

DRY OIL ANTIOXIDANT SUN PROTECTION- avobenzone, homosalate, octinoxate, octocrylene, oxybenzone cream
Natura Bisse International SA

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.

Active Ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 10%	Sunscreen
Octinoxate 4%	Sunscreen
Octocrylene 10%	Sunscreen
Oxybenzone 5%	Sunscreen

Uses

helps prevent sunburn

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

Natura Bissé Barcelona

C+C Dry Oil Antioxidant Sun Protection

Broad Spectrum SPF 30

3.5 Fl. Oz. 100 ml

Made in Spain by

Natura Bisse Int. S.A.

Pque. Tecnol. del Valles

Cerdanyola - Barcelona

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor
- **Sun Protection Measures:** 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 sun-glasses.

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

Inactive Ingredients

alcohol denat., diisopropyl sebacate, benzotriazolyl dodecyl p-cresol, tocopheryl acetate, glyceryl

linoleate, vitis vinifera (grape) seed oil, bisabolol, helianthus annuus (sunflower) seed oil, citrus nobilis (mandarin orange) oil, glyceryl linolenate, daucus carotiva sativa (carrot) seed oil, beta-carotene, 7-dehydrocholesterol, ascorbyl palmitate, acrylates/octylacrylamide copolymer, fragrance, limonene, linalool, amyl cinnamal, geraniol, citral.

<p>Natura Bissé Barcelona</p> <p>SPF 30 C+C DRY OIL ANTIOXIDANT SUN PROTECTION</p> <p>Aceite seco con vitamina D Protector solar para cuerpo, rostro y cabello Dry oil sunscreen with vitamin D Body, face and hair Huile sèche avec vitamine D Écran solaire corps, visage et cheveux Сухое масло с витамином D Солнцезащитное средство для тела, лица и волос والتي تسمى الزيت الجاف مع فيتامين د للجسم والوجه والشعر Trockene Öl-Sonnencreme mit Vitamin D Körper, Gesicht und Haar Óleo seco com vitamina D Protector solar para corpo, rosto e cabelo Olio secco con vitamina D Protezione solare per corpo, viso e capelli</p> <p>SIN PARABENOS/ PARABEN FREE CONTIENE OMBENZONA / CONTAINS BENZOPHENONE-3</p> <p>Ingredients / Ingredientes: ALCOHOL DENAT., DISOPROPYL SEBACATE, HOMOSALATE, OCTOCRYLENE, BENZOPHENONE-3, ETHYLHEXYL METHOXYCINNAMATE, BUTYL METHOXYBENZOYL METHANE, BENZO TRAZOLYL DOXYL P-QUINOLIN, TOCOPHERYL ACETATE, GLYCERYL LINOLEATE, VITIS VINIFERA (GRAPE) SEED OIL, BISABOLYL, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, CITRUS NOBILIS (MANDARIN ORANGE) OIL, CITRUS AURANTIUM DULCIS (ORANGE) OIL, GLYCERYL LINOLENATE, DAUCUS CAROTA SATIVA (CARROT) SEED OIL, BETA-CAROTENE, 7-DEHYDROCHOLESTEROL, ASCORBYL PALMITATE, ACRYLATES/OCTYLACRYLAMIDE COPOLYMER, FRAGRANCE, PARFUM, LIMONENE, LINALOOL, AMYL CINNAMAL, GERANIOL, CITRAL.</p>	<p>Natura Bissé Barcelona</p> <p>Made in Spain by NATURA BISSÉ INT. S. A. PQUE, TECNOL. del VALLÉS Cardanyola - BARCELONA</p>	<p>Natura Bissé Barcelona</p> <p>C+C DRY OIL ANTIOXIDANT SUN PROTECTION</p> <p>Broad Spectrum SPF 30</p> <p>3.5 FL. OZ. e 100 ml</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Avobenzone 3%</td> <td rowspan="5">Sunscreen</td> </tr> <tr> <td>Homosalate 10%</td> </tr> <tr> <td>Octinoxate 4%</td> </tr> <tr> <td>Octocrylene 10%</td> </tr> <tr> <td>Oxybenzone 5%</td> </tr> </tbody> </table> <p>Uses - helps prevent sunburn</p> <p>Warnings</p> <ul style="list-style-type: none"> 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. <p>Directions</p> <ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure Use a water resistant sunscreen if swimming or sweating Reapply at least every 2 hours Children under 6 months: Ask a doctor Sun Protection Measures. 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 sun-glasses. <p>Inactive ingredients Alcohol Denat., Disopropyl Sebacate, Benzotriazolyl Dodecyl p-Cresol, Tocopheryl Acetate, Glyceryl Linoleate, Vitis Vinifera (Grape) Seed Oil, Bisabolol, Helianthus Annuus (Sunflower) Seed Oil, Citrus Nobilis (Mandarin Orange) Oil, Citrus Aurantium Dulcis (Orange) Oil, Glyceryl Linolenate, Daucus Carota Sativa (Carrot) Seed Oil, Beta-Carotene, 7-Dehydrocholesterol, Ascorbyl Palmitate, Acrylates/Octylacrylamide Copolymer, Fragrance, Limonene, Linalool, Amyl Cinnamal, Geraniol, Citral.</p> <p>Other information protect this product from excessive heat and direct sun.</p> <p>Questions? 1-800-762-8872</p> <p>ESTE PRODUCTO SOLO PUEDE VENDERSE EN ESTABLECIMIENTOS AUTORIZADOS POR NATURA BISSÉ</p> <p>THIS PRODUCT CAN BE SOLD ONLY BY AUTHORIZED NATURA BISSÉ RETAILERS</p>	Active ingredients	Purpose	Avobenzone 3%	Sunscreen	Homosalate 10%	Octinoxate 4%	Octocrylene 10%	Oxybenzone 5%
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DRY OIL ANTIOXIDANT SUN PROTECTION

avobenzone, homosalate, octinoxate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63730-364
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
BENZOTRIAZOLYL DODECYL P-CRESOL (UNII: 298PX4M11X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL LINOLEATE (UNII: 4763AXI84L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
LEVOMENOL (UNII: 24WE03BX2T)	
HELIANTHUS ANNUUS WHOLE (UNII: 17S27ZT6KR)	
CITRUS NOBILIS (UNII: 8MFF77J91V)	
CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)	
GLYCERYL LINOLENATE (UNII: SGB6X4G86K)	
DAUCUS CAROTA SUBSP. SATIVUS WHOLE (UNII: F9I9HZH3O3)	
BETA CAROTENE (UNII: 01YAE03M7J)	
7-DEHYDROCHOLESTEROL (UNII: BK1IU07GKF)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
GERANIOL (UNII: L837108USY)	
CITRAL (UNII: T7EU009VPP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63730-364-01	100 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/30/2015	

Labeler - Natura Bisse International SA (464431576)**Establishment**

Name	Address	ID/FEI	Business Operations
Natura Bisse International SA		464431576	manufacture(63730-364)

Revised: 1/2015

Natura Bisse International SA