

MACROANTIOXIDANT SUN PROTECTION- avobenzene, homosalate, octinoxate, octocrylene, oxybenzone cream
Natura Biss e 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
Avobenzene 3%	Sunscreen
Homosalate 10%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octocrylene 10%	Sunscreen
Oxybenzone 3%	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 Oil-Free MacroAntioxidant Sun Protection

Broad Spectrum SPF 30

Net Wet 1 oz 30 ml

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. - 2p.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

water, alcohol denat., propanediol, glycerin, propylheptyl caprylate, glyceryl stearate, oryza sativa (rice) starch, PEG-100 stearate, benzotriazolyl dodecyl p-cresol, citrus sinensis (orange) peel extract, tocopheryl acetate, glyceryl linoleate, hydrolyzed collagen, bisabolol, citrus nobilis (mandarin orange) oil, citrus aurantium dulcis (orange) oil, glyceryl linolenate, 7-dehydrocholesterol, polyacrylate crosspolymer-11, disodium EDTA, glyceryl polyacrylate, ethylhexylglycerin, tricalcium phosphate, citric acid, phenoxyethanol, fragrance, limonene, linalool, amyl cinnamal, geraniol, yellow 5 (CI

19140), red 4 (CI 14700).

Natura Bissé
Barcelona

SPF 30

Protector solar antiedad con
Macro-Antioxidantes® y vitamina D

Anti-aging sunscreen with
MacroAntioxidants® and vitamin D

Écran solaire anti-âge
avec Macro-Antioxydants® et vitamine D

Антивозрастное солнцезащитное средство
с МакроАнтиоксидантами® и витамином D

واقى شمس مقاوم لعلامات الشيخوخة
يحتوي على MacroAntioxidants® وفيتامين د

Anti-Aging Sonnencreme
mit Macro Antioxidantien® und Vitamin D

Protetor solar antiedade
com Macro-Antioxidantes® e vitamina D

Protezione solare antietà
con MacroAntioxidants® e vitamina D

SIN PARABENOS/ PARABEN FREE
CONTIENE OXIBENZONA / CONTAINS BENZOPHENONE-3

Ingredients / Ingredientes: WATER (AQUA), HOMOSALATE, OCTOCRYLENE, ALCOHOL DENAT., ETHYLHEXYL METHOXYCINNAMATE, PROPANEDIOL, GLYCERIN, PROPYLHEPTYL CAPRYLATE, GLYCERYL STEARATE, BENZOPHENONE-3, BUTYL METHOXYDIBENZOYL METHANE, ORYZA SATIVA (RICE) STARCH, PEG-100 STEARATE, BENZOTRIAZOLYL DODECYL P-CRESOL, CITRUS SINENSIS (ORANGE) PEEL EXTRACT, TOCOPHERYL ACETATE, GLYCERYL LINOLEATE/HYDROLYZED COLLAGEN, BISABOLOL, CITRUS NOBILIS (MANDARIN ORANGE) OIL, CITRUS AURANTILUM DULCIS (ORANGE) OIL, GLYCERYL LINOLATE, 7-DEHYDROCHOLESTEROL, POLYACRYLATE CROSSPOLYMER-11, DISODIUM EDTA, GLYCERYL POLYACRYLATE, ETHYLHEXYLGLYCERIN, TRICALCIUM PHOSPHATE, CITRIC ACID, PHENOXYETHANOL, FRAGRANCE (PARFUM), LIMONENE, LINALOOL, AMYL CINNAMAL, GERANIOL, YELLOW 5 (CI 19140), RED 4 (CI 14700).

Drug Facts (continued)

Inactive ingredients
Water, Alcohol Denat., Propanediol, Glycerin, Propylheptyl Caprylate, Glyceryl Stearate, Oryza Sativa (Rice) Starch, PEG-100 Stearate, Benzotriazolyl Dodecyl p-Cresol, Citrus Sinensis (Orange) Peel Extract, Tocopheryl Acetate, Glyceryl Linoleate, Hydrolyzed Collagen, Bisabolol, Citrus Nobilis (Mandarin Orange) Oil, Citrus Aurantium Dulcis (Orange) Oil, Glyceryl Linolate, 7-Dehydrocholesterol, Polyacrylate Crosspolymer-11, Disodium EDTA, Glyceryl Polyacrylate, Ethylhexylglycerin, Tricalcium Phosphate, Citric Acid, Phenoxyethanol, Fragrance, Limonene, Linalool, Amyl Cinnamal, Geraniol, Yellow 5 (CI 19140), Red 4 (CI 14700).

Other information protect this product from excessive heat and direct sun.

Questions? 1-800-762-8872

Macro-Antioxidantes®, proceso base bajo licencia de patente del Consejo Superior de Investigaciones Científicas (CSIC).
MacroAntioxidants® processed under patent licensed by the Spanish National Research Council (CSIC)

Made in Spain by
NATURA BISSÉ INT. S. A.
PQUE. TECNOL. del VALLÉS
Cerdanyola - BARCELONA

Natura Bissé
Barcelona

C+C
OIL-FREE
MACROANTIOXIDANT®
SUN PROTECTION

Broad Spectrum SPF 30

NET WT. 1 OZ. e 30 ml

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ESTE PRODUCTO SOLO PUEDE VENDERSE EN ESTABLECIMIENTOS AUTORIZADOS POR NATURA BISSÉ
THIS PRODUCT CAN BE SOLD ONLY BY AUTHORIZED NATURA BISSÉ RETAILERS

MACROANTIOXIDANT SUN PROTECTION

avobenzene, homosalate, octinoxate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63730-340
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	7.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

ALCOHOL (UNII: 3K9958V90M)
PROPANEDIOL (UNII: 5965N8W85T)
GLYCERIN (UNII: PDC6A3C0OX)
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)
PEG-100 STEARATE (UNII: YD01N1999R)
BENZOTRIAZOLYL DODECYL P-CRESOL (UNII: 298PX4M11X)
CITRUS SINENSIS FRUIT OIL (UNII: WV48LBL15Q)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
GLYCERYL LINOLEATE (UNII: 4763AXI84L)
GELATIN (UNII: 2G86QN327L)
LEVOMENOL (UNII: 24WE03BX2T)
CITRUS NOBILIS (UNII: 8MFF77J91V)
CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)
GLYCERYL LINOLENATE (UNII: SGB6X4G86K)
7-DEHYDRO CHOLESTEROL (UNII: BK1IU07GKF)
EDETATE DISODIUM (UNII: 7FLD91C86K)
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+)- (UNII: F4VNO44C09)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
GERANIOL (UNII: L837108USY)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
FD&C RED NO. 4 (UNII: X3W0AMIJLX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63730-340-01	30 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/02/2015	

Labeler - Natura Bisse International SA (464431576)

Establishment

Name	Address	ID/FEI	Business Operations
Natura Bisse International SA		464431576	manufacture(63730-340)

