

MOISTURIZING TINT SPF 30 - octinoxate, octisalate, oxybenzone, avobenzone lotion
Hayden Caleel 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:

Avobenzone (3.0%)

Octinoxate (7.5%)

Octisalate (5.0%)

Oxybenzone (4.0%)

Purpose:

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), helps decrease 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 the eyes. Rinse with water to remove.

Stop use and ask a doctor if skin rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- 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 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 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

Other information

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

Inactive ingredients

Aqua (Water/Eau)

Isoeicosane

Potassium Cetyl Phosphate

Cetearyl Alcohol

Cetyl Dimethicone

Dimethicone

Ethyhexyl Methoxycrylene

Glycerin

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer

Silica

Sorbitan Sesquioleate

Isohexadecane

Phenoxyethanol

Caprylyl Glycol

Ethylhexylglycerin

Polysorbate 60

Hexylene Glycol

Citric Acid

MAY CONTAIN (+/-):

Titanium Dioxide (CI 77891)

Iron Oxides (CI 77491, CI 77492, CI 77499)

Principal Display Panel - 50mL Carton Label**SUNSCREEN**

*broad
spectrum
spf 30*

glo·therapeutics

**Mois turizing
Tint SPF 30+**

FAIR

FACIAL SUNSCREEN

50 mL / 1.7 fl. oz. e

Moisturizing Tint SPF 30+

A lightweight, oil-free formula that provides moisture, broad spectrum UVA/UVB protection and a sheer hint of color to softly even tone and enhance skin's radiance.

RECOMMENDED FOR:
All skin types.

Drug Facts

Active ingredients

Avobenzone (3.0%), Octinoxate (7.5%), Octisalate (5.0%), Oxybenzone (4.0%)

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Drug Facts (continued)

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

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every two hours
- children under 6 months: 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 sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses

Other information

- protect this product from excessive heat and direct sun

Inactive ingredients

Aqua (Water/Eau), Isoeicosane, Potassium Cetyl Phosphate, Cetearyl Alcohol, Cetyl Dimethicone, Dimethicone, Ethylhexyl Methoxycrylene, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Silica, Sorbitan Sesquioxide, Isohexadecane, Phenoxethanol, Caprylyl Glycol, Ethylhexylglycerin, Polysorbate 60, Hexylene Glycol, Citric Acid, **MAY CONTAIN (+/-):** Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499)

SUNSCREEN

broad spectrum 

glō·therapeutics

Moisturizing
Tint SPF 30+

FAIR

FACIAL SUNSCREEN
50 mL / 1.7 fl. oz. 



Distributed By: glō
Denver, CO 80223, MADE IN THE USA
Lecceur Ltd Plaza 1 Salford M50 3UB UK

www.gloprofessional.com



MOISTURIZING TINT SPF 30

octinoxate, octisalate, oxybenzone, avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60541-0706
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	5 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	4 g in 1 mL
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	3 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isoeicosane (UNII: AR294KAG3T)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetyl Dimethicone 45 (UNII: IK315POC44)	
Dimethicone (UNII: 92RU3N3Y1O)	
Ethylhexyl Methoxycrylene (UNII: S3KFG6Q5X8)	
Glycerin (UNII: PDC6A3C0OX)	
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (45000 Mpa.S At 1%) (UNII: 86FQE96TZ4)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sorbitan Sesquioleate (UNII: 0W8RRE5W5A)	
Isohexadecane (UNII: 918X1OUF1E)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Hexylene Glycol (UNII: KEH0A3F75J)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Ferric Oxide Red (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60541-0706-7	1 in 1 BOX		
1		50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2014	

Labeler - Hayden Caleel LLC (011367468)

Establishment

Name	Address	ID/FEI	Business Operations
Hayden Caleel LLC		011367468	MANUFACTURE(60541-0706)

Revised: 3/2014

Hayden Caleel LLC