# AURORA BODY WASH CRISP WATERS- benzalkonium chloride liquid APOLLO HEALTH AND BEAUTY CARE

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.

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## **DRUG FACTS**

### **ACTIVE INGREDIENT**

BENZALKONIUM CHLORIDE 0.13%

#### **PURPOSE**

ANTIBACTERIAL

#### **USES**

FOR WASHING TO DECREASE BACTERIA ON THE SKIN

### WARNINGS

FOR EXTERNAL USE ONLY

### WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION AND REDNESS DEVELOPS

KEEP OUT OF REACH OF CHILDREN

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

## **DIRECTIONS**

SQUEEZE A SMALL AMOUNT ONTO A WET WASHCLOTH, SPONGE, POUF OR HAND AND APPLY TO BODY. WORK INTO A RICH LATHER AND RINSE OFF

## OTHER INFORMATION

STORE AT ROOM TEMPERATURE

## INACTIVE INGREDIENTS

WATER (AQUA), COCAMIDOPROPYL BETAINE, GLYCERIN, DECYL GLUCOSIDE, HYDROXYETHYLCELLULOSE, CITRIC ACID, POLOXAMER 124, FRAGRANCE (PARFUM), TETRASODIUM EDTA, POLYQUATERNIUM-7, SODIUM CITRATE, ALOE BARBADENSIS LEAF JUICE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, BLUE 1 (CI 42090), EXT. VIOLET 2 (CI 60730)

## **QUESTIONS OR COMMENTS?**

1-866-695-3030

### LABEL COPY



## AURORA BODY WASH CRISP WATERS

benzalkonium chloride liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-807	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
HYDROXYETHYL CELLULOSE (5000 CPS AT 1%) (UNII: X70SE62ZAR)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C VIOLET NO. 2 (UNII: 350 KA7O6 HK)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-807-21	621 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	03/03/2015	

## Labeler - APOLLO HEALTH AND BEAUTY CARE (201901209)

## **Registrant -** APOLLO HEALTH AND BEAUTY CARE (201901209)

## Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(63148-807)

Revised: 3/2015

APOLLO HEALTH AND BEAUTY CARE