

**SAGE AND ZINC FACIAL HYDRATING SPF15- zinc oxide lotion**  
**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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**Sage & Zinc Facial Hydrating Lotion SPF15**

**Drug Facts**

**Active ingredient**

Zinc Oxide 19.5%

**Purpose**

Sunscreen

**Uses**

- 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.

**Warnings**

**For external use only.**

**Do not use**

on damaged or broken skin.

**When using this product**

keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor**

if rash occurs.

**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.
- Children under 6 months of age: Ask a doctor.

- Reapply:
- At least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- **Sun Protection Measures.** Spending time in the sun increases risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10 a.m. - 2 p.m..
- Wear long-sleeve shirts, pants, hats and sunglasses.

### **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**

Water (Aqua), Glycerin, Coco-Caprylate/Caprates, Octyldodecanol, Acrylates Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Macadamia Integrifolia Seed Oil, Squalane, Polyglyceryl-3 Polyricinoleate, Octyldodecyl Xyloside, PEG-30 Dipolyhydroxystearate, Phenoxyethanol, Tocopheryl Acetate, Saccharide Isomerate, Oenothera Biennis (Evening Primrose) Oil, Silica, Isostearic Acid, Lavandula Angustifolia (Lavender) Oil, Glycine Soja (Soybean) Oil, Salvia Officinalis (Sage) Oil, 1,2-Hexanediol, Caprylyl Glycol, Sodium Gluconate, Fusanus Spicatus Wood Oil, Tocopherol, Polysorbate 60, Sorbitan Isostearate, Ethylhexylglycerin, Calcium Chloride, Glycine Soja (Soybean) Seed Extract, Citric Acid, Sodium Citrate, Potassium Sorbate, Xylose, Beta-Carotene, Daucus Carota Sativa (Carrot) Root Extract, Linalool, Farnesol, Limonene, Geraniol.

### **Company Information**

Manufactured in Australia.

Aesop, 25 Smith Street,

Fitzroy 3065, Australia.

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aesop@aesop.com

Distributed by Aesop USA Inc,

48 West 25th St. New York, NY,

10010

### **Product Packaging**

Aesop.

SPF 15 Sage & Zinc Facial Hydrating Lotion

Zinc Oxide

Tocopheryl Acetate

Sage Leaf

Broad-spectrum SPF15 Sunscreen

Daily-use moisturiser providing mineral-based, SPF15 sunscreen protection. Suitable for most skin types, including sensitive. Massage evenly over the face and neck after cleansing and reapply during the day to maintain protection

aesop.com

Net wt. 57 g/2.00z.

