

**SUSANNE KAUFMANN SUNCARE FACE BROAD SPECTRUM PROTECTION
SUNSCREEN SPF 30 UVB UVA- zinc oxide lotion**

Susanne Kaufmann Kosmetik GmbH

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.

Zinc oxide 3.0%

Sunscreen

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Retains SPF after 40 minutes of activity in the water or sweating

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 a doctor if rash occurs

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away.

- For sunscreen use
- Apply generously and evenly 15 minutes before sun exposure to all skin exposed to the sun
- Reapply
- after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- Sun Protection Measures. Do not remain in the sun for too long, even if you are using a sunscreen product. Even with UV light protection, direct sunlight at noontime is to be avoided. If not enough of the product is used, the sun protection provided is significantly reduced. Avoid excessive sunbathing. Do not expose infants and small children to direct sunlight. 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 from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - Ask a doctor before use on children under six month of age

Do not store above 25°C. protect the product in this container from excessive heat and direct sun

coco caprylate, pongamia glabra seed oil, tocopherol, capric caprylic triglyceride, polyhydroxystearic acid, cetearyl alcohol, cetearyl olivate, sorbitan olivate, water, pentylene glycol nat., carrageenan, xanthan gum, sodium polyphosphate, sodium stearyl glutamate, cardiospermum halicacabum seed extract, glycerin, polygonum aviculare extract, simmondsia chinensis (jojoba) oil, squalene, solanum lycopersicum (tomato) fruit extract, ectoine, lactic acid, parfum (fragrance).

se Hinweis zur sicheren Anwendung von Sonnenschutzmitteln. Bleiben Sie vor Verwendung eines Sonnenschutzmittels nicht zu lange in der Sonne. Auch mit UV-Lichtschutz eine direkte Sonneneinstrahlung in der Mittagshitze meiden. Der Sonnenschutz wird durch Verwendung einer zu geringen Menge erheblich gemindert. Vermeiden Sie exzessive Sonnenbäder. Säuglinge und Kleinkinder nicht dem direkten Sonnenlicht aussetzen.

Hinweise zur Verpackung: Eine spezielle Dose mit airless-System und selbstausgender Pumpe gewährleistet eine präzise Dosierung, eine Anwendungsmöglichkeit in jeder Position (360° Funktion), einen maximalen Schutz des Doziments vor Verunreinigung durch Umwelteinflüsse und eine minimale Restmenge nach Aufbrauchen. Den kleinen Stempelverschluss am Dispenserkopf (= Originalverschluss) vor Verwendung entfernen. Bei erstmaliger Anwendung ist es notwendig den Pumpenkopf öfters zu betätigen bis Gel aus dem Dispenser austritt.

Lagerung: Nicht über 25°C lagern. Den Inhalt inner 6 Monaten nach Anbruch aufbrauchen.

se Packaging instructions: A special container using an airless system and self-priming pump ensures a precise dosage, application in every position (360° function), maximum protection of the contents against soiling and a minimum amount of residual product after use. Remove the small plug from the dispenser head (= original seal) before use. When using this product for the first time, press down on the pump button multiple times until gel emerges from the dispenser.

Storage: Use the product within 6 months of opening the container.



MADE IN AUSTRIA
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SUSANNE KAUFMANN™

Suncare

Face Broad Spectrum
 Protection Sunscreen



SPF 30 UVB UVA

Water Resistant (40 minutes)

50 ml (1.7 FL OZ)

NDC 69937-002-02

Die innovative Sonnencreme mit SPF 30 schützt die Haut nicht nur optimal vor der Sonne*, sondern auch vor den Zeichen der Hautalterung. Sie gewährleistet einen maximalen UVB- und UVA-Schutz sowie einen Infrarot-A (IR)-Schutz*, der die tiefen Schichten der Dermis vor diesen Strahlen schützt. Der patentierte Wirkstoff Elix-IR™ zielt speziell auf infrarotinduzierte Hautalterung* ab, erhöht nachweislich die Elastizität* und verbessert die Spannkraft des Gewebes. Ectoin beschleunigt die Zellerneuerung* und verhilft der Haut so zu einem jugendlichen und glatten Aussehen. Die Sonnencreme ist wasserabweisend und enthält ausschließlich natürliche Inhaltsstoffe. Mindestens 15 Minuten vor der ersten Sonneneinstrahlung auf das Gesicht auftragen, alleine oder mit weiteren Susanne Kaufmann Produkten.

