

## **MALLY LIP DEFENDER - avobenzone, octinoxate gel**

**MallyGirl, LLC**

*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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### **mally Lip Defender - Conquering Red - Broad Spectrum SPF 15**

#### **DRUG FACTS**

##### **Active Ingredients**

Avobenzone 2.0%

Octinoxate 7.0%

##### **Purpose**

Sunscreen

Sunscreen

##### **Use**

- 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.

##### **For external use only**

**Do not use** on damaged or broken skin.

**Stop use and ask 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**

- 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 risk of skin cancer and early 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 10:00 a.m. - 2:00 p.m.
  - Wear long sleeved shirts, pants, hats and sunglasses

##### **Inactive Ingredients**

Polybutene, Helianthus annuus (sunflower) seed oil, Polyglyceryl-2 triisostearate, Octyldecanol,

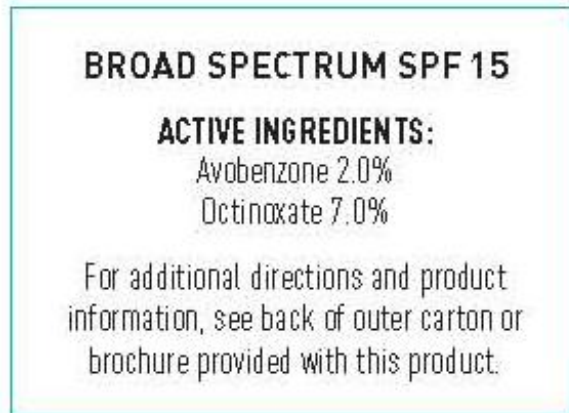
Euphorbia cerifera (candelilla) wax (candelilla cera), Trihydroxystearin, Copernicia cerifera (carnauba) wax (cera carnauba), Microcrystalline wax (microcristallina cera), Phospholipids, Calcium aluminum borosilicate, Calcium sodium borosilicate, Tocopheryl acetate, Silica, Sodium chondroitin sulfate, Saccharomyces cerevisiae extract, Hyaluronic acid, Tocopherol, Alumina, Tripeptide-29, Tin oxide, Titanium dioxide (CI 77891) **May Contain:** Mica (CI 77019), Red 28 Lake (CI 45410), Yellow 5 Lake (CI 19140), Red 6 (CI 15850), Red 7 Lake (CI 15850), Yellow 6 Lake (CI 15985), Iron Oxides (CI 77491, CI 77492, CI 77499), Blue 1 Lake (CI 42090)

