

**AUSTRALIAN GOLD KIDS SPF 50 SUNSCREEN- homosalate, octinoxate, octisalate and titanium dioxide lotion**

**Prime Enterprises Inc.**

*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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**Australian Gold Kids SPF 50 Broad Spectrum Lotion Sunscreen**

***Active Ingredients***

Homosalate 10%

Octinoxate 7.5%

Octisalate 5%

Titanium Dioxide 2.4%

***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

**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 product is swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 80 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 this risk, regularly use a sunscreen with broad spectrum SPF 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
  - children under 6 months: Ask a doctor

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Caprylhydroxamic Acid, Caprylyl Glycol, Carbomer,

Dimethicone, Disodium EDTA, Fragrance, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Polyethylene, Polyhydroxystearic acid, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Styrene/Acrylates Copolymer, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

***Other Information***

- protect this product from excessive heat and direct sun

***Questions or Comments?***

Call toll free 1-855-LIV-GOLD (548-4653)

**Australian Gold Kids SPF 50 Lotion Sunscreen**



<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Homosalate 10% Octinoxate 7.5% Octisalate 5% Titanium Dioxide 2.4%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>helps prevent sunburn</li> <li>if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>	
<b>Warnings</b>	
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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 product is swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply:               <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>immediately after towel drying</li> <li>at least every 2 hours</li> </ul> </li> <li><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 of 15 or higher and other sun protection measures including:               <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> <li>children under 6 months: Ask a doctor</li> </ul> </li> </ul>	
<b>Inactive ingredients</b> Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadosensis Leaf Juice, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Caprylhydroxamic Acid, Caprylyl Glycol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Polyethylene, Polyhydroxystearic acid, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Styrene/Acrylates Copolymer, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>protect this product from excessive heat and direct sun</li> </ul>	
<b>Questions or comments?</b>	
Call toll free 1-855-LIV-GOLD (548-4653)	

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## AUSTRALIAN GOLD KIDS SPF 50 SUNSCREEN

homosalate, octinoxate, octisalate and titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0200
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	24.5 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	102 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	76.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TEA TREE OIL (UNII: VIF565UC2G)	
COCOA BUTTER (UNII: 512OYT1CRR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHACRYLATE/METHOXY PEG-10 MALEATE/STYRENE COPOLYMER (UNII: 39DK5WQ2PR)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0200-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/02/2015	

**Labeler** - Prime Enterprises Inc. (101946028)

**Registrant** - Prime Enterprises Inc. (101946028)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0200) , manufacture(58443-0200) , label(58443-0200)

Revised: 1/2020

Prime Enterprises Inc.