The innovative sunscreen with SPF 30 not only provides the skin with optimal protection from the sun*, it also works against signs of aging skin. The patented active ingredient Elix-IR™ specially targets sunexposed aging of the skin*, verifiably increases the elasticity* and improves the buoyancy of the tissue. Ectoin improves the skin repair mechanism and helps the skin achieve a youthful and smooth appearance. The sunscreen is water-resistant (40 minutes) and contains a mineral-based sun protection filter. Apply at least 15 minutes before sun exposure to the face – alone or with other Susanne Kaufmann products.

* In vivo test of the active ingredients

Drug Facts

Active ingredients	Purpose
Zinc oxide 3.0%	Sunscreen
Use	
<ul style="list-style-type: none"> Helps prevent sunburn Higher SPF gives more sunburn protection Retains SPF after 40 minutes of activity in the water or sweating 	
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 a doctor if rash occurs	
Keep out of reach of children	
If swallowed get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> For sunscreen use Apply generously and evenly 15 minutes before sun exposure to all skin exposed to the sun Reapply <ul style="list-style-type: none"> after 40 minutes of swimming or sweating immediately after towel drying at least every 2 hours Sun Protection Measures. Do not remain in the sun for too long, even if you are using a sunscreen product. Even with UV light protection, direct sunlight at noontime is to be avoided. If not enough of the product is used, the sun protection provided is significantly reduced. Avoid excessive sunbathing. Do not expose infants and small children to direct sunlight. 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: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. - 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses ask a doctor before use on children under six months of age 	
Other information	
Do not store above 25°C, protect the product in this container from excessive heat and direct sun	
Inactive ingredients coco caprylate, pongamia glabra seed oil, tocopherol, capric caprylic triglyceride, polyhydroxystearic acid, cetearyl alcohol, cetearyl olivate, sorbitan olivate, water, pentylene glycol, nat., carrageenan, xanthan gum, sodium polyphosphate, sodium stearyl glutamate, cardiospermum halicacabum seed extract, glycerin, polygonum aviculare extract, simmondsia chinensis (jojoba) oil, squalene, solanum lycopersicum (tomato) fruit extract, octane, lactic acid, parfum (fragrance).	
Susanne Kaufmann Kosmetik GmbH Brugg 35, 6870 Bezau, Austria	

SUSANNE KAUFMANN SUNCARE FACE BROAD SPECTRUM PROTECTION SUNSCREEN SPF 30 UVB UVA

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69937-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SQUALENE (UNII: 7QWM220FJH)	
TOMATO (UNII: Z4KHF2C175)	
ECTOINE (UNII: 7GXZ3858RY)	
LACTIC ACID (UNII: 33X04XA5AT)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
XANTHAN GUM (UNII: TTV12P4NEE)	

SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL OLIVATE (UNII: 58B69Q84JO)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
GLYCERIN (UNII: PDC6A3C0OX)
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)
CARDIOSPERMUM HALICACABUM SEED (UNII: Y5T803X015)
WATER (UNII: 059QF0K00R)
KARUM SEED OIL (UNII: 62160PU6FJ)
TOCOPHEROL (UNII: R0ZB2556P8)
SORBITAN OLIVATE (UNII: MDL271E3GR)
JOJOBA OIL (UNII: 724GKU717M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69937-002-02	1 in 1 CARTON	06/01/2017	
1		50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/01/2017	

Labeler - Susanne Kaufmann Kosmetik GmbH (300087547)

Registrant - Susanne Kaufmann Kosmetik GmbH (300087547)

Establishment

Name	Address	ID/FEI	Business Operations
Island Kinetics, Inc. d.b.a. Co Valence Laboratories		959735002	manufacture(69937-002)

Revised: 7/2017

Susanne Kaufmann Kosmetik GmbH