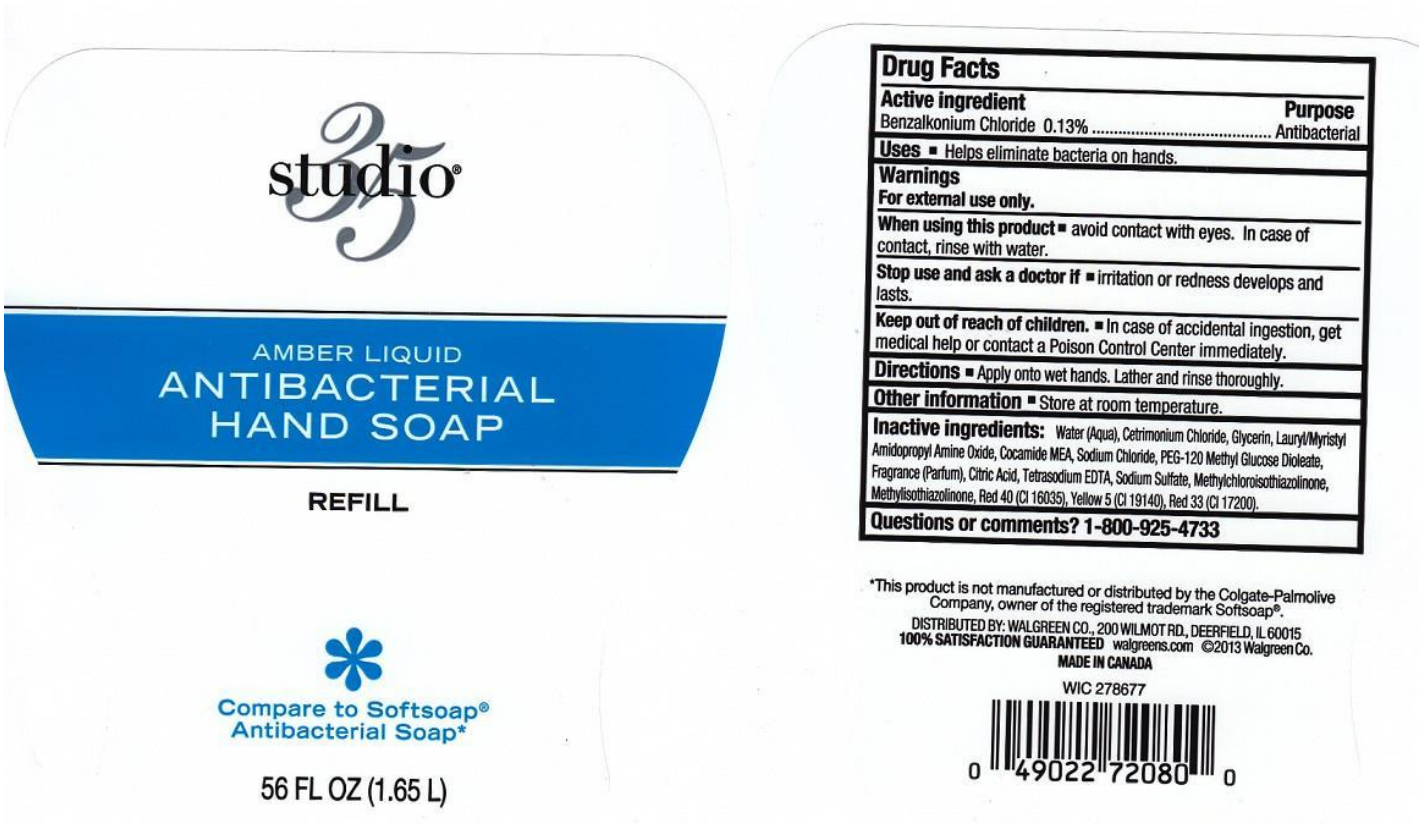
INACTIVE INGREDIENTS:

WATER (AQUA), CETRIMONIUM CHLORIDE, GLYCERIN, LAURYL/MYRISTYL AMIDOPROPYL AMINE OXIDE, COCAMIDE MEA, SODIUM CHLORIDE, PEG-120 METHYL GLUCOSE DIOLEATE, FRAGRANCE (PARFUM), CITRIC ACID, TETRASODIUM EDTA, SODIUM SULFATE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, RED 40 (CI 16035), YELLOW 5 (CI 19140), RED 33 (CI 17200).

QUESTIONS OR COMMENTS?

1-800-925-4733

LABEL COPY



STUDIO 35 AMBER

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-7215
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)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-7215-60	1650 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/08/2013	

Labeler - WALGREEN COMPANY (008965063)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HALTH AND BEAUTY CARE		201901209	manufacture(0363-7215)

Revised: 7/2013 WALGREEN COMPANY