

## **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 or redness 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 thoroughly

#### **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**

Antibacterial

**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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73696-104
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

## Inactive Ingredients

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

## Packaging

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

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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: 1/2022

NV Labs