**ORAL DENT FRESH MINT- eucalyptol, thymol, methyl salicylate, menthol mouthwash**
**International Cosmetics Ltd.**

*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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**Oral Dent Fresh Mint**

***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 ($59^0$-$86^0$ F)
- Do not use if security band around cap is missing or broken

***Inactive ingredients***

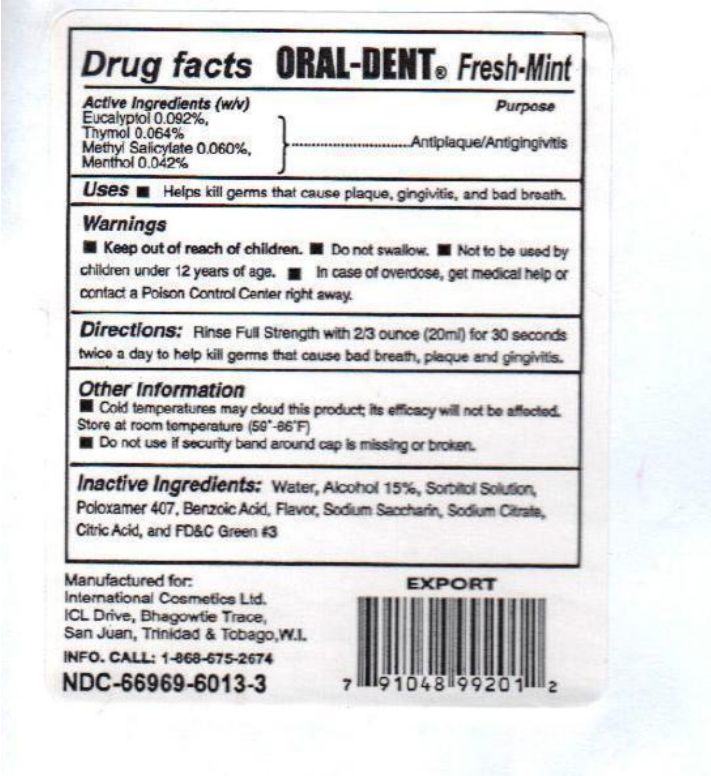
Water, Alcohol (15%), Sorbitol Solution, Poloxamer 407, Benzoic Acid, Flavour, Sodium Saccharin, Sodium Citrate, Citric Acid and FD&C Green No.3.

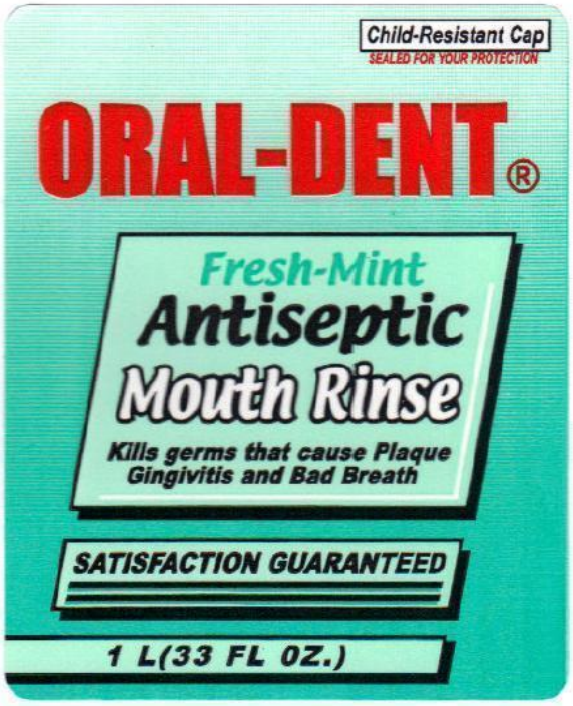
Manufactured for

International Cosmetics Ltd.

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

**Packaging**




## ORAL DENT FRESH MINT

eucalyptol, thymol, methyl salicylate, menthol mouthwash

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:66969-6013 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **EUCALYPTOL** (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK) | EUCALYPTOL | 0.092 g in 100 mL |
| **THYMOL** (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E) | 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: 8SKN0B0MIM) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **FD&C GREEN NO. 3** (UNII: 3P3ONR6O1S) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | MINT | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:66969-6013-3 | 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 | 01/10/2013 | |

## Labeler - International Cosmetics Ltd. (857266290)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| International Cosmetics Ltd. | | 857266290 | manufacture(66969-6013) |

Revised: 3/2014 International Cosmetics Ltd.