AMBER AND BLACK- benzalkonium chloride soap
NV Labs

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.

Amber and Black Antibacterial Hand Soap (16 Fl. Oz .)

Active Ingredient

Active Ingredient Purpose

Benzalkonium Chloride 0.13% v Antibacterial

USES

For handwashing to decrease bacteria of the skin

WARNING

Warnings

For External Use only

When using this product

Avoid Contact with eyes

In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation orredness develops.

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

Directions

Directions

- Apply to Dry Hands
- Lather vigorously for at least 15 seconds
- Rinse and dry throughly

In active Ingredients

Water (Aqua) , Lauramidopopylamine Oxide, cocamidopropyl Betaine, lauramine Oxide, Sodium Chloride, Glycerin, Myristamine Oxide, Cetrimonium Chloride, Fragrance, PEG-120 Methy Glucose Dioleate, PEG-150 Distearate, Citric Acid, Tetrasodium EDTA, Sodium Benzoate, RED 40, Red 33, Yellow 5.

Manufactured By:
Questions or Comments

Manufactured By: Reforma Group, Southfield, Michigan 48033

Questions or comments? Call 1-248-358-9022

Keep out of Reach of Children

Keep out of Reach of Children. If swallowed , get medical help or contact a Poison Control Center right away.

Purpose

Antbacterial

Package Label Principle Display Panel


amber
AND black™
BY OCEAN
ANTIBACTERIAL HAND SOAP
Passion Fruit Scent
SILICONE FREE, PARABEN FREE
AND TRICLOSAN FREE
16 fl oz (473 mL)

AMBER AND BLACK

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73696-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	1.4483 g in 100 g
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	0.05 g in 100 g
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.1 g in 100 g
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	11 g in 100 g
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	0.33 g in 100 g
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	0.1 g in 100 g
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	1 g in 100 g
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	0.1 g in 100 g
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	0.3 g in 100 g
FD&C RED NO. 40 (UNII: WZB9127XOA)	2.15 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 100 g
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	4 g in 100 g
MYRISTAMINE OXIDE (UNII: J086PM3RRT)	3.8 g in 100 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1.2 g in 100 g
WATER (UNII: 059QF0KO0R)	68.4896 g in 100 g
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	9 g in 100 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73696-104-16	473 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/29/2020	

Labeler - NV Labs (019662814)

Registrant - NV Labs (019662814)

Establishment

Name	Address	ID/FEI	Business Operations
NV Labs		019662814	manufacture(73696-104)

Revised: 4/2020

NV Labs