

**CREMO ALL-SEASON LIP BALM SPF 25 VANILLA MINT- avobenzone, homosalate, octisalate, octocrylene, petrolatum ointment
Cremo Company**

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.

Lip Balm SPF 25 Vanilla Mint

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 8%

Petrolatum 40%

Purpose

Sunscreen

Skin Protectant

Uses

Helps Prevent sunburn and chapped lips.

Warnings

For external use only

Do not use on damaged or broken skin.

If rash occurs, discontinue use and consult a health care practitioner

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

Keep out of reach of children.

If swallowed, get medical treatment help or contact a Poison Control Center right away.

Directions

Apply liberally 15 minutes before sun exposure and as needed. Children under 6 months, consult a doctor.

Inactive Ingredients

Theobroma Cacao (Cocoa) Seed Butter, Beeswax, Flavor, Polyglyceryl-3 Beeswax, Lanolin, C18-38 Alkyl Hydroxystearoyl Stearate, Hydrogenated Poly (C6-14 Olefin), Ethylene/Propylene/Styrene Copolymer, Butylene/Ethylene/Styrene Copolymer, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Cannabis Sativa Seed Oil*, Bisabolol, Tocopherol.

*Organic

Other Information

Protect product from excessive heat and direct sunlight. You may report a serious adverse reaction from using this product to Cremo Company at 1-800-853-1762.

Questions?

1-800-853-1762 www.cremocompany.com

 <p>CREMO <i>Astonishingly Superior</i></p> <p>ALL-SEASON LIP BALM</p> <p>SKIN PROTECTANT & BROAD SPECTRUM SPF 25 SUNSCREEN</p> <p>SPF 25</p> <p><i>Essential</i> skincare</p> <p>NET WT. 0.25 OZ / 7g</p> <p>VANILLA MINT</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Avoobenzone 3%</td> <td rowspan="4">Sunscreen</td> </tr> <tr> <td>Homosalate 10%</td> </tr> <tr> <td>Octisalate 5%</td> </tr> <tr> <td>Octocrylene 8%</td> </tr> <tr> <td>Petrolatum 40%</td> <td>Skin Protectant</td> </tr> </tbody> </table> <p>Uses • Helps prevent sunburn and chapped lips.</p> <p>Warnings • For external use only • Do not use on damaged or broken skin • If rash occurs, discontinue use and consult a health care practitioner • When using this product keep out of eyes • Rinse with water to remove, and • Keep out of reach of children. If swallowed, get medical treatment help or contact a Poison Control Center right away.</p> <p>Directions • apply liberally 15 minutes before sun exposure and as needed • Children under 6 months, consult a doctor</p> <p>Other information Protect product from excessive heat and direct sunlight • You may report a serious adverse reaction from using this product to Cremo Company at 1-800-853-1762</p> <p>Inactive ingredients Theobroma Cacao (Cocoa) Seed Butter, Beeswax, Flavor, Polyglyceryl-3 Beeswax, Lanolin, C18-38 Alkyl Hydroxystearoyl Stearate, Hydrogenated Poly(C6-14 Olefin), Ethylene/Propylene/Styrene Copolymer, Butylene/Ethylene/Styrene Copolymer, Pentaerythrityl Tetra-di-t-Butyl Hydroxyhydrocinnamate, Cannabis Sativa Seed Oil*, Bisabolol, Tocopherol (*Organic)</p> <p>Questions? 1-800-853-1762 www.cremocompany.com</p> <p><small>Distributed by Cremo Company, LLC Laguna Beach, CA 90651 1-800-853-1762, © 2021 Cremo Company Not tested on animals.</small></p>	Active ingredients	Purpose	Avoobenzone 3%	Sunscreen	Homosalate 10%	Octisalate 5%	Octocrylene 8%	Petrolatum 40%	Skin Protectant
Active ingredients	Purpose									
Avoobenzone 3%	Sunscreen									
Homosalate 10%										
Octisalate 5%										
Octocrylene 8%										
Petrolatum 40%	Skin Protectant									

Crema All-Season Lip Balm SPF 25

CREMO ALL-SEASON LIP BALM SPF 25 VANILLA MINT

avobenzone, homosalate, octisalate, octocrylene, petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71825-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 1000 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 1000 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 1000 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	40 g in 1000 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
C18-38 ALKYL HYDROXYSTEAROYL STEARATE (UNII: WW4FVB2PEM)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
COCOA BUTTER (UNII: 512OYT1CRR)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LEVOMENOL (UNII: 24WE03BX2T)	
LANOLIN (UNII: 7EV65EAW6H)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71825-120-61	7 g in 1 TUBE; Type 0: Not a Combination Product	01/06/2022	



**ALL-SEASON
LIP BALM**

**SKIN PROTECTANT & BROAD SPECTRUM
SPF 25 SUNSCREEN**

**SPF
25**

Essential
skincare

NET WT. 0.25 OZ / 7g

**VANILLA
MINT**

Drug Facts

Active ingredients	Purpose
Azobenzene 3%Sunscreen
Homosalate 10%	
Octisalate 5%	
Octocrylene 8%	
Petrolatum 40%Skin Protectant

Uses • Helps prevent sunburn and chapped lips.

Warnings • For external use only • Do not use on damaged or broken skin • If rash occurs, discontinue use and consult a health care practitioner • When using this product keep out of eyes • Rinse with water to remove, and • Keep out of reach of children, If swallowed, get medical treatment help or contact a Poison Control Center right away.

Directions • apply liberally 15 minutes before sun exposure and as needed • Children under 6 months, consult a doctor.

Other information Protect product from excessive heat and direct sunlight • You may report a serious adverse reaction from using this product to Cremo Company at 1-800-853-1762

Inactive ingredients Theobroma Cacao (Cocoa) Seed Butter, Beeswax, Flavor, Polyglyceryl-3 Beeswax, Lanolin, C18-38 Alkyl Hydroxystearoyl Stearate, Hydrogenated Poly(C6-14 Olefin), Ethylene/Propylene/Styrene Copolymer, Butylene/Ethylene/Styrene Copolymer, Pentaerythrityl Tetra-d-1-butyl Hydroxyhydrocinnamate, Cannabis Sativa Seed Oil*, Bisabolol, Tocopherol (*Organic)

Questions?
1-800-853-1762 www.cremocompany.com

Distributed by Cremo Company, LLC Laguna Beach, CA 92651
1-800-853-1762, © 2021 Cremo Company
Not tested on animals.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/06/2022	

Labeler - Cremo Company (078708508)

Revised: 1/2022

Cremo Company