AURORA ANTIBACTERIAL SANITIZER SWEET LYCHEE BERRY- ethyl alcohol 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.

ACTIVE INGREDIENT

ETHYL ALCOHOL 65%

PURPOSE

ANTISEPTIC

USES

TO DECREASE BACTERIA ON THE SKIN

WARNINGS

- FOR EXTERNAL USE ONLY
- FLAMMABLE
- KEEP AWAY FROM SOURCE OF HEAT OR FIRE

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, 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 A SMALL AMOUNT TO YOUR PALM AND RUB HANDS TOGETHER BRISKLY UNTIL DRY. CHILDREN 6 YEARS OF AGE AND UNDER SHOULD BE SUPERVISED WHEN USING THIS PRODUCT

OTHER INFORMATION

STORE AT A TEMPERATURE BELOW 110°F (43°C)

INACTIVE INGREDIENTS

WATER (AQUA), PROPYLENE GLYCOL, FRAGRANCE (PARFUM), BENZOPHENONE-4, CARBOMER, GLYCERIN, AMINOMETHYL PROPANOL, ISOPROPYL ALCOHOL, BLUE 1 (CI 42090), RED 33 (CI 17200)

QUESTIONS OR COMMENTS?

LABEL COPY





AURORA ANTIBACTERIAL SANITIZER SWEET LYCHEE BERRY

ethyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63148-407

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	650 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SULISOBENZONE (UNII: 1W6L629B4K)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:63148-407-02	59 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	0 1/12/20 15	

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(63148-407)

Revised: 1/2015 APOLLO HEALTH AND BEAUTY CARE