

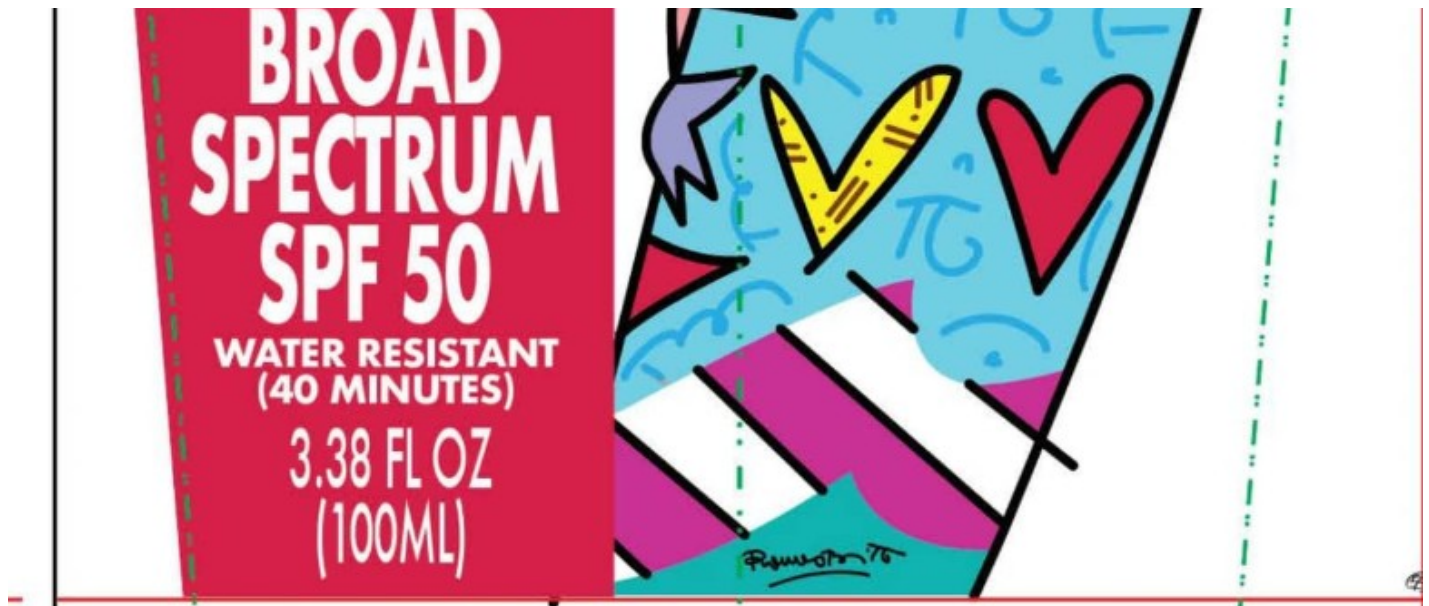
**BRITTO BODY SUNSCREEN BROAD SPECTRUM SPF 50- avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone cream**  
**MR2 USA Corporation**

*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.*

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**NO CHANGE NOTIFICATION**

**Principal Display Panel - Statement of Identity**





**Drug Facts Panel - Active Ingredients**

**BRITTO**  
**BODY SUNSCREEN BROAD SPECTRUM SPF 50**  
**WATER RESISTANT (40 MINUTES)**  
**3.38 FL OZ (100ML)**

MANUFACTURED BY:  
 COSMODERMA IND. E.COM. LTDA.  
 CNPJ: 09.601.610/0001-15  
 www.cosmoderma.com.br  
 Imported and Distributed by:  
 MRZ USA CORPORATION  
 2290 NW 82nd AVE, DORAL, FL 33122, USA.

| Drug Facts         |           |
|--------------------|-----------|
| Active ingredients | Purpose   |
| Avobenzene 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. • **Children under 6 months of age:** ask a doctor.

**Other information**  
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**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, Methylparaben, Neopentyl Glycol Diheptanoate, Polyester-7, Potassium Cetyl Phosphate, Potassium Stearate, Propylene Glycol, Propylparaben, Stearic Acid, Tetrasodium EDTA, Water, Xanthan Gum.

