# BUENOS DIAS DE PERSONNA MINT- eucalyptol, menthol, methyl salicylate, thymol 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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#### Buenos Dias de Personna mint

# Active ingredients (W/V)

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

#### **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<sup>0</sup>-86<sup>0</sup> F)
- Do not use if security band around cap is missing or broken

#### **Inactive ingredients**

Water, Alcohol 21.6%, Sorbitol Solution, Poloxamer 407, Benzoic Acid, Sodium Benzoate ,Flavour, Sodium Saccharin & FD&C Yellow No.10 and FD&C Green no.3

### Distributed By

2011 Energiser Personal Care LL dba Personna International of PR #36 Carr 20 Kim 2.2 Suite 203, Guaynabo PR00966 787-761-9500 Made in Trinidad & Tobago, W.I.

### **Packaging**





#### **BUENOS DIAS DE PERSONNA MINT**

eucalyptol, menthol, methyl salicylate, thymol mouthwash

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66969-6002
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		
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	0.042 g in 100 mL		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.060 g in 100 mL		
THYMOL (UNII: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E)	THYMOL	0.064 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength

<u> </u>	<u> </u>
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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:66969-6002-2	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 Cosmetics Ltd. (857266290)

Establishment				
Name	Address	ID/FEI	Business Operations	
International Cosmetics Ltd.		857266290	manufacture(66969-6002)	

Revised: 3/2014 International Cosmetics Ltd.