

**365 WHOLE FOODS MARKET ANTICAVITY/ANTIGINGIVITIS MOUTHWASH-
eucalyptol, menthol, methyl salicylate, thymol, sodium fluoride mouthwash
Whole Foods Market, 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.

WFM PLD Listing Mouthwash with Fluoride

Eucalyptol 0.092%

Menthol 0.042%

Methyl Salicylate 0.060%

Thymol 0.064%

Sodium Fluoride 0.02% (0.01% w/v fluoride ion)

Directions Adults and children 12 years of age and older: Use twice a day after brushing your teeth with a toothpaste • Vigorously swish 10mL of rinse between your teeth for 30 seconds and then spit out. Do not swallow the rinse • Do not eat or drink for 30 minutes after rinsing. • **Children under 12 years of age:** do not use/consult a doctor.

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.

• **Stop use and ask a dentist if** • Gingivitis, bleeding, or redness persists for more than 2 weeks. • You have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

If pregnant or breast-feeding, ask a health professional before use.

Inactive ingredients: water, ethyl alcohol (21.6% v/v), sorbitol, flavor, cocamidopropyl betaine, citric acid, stevia rebaudiana leaf extract, sodium citrate, sodium benzoate, mentha piperita (peppermint) oil, mentha spicata (spearmint) oil.

Uses • Aids in the prevention of dental cavities. • Helps remove plaque that leads to gingivitis, an early form of gum disease. • The combined daily use of a fluoride preventative treatment rinse and a fluoride toothpaste can help reduce the incidence of dental cavities.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42681-0036
Route of Administration	DENTAL		

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
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ALCOHOL (UNII: 3K9958V90M)	

WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SPEARMINT OIL (UNII: C3M81465G5)	
STEVIA LEAF (UNII: 6TC6NN0876)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42681-0036-1	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/31/2022	

Labeler - Whole Foods Market, Inc. (196175616)

Revised: 5/2022

Whole Foods Market, Inc.