

**ROYAL MOUTHWASH FRESH AND CLEAN ORIGINAL MINT- eucalyptol, menthol, methyl salicylate, thymol liquid**

**Filo America**

*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.*

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**DRUG FACTS**

**ACTIVE INGREDIENT**

EUCALYPTOL 0.092%, MENTHOL 0.042%, METHYL SALICYLATE 0.060%, THYMOL 0.064%

**PURPOSE**

ANTIPLAQUE/ANTINGINGIVITIS

**USES**

TO HELP 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 PERIODONTITIS, A SERIOUS FORM OF GUM DISEASE.

DO NOT USE FOR CHILDREN UNDER 12 YEARS OF AGE.

STOP USE AND ASK A DENTIST IF GINGIVITIS, BLEEDING OR REDNESS PERSISTS FOR MORE THAN 72 HOURS.

**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**

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER.

VIGOROUSLY SWISH 20 ML (2/3 FLUID OUNCE OR 4 TEASPOONFULS) BETWEEN TEETH FOR 30 SECONDS THEN SPIRT OUT;DO NOT SWALLOW.

CHILDREN UNDER 12 YEARS OF AGE, CONSULT A DENTIST OR DOCTOR.

THIS RINSE IS NOT INTENDED TO REPLACE BRUSHING OR FLOSSING.

**OTHER INFORMATION**

COLD WATER MAY CLOUD THIS PRODUCT. ITS ANTISEPTIC PROPERTIES ARE NOT AFFECTED. STORE AT ROOM TEMPERATURE (59°-77°F).

**INACTIVE INGREDIENTS:**

WATER (AQUA), ALCOHOL (21.6%), SORBITOL SOLUTION, FLAVOR, POLOXAMER 407, BENZOIC ACID, SODIUM SACCHARIN, SODIUM BENZOATE, YELLOW 5, BLUE 1



## ROYAL MOUTHWASH FRESH AND CLEAN ORIGINAL MINT

eucalyptol, menthol, methyl salicylate, thymol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50438-304
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
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-304-01	1000 mL in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/17/2013	

**Labeler** - Filo America (943873703)**Registrant** - Ningbo Pulisi Daily Chemical Products Co., Ltd. (529047265)**Establishment**

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co., Ltd.		529047265	manufacture(50438-304)

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