

AUBIO LIFE SCIENCES LIP- homosalate, avobenzone, octisalate and octocrylene lipstick
Aubio Life Sciences 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.

Drug Facts

Active Ingredients

Homosalate 15.00%

Octisalate 5.00%

Avobenzone 3.00%

Octocrylene 2.70%

Purpose

Sunscreen

Sunscreen

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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** immediately

Directions

- Apply generously and evenly 15 minutes before sun exposure
- 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 BROAD SPECTRUM SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially between 10am to 2pm
 - Wear long sleeve shirts, pants, hats, and sunglasses

- Reapply at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating

Inactive Ingredients

Butyrospermum Parkii (Shea) Butter, Cocos Nucifera (Coconut) Oil, Bis-Diglyceryl Polycyladipate-2, Caprylic/Capric Triglyceride, Beeswax, Ozokerite, Polyisobutene, Copernicia Cerifera (Carnauba Wax), Euphorbia Cerifera (Candelila) Wax, Sarracenia Leucophylla Leaf/Stem/Flower/Seed Extract (and) Sarracenia Purpurea Leaf/Stem/Flower/Seed Extract, Lavandula Augustifolia (Lavender) Flower Extract Melissa Officinalis (Balm Mint) Extract Zanthoxylum Bungeanum Fruit Extract Vaccinium Myrtillus Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Unsaponifiables, Dipotassium Glycyrtriizate) Phytosphingosine, Ceramide AP, Ceramide EOP, Ceramide NP, Glycerin, Water (Aqua), Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum, Flavor

Other Information

- Recap after each use
- Store at room temperature
- Protect the product in this container from excessive heat and direct sun

Questions or comments?

Call Toll-free 1 -844-My-Aubío

(1-844-692-8246)

Weekdays 9am-5pm PT. If you are not completely satisfied, save receipt and remaining product and call us.

Principal Display Panel - Blister Pack Label

Aubío[™]

Hydrating Lip Therapy

Broad Spectrum SPF 30 Sunscreen

Nourishing botanical formula

**Contains skin lipids for
intense moisturizing**

Revitalizes and soothes

NET WT 4.25g (0.15 oz)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70365-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	150 mg in 1 g
Avobenzene (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	30 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	30 mg in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	27 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Glycerin (UNII: PDC6A3C0OX)	
Carbomer Interpolymer Type A (allyl sucrose crosslinked) (UNII: 59TL3WG5CO)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Phytosphingosine (UNII: GIN46U9Q2Q)	
Sodium Lauroyl Lactylate (UNII: 7243K85WFO)	
Xanthan Gum (UNII: TTV12P4NEE)	
Cholesterol (UNII: 97C5T2UQ7J)	
Ceramide NP (UNII: 4370DF050B)	
3-DEHYDROXY CERAMIDE 1 (UNII: CR0J8RN66K)	
Ceramide AP (UNII: F1X8L2B00J)	
Shea Butter (UNII: K49155WL9Y)	
Coconut Oil (UNII: Q9L0O73W7L)	
Bis-Diglyceryl Polyacyladipate-2 (UNII: 6L246LAM9T)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Ceresin (UNII: Q1LS2UJO3A)	
Isohexadecane (UNII: 918X1OUF1E)	
Carnauba Wax (UNII: R12CBM0EIZ)	
Candelilla Wax (UNII: WL0328HX19)	
Lavandula Angustifolia Flower (UNII: 19AH1RAF4M)	
Melissa Officinalis (UNII: YF70189L0N)	
Zanthoxylum Bungeanum Fruit (UNII: 3CIP16A418)	
Bilberry Seed Oil (UNII: KK0KHX972K)	
Sunflower Oil (UNII: 3W1JG795YI)	
Sarracenia Purpurea (UNII: FOP08H143P)	
Raspberry (UNII: 4N14V5R27W)	
Mango (UNII: I629I3NR86)	

Cucumber (UNII: YY7C30 VXJT)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70365-002-01	4.25 g in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/28/2016	

Labeler - Aubio Life Sciences LLC (080080743)

Establishment

Name	Address	ID/FEI	Business Operations
KLEEN CONCEPTS		012989797	MANUFACTURE(70365-002) , LABEL(70365-002)

Revised: 1/2016

Aubio Life Sciences LLC