ORAL DENT CITRUS- eucalyptol, thymol, methyl salicylate, menthol mouthwash International Cosmetic Limited

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.

Oral Dent Citrus

Active ingredients (W/V)

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

Purpose

Antiplaque/Antigingivitis

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Uses

Helps kill germs that cause plaque, gingivitis and bad breath.

Warnings

- Do not swallow
- Not to be used by children under 12 years of age

Directions

Rinse Full Strength with 2/3 ounce (20 ml) for 30 seconds twice a day to help kill germs that cause bad breath, plaque and gingivitis.

Other information

- Cold temperature may cloud this product; its efficacy will not be affected. Store at room temperature (59⁰-86⁰ F)
- Do not use if security band around cap is missing or broken

Inactive ingredients

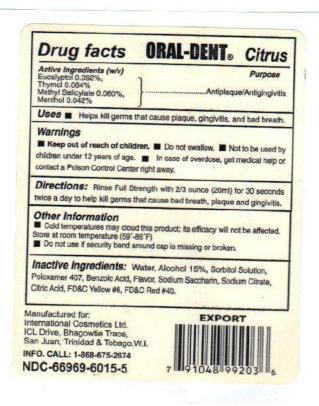
Water, Alcohol (15%), Sorbitol Solution, Poloxamer 407, Benzoic Acid, Flavour, Sodium Saccharin, Sodium Citrate, Citric Acid, FD&C Yellow No.6, FD&C Red No. 40.

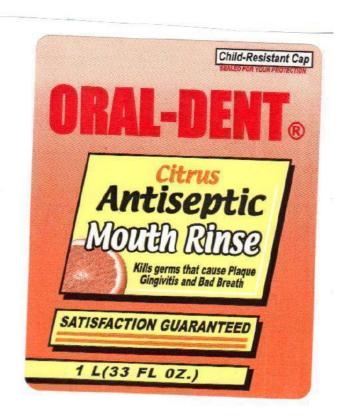
Manufactured for

International Cosmetics Ltd.

ICL Drive, Bhagowtie Trace, San Juan, Trinidad & Tobago, W.I. INFO. CALL:1-868-675-2674

Packaging





ORAL DENT CITRUS

eucalyptol, thymol, methyl salicylate, menthol mouthwash

Product	Information	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66969-6015

Route of Administration ORAL

Active Ingredient/Active Moiety

neuve ingredient/neuve molety				
Ingredient Name	Basis of Strength	Strength		
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.092 g in 100 mL		
THYMOL (UNII: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E)	THYMOL	0.064 g in 100 mL		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	$0.060\ g\ in\ 100\ mL$		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.042 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CITRUS	Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:66969-6015-5	1000 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	0 1/10/20 13	

Labeler - International Cosmetic Limited (857266290)

Establishment				
Name	Address	ID/FEI	Business Operations	
International Cosmetic Limited		857266290	manufacture(66969-6015)	

Revised: 3/2014 International Cosmetic Limited