**BRITTO**  
 ©Britto Central, Inc.  
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**Questions or Comments? Contact weekdays from 9AM to 5PM at 1-305-646-1169**

**MADE IN BRAZIL**  
 Lot and Expiration date:  
 See packaging

**Drug Facts Panel - Purpose**



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Drug Facts Panel - Uses



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Drug Facts Panel - Warnings



# BRITTO™

## BODY SUNSCREEN BROAD SPECTRUM SPF 50

WATER RESISTANT (40 MINUTES)  
3.38 FL OZ (100ML)

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MADE IN BRAZIL  
Lot and Expiration date:  
See packaging



**Drug Facts Panel - Warnings - Do not use**



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MADE IN BRAZIL  
 Lot and Expiration date:  
 See packaging

Drug Facts Panel - Warnings - Stop use



# BRITTO™

## BODY SUNSCREEN BROAD SPECTRUM SPF 50

WATER RESISTANT (40 MINUTES)  
3.38 FL OZ (100ML)

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Lot and Expiration date:  
See packaging



**Drug Facts Panel - Warnings - Ask a doctor**



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Drug Facts Panel - Warnings - When using this product





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SUNSCREEN  
BROAD  
SPECTRUM  
SPF 50**  
WATER RESISTANT  
(40 MINUTES)  
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Drug Facts Panel - Warnings - Keep out of reach of children



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Drug Facts Panel - Directions



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Durg Facts Panel - Other Information



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3.38 FL OZ (100ML)

MANUFACTURED BY:  
COSMODERMA IND. E. COM. LTDA.  
CNPJ: 09.601.610/0001-15  
www.cosmoderma.com.br  
Imported and Distributed by:  
MR2 USA CORPORATION  
2290 NW 82nd AVE, DORAL, FL 33122, USA.

### Drug Facts

| Active ingredients     | Purpose   |
|------------------------|-----------|
| Avobenzone 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. • **Children under 6 months of age:** ask a doctor.

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

**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, Methylparaben, Neopentyl Glycol Diheptanoate, Polyester-7, Potassium Cetyl Phosphate, Potassium Stearate, Propylene Glycol, Propylparaben, Stearic Acid, Tetrasodium EDTA, Water, Xanthan Gum.

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www.britto.com

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

MADE IN BRAZIL  
Lot and Expiration date:  
See packaging



Drug Facts Panel - Inactive Ingredients



# BRITTO™

## BODY SUNSCREEN BROAD SPECTRUM SPF 50

WATER RESISTANT (40 MINUTES)  
3.38 FL OZ (100ML)

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www.britto.com

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MADE IN BRAZIL  
Lot and Expiration date:  
See packaging



Questions and reporting of adverse events



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**BRITTO™**

**BODY SUNSCREEN BROAD SPECTRUM SPF 50**

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3.38 FL OZ (100ML)

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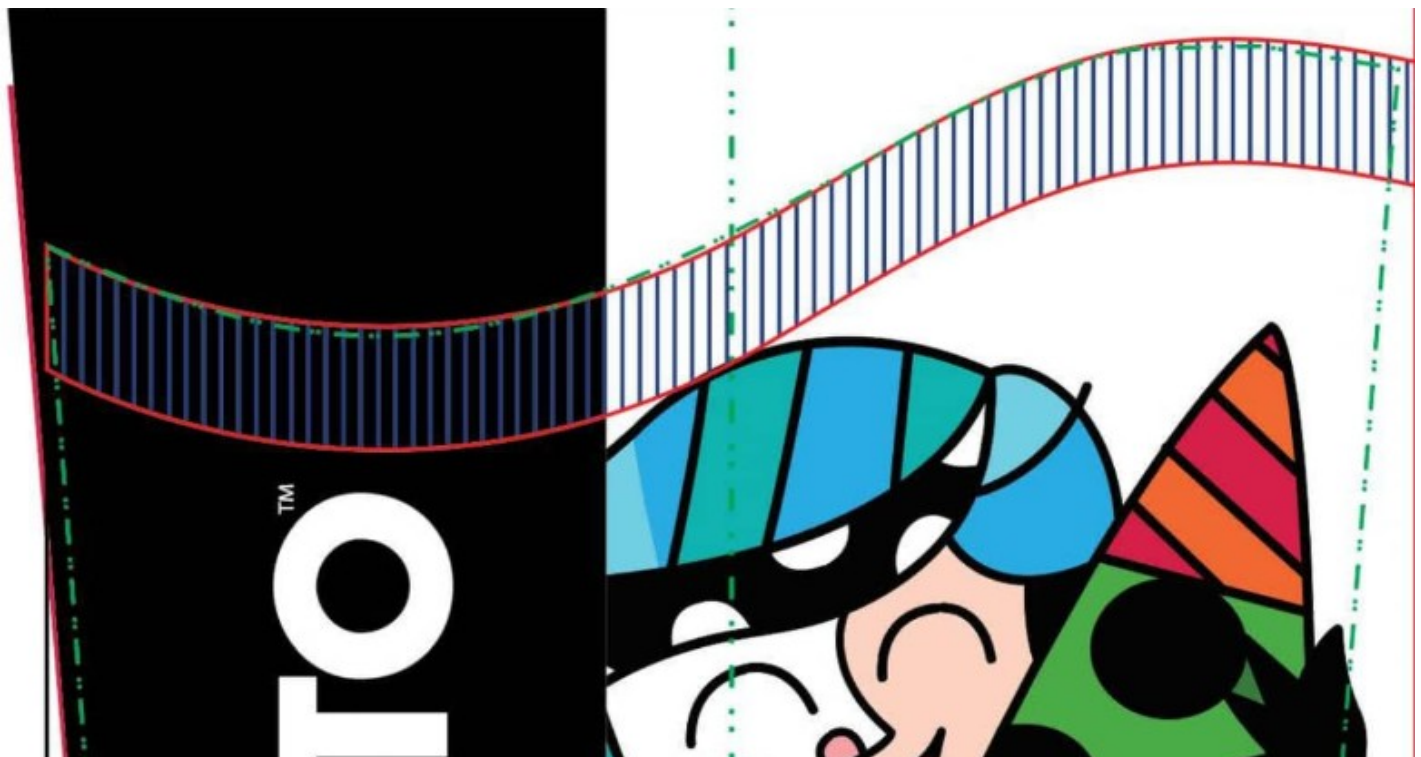
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**MADE IN BRAZIL**  
Lot and Expiration date:  
See packaging



