

**HYDRATING LIP BALM SPF 15 SUNSCREEN ASAP- avobenzene, homosalate, octocrylene, octisalate gel**

**AUSTRALIAN SKIN PRODUCTS 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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**hydrating lip balm SPF 15 Sunscreen**

Active Ingredients      Purpose

Avobenzene 3.5%      Sunscreen

Homosalate 5.0%      Sunscreen

Octocrylene 5.0%      Sunscreen

Octisalate 5.0%      Sunscreen

Uses: Helps prevent sunburn and chapped lips. 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.

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

Stop use and ask a doctor if rash occurs.

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

Directions

Apply Liberally to lips as often as desired

Apply liberally 15 minutes before sun exposure

Reapply: at least every 2 hours

Use a water resistant sunscreen if swimming or sweating

**Sun Protection measures.** 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 15 or higher and other skin protection measures including:

- Limit time in the sun especially from 10 a.m. -2 p.m.
- Wear long-sleeve shirts, pants, and sunglasses
- Children under 6 months ask a doctor

Hydrogenated Polysobutene, Ethylene/Propylene/Styrene Copolymer, Nicinamide, Rohododendron Ferruineum (Alpine Rose) Extract, Tricaprylin, Polyamide-3, Ethyl Macadamiate, Bisabolol, Tocopherol, Zingiber Officinale (Ginger) Root Extract, Glycerin, Malic Acid, Citrus Reticulata (Tangerine) Peel Oil, Citrus Paradisi (Grapefruit) Peel Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Medica Limonium (Lemon) peel Oil, Ethyl Methylphenylglycidate, Butylene/Ethylene/Styrene Copolymer, BHT,limonene.

asap

the science of beautiful

hydrating lip balm+

with niacinamide +Alpine Rose

protect

SPF 15 SUNSCREEN

10mL/0.34floz



asap  
the science of beautiful skin



hydrating  
lip balm+

WITH NIACINAMIDE

Drug Facts

Active ingredients  
Avobenzone 3.5%  
Homosalate 5.0%  
Octocrylene 5.0%  
Octisalate 5.0%  
Purpose Sunscreen

Uses: Helps prevent sunburn and chapped lips. 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

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

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Directions  
• Apply liberally to lips as often as desired  
• Apply liberally 15 minutes before sun exposure  
• Reapply: At least every 2 hours  
• Use a water resistant sunscreen if swimming or sweating.  
Sun Protection Measures  
Spending time in the sun

australian skin active products

asap hydrating lip balm+ contains Niacinamide to moisturise, antioxidants to soothe and protect plus Alpine Rose to help reduce cold sore occurrence.

Drug Facts (continued)

Inactive ingredients:  
Hydrogenated Polyisobutene, Ethylene/Propylene/Styrene Copolymer, Niacinamide, Rhododendron Ferrugineum (Alpine Rose) Extract, Tricaprylin, Polyamide-3, Ethyl Macadamiate, Bisabolol, Tocopherol, Zingiber Officinale (Ginger) Root Extract, Glycerin, Malic Acid, Citrus Reticulata (Tangerine) Peel Oil, Citrus Paradisi (Grapefruit) Peel Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Medica Limonum (Lemon) Peel Oil, Ethyl Methylphenylglycidate, Butylene/Ethylene/Styrene Copolymer, BHT, Limonene.

Other Information:  
Protect this product from excessive



## HYDRATING LIP BALM SPF 15 SUNSCREEN ASAP

avobenzone, homosalate, octocrylene, octisalate gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:76261-127 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 3.5 g in 100 mL |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 5.0 g in 100 mL |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 5.0 g in 100 mL |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 5.0 g in 100 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>HYDROGENATED POLYBUTENE (1300 MW)</b> (UNII: 7D1YQ9Y5EZ) |          |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4)                       |          |
| <b>TRICAPRYLIN</b> (UNII: 6P92858988)                       |          |
| <b>ETHYL MACADAMIATE</b> (UNII: ANA2NCS6V1)                 |          |
| <b>.ALPHA.-BISABOLOL, (+)-</b> (UNII: 105S6I733Z)           |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                        |          |
| <b>GINGER</b> (UNII: C5529G5JPQ)                            |          |
| <b>MALIC ACID</b> (UNII: 817L1N4CKP)                        |          |
| <b>MANDARIN OIL</b> (UNII: NJO720F72R)                      |          |
| <b>GRAPEFRUIT OIL</b> (UNII: YR377U58W9)                    |          |

|   |  |
|---|--|
| <b>BERGAMOT OIL</b> (UNII: 39W1PKE3J)                 |  |
| <b>LEMON OIL</b> (UNII: I9GRO824LL)                   |  |
| <b>ETHYL METHYLPHENYLGLYCIDATE</b> (UNII: UD51D5KR4A) |  |
| <b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)    |  |
| <b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)              |  |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:76261-127-02 | 1 in 1 CARTON       |                      |                    |
| 1 | NDC:76261-127-01 | 10 mL in 1 TUBE     |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352                                  | 08/07/2014           |                    |

**Labeler** - AUSTRALIAN SKIN PRODUCTS PTY LTD (752403019)

**Registrant** - AUSTRALIAN SKIN PRODUCTS PTY LTD (752403019)

### Establishment

| Name                        | Address | ID/FEI    | Business Operations    |
|-----------------------------|---------|-----------|------------------------|
| Natural Beauty Care Pty Ltd |         | 749369716 | manufacture(76261-127) |

Revised: 8/2014

AUSTRALIAN SKIN PRODUCTS PTY LTD