## AVAIL LIP BALM WITH SUNSCREEN- zinc oxide and octocrylene stick Emeis Cosmetics Pty 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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#### **Avail Lip Balm with Sunscreen**

#### **Drug Facts**

Active ingredients:	Purpose
Octocrylene 4.25%	Sunscreen
Zinc Oxide 5.25%	Sunscreen

#### Uses

• Helps prevent sunburn.

#### Warnings

#### **Skin Cancer/Skin Aging Alert**

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

#### For external use only.

Do not use on damaged or broken skin.

**Stop use and ask a doctor** if rash occurs.

**When using this product** keep out of eyes. Rinse with water to remove.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Apply liberally 15 minutes before sun exposure
- Use a water-resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months of age: Ask a doctor

#### Other information

- Protect the product in this container from excessive heat and direct sun.
- You may report a serious adverse reaction to: Report Reaction LLC, PO Box 22, Plainsboro, NJ 08536-0222.

#### **Inactive ingredients**

Ricinus Communis (*Castor*) Seed Oil, Jojoba Esters, Pentaerythrityl Tetraisostearate, Euphorbia Cerifera (*Candelilla*) Wax, Helianthus Annuus (*Sunflower*) Seed Oil, Tocopherol, Simmondsia Chinensis (*Jojoba*) Seed Oil, Glyceryl Behenate, Copernicia Cerifera (*Carnauba*) Wax, Citrus Tangerina (*Tangerine*) Peel Oil, Hydrogenated Castor Oil, Glyceryl Isostearate, Polyhydroxystearic Acid, Lavandula Angustifolia (*Lavender*) Oil, Cananga Odorata Flower Oil.

### PRINCIPAL DISPLAY PANEL - 5.5 g Cylinder Carton

### Aēs op<sub>®</sub>

SPF

30

Avail Lip Balm with Sunscreen

### Zinc Oxide • Tocopherol • Castor Seed

Rich hydration for lips, with SPF30 protection. Apply generously as often as required.

www.aesop.com Net Wt. 5.5 g / 0.2 Oz.

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> Helps prevent sunburn. :sasn

> > Octocrylene 4.25% Zinc Oxide 5.25%

Active ingredients:

Drug Facts

Sunscreen Sunscreen əsodınd

Lift for Drug Facts continued 72900<sub>11</sub>776612<sub>11</sub>6

Aesop, 25 Smith Street, Fitzroy 3065, Australia \$2 + 61 3 9412 8900 ☑ aesop@aesop.com Aesop USA Inc., P.O. Box 8045, New York, NY 10150 Manufactured in Australia.

# Aēsop.

SPF Avail Lip Balm with Sunscreen Baume à Lèvres avec Protection Solaire

Zinc Oxide • Tocopherol • Castor Seed

Rich hydration for lips, with SPF30 protection. Apply generously as often as required.

www.aesop.com

Net Wt. 5.5g / 0.2Oz.

Wax, Helianthus Annuus (Sunflower) Seed Oil, Tocopherol, Simmondsia Chinensis (Jojoba) Seed Oil, Glyceryl Behenate, Copernicia Cerifera (Camauba) Wax, Citrus Tangerina (Tangerine) Peel Oil, Hydrogenated Castor Oil, Glyceryl Isostearate, Polyhydroxystearic Acid, Lavandula Angustifolia (Lavender) Oil, Cananga Odorata Flower Oil, Ricinus Communis (Castor) Seed Oil, Jojoba Esters, Pentaerythrityl Tetraisostearate, Euphorbia Cerifera (Candelilla) Inactive ingredients:

Drug Facts (continued)

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Orug Facts (continued)

## Drug Facts (continued)

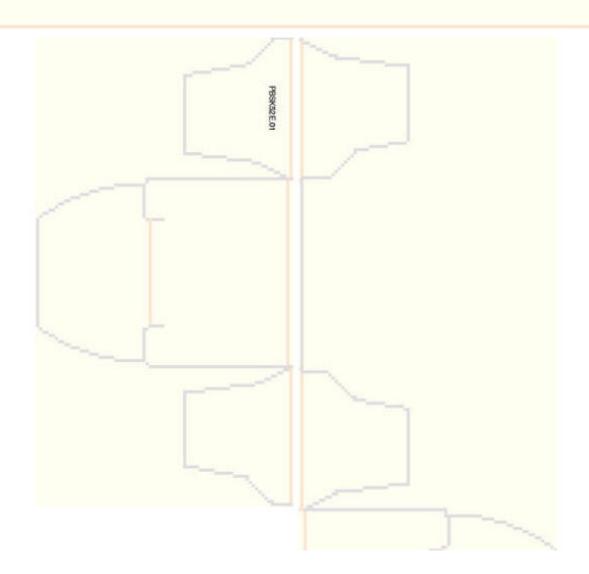
For external use only.

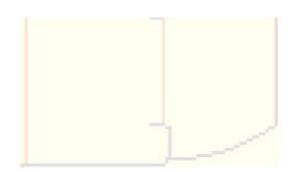
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## AVAIL LIP BALM WITH SUNSCREEN

zinc oxide and octocrylene stick

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76293-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.00058 g in 0.011 g		
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.00047 g in 0.011 g		

Inactive Ingredients	
Ingredient Name	Strength
Castor Oil (UNII: D5340 Y2I9 G)	
Hydrogenated Jojoba Oil/Jojoba Oil, Randomized (Iodine Value 57-61) (UNII: 12GIN16K1G)	
Pentaerythrityl tetraisostearate (UNII: 9D7IK5483F)	
Candelilla Wax (UNII: WL0328 HX19)	
Sunflower Oil (UNII: 3W1JG795YI)	
Tocopherol (UNII: R0ZB2556P8)	
Jojoba Oil (UNII: 724GKU717M)	
Glyceryl Dibehenate (UNII: R8WTH25YS2)	
Carnauba Wax (UNII: R12CBM0EIZ)	
Mandarin Oil (UNII: NJO720F72R)	
Hydrogenated Castor Oil (UNII: ZF94AP8MEY)	
Glyceryl Isostearate (UNII: HYE7O27HAO)	
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Cananga Oil (UNII: 8YOY78GNNX)	

Color YELLOW (Pale yellow) Score Shape Size Flavor	Product Characteristics			
	Color	YELLOW (Pale yellow)	Score	
Flavor Imprint Code	Shape		Size	
mprine code	Flavor		Imprint Code	
Contains	Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76293-052-47	1 in 1 CARTON		
1	5.5 g in 1 CYLINDER		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part352	12/0 1/20 13		

## Labeler - Emeis Cosmetics Pty Ltd (754271146)

Revised: 10/2013 Emeis Cosmetics Pty Ltd