

**STANDARD PROCEDURE SPF 50 SUNSCREEN- homosalate, octocrylene, octisalate, avobenzone lotion**  
**Standard Procedure Inc**

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**Active Ingredients**

Homosalate 10%

Octocrylene 8%

Octisalate 5%

Avobenzone 3%

**Purpose**

Sunscreen

**Uses**

Helps prevent sunburn

If used as directed with other sun protection measures (see Directions), decrease 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
- 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**

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

**Directions**

- Apply generously and evenly 15 minutes before sun exposure
- Reapply at least every 80 minutes
- 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 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

## **Other Information**

Protect the product in this container from excessive heat and direct sun

## **Inactive Ingredients**

BEESWAX, CYCLOPENTASILOXANE, CETEARYL ALCOHOL, ISOPROPYL PALMITATE, CYCLOHEXASILOXANE, CETEARETH-20, ALOE BARBADENSIS LEAF JUICE, ANANAS SATIVUS (PINEAPPLE) FRUIT EXTRACT, BENZYL ALCOHOL, CARBOMER, CARICA PAPAYA (PAPAYA) FRUIT EXTRACT, CITRIC ACID, GLYCERIN, HYDROXYACETOPHENONE, MALTODEXTRIN, MANGIFERA INDICA (MANGO) FRUIT EXTRACT, SODIUM STEAROYL GLUTAMATE, TOCOPHERYL ACETATE, TRIETHANOLAMINE, PHENOXYETHANOL, WATER

## **Contact**

Standard Procedure Inc

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## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

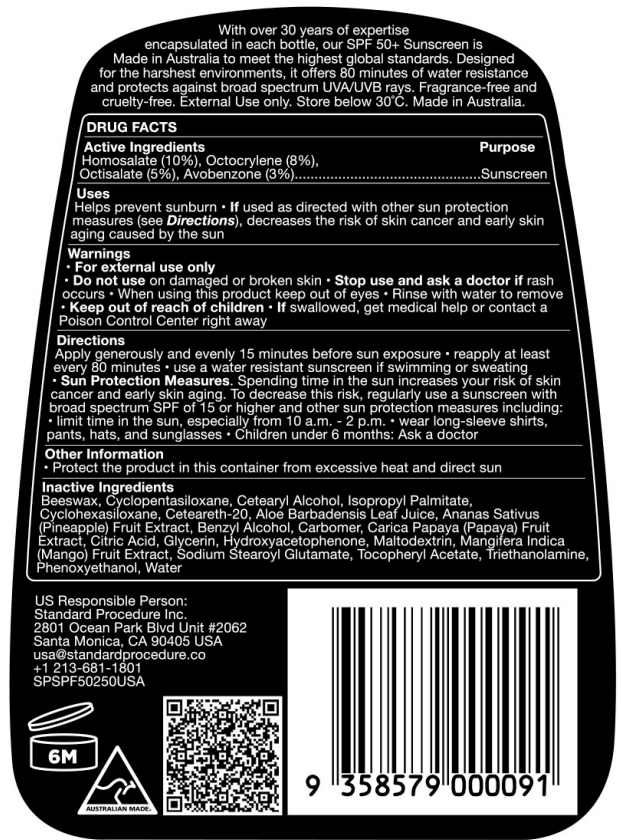
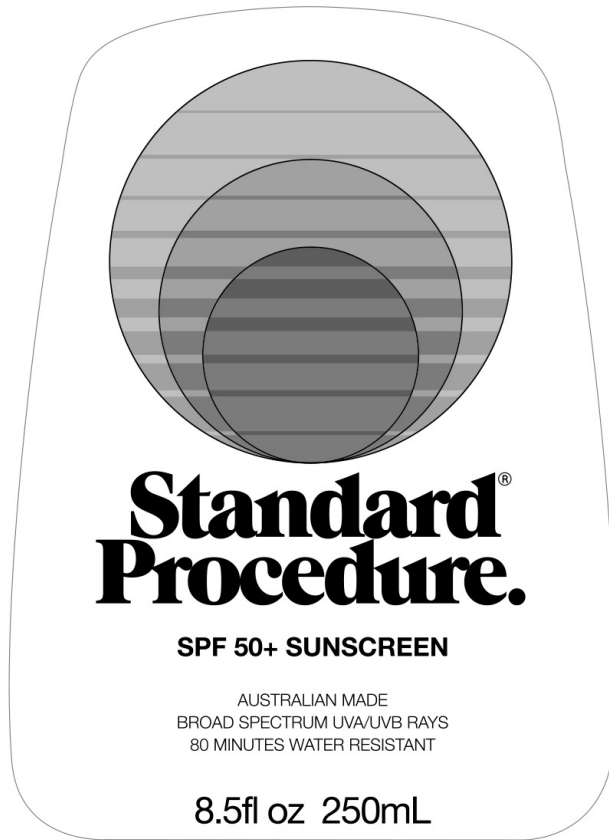
Standard Procedure.

SPF 50+ Sunscreen

Australian Made

Broad Spectrum UVA/UVB Rays

80 minutes Water Resistant



## STANDARD PROCEDURE SPF 50 SUNSCREEN

homosalate, octocrylene, octisalate, avobenzone lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84425-101
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>PEG-8 BEESWAX</b> (UNII: 3C1QUF1TIR)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>MANGO</b> (UNII: I629I3NR86)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWJY)	
<b>PAPAYA</b> (UNII: KU94FIY6JB)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84425-101-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2024	
2	NDC:84425-101-03	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2024	
3	NDC:84425-101-04	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/15/2024	

**Labeler** - Standard Procedure Inc (119276141)