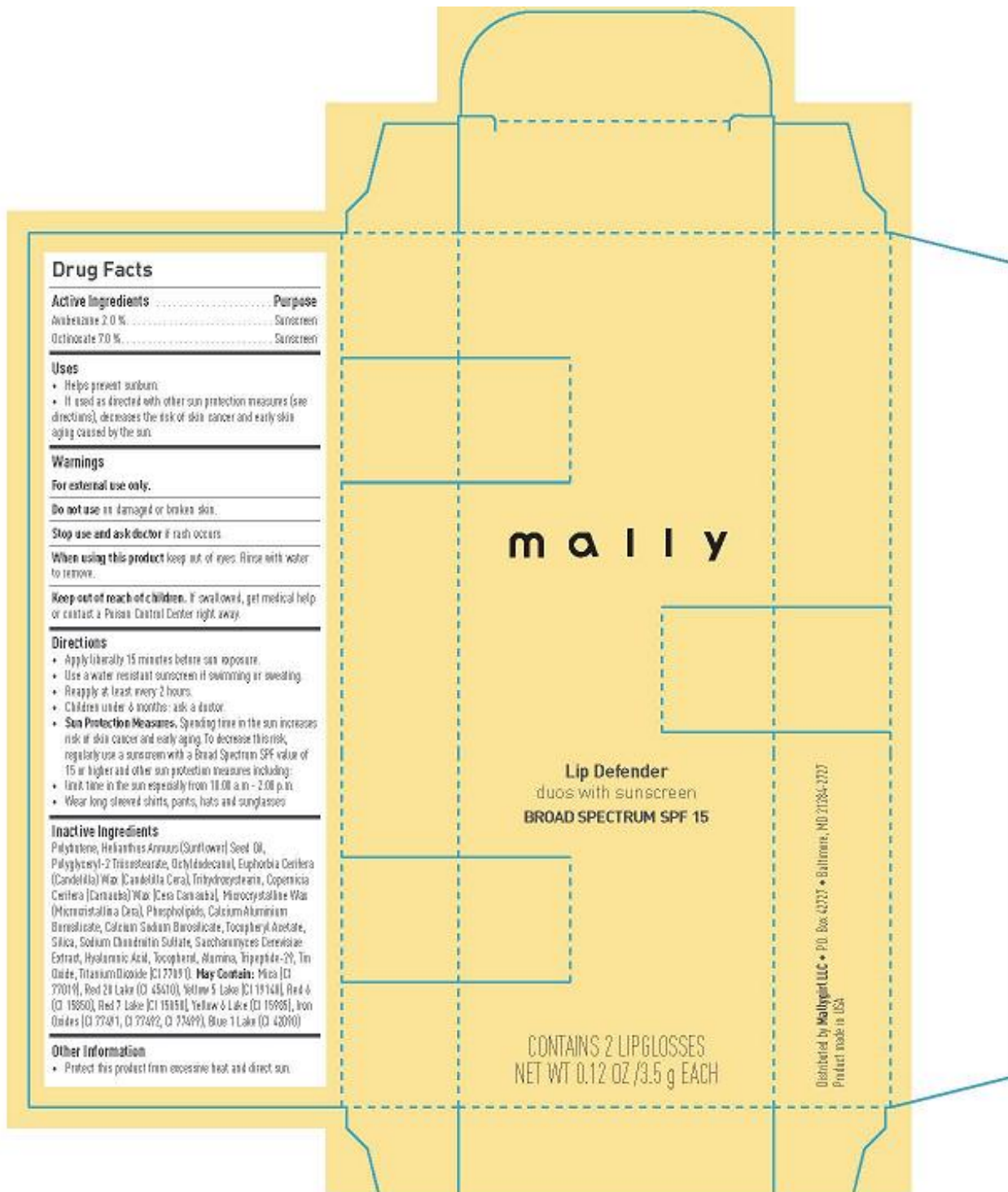
#### **Other Information**

- Protect this product from excessive heat and direct sun.

#### **Principal Display Panel**

mally  
Lip Defender  
Conquering Red  
duos with sunscreen  
Broad Spectrum SPF 15





**Drug Facts**

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**Inactive Ingredients**

Polyethylene, Helianthus Annuus (Sunflower) Seed Oil, Polyglyceryl-2 Triisostearate, Octyldecanol, Euphorbia Cerifera (Candelilla) Wax, Candelilla Wax, Trihydroxytrierythrin, Copernicia Cerifera (Carnauba) Wax, Cera Carnauba, Microcrystalline Wax (Microcrystallin Wax), Phospholipids, Calcium Aluminum Borosilicate, Calcium Sodium Borosilicate, Tocopheryl Acetate, Silica, Sodium Chondroitin Sulfate, Saccharomyces cerevisiae Extract, Hyaluronic Acid, Tocopherol, Alumina, Tripeptide-29, Tin Oxide, Titanium Dioxide [CI 77891], **May Contain:** Mica [CI 77019], Red 28 Lake [CI 45410], Yellow 5 Lake [CI 19140], Red 6 [CI 19850], Red 7 Lake [CI 19858], Yellow 6 Lake [CI 19905], Iron Oxides [CI 77491, CI 77492, CI 77499], Blue 1 Lake [CI 42090]

**Other Information**

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mally

Lip Defender  
duos with sunscreen  
BROAD SPECTRUM SPF 15

CONTAINS 2 LIP GLOSSES  
NET WT 0.12 OZ./3.5 g EACH

Distributed by Mallygill LLC • P.O. Box 42727 • Baltimore, MD 21284-2727  
Product made in USA

**MALLY LIP DEFENDER**  
avobenzone, octinoxate gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76 119-5310
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	0.07 g in 3.5 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	.245 g in 3.5 g	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
OCTYLDECANOL (UNII: 07UG7TSU58)				
CANDELILLA WAX (UNII: WL0328HX19)				
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)				
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)				
HYALURONIC ACID (UNII: S270N0TRQY)				
TOCOPHEROL (UNII: R0ZB2556P8)				
ALUMINUM OXIDE (UNII: LM26O6933)				
STANNIC OXIDE (UNII: KM7N50LOS6)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
MICA (UNII: V8A1AW0880)				
D&C RED NO. 28 (UNII: 767IP0Y5NH)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
D&C RED NO. 6 (UNII: 481744AI4O)				
D&C RED NO. 7 (UNII: ECW0LZ41X8)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76119-5310-1	1 in 1 BOX		
1		3.5 g in 1 TUBE, WITH APPLICATOR		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	05/01/2012		

**Labeler** - MallyGirl, LLC (167262554)