

MOUTH ORAL SHIELD- eucalyptol, menthol, methyl salicylate, and thymol spray
Nutralife Biosciences, 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.

Mouth Oral Shield Spray

Eucalyptol 0.092% Menthol 0.042% Methyl Salicylate 0.060% Thymol 0.064%

Active ingredients

Purposes

Eucalyptol 0.092% }

Menthol 0.042% }

Methyl salicylate 0.060% }

Thymol 0.064% }

Antiplaque/antigingivitis

Uses

Helps prevent and reduce:

- plaque
- gingivitis

Warnings

Do not use

in children under 12 years of age

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.

Other information

- Store at room temperature.
- Cold weather may cloud this product. Its antiseptic properties are not affected

Directions

- Shake well before use
- Apply 2 sprays directly into mouth
- Use up to 3 times daily

Inactive ingredients

Water, Alcohol (21.6%), Xylitol, Poloxamer 407, Vitamin C Citrus Bioflavonoid Complex, Mint Flavor, Sucralose, Potassium Sorbate, Zinc Chloride, Beta Cyclodextrin, FD&C Green 3

Mouth Oral Shield Spray



MOUTH ORAL SHIELD

eucalyptol, menthol, methyl salicylate, and thymol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73761-104
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.6 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BETADEX (UNII: JV039JZZ3A)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
XYLITOL (UNII: VCQ006KQ1E)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73761-104-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/01/2020	

Labeler - Nutralife Biosciences, Inc. (078834338)

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Nutralife Biosciences, Inc.