Principal Display Panel





## BRITTO BODY SUNSCREEN BROAD SPECTRUM SPF 50

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

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:77069-002 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 10 g in 100 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 5 g in 100 mL  |

|   |            |                 |
|---|------------|-----------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 3 g in 100 mL   |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 6 g in 100 mL   |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 15 g in 100 mL  |
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 g in 100 mL |

### Inactive Ingredients

| Ingredient Name   | Strength          |
|---|-------------------|
| <b>GLYCERYL PALMITATE</b> (UNII: 6Y2XJ05B35)  | 1.32 g in 100 mL  |
| <b>WATER</b> (UNII: 059QF0K00R)   | 37.05 g in 100 mL |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)   | 2.24 g in 100 mL  |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)  | 2 g in 100 mL     |
| <b>GLYCERYL DIPALMITATE</b> (UNII: 7775E5R3L)   | 1.32 g in 100 mL  |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)   | 0.2 g in 100 mL   |
| <b>POLYESTER-7</b> (UNII: 0841698D2F)   | 0.6 g in 100 mL   |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)  | 0.6 g in 100 mL   |
| <b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 809Y72KV36) | 0.2 g in 100 mL   |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                                      | 0.5 g in 100 mL   |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)   | 0.2 g in 100 mL   |
| <b>GLYCERYL DISTEARATE</b> (UNII: 73071MW2KM)   | 1.84 g in 100 mL  |
| <b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)   | 3 g in 100 mL     |
| <b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)                                     | 1 g in 100 mL     |
| <b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)                                 | 0.4 g in 100 mL   |
| <b>POTASSIUM STEARATE</b> (UNII: 17V812XK50)  | 0.36 g in 100 mL  |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  | 0.32 g in 100 mL  |
| <b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)                                      | 0.1 g in 100 mL   |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)   | 0.1 g in 100 mL   |
| <b>EDETATE SODIUM</b> (UNII: MPIJ8420LU)  | 0.05 g in 100 mL  |

### Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:77069-002-01 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 07/15/2020           |                    |
| 2 | NDC:77069-002-02 | 200 mL in 1 TUBE; Type 0: Not a Combination Product | 07/15/2020           |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 07/15/2020           |                    |



**Labeler** - MR2 USA Corporation (080950597)

## Establishment

| Name                                 | Address | ID/FEI    | Business Operations   |
|--------------------------------------|---------|-----------|---|
| COSMODERMA INDUSTRIA E COMERCIO LTDA |         | 899462110 | manufacture(77069-002) , pack(77069-002) , label(77069-002) |

Revised: 12/2020

MR2 USA Corporation