

STANDARD PROCEDURE SPF 50 SUNSCREEN- homosalate, octocrylene,

octisalate, avobenzone lotion

Standard Procedure Inc

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

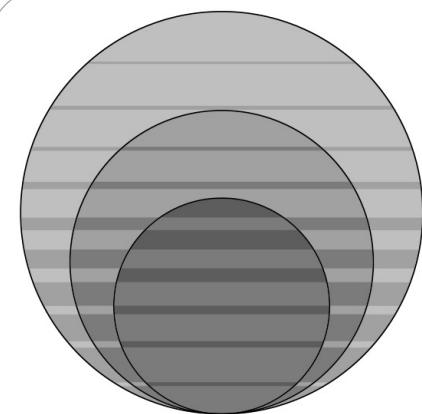
BEESWAX, CYCLOPENTASILOXANE, CETEARYL ALCOHOL, ISOPROPYL PALMITATE, CYCLOHEXASILOXANE, CETEARETH-20, ALOE BARBADENSIS LEAF JUICE, ANANAS SATIVUS (PINEAPPLE) FRUIT EXTRACT, BENZYL ALCOHOL, CARBOMER, CARICA PAPAYA (PAPAYA) FRUIT EXTRACT, CITRIC ACID, GLYCERIN, HYDROXYACETOPHENONE, MALTODEXTRIN, MANGIFERA 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

AUSTRALIAN MADE
BROAD SPECTRUM UVA/UVB RAYS
80 MINUTES WATER RESISTANT

8.5fl oz 250mL

With over 30 years of expertise encapsulated in each bottle, our SPF 50+ Sunscreen is Made in Australia to meet the highest global standards. Designed for the harshest environments, it offers 80 minutes of water resistance and protects against broad spectrum UVA/UVB rays. Fragrance-free and cruelty-free. External Use only. Store below 30°C. Made in Australia.

DRUG FACTS

Active Ingredients	Purpose
Homosalate (10%), Octocrylene (8%), Octisalate (5%), Avobenzene (3%)	Sunscreen
Uses	
Helps prevent sunburn. 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.	
Warnings	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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 Stearyl Glutamate, Tocopherol Acetate, Triethanolamine, Phenoxyethanol, Water

US Responsible Person:
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STANDARD PROCEDURE SPF 50 SUNSCREEN

homosalate, octocrylene, octisalate, avobenzene 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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

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

WATER (UNII: 059QF0KO0R)
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)
GLYCERIN (UNII: PDC6A3C00X)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
TROLAMINE (UNII: 9O3K93S3TK)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
BENZYL ALCOHOL (UNII: LKG8494WBH)
MANGO (UNII: I629I3NR86)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
PAPAYA (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)

Revised: 1/2026

Standard Procedure Inc