

**PER SOLE BY BRITTO LIP BALM SUNSCREEN BROAD SPECTRUM SPF 30- avobenzone, homosalate, octinoxate, octocrylene lipstick**  
**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**

Lip Balm Sunscreen Broad Spectrum SPF 30

**Drug Facts Panel - Active Ingredients**

Avobenzone 3.0% ----- Sunscreen

Homosalate 8.2% ----- Sunscreen

Octinoxate 7.5% ----- Sunscreen

Octocrylene 7.0% ----- Sunscreen

**Drug Facts Panel - Purpose**

Purpose: sunscreen

**Drug Facts Panel - Use**

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.

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.

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

Do not use on damaged or broken skin.

**Drug Facts Panel - Warnings - When using this product**

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

**Drug Facts Panel - Warnings - Stop use**

Stop use and ask a doctor if rash occurs.

**Drug Facts Panel - Warnings - Keep out of reach of children,**

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

**Drug Facts Panel - Directions**

Apply liberally 15 minutes before sun exposure.

Reapply at least every 2 hours.

Use a water-resistant sunscreen if swimming or sweating.

Children under 6 months of age: 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 sunglasses.

**Drug Facts Panel - Other information**

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

**Drug Facts Panel - Inactive ingredients**

Beeswax, Butylated Hydroxytoluene, C12-15 Alkyl Benzoate, Carnauba Wax, Fragrance, Hydrogenated Vegetable Glycerides, Isopropyl Palmitate, Mineral Oil, Ozokerite, Paraffin, Synthetic Candellila Wax, Theobroma Cacao (Cocoa) Seed Butter.

**Questions or comments**

Contact weekdays from 9AM to 5PM at 1-305-646-1169.

**Package Label - Principal Display Panel**

NDC 77069-001-01

Level 1 - cylinder (stick)

*Per Sole by* **BRITTO**  
LIP BALM  
**SUNSCREEN  
BROAD  
SPECTRUM  
SPF 30**  
NET WT  
0.12 OZ (3,5 g)

For Drug Facts information, see outer package.

IMPORTED AND DISTRIBUTED BY:  
MR2 USA CORPORATION 2290 NW  
82nd AVE, DORAL, FL 33122, USA  
**BRITTO**  
©Britto Central, Inc.  
[www.britto.com](http://www.britto.com)  
**SUNSCREEN BROAD  
SPECTRUM SPF 30**

*Per Sole by* **BRITTO**  
LIP BALM  
**SUNSCREEN  
BROAD  
SPECTRUM  
SPF 30**  
NET WT  
0.12 OZ (3,5 g)

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

NDC 77069-001-01

Level 2 - blister (3 x stick)



# LIP BALM

PROTECTS AGAINST  
SUNLIGHT

# BRITTO™

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www.britto.com

## SUNSCREEN BROAD SPECTRUM SPF 30

## Drug Facts

### Active ingredients

### Purpose

Avobenzone 3.00%.....	Sunscreen
Homosalate 8.2%.....	Sunscreen
Octinoxate 7.50%.....	Sunscreen
Octocrylene 7.0%.....	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.

**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

• Apply liberally 15 minutes before sun exposure. • **Reapply** at least every 2 hours. • Use a water-resistant sunscreen if swimming or sweating. • Children under 6 months of age: 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 sunglasses.

### Other information

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

### Inactive ingredients

Beeswax, Butylated Hydroxytoluene, C12-15 Alkyl Benzoate, Carnauba Wax, Fragrance, Hydrogenated Vegetable Glycerides, Isopropyl Palmitate, Mineral Oil, Ozokerite, Paraffin, Synthetic Candellila Wax, Theobroma Cacao (Cocoa) Seed Butter.

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

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



**MANUFACTURED BY:**  
PHARMATURA IND. DE COSMÉTICOS LTDA.  
CNPJ: 00.248.776/0001-25 ROD. SP 101, KM 46, CAPIVARI/SP,  
13360-000, BRAZIL  
**IMPORTED AND DISTRIBUTED BY:** MR2 USA CORPORATION 2290  
NW 82nd AVE, DORAL, FL 33122, USA



**PER SOLE BY BRITTO LIP BALM SUNSCREEN BROAD SPECTRUM SPF 30**

avobenzone, homosalate, octinoxate, octocrylene lipstick

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:77069-001

<b>Route of Administration</b>		TOPICAL		
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.5 g in 100 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	3 g in 100 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	8.2 g in 100 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	7 g in 100 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		3 g in 100 g		
COCOA BUTTER (UNII: 512OYT1CRR)		8 g in 100 g		
CERESIN (UNII: Q1LS2UJO3A)		2.8 g in 100 g		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		0.05 g in 100 g		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		10 g in 100 g		
MINERAL OIL (UNII: T5L8T28FGP)		7 g in 100 g		
WHITE WAX (UNII: 7G1J5DA97F)		3 g in 100 g		
CARNAUBA WAX (UNII: R12CBM0EIZ)		6 g in 100 g		
PARAFFIN (UNII: I9O0E3H2ZE)		6.2 g in 100 g		
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77069-001-01	3 in 1 BLISTER PACK	07/23/2020	
1		3.5 g in 1 CYLINDER; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part352	07/23/2020	

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

Establishment			
Name	Address	ID/FEI	Business Operations
PHARMATURA-INDUSTRIA DE COSMETICOS LTDA		903405397	manufacture(77069-001) , pack(77069-001) , label(77069-001)