

**OUTBACK 2-IN-1 INSECT REPELLENT AND PROTECTIVE SUNSCREEN- octinoxate,4-methylbenzylidene camphor and zinc cream**

**Elmore Oil Company Pty Ltd**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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**Active ingredient**

Octyl Methoxycinnamate - 9% (90 mg/ml)

4-Methylbenzylidene Camphor - 1.3% (13 mg/ml)

Zinc Oxide - 8% (80 mg/ml)

**Purpose**

Sunscreen and Insect Repellent.

**Indication and Usage**

Helps prevent sunburn. if used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.

**Dosage and Administration**

Apply liberally 15 minutes before sun exposure reapply: after 40 minutes of swimming or sweating immediately after towel drying at least every 2 hours.

**Warnings**

For external use only. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if a rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact the Poison Control Center right away.

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: limit time in the sun, especially between 10 a.m – 2 p.m. wear long-sleeve shirts, pants, hats and sunglasses. children under 6 months: Ask a doctor.

**Inactive Ingredients**

Eucalyptus Leaf Oil (Eucalyptus Polybractea), Leptospermum Petersonii Leaf Oil (Leptospermum Petersonii), Tea Tree Oil ( Melaleuca Alternifolia) Vanilla,Actilastin 1000,

**Keep out of Reach of Children**

Keep Out of Reach of Children

**Product Label**





Drug Facts	
<b>Active Ingredients</b> Octyl Methoxycinnamate 9% 4-Methylbenzylidene Camphor 1.0% Zinc Oxide 8%	<b>Purpose</b> Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.	
<b>Warnings</b> For external use only When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if a rash occurs. Keep out of reach of children. If product is swallowed get medical help or contact the Poison Control Center immediately.	
<b>Directions</b> • Apply liberally 15 minutes before sun exposure • reapply: → after 40 minutes of swimming or sweating → immediately after towel drying → at least every 2 hours • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: → limit time in the sun, especially between 10 a.m. - 2 p.m. → wear long-sleeve shirts, pants, hats, and sunglasses. • Children under 6 months: Ask a doctor.	
<b>Inactive Ingredients</b> Actinon 1000, Eucalyptol, Polybutene, Lipoic acid, Potassium Persulfate, Methylene Alcohol, Vanilla	
<b>Other Information</b> • Protect this product from excessive heat and direct sun.	
<b>Questions or Comments?</b> Call 1-866-215-8799	

## OUTBACK 2-IN-1 INSECT REPELLENT AND PROTECTIVE SUNSCREEN

octinoxate, 4-methylbenzylidene camphor and zinc cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43979-445
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	90 mg in 1 mL
ENZACAMENE (UNII: 8B3XWY40L9) (ENZACAMENE - UNII:8B3XWY40L9)	ENZACAMENE	13 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	80 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS POLYBRACTEA LEAF OIL (UNII: J1XGA6WROO)	
LEPTOSPERMUM PETERSONII LEAF OIL (UNII: N37UWG52T3)	
TEA TREE OIL (UNII: VIF565UC2G)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA (vanila)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43979-445-01	3 mL in 1 POUCH		
2	NDC:43979-445-03	50 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2012	

**Labeler** - Elmore Oil Company Pty Ltd (755881968)

### Establishment

Name	Address	ID/FEI	Business Operations
Elmore Oil Company Pty Ltd		755881968	manufacture, pack, label

Revised: 6/2012

Elmore Oil Company Pty Ltd