

**SUSANNE KAUFMANN SUNCARE BODY BROAD SPECTRUM PROTECTION
SUNSCREEN SPF 25 UVB UVA- avobenzone, ensulizole, octocrylene 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.

Octocrylene 4.0%

Avobenzone 3.0%

Ensulizole 2.5%

Sunscreen

Helps prevent sunburn

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

- Apply generously and evenly 15 minutes before sun exposure
- 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

water (aqua), caprylyl-caprylate/caprato, coco-caprylate, pentylene glycol, glycerin, cetearyl olivate, sorbitan olivate, polysilicone-15, sodium hydroxide, pvp/eicosene copolymer, sodium stearyl glutamate, ectoin, cetyl alcohol, saccharide isomerate (pentavitin), octyldodecanol, cardiospermum halicacabum extract, echium plantagineum seed oil, helianthus annuus (sunflower) oil unsaponifiables, simmondsia chinensis (jojoba) seed oil, squalane, solanum lycopersicum (tomato) fruit extract, brassica oleracea italica (broccoli) seed oil, xanthan gum, tocopheryl acetate, parfum (fragrance), citric acid, sodium phytate.


Die Hinweise zur sicheren Anwendung von Sonnenschutzmitteln. Besuchen Sie vor der Verwendung eines Sonnenschutzmittels nicht zu lange in der Sonne. Auch mit UV-Lichtschutz eine direkte Sonneneinstrahlung in die Mitageszenen. Der Sonnenschutz wird durch Verwendung einer zu geringen Menge nicht richtig gesenkt. Vermeiden Sie excessive Sonnenbäder. Säuglinge und Kleinkinder nicht dem direkten Sonnenlicht aussetzen.

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

Lagerung: Nicht über 26°C lagern. Den Inhalt innerhalb 6 Monaten nach Anbruch aufbrauchen.

Use Following 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 the product for the first time, press down on the pump head several times until gel emerges from the dispenser.

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




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SUSANNE KAUFMANN™

Suncare

Body Broad Spectrum Protection Sunscreen



SPF 25 UVB UVA

Water Resistant (40 minutes)

100 ml (3.5 FL OZ)

NDC 69937-001-01

Die Sonnencreme ist der perfekte Sonnenschutz für den ganzen Körper. Sie bewahrt die Haut vor vorzeitiger Hautalterung durch neueste hochwirksame UVA- und UVB-Filter*. Regeneriert* und repariert* geschädigte Hautzellen mit einem pflanzlichen Wirkstoffkomplex aus Ectoin und Pentavitin. Die Kombination aus zellschutzaktivierenden Wirkstoffen hat eine antioxidante* Wirkung und bekämpft freie Radikale*. Die pflegende Sonnencreme hat einen wasserfesten Filter mit LSF 25 und UVA-/UVB-Schutz gemäß EU-Empfehlung. Sie ist für alle Hauttypen geeignet, besonders für empfindliche Haut und für Kinder. Dermatologisch getestet. Die leichte Creme zieht schnell ein und versorgt die Haut intensiv mit Feuchtigkeit.

EN The body broad spectrum protection sunscreen is the perfect sun protection for the whole body. An herbal combination of Pentavitin and Ectoin strengthens the regeneration* and the repair mechanism* of the skin and protects skin from damage from UVA rays. Those UVA rays may contribute to skin damage and premature aging. The cream has an antioxidant* effect and protects against free radicals*. The nourishing sunscreen SPF 25 contains water-resistant UVA/UVB protection in accordance with the recommendations of the EU. Suitable for all skin types, even sensitive skin and for children. Dermatologically tested. The light cream is quickly absorbed by the skin and provides the skin with intensive moisture.

* In vivo test of the active ingredients

Drug Facts

Active ingredients	Purpose
Octocrylene 4,0%	Sunscreen
Avobenzon 3,0%	
Ensulizole 2,5%	
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 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 water (aqua), caprylyl-caprylate/caprate, coco-caprylate, pentylene glycol, glycerin, cetearyl olivate, sorbitan olivate, polysilicone-15, sodium hydroxide, pvp/icosene copolymer, sodium stearoyl glutamate, ectoin, octyl alcohol, saccharide isomerate (pentavitin), oleyldodecanol, cardiospermum halicacabum extract, echium plantagineum seed oil, helianthus annuus (sunflower) oil unsaponifiables, simmondsia chinensis (jojoba) seed oil, squalane, sclarium hypopercum (tomato) fruit extract, brassica oleracea italica (broccoli) seed oil, xanthan gum, lauroperyl acetate, parium (fragrance), citric acid, sodium phylate.	
Susanne Kaufmann Kosmetik GmbH Brugg 35, 6870, Bezau, Austria	

SUSANNE KAUFMANN SUNCARE BODY BROAD SPECTRUM PROTECTION SUNSCREEN SPF 25 UVB UVA

avobenzon, ensulizole, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69937-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4 mg in 100 mL
AVOBENZON (UNII: G63QQF2NOX) (AVOBENZON - UNII:G63QQF2NOX)	AVOBENZON	3 mg in 100 mL
ENSULIZOLE (UNII: 9YQ9DIIW42) (ENSULIZOLE - UNII:9YQ9DIIW42)	ENSULIZOLE	2.5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BROCCOLI SEED OIL (UNII: SY01LVD4G4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
ECTOINE (UNII: 7GXZ3858RY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CARDIOSPERMUM HALICACABUM WHOLE (UNII: 185RQ97K0V)	
ECHIU PLANTAGINEUM SEED OIL (UNII: PIB7XBU8XW)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
JOJOBA OIL (UNII: 724GKU717M)	
SQUALANE (UNII: GW89575KF9)	
TOMATO (UNII: Z4KHF2C175)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
WATER (UNII: 059QF0K00R)	
CAPRYLYL CAPRYLATE/CAPRATE (UNII: 22MCG4RSMR)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69937-001-01	1 in 1 CARTON	07/27/2015	
1		100 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 not final	part352	07/27/2015	

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(69937-001)

Revised: 7/2017

Susanne Kaufmann Kosmetik GmbH