

**SUGAR BLOOM LIP TREATMENT SUNSCREEN SPF 15- avobenzone, octinoxate paste
Fresh Inc.**

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.

Sugar Bloom Lip Treatment Sunscreen SPF 15

Drug Facts

Active Ingredients

Avobenzone 2.00%

Octinoxate 7.49%

Purpose

Sunscreen

Use

Helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert; Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- 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

Other Information

Protect this product in container from excessive heat and direct sun

Questions or Comments?

Call toll free 1(800)FRESH-20

Monday-Friday (9 a.m. to 5p.m EST)

Inactive Ingredients

Cera Alba (Beeswax), Simmondsia Chinensis (Jojoba) Seed Oil, Ricinus Communis (Castor) Seed Oil, Hydrogenated Olive Oil Decyl Esters, Vitis Vinifera (Grape) Seed Oil, Parfum (Fragrance), Synthetic Fluorphlogopite, Copernicia Cerifera (Carnauba) Wax, Persea Gratissima (Avocado) Oil, Limnanthes Alba (Meadowfoam) Seed Oil, Passiflora Incarnata Seed Oil, Ribes Nigrum (Black Currant) Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Sucrose Tetrastearate Triacetate, Retinyl Palmitate, Tocopherol, Ascorbyl Tetraisopalmitate, Ascorbyl Palmitate, Ammonium Glycyrrhizate, Polyglyceryl-3 Polyricinoleate, Vanillin, BHT, Propyl Gallate, Limonene, Citral, Benzyl Alcohol, Linalool, Geraniol, [May Contain: CI 15850 (Red 6, Red 7, Red 7 Lake), CI 15985 (Yellow 6, Yellow 6 Lake), CI 19140 (Yellow 5, Yellow 5 Lake), CI 42090 (Blue 1 Lake), CI 45410 (Red 27, Red 27 Lake, Red 28 Lake), CI 77491, CI 77492, CI 77499 (Iron Oxides), CI 77891 (Titanium Dioxide)] <10938/Z>

Package Labeling:

2.67717

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Dist. Fresh Inc NYC 10022 USA

Drug Facts *(continued)*

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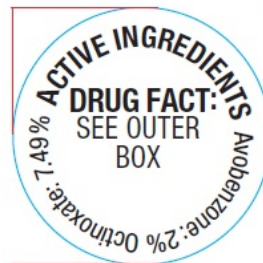
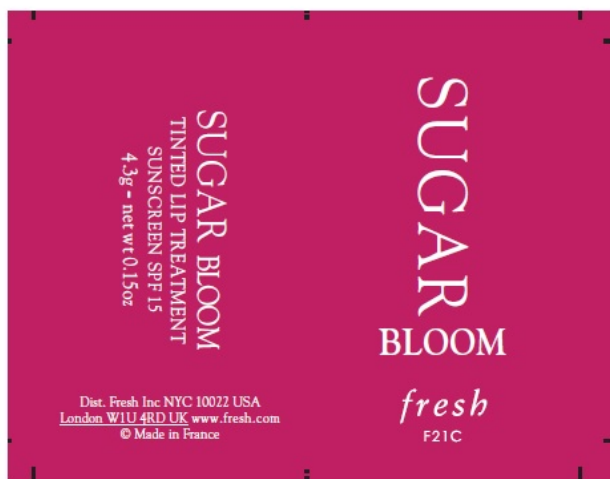


H13004048 / H00004090

Drug Facts *(continued)*

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avobenzone, octinoxate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42406-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	74.9 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WHITE WAX (UNII: 7G1J5DA97F)	
JOJOBA OIL (UNII: 724GKU717M)	
CASTOR OIL (UNII: D5340Y2I9G)	
HYDROGENATED OLIVE OIL DECYL ESTERS (UNII: XQ691JJ99N)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
PASSIFLORA INCARNATA SEED OIL (UNII: S0SU5AC95J)	
RIBES NIGRUM SEED OIL (UNII: GKE1188837)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
SUCROSE TETRASTEARATE TRIACETATE (UNII: 1K7LBQ045N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
VANILLIN (UNII: CHI530446X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
CITRAL (UNII: T7EU0O9VPP)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
GERANIOL (UNII: L837108USY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42406-019-00	1 in 1 CARTON	07/13/2016	
1		4.3 g in 1 BOX; 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	07/13/2016	

Labeler - Fresh Inc. (021403729)