

BRITTO FACIAL SUNSCREEN BROAD SPECTRUM SPF 50- avobenzene, homosalate, octinoxate, octisalate, octocrylene, oxybenzone cream
MR2 USA Corporation

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.

NO CHANGE NOTIFICATION

Principal Display Panel - Statement of identity

Britto Facial Sunscreen Broad Spectrum SPF 50 Water Resistant (40 minutes)

Drug Facts Panel - Active Ingredients

Avobenzene 3.00% ----- Sunscreen

Homosalate 15.00% ----- Sunscreen

Octinoxate 7.50% ----- Sunscreen

Octisalate 5.00% ----- Sunscreen

Octocrylene 10.00% ---- Sunscreen

Oxybenzone 6.00% ----- Sunscreen

Drug Facts Panel - Purpose

Purpose: sunscreen

Drug Facts Panel - Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin ageing caused by the sun

Drug Facts Panel - Warnings

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

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

Do not use on damaged or broken skin.

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Drug Facts Panel - Directions

- Apply liberally 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.** 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.
- **Children under 6 months of age:** ask a doctor.

Drug Facts Panel - Other information

Protect the product in this container from excessive heat and direct sun.

Drug Facts Panel - Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Alpha-Tocopherol Acetate, Butylated Hydroxytoluene, Ethylhexyl Stearate, Fragrance, Glycerin, Glyceryl Dipalmitate, Glyceryl Distearate, Glyceryl Palmitate, Glyceryl Stearate, Hydrolyzed Collagen, Methylparaben, Neopentyl Glycol Diheptanoate, Polyester-7, Potassium Cetyl Phosphate, Potassium Stearate, Propylene Glycol, Propylparaben, Stearic Acid, Tetrasodium EDTA, Water, Xanthan Gum.

Questions or comments

Questions or comments? Contact weekdays from 9AM to 5PM at 1-305-646-1169.

Package Label - Principal Display Panel

50 ml NDC 77069-003-01



BRITTO™

FACIAL SUNSCREEN BROAD SPECTRUM SPF 50
 WATER RESISTANT (40 MINUTES)
 NET WT. 1.69 FL OZ (50 ML)

BRITTO
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www.britto.com

MANUFACTURED BY: COSMODERMA IND. E. COM. LTDA.
 CNPJ: 09.631.610/0001-15. www.cosmoderma.com.br
 Imported and Distributed by:
 MR2 USA CORPORATION
 2290 NW 82nd AVE, DORAL, FL 33122, USA.

Drug Facts

Active ingredients	Purpose
Avo benzene 3.00%	Sunscreen
Homosalate 15.00%	Sunscreen
Octinoxate 7.50%	Sunscreen
Octisalate 5.00%	Sunscreen
Octocrylene 10.0%	Sunscreen
Oxybenzone 6.00%	Sunscreen

Uses • Helps prevent sunburn. • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings
For external use only.
Do not use • on damaged or broken skin.
Stop use and ask a doctor • if rash occurs.
When using this product • keep out of eyes. Rinse with water to remove.
Keep out of reach of children • If swallowed, get medical help or contact a Poison Control Center right away.

Directions
 Shake before use. • Apply liberally 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. 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.
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Other information
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MADE IN BRAZIL

Lot and Expiration date:
See packaging  

100 ml NDC 77069-003-02



MANUFACTURED BY:
CCSMODERMA IND. E.COM. LTDA.
CNPJ: 09.691.610/0001-15. www.cosmoderma.com.br
Imported and Distributed by:
MR2 USA CORPORATION
2290 NW 82nd AVE, DORAL, FL 33122, USA.

Drug Facts

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Avobenzone 3.00%.....	Sunscreen
Homosalate 15.00%.....	Sunscreen
Octinoxate 7.50%.....	Sunscreen
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Octocrylene 10.0%.....	Sunscreen
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MADE IN BRAZIL
Lot and Expiration date:
See packaging

BRITTO
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Questions or Comments? Contact weekdays from
9AM to 5PM at 1-305-646-1169

BRITTO FACIAL SUNSCREEN BROAD SPECTRUM SPF 50

avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77069-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	6 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	2.24 g in 100 mL
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	1 g in 100 mL
POLYESTER-7 (UNII: 0841698D2F)	0.6 g in 100 mL
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	0.4 g in 100 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	1 g in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.2 g in 100 mL
EDETATE SODIUM (UNII: MP1J8420LU)	0.05 g in 100 mL
WATER (UNII: 059QF0KO0R)	34.55 g in 100 mL
POTASSIUM STEARATE (UNII: 17V812XK50)	0.36 g in 100 mL
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	3 g in 100 mL
METHYL PARABEN (UNII: A2I8C7HI9T)	0.2 g in 100 mL
PROPYL PARABEN (UNII: Z8IX2SC1OH)	0.1 g in 100 mL
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	0.1 g in 100 mL
GLYCERYL DISTEARATE (UNII: 73071MW2KM)	1.84 g in 100 mL
GLYCERYL PALMITATE (UNII: 6Y2XJ05B35)	1.32 g in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.2 g in 100 mL
STEARIC ACID (UNII: 4ELV7Z65AP)	0.6 g in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	2 g in 100 mL
GLYCERYL DIPALMITATE (UNII: 7775E5I3L)	1.32 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.32 g in 100 mL
PORK COLLAGEN (UNII: I8442U2G7J)	2 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77069-003-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	08/26/2020	
2	NDC:77069-003-02	100 mL in 1 TUBE; Type 0: Not a Combination Product	08/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/26/2020	

Labeler - MR2 USA Corporation (080950597)

Establishment

Name	Address	ID/FEI	Business Operations
COSMODERMA INDUSTRIA E COMERCIO LTDA		899462110	manufacture(77069-003) , pack(77069-003) , label(77069-003)