

**MINI BERRY LIP BALM BLUEBERRY- octinoxate, titanium dioxide cream
TONYMOLY CO., LTD.**

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.

ACTIVE INGREDIENT

Active ingredients: Ethylhexyl Methoxycinnamate 5.00%, Titanium Dioxide 0.23%

INACTIVE INGREDIENT

Inactive ingredients: Polyglyceryl-2 Triisostearate, Petrolatum, Diisostearyl Malate, Bis-Diglyceryl Polyacyladipate-2, Polybutene, Benzophenone-3, Hydroxystearic Acid, Microcrystalline Wax, Silica Dimethyl Silylate, VP/Hexadecene Copolymer, Mica (CI 77019), Sorbitan Isostearate, Red 28 Lake (CI 45410), Fragrance(Parfum), Butylparaben, Tocopheryl Acetate, Methicone, Polyglyceryl-2 Diisostearate, Red 6 (CI 15850), Yellow 5 Lake (CI 19140), Vaccinium Angustifolium (Blueberry) Fruit Extract, Water, Butylene Glycol, Vaccinium Macrocarpon (Cranberry) Fruit Extract, Fragaria Chiloensis (Strawberry) Fruit Extract, Rubus Idaeus (Raspberry) Fruit Extract, Rubus Fruticosus (Blackberry) Fruit Extract, Phenoxyethanol, Methylparaben, Ethylparaben, Isobutylparaben, Propylparaben

PURPOSE

PURPOSE: Sunscreen

WARNINGS

Warnings: 1. In case of having following symptoms after using this, you're advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist. 1) In case of having problems such as red rash, swollenness, itching, stimulation during usage. 2) In case of having the same symptoms above on the part you put this product on by direct sunlight. 2. You are banned to use it on the part where you have a scar, eczema, or dermatitis. 3. In case of getting it into your eyes, you have to wash it immediately.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children: Keep out of reach of babies and children

INDICATIONS & USAGE

INDICATIONS AND USAGE: Apply on lip with fingers

DOSAGE & ADMINISTRATION

DOSAGE AND ADMINISTRATION: Take an adequate amount of this product.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Image of carton

TONYMOLY MINI BERRY LIP BALM BLUEBERRY

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[Keep out of reach of Children] Keep out of reach of babies and children

[Indication & Usage] Apply on your lips with your finger

[Dosage & Administration] Take an adequate amount of this product.

[Active Ingredients] Ethylhexyl Methoxycinnamate 5.00%, Titanium Dioxide (CI 77891) 0.23 %

[Ingredients] Polyglyceryl-2 Triisostearate, Petrolatum, Diisostearyl Malate, Bis-Diglyceryl Polyacyladipate-2, Polybutene, Benzophenone-3, Hydroxystearic Acid, Microcrystalline Wax, Silica Dimethyl Silylate, VP/Hexadecene Copolymer, Mica (CI 77019), Sorbitan Isostearate, Red 28 Lake (CI 45410), Tocopheryl Acetate, Methicone, Polyglyceryl-2 Diisostearate, Red 6 (CI 15850), Yellow 5 Lake (CI 19140), Vaccinium Angustifolium (Blueberry) Fruit Extract, Water, Butylene Glycol, Vaccinium Macrocarpon (Cranberry) Fruit Extract, Fragaria Chiloensis (Strawberry) Fruit Extract, Rubus Idaeus (Raspberry) Fruit Extract, Rubus Fruticosus (Blackberry) Fruit Extract, Phenoxyethanol, Butylparaben, Methylparaben, Ethylparaben, Isobutylparaben, Propylparaben, Fragrance(Parfum)

[Volume] Net Wt. 0.25 Oz / 7.2 g

Manufactured for Tonymoly Co., Ltd. 180 Bangbae-ro, Seocho-gu, Seoul, 137837, Korea

Manufactured by COSMAX INC., 46, Jeyakgongdan 2-gil, Hyangnam-eup, Hwaseong, Kyonggi 445746, Korea

MADE IN KOREA



MINI BERRY LIP BALM BLUEBERRY

octinoxate, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59078-038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.36 g in 7.2 g
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	0.01 g in 7.2 g

Inactive Ingredients

Ingredient Name	Strength
Petrolatum (UNII: 4T6H12BN9U)	
Diisostearyl Malate (UNII: QBS8A3XZGQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59078-038-01	7.2 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2013	

Labeler - TONYMOLY CO., LTD. (688216798)**Registrant** - TONYMOLY CO., LTD. (688216798)**Establishment**

Name	Address	ID/FEI	Business Operations
TONYMOLY CO., LTD.		688216798	repack(59078-038)

Establishment

Name	Address	ID/FEI	Business Operations
COSMAX INC.		689019313	manufacture(59078-038)

Revised: 3/2015

TONYMOLY CO., LTD.