

**SOLEO ORGANICS SUNSCREEN - zinc oxide cream**  
**SE Operations 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.*

-----  
**Soléo® Organics**

**Drug Facts**

**Active Ingredients (USA/AUS)**

Zinc oxide 22.3% w/w

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn
- higher SPF gives more sunburn protection
- provides high protection against sunburn
- retains SPF after 80 minutes of activity in the water

**Warnings**

- **For external use only**
- **When using this product** keep out of eyes, rinse with water to remove
- Keep out of reach of children
- Avoid prolonged exposure to the sun
- Wear protective clothing, hats and eye wear when in the sun
- Stop use and ask a doctor if rash or irritation develops and lasts

**Directions**

- Squeeze cream and shake tube well before use
- apply liberally 20 minutes before sun exposure and as needed
- store below 30°C/86°F

**Inactive Ingredients**

Beeswax, candelilla wax, caprylic/capric triglyceride (plant sourced), coconut extract,

cucumber extract, cupuacu butter, grapeseed oil, green tea leaf extract, lecithin, macadamia oil, roman chamomile extract, safflower oil, sunflower oil, vegetable oil, vitamin E (natural)

**PRINCIPAL DISPLAY PANEL - 80 g Tube Carton**

MULTI  
AWARD  
WINNING  
#1  
SUNSCREEN

soléo®  
organics

ORIGINAL FORMULA  
HIGH PERFORMANCE

• SE FORMULA •  
SE FORMULA

ALL NATURAL  
SUNSCREEN

SPF  
30

3hour  
very water  
resistant\*

UV-A  
UV-B  
Broad Spectrum

80g/2.8 oz e AUST-L 116246



# SOLEO ORGANICS SUNSCREEN

zinc oxide cream

## Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:11045-0303

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	223 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
GRAPE SEED OIL (UNII: 930MLC8XGG)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MACADAMIA OIL (UNII: 515610SU8C)	
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CUCUMBER (UNII: YY7C30VXJT)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11045-0303-1	40 g in 1 TUBE; Type 0: Not a Combination Product	01/20/2007	
2	NDC:11045-0303-2	1 in 1 CARTON	01/20/2007	
2		80 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:11045-0303-3	1 in 1 CARTON	01/20/2007	
3		150 g 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	part352	01/20/2007	

Labeler - SE Operations Pty Ltd (752826854)

