

**SUNNY SKIN GLOW FILTER 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**

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



SUNNY SKIN GLOW FILTER SPF50			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83070-002
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CASTOR OIL (UNII: D5340Y2I9G)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
CANDELILLA WAX (UNII: WL0328HX19)	
COCONUT OIL (UNII: Q9L0O73W7L)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
JOJOBA OIL (UNII: 724GKU717M)	
SOLANUM LYCOCARPUM FRUIT (UNII: GL29VWX729)	
SQUALANE (UNII: GW89575KF9)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83070-002-01	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

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