AQUA BLUE MOUTHWASH- methyl salicylate, menthol, unspecified form, eucalyptol, and thymol liquid
Body One Products Inc

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.

Aqua Blue Mouthwash

Drug Facts

Active ingredient	***Purpose***
Eucalyptol 0.092%	Antiplaque/Antigingivitis
Menthol 0.042%	Antiplaque/Antigingivitis
Methyl Salicylate 0.060%	Antiplaque/Antigingivitis
Thymol 0.064%	Antiplaque/Antigingivitis

Use

helps control plaque that leads to gingivitis

Warnings

Do not use if you have painful or swollen gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontis, a serious form of gum disease.

Stop use and ask a dentist if gingivitis, bleeding, or redness persists for more than 2 weeks

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- do not swallow
- not intended to replace brushing or flossing.

Adults and children 12 years of age and older	Vigorously swish 20mL between teeth twice a day for 30 seconds then spit out.
children under 12 years of age	consult a dentist or doctor

Other information

Store at room temperature (59°-77°F).

Inactive ingredients

Water,Alcohol (21.6%),Polysorbate 80,Sorbitol,Flavor,Benzoic Acid,Sodium Saccharin,Sodium Benzoate,Blue 1,Yellow 5

PRINCIPAL DISPLAY PANEL - 128 FL.OZ. Jug Label

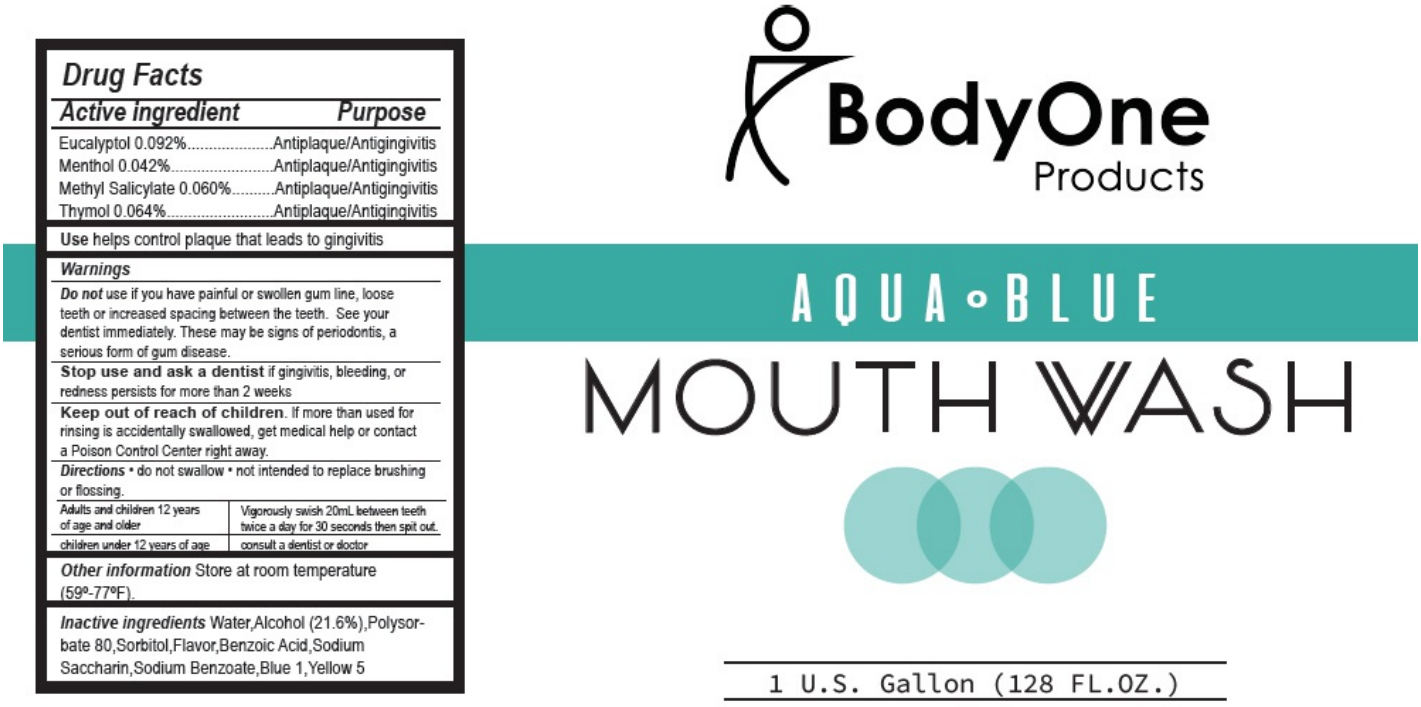
BodyOne

Products

AQUA BLUE

MOUTH WASH

1 U.S. Gallon (128 FL.OZ.)



AQUA BLUE MOUTHWASH

methyl salicylate, menthol, unspecified form, eucalyptol, and thymol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73563-022
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Methyl Salicylate (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Methyl Salicylate	0.6 mg in 1 mL
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.42 mg in 1 mL
Eucalyptol (UNII: RV6J6604TK) (Eucalyptol - UNII:RV6J6604TK)	Eucalyptol	0.92 mg in 1 mL
Thymol (UNII: 3J50XA376E) (Thymol - UNII:3J50XA376E)	Thymol	0.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
alcohol (UNII: 3K9958V90M)	216 mg in 1 mL
SORBITOL (UNII: 506T60A25R)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
FD&C Yellow No. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	BLUE	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73563-022-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	02/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	02/01/2020	

Labeler - Body One Products Inc (117376115)

Registrant - BMC 1092,Inc dba Solo Laboratories, Inc (078831987)

Establishment

Name	Address	ID/FEI	Business Operations
BMC 1092,Inc dba Solo Laboratories, Inc		078831987	MANUFACTURE(73563-022)

Revised: 2/2020 Body One Products Inc