

**TEINT MIRACLE OCTINOXATE SUNSCREEN BROAD SPECTRUM SPF 15-
octinoxate cream
BPS 60**

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.

Tint Miracle Octinoxate Sunscreen Broad Spectrum SPF 15

Drug Facts

Active ingredient

Octinoxate 3%

Purpose

Sunscreen

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

Flammable until dry. Do not use near fire, flame or heat.

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 right away.

Directions

For sunscreen use: •shake well • apply liberally 15 minutes before sun exposure • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating

• **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 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 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses

- children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, cyclopentasiloxane, alcohol denat., phenyl trimethicone, glycerin, PEG-10 dimethicone, bis-PEG/PPG-14/14 dimethicone, tin oxide, PEG/PPG/polybutylene glycol-8/5/3 glycerin, rosa gallica flower extract, talc, dimethicone, dimethicone/polyglycerin-3 crosspolymer, methicone, silica silylate, alumina, aluminum hydroxide, magnesium silicate, magnesium sulfate, disodium stearyl glutamate, synthetic fluorophlogopite, ethylhexyl hydroxystearate, tocopheryl acetate, fragrance, linalool, limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, butylphenyl methylpropional, hexyl cinnamal; may contain: red28 lake, red 7, mica, titanium dioxide, blue 1 lake, bismuth oxychloride, Iron oxides

Questions or comments?

1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)

Package Labeling:

TEINT MIRACLE

Octinoxate Sunscreen
 Broad Spectrum SPF 15
 Lit-From-Within Makeup - Natural Skin Perfection

LANCÔME**Drug Facts****Active ingredient**

Octinoxate 3%

Purpose

Sunscreen

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**

Flammable until dry. Do not use near fire, flame or heat.

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 right away.

Directions

- For sunscreen use: • shake well • apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating
 - **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 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 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, cyclopentasiloxane, alcohol denat., phenyl trimethicone, glycerin, PEG-10 dimethicone, bis-PEG/PPG-14/14 dimethicone, lin oxide, PEG/PPG/polybutylene glycol-8/5/3 glycerin, rosa gallica flower extract, talc, dimethicone, dimethicone/polyglycerin-3 crosspolymer, methicone, silica silylate, alumina, aluminum hydroxide, magnesium silicate, magnesium sulfate, disodium stearyl glutamate, synthetic fluorophlogopite, ethylhexyl hydroxystearate, tocopheryl acetate, fragrance, linalool, limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, butylphenyl methylpropional, hexyl cinnamal; may contain: red 28 lake, red 7, mica, titanium dioxide, blue 1 lake, bismuth oxychloride, iron oxides

Questions or comments?

1-800-LANCOME (1-800-526-2663) Monday – Friday (9 a.m. – 5 p.m. EST)

B172952/3

3.71 FL. OZ. (110 ml)

**TESTER. NOT FOR SALE.**

LANCÔME, LUXURY PRODUCTS LLC, NEW YORK, NY 10017

IMP. BY LANCÔME CANADA, MONTRÉAL, H4T 1K5

TSA 10007 F 92667 ASNIERES CEDEX Made in France Lancome.com



G862083

TEINT MIRACLE OCTINOXATE SUNSCREEN BROAD SPECTRUM SPF 15

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70581-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)
ETHYLHEXYL HYDROXYSTEARATE (UNII: B7I80BVV5E)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
WATER (UNII: 059QF0KO0R)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
ALCOHOL (UNII: 3K9958V90M)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
GLYCERIN (UNII: PDC6A3C0OX)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
BIS-PEG/PPG-14/14 DIMETHICONE (UNII: X2I70H0QJE)
STANNIC OXIDE (UNII: KM7N50LOS6)
ROSA GALLICA FLOWER (UNII: X8W61WUV70)
TALC (UNII: 7SEV7J4R1U)
DIMETHICONE (UNII: 92RU3N3Y1O)
METHICONE (20 CST) (UNII: 6777U11MKT)
ALUMINUM OXIDE (UNII: LM26O6933)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
MAGNESIUM SILICATE (UNII: 9B9691B2N9)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70581-004-01	1 in 1 BOX	04/06/2016	
1		110 mL in 1 BOTTLE; 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	04/06/2016	

Labeler - BPS 60 (272259304)

Establishment

Name	Address	ID/FEI	Business Operations
BPS 60		272259304	pack(70581-004)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(70581-004)