MELVITA PROSUN SPF 15 SUN - titanium dioxide and zinc oxide cream Laboratoires M&L

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.

Melvita PROSUN SPF 15 Sun Cream

Active Ingredients

Titanium Dioxide 5.905% Zinc Oxide 12%

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides moderate protection against sunburn

Warnings

For external use only.

When using this product

- Keep out of eyes. Rinse with water to remove.

Stop use and ask doctor if:

- Rash or irritation develops and lasts.

Keep Out Of Reach Of Children

Keep out of the reach of children, if swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply liberally before sun exposure and as needed

Children under 6 months of age: ask a doctor - Reapply as needed or after towel drying, swimming or sweating

Other information

Moderate sun protection product sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Inactive Ingredients

Citrus Aurantium Dulcis FruitWater [Citrus Aurantium Dulcis (Orange)FruitWater]*, Caprylic/Capric Triglyceride, Aqua[Water], Helianthus Annuus Seed Oil [Helianthus Annuus (Sunflower) Seed Oil]*, Polyglyceryl-2 polyhydraystearate, Glycerin, Octyldecanol, Silica, Lauryl Laurate, Mangifera Indica

Seed Oil [Mangifera Indica (Mango) Seed Butter], Sesamum Indicum Seed Oil [Sesamum Indicum (Sesame) Seed Oil]*, Simmondsia Chinensis Seed Oil [Simmondsia Chinensis (Jojoba) Seed Oil]*, Glyceryl Isostearate, Benzyl Alcohol, Olus Oil (Vegatable Oil), Polyglyceryl-3 Disostearate, Pongamol, Alumina, Stearic Acid, PolyhydroxyStearic Acid, Cera Alba [Beeswax], Magnesium Sulfate, Parfum [Fragrance], Tocopherol, Dehydroacetic Acid, Hydrogenated Vegetable Oil, Inositol, Sodium Phytate, Candelila Cera [Euphorbia Cerifera (Candelilla) Wax], Linalool**, Citronellol**, Limonene**, Alcohol. * Ingredients from Organic Farming

Description

Packaging from sustainably managed forests and printed with vegetable inks. SPF 15 sun cream medium protection - darker skin. This nano-particle free formulation contains natural mineral sun filters to provide medium protection. The cream is recommended for darker skins, offering protection against Atype ultra-violet rays and helping towards a radiant, lasting tan. It is also recommended for moderate sun exposure. It owes its protective, moisturizing properties to the Pongamia extract, Mango butter and Sesame and Jojoba oils. Carob extract intensifies the quality of the tan and helps to sustain it. Usage instructions: apply generously to dry skin on the face and body before and during exposure to the sun. Renew the applications approximately every 2 hours and after swimming or sporting activities. Avoid the eye contour, Sun advice: Choose your level of sun protection based on your skin type. Avoid exposure between 12.00 and 4.00 pm and do not extend your exposure time. Protect children from the sun's direct rays and always shelter children under the age of 3. Sun Protection indicee UVA and SPF calculated by an independent laboratory UVA protection complient with the European SPF/UVA Less than or equal to 3 ratio Critical wavelength Less than or equal to 370 mm 100% mineral origin sun block. Natural and Organic Cosmetic certified by ECOCERT Greenlife according to ECOCERT Standard available at http://cosmetic.eccocert.com 98.95% of the total ingredients from natural origin. 32% of the total ingredients from Organic Farming.

Purpose

Sunscreen

Melvita PROSUN SPF 15 Sun Cream 75ml (43611-002-00)

chémie solaire SPF 15
protection moyenne - peaux mates
Présentant un indue de moyenne protection conféré
par des fitres minéraux sans nanoparticules, cette crême
solarie est recommandée pour les peaux mates.
Assurant en outre une excelente protection contre les
ayons utra-violats de type à leit avantes un pronzage
solatant et dunable. Elle est aussi recommandée
lors d'expositions d'ensolaiement impéré. Elle doit
aes qualités protectiones et hydratantes à fectient de
Pongamia, au beurre de Mangue et aux huiles de
Sesame et Jojoba. Un extrait de Caroube interséne la
quetité du bronzage et en optimée la tenue.
Obiseits d'utilisation : appliquer géndreusement sur
peau séche sur le visage et le comps avant et pendant
rexposition au soteit. Benouveer fapolication environ
toutes les 2 heures et après chaque bagnade ou la
pratique d'un sport. Eviter le controur des yeux.
Préseautione face au soteit : photsir un riveau de
protection au soteit son type de peau. Ne pass exposer
les entents de moins de s'ans. Eviter l'exposition entra
12h et 16h; ainsi qu'une exposition trop protongée.
Protége ne sontants des repors dimons du soteit.

Indoce de protection soulie UVA et SPF

mando i godo assicino.

Consejos de utilización ; aplicar generosamente, sobre la pel soca de rostro y el quelo amiss y durante la exposición al sol. Repetir la aplicación cada 2 horas, así como después de bañarse o practicar deporte. Extrar el contorno de los ejos.

Precauciónes frente al sol : elegir un nivel de protección adaptado el tipo de piet. No exponer a los niflos menores de 3 años. Evitar la exposición entre la 12n y las 15n así como la exposición demasiado.



