

**SUNNY SKIN SUPER SUN SPF50- zinc oxide cream**  
**MCDONALD MULTINATIONAL 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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**Active ingredient**

Zinc Oxide 22.75%

**Purpose**

Mineral Sunscreen

**Uses**

Help Prevent Sunburn. If uses as directed with other sun protection measures (see **directions**) decreases the risk of skin cancer and early ageing 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 doctor** is rash occurs.

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control centre right away.

**Directions**

**For sunscreen use:** • apply liberally 15 mins before sun exposure • apply to all skin exposed to the sun • use a water resistant sunscreen if swimming or sweating • reapply at least every 2 hours.

**Children under 6 months old of age:** ask doctor. **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 value of 15 or higher and other sun protection measures including: • limit time in the sun, especially 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats and sunglasses.

**Inactive Ingredients**

MediumChain(Caprylic/capric) triglycerides, Castor (Ricinus communis) Seed Oil, Coco-octanoate (Coco-caprylate/caprinate), Coconut (Cocos nucifera) Oil, Candellila wax,

Hydrogenated castor oil, polyglyceryl-3 polyricinoleate, Tocopheryl acetate, Iron oxides, isostearic acid, IBR-TCLC in Jojoba Oil 0705 (Simmondsia Chinensis (Jojoba) Seed Oil (and) Squalane (and) Solanum Lycopersicum (Tomato) Fruit Extract).

## Other information

protect this product from excessive heat and direct sun.

## Questions or Comments?

Email [hello@sunnyskin.com](mailto:hello@sunnyskin.com)

## Product label

**Hello!** I'm a mineral SPF50, antioxidant-rich sunscreen created for daily use by a real Facialist. Fragrance free & no nasties makes me safe for sensitive skin, during pregnancy & breastfeeding. I'm also vegan, cruelty free, Aussie made & owned.  
Water Resistant (80 minutes).

**DRUG FACTS**

Active Ingredient	Purpose
Zinc Oxide 22.75%	Sunscreen

**Uses**  
• Helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early 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 doctor if rash occurs.  
Keep out of reach of children.  
If swallowed, get medical help or contact a poison control center right away.

**Directions**  
**For sunscreen use:** • apply liberally 15 mins before sun exposure • apply to all skin exposed to the sun • use a water resistant sunscreen if swimming or sweating • reapply at least every 2 hours.  
**Children under 6 months old of age:** ask doctor.  
**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 value of 15 or higher and other sun protection measures including: • limit time in the sun, especially 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats and sunglasses.

**Inactive ingredients** • Medium Chain (Caprylic/capric) triglycerides, Castor (Ricinus communis) Seed Oil, Cocooctanoates (Cocooctylates/caprylates), Candelilla wax, Coconut (Cocos nucifera) Oil, Polyglyceryl-3 polyricinoleate, isostearic acid, d-alpha tocopheryl acetate, Simmondsia chinensis (jojoba) oil, Solanum lycopersicum (Tomato) fruit extract, Squalane.

**Other information** • protect this product from excessive heat and direct sun.

**Questions or Comments?**  
Email [hello@sunnyskin.com](mailto:hello@sunnyskin.com)

Made in Australia by Sunny Skin  
McDonald Multinational Pty Ltd  
Suite 88, Level 54, 111 Eagle St,  
Brisbane, QLD 4000 Australia.  
[sunnyskin.com](http://sunnyskin.com)

**Mineral Face Sunscreen**  
With Antioxidants  
Broad Spectrum SPF50

**Environmental & Blue Light Defense**

Écran solaire minéral pour  
Le visage avec antioxydants  
Large spectre FPS50  
Défense environnementale et lumière bleue

**SS.**

50ml e / 1.7 fl. oz. AUST L 350811

**SUPER SUN is ...**

Cruelty free	Vegan	Paraben free
Fragrance free	Sensitive skin safe	Australian made

share the sunshine @mysunnyskin

## SUNNY SKIN SUPER SUN SPF50

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83070-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	22.75 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>COCOYL CAPRYLOCAPRATE</b> (UNII: 8D9H4QU99H)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>SOLANUM LYCOCARPUM FRUIT</b> (UNII: GL29VWX729)	
<b>SQUALANE</b> (UNII: GW89575KF9)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83070-001-01	1 in 1 BOX	10/27/2022	
1		50 mL in 1 TUBE; 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	part348	10/27/2022	

**Labeler** - MCDONALD MULTINATIONAL PTY LTD (746817764)

Revised: 10/2022

MCDONALD MULTINATIONAL PTY LTD