

SOLEO ORGANICS SUNSCREEN - zinc oxide cream
SE Operations Pty Ltd

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)	
SOYBEAN LECITHIN (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 drug	M020	01/20/2007	

Labeler - SE Operations Pty Ltd (752826854)