MELVITA - La Fontaine du Oade 07150 Lagorce - France - www.melvita.com

mittierer schutz- dunise Haut Marigo - Jujoba - Sasarin Diese Sonnenbrerne ohne Nanoparitike bestät dank das 180% mitantschar Flüss einer mittleren Schutzfeaktor und sit für dunide Haut gesignet. Barbunde hinaus schutzt alle hervorragend vor UVA-Strahlen und fördet ane filsone und länganhattende. Erzune Diese Sonnenbrattende Bertranderster sinst für ein Sonnenbad bei moderater sonnenbratterlung geognat. Anwendung: vor dem Sonnenbad porfotzug jauf dietrocknen Hauf von Gesicht und Körper auftragen, Anwendung auf die Vor allem aug die auf die Stunden und vor allem nach wiederholen. Augenikontur aussparen. Vorsichtenaßrahmen gegen Schmen-Vorsichtenaßrahmen gegen Schmen-Vorsichtenaßrahmen gegen Schmendem Baden und sportschen Ast masso-wiederholen. Augenkontur aussparen. Vorschlistmaßnahmen gegen Sonnen-brand ; einen für den indiruduslen Hauf-tip geognation Schutztaltor auswählen. Kinder unter 3. Jehren nichtt der Sonne aussatzen. Zwischen 12.00. und 16.00. Uhr nichtlin der Sonne aufhalten und nicht zu lange in der Sonne beisben. Kinder vor direkten Sonnenstrehlen schützen.

Precauzioni nell'esposizione al sole: scagliare un liveto di protezione adatto al proprio tipo di pelle. Non esporre ai sole bambhi di meno 3 anni. Evitare un'espoestione prolungata tra le 12 e le 15. Proteggere i bambini dai raggi diretti



PROSUN

Crème solaire

Moyenne protection peaux mates

Sun cream

medium protection - darker skin

Sonnencreme mi...derer Schutz - dunkle Taut.

mangue - Jojoba - sésame

SPF 15 sum cream medium protection - darker skin. This rano-particle free romulation contains return immediate skin filter and the protection. The organisms commended for deriver skins offering protection against A-type ultra-violer tays and helping towards a radient, lacting tan it is also recommended for impoderess undeposure, it lowes its protection, mosturary properties to the Pongamia extent. Mango butter and Sosame and Jopbia ols. Carob extent intensifies the quetty of the tan and helps to sustain it. Usage instructions: apply generously only skin on the face and body before and during exposure to the sun. Renew the appreciation appreciation structure and start evimming or sporting activities. Avoid the eye opticul. Sun advices: choose your level of sun protection to based on your skin type. Avoid exposure between 12:00 and 4:00 pm and do not extend you exposure in the Protect children from the sun's direct rays and always shelter children under the age of 3.

mengo - jojoba - sesam Gebruikeadvies : Royad æmbrenger op de droge huld van gezicht en Ichaam, voor en tigens de bioosteling ann de zon De toepassing om de 2 uur harhalan en eveneens na het zwemmen









2.53 fl.oz





e 75 ml



Active Ingredients Titanium Dioxide 5.905% Zinc Oxide 12%

Purpose Sunscreen Sunscreen

Uses

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Melvita

PROSUN

Crème solaire

15 15

moyenne protection peaux mates

Sun cream

medium protection





2,53 fl.oz.



Conseils d'utilisation: appliquer généreusement sur peau sèche sur le visage et le corps avant et pendant l'exposition au soleil. Renouveler l'application environ toutes les 2 heures et après chaque balgnade ou la pratique d'un sport.

Usage instructions: apply generously to dry skin on the face and body before and during exposure to the sun. Renew the application approximately every 2 hours and after swimming or sporting activities.

Sonnencreme LSF 15 mittlerer Schutz

Crema solar SPF 15 protección media

Crema solare SPF 15 protezione media

Zonnecrème SPF 15 middelhoge bescherming

Cosmétique Ecologique et Biologique certifié par ECOCERT Greenlife.

Natural and Organic Cosmetic certified by ECOCERT Greenlife.





Made in France

MELVITA - La Fontaine du Cade 07150 Lagorœ - France www.melvita.com

MELVITA PROSUN SPF 15 SUN

titanium dioxide, zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:43611-002

Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIO XIDE (TITANIUM DIO XIDE)	TITANIUM DIO XIDE	59.05 mg in 1 mL
ZINC OXIDE (ZINC OXIDE)	ZINC OXIDE	120 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ORANGE	
MEDIUM-CHAIN TRIGLYCERIDES	
WATER	
SUNFLO WER O IL	
GLYCERIN	
OCTYLDECANOL	
SILICON DIO XIDE	
LAURYL LAURATE	
MANGIFERA INDICA SEED BUTTER	
SESAME OIL	
SIMMONDSIA CHINENSIS SEED	
GLYCERYL ISOSTEARATE	
BENZYL ALCOHOL	
PONGAMOL	
ALUMINUM O XIDE	
STEARIC ACID	
POLYHYDRO XYSTEARIC ACID (2300 MW)	
MAGNESIUM SULFATE, UNSPECIFIED	
TOCOPHEROL	
DEHYDRO ACETIC ACID	
INOSITOL	
CANDELILLA WAX	
LINALOOL, (+/-)-	
.BETACITRONELLOL, (R)-	
ALCOHOL	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:43611-002-00	1 in 1 BOX		
1	75 mL in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	09/12/2011		

Labeler - Laboratoires M&L (263910193)

Registrant - Laboratoires M&L (263910193)

Establishment				
Name	Address	ID/FEI	Business Operations	
Laboratoires M&L		263910193	manufacture(43611-002)	

Revised: 4/2013 Laboratoires M&L