CAREONE ANTIBACTERIAL SANITIZER GINGERBREAD HOUSE- ethyl alcohol liquid AMERICAN SALES 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

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

- PUT ENOUGH PRODUCT IN YOUR PALM TO COVER HANDS AND RUB HANDS TOGETHER UNTIL DRY
- CHILDREN UNDER 6 YEARS SHOULD BE SUPERVISED WHEN USING THIS PRODUCT

INACTIVE INGREDIENTS

WATER (AQUA), PROPYLENE GLYCOL, ISOPROPYL ALCOHOL, CARBOMER, AMINOMETHYL PROPANOL, BENZOPHENONE-4, GLYCERIN, FRAGRANCE (PARFUM), MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, IRON OXIDES (CI 77491, CI 77492, CI 77499), ORANGE 4 (CI 15510)

LABEL COPY



CAREONE ANTIBACTI	ERIAL SANITIZER	GINGE	RBREAD HOU	SE		
ethyl alcohol liquid						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		ND	NDC:41520-414	
Route of Administration	TOPICAL					
	-					
Active Ingredient/Active Mo	5					
Ingre	Ingredient Name		Basis of Strength		Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALC			ALCOHOL		650 mg in 1 mL	
Inactive Ingredients						
	Ingredient Name				Strength	
WATER (UNII: 059QF0KO0R)						
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
ISOPROPYL ALCOHOL (UNII: ND2M416302)						
CARBOMER 934 (UNII: Z135WT9208)					
AMINOMETHYLPROPANOL (UNII: I	LU49E6626Q)					
SULISOBENZONE (UNII: 1W6L629B4K)						
GLYCERIN (UNII: PDC6A3C0OX)						
MANNITOL (UNII: 30WL53L36A)						
POWDERED CELLULOSE (UNII: SMI	D1X3XO9M)					
HYPROMELLOSES (UNII: 3NXW29V	,					
FERRIC OXIDE RED (UNII: 1K09F3G6	575)					

DE (UNII: XM0 M8 7F357) JNII: Q1LIY3BO0 U)						
JNII: Q1LIY3BO0U)						
Package Description	Marketing Start	Marketing End				
0 1	Date	Date				
mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination duct						
Marketing Information						
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
l part333E	06/22/2015					
	rmation Application Number or Monograph Citation	Package Description Date mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination duct Date				

Labeler - AMERICAN SALES COMPANY (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(41520-414)

Revised: 6/2015

AMERICAN SALES COMPANY