<p><b>Drug Facts</b> <i>(continued)</i></p> <p><b>Other information</b></p> <ul style="list-style-type: none"><li>• Protect the product in this container from excessive heat and direct sun.</li><li>• You may report a serious adverse reaction to Report Reaction LLC, PO Box 22, Plainsboro, NJ 08536-0222.</li></ul> <p><b>Inactive ingredients</b></p> <p>Water (Aqua), Glycerin, Coco-Caprylate/Caprates, Octyldodecanol, Acrylates Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Macadamia Integrifolia Seed Oil, Squalane, Polyglyceryl-3 Polyricinoleate, Octyldodecyl Xyloside, PEG-30 Dipolyhydroxystearate, Phenoxyethanol, Tocopheryl Acetate, Saccharide Isomerate, Oenothera Biennis (Evening Primrose) Oil, Silica, Isostearic Acid, Lavandula Angustifolia (Lavender) Oil, Glycine Soja (Soybean) Oil, Salvia Officinalis (Sage) Oil, 1,2-Hexanediol, Caprylyl Glycol, Sodium Gluconate, Fusanus Spicatus Wood Oil, Tocopherol, Polysorbate 60, Sorbitan Isostearate, Ethylhexylglycerin, Calcium Chloride, Glycine Soja (Soybean) Seed Extract, Citric Acid, Sodium Citrate, Potassium Sorbate, Xylose, Beta-Carotene, Daucus Carota Sativa (Carrot) Root Extract, Linalool, Farnesol, Limonene, Geraniol.</p>	<p><b>Aēsop.</b></p> <p><b>SPF 15 Sage &amp; Zinc Facial Hydrating Lotion</b></p> <p>Lotion Hydratante à la Sauge et au Zinc pour le Visage</p> <p>Zinc Oxide • Tocopheryl Acetate • Sage Leaf</p> <p>Oxyde de Zinc • Acétate de Tocophéryle • Feuille de Sauge</p> <p>Broad-spectrum SPF15 Sunscreen Ecran Solaire à Large Spectre SPF15</p> <p>Daily-use moisturiser providing mineral-based, SPF15 sunscreen protection. Suitable for most skin types, including sensitive. Massage evenly over the face and neck after cleansing and reapply during the day to maintain protection.</p> <p>Soin hydratant pour usage quotidien, assurant une protection solaire SPF15 à base minérale. Lotion adaptée à la plupart des types de peaux, y compris sensibles. Massez uniformément du front jusqu'au cou après nettoyage du visage et renouvelez l'application en cours de journée pour maintenir la protection.</p> <p>aesop.com Netwt. 57g/2.00z.</p>	<p><b>Drug Facts</b></p> <table border="1"><thead><tr><th>Active ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Zinc Oxide 19.5%</td><td>Sunscreen</td></tr></tbody></table> <p><b>Uses</b></p> <ul style="list-style-type: none"><li>• Helps prevent sunburn.</li><li>• 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.</li></ul> <p><b>Warnings</b></p> <p>For external use only.</p> <p>Do not use on damaged or broken skin.</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>• Apply liberally 15 minutes before sun exposure.</li><li>• Children under 6 months of age: Ask a doctor.</li></ul> <p><b>Reapply</b></p> <ul style="list-style-type: none"><li>• At least every 2 hours.</li><li>• Use a water resistant sunscreen if swimming or sweating.</li></ul> <p><b>Sun Protection Measures.</b> Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:</p> <ul style="list-style-type: none"><li>• Limit time in the sun, especially from 10 a.m. - 2 p.m.</li><li>• Wear long-sleeve shirts, pants, hats, and sunglasses.</li></ul>	Active ingredient	Purpose	Zinc Oxide 19.5%	Sunscreen
Active ingredient	Purpose					
Zinc Oxide 19.5%	Sunscreen					

For me, beauty and sunlight and joy are all one. Sappho

## SAGE AND ZINC FACIAL HYDRATING SPF15

zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76293-372
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	195 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CALCIUM CHLORIDE</b> (UNII: M4I0D6VV5M)	
<b>SOYBEAN</b> (UNII: L7HT8F1ZOD)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>XYLOSE</b> (UNII: A1TA934AKO)	
<b>CARROT</b> (UNII: L56Z1JK48B)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)</b> (UNII: 86FQE96TZ4)	
<b>MACADAMIA OIL</b> (UNII: 515610SU8C)	
<b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)	
<b>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SAGE OIL</b> (UNII: U27K0H1H2O)	
<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>SANTALUM SPICATUM OIL</b> (UNII: H9LVS6REV4)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>LUVISET 360</b> (UNII: 05BG6GY6YK)	
<b>BETA CAROTENE</b> (UNII: 01YAE03M7J)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>FARNESOL</b> (UNII: EB41QIU6JL)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>GERANIOL</b> (UNII: L837108USY)	
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>OCTYLDODECYL XYLOSIDE</b> (UNII: 8Z6VNR46QM)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	

<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76293-372-01	1 in 1 CARTON	01/01/2022	
1		57 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2022	

**Labeler** - Emeis Cosmetics Pty Ltd (754271146)

Revised: 9/2021

Emeis Cosmetics Pty Ltd