MINERAL TINTED FACE SUNSCREEN SPF 30 - LIGHT/ MEDIUM- zinc oxide and titanium dioxide cream
MINERAL TINTED FACE SUNSCREEN SPF 30 - MEDIUM/ DARK- zinc oxide and

titanium dioxide cream
Unsun Cosmetics

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.

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#### Mineral Tinted Face Sunscreen SPF 30

## **Drug Facts**

Medicinal ingredients	Purpose
Titanium dioxide 5.5%	Sunscreen
Zinc oxide 6.5%	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

# 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 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** avoid contact with eyes. If contact occurs, rinse thoroughly with water. **Stop use and ask a doctor** if rash occurs.

**Keep out of reach of children.** If swallowed, call a poison control center or get medical help right away.

#### **Directions**

Adults and children over 6 months of age: Apply liberally and evenly 15 minutes before sun exposure. Reapply after 80 minutes of swimming or perspiring heavily or immediately after towel drying or washing, 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.

## **Non-medicinal ingredients**

Water/Aqua/Eau, Caprylic/Capric Triglyceride, Isoamyl Laurate, Glycerin, Polyglyceryl-2 Sesquioleate, Coconut Alkanes, Polyglyceryl-3 Ricinoleate, Crambe Abyssinica (Abyssinian) Seed Oil, Sorbitan Sesquioleate, Polyhydroxystearic Acid, Heptyl Undecylenate, Alumina, Stearic Acid, Magnesium Sulfate, Sodium Chloride, Coco-Caprylate/Caprate, Benzyl Alcohol, Butyrospermum Parkii (Shea) Butter, Carthamus Tinctorius (Safflower) Seed Oil, Aloe Barbadensis Leaf Juice, Beeswax/Cera Alba/Cire d' Abeille, Cocos Nucifera (Coconut) Oil, Cucumis Sativus (Cucumber) Fruit Extract, Olea Europaea (Olive) Fruit Oil, Ascorbic Acid, Beta Vulgaris (Beet) Root Extract, Citric Acid, Citrus Aurantium Amara (Bitter Orange) Fruit Extract, Citrus Aurantium Sinensis Peel Extract, Citrus Reticulata (Tangerine) Fruit Extract, Glycine Soja (Soybean) Oil, Hydrolyzed Corn Starch, Lactic Acid, p-Anisic Acid, Tocopherol, Triethoxycaprylylsilane, Iron Oxides (CI 77491, CI 77492, CI 77499).

#### Other information

• protect this product from excessive heat and direct sun

## PRINCIPAL DISPLAY PANEL - 50 mL Tube Label - Light Medium

unsun™

MINERAL TINTED FACE SUNSCREEN LOTION

30

BROAD SPECTRUM SPF 30

WATER RESISTANT (80 MINUTES)

NPN xxxxx

**LIGHT - MEDIUM** 

1.7 FL OZ | 50 mL

# Tone Indicates Non-Print Areas

# **Drug Facts**

## Medicinal ingredients

### Purpose

Titanium dioxide 5.5%..... Zinc oxide 6.5%.....Sunscreen

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

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Other information • protect this product from excessive heat and direct sun

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Lot No. xxxxx

Exp. xx/xxxx







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MINERAL TINTED FACE SUNSCREEN LOTION

BROAD SPECTRUM SPF 30

WATER RESISTANT (80 MINUTES)

NPN xxxxx

LIGHT - MEDIUM

1,7 FL OZ | 50 mL

# PRINCIPAL DISPLAY PANEL - 50 mL Tube Label - Medium Dark

unsun™

MINERAL TINTED FACE SUNSCREEN LOTION

30

BROAD SPECTRUM SPF 30

WATER RESISTANT (80 MINUTES)

NPN xxxxx

MEDIUM - DARK

1.7 FL OZ | 50 mL

# Tone Indicates Non-Print Areas

# **Drug Facts**

# Medicinal ingredients

#### Purpose

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Non-medicinal ingredients Water/Aqua/Eau, Caprylic/Capric Triglyceride, Isoamyl Laurate, Glycerin, Polyglyceryl-2 Sesquioleate, Coconut Alkanes, Polyglyceryl-3 Ricincleate, Crambe Abyssinica (Abyssinian) Seed Oil, Sorbitan Sesquioleate, Polyfrydoxystearic Acid, Heptyl Undecylenate, Alumina, Stearic Acid, Magnesium Sulfate, Sodium Chloride, Coco-Caprylate/Caprate, Benzyl Alcohol, Butyrospermum Parkii (Shea) Butter, Carthamus Tinctorius (Safflower) Seed Oil, Aloe Barbadensis Leaf Juice, Beeswax/Cera Alba/Cire d' Abeille, Cocos Nucifera (Coconut) Oil, Cucumis Sativus (Cucumber) Fruit Extract, Clea Europaea (Olive) Fruit Oil, Alsorbic Acid, Beta Vulgaris (Beet) Root Extract, Citric Acid, Citrus Aurantium Amara (Bitter Orange) Fruit Extract, Citrus Aurantium Sinensis Peel Extract, Citrus Reticulata (Tangerine) Fruit Extract, Glycine Soja (Soybean) Oil, Hydrolyzed Com Starch, Lactic Acid, p-Anisic Acid, Tocopherol, Triethoxycaprylylsilane, Iron Oxides (Cl. 177491, Cl. 777492, Cl. 777499).

**Other information** • protect this product from excessive heat and direct sun

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Lot No. xxxxx

Exp. xx/xxxx







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MINERAL TINTED FACE SUNSCREEN LOTION

30

BROAD SPECTRUM SPF 30

WATER RESISTANT (80 MINUTES)

NPN xxxxx

MEDIUM - DARK

1,7 FL OZ | 50 mL

# MINERAL TINTED FACE SUNSCREEN SPF 30 - LIGHT/ MEDIUM

zinc oxide and titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73455-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.065 g in 1 mL	
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.055 g in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL (UNII: 0QW9S92J3K)	
Sorbitan Sesquioleate (UNII: 0W8RRI5W5A)	
Heptyl Undecylenate (UNII: W77QUB6GXO)	

Product Characteristics			
Color	BROWN (tan)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73455-011- 28	1 in 1 BOX	04/15/2019	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC monograph final	part352	04/15/2019		

# MINERAL TINTED FACE SUNSCREEN SPF 30 - MEDIUM/ DARK

zinc oxide and titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73455-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
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Sorbitan Sesquioleate (UNII: 0W8RRI5W5A)	
Heptyl Undecylenate (UNII: W77QUB6GXO)	

Product Characteristics			
Color	BROWN (beige)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73455-111- 30	1 in 1 BOX	04/15/2019	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part352	04/15/2019			

# Labeler - Unsun Cosmetics (080766704)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pack On Demand		610511326	MANUFACTURE(73455-011, 73455-111)	

Revised: 3/2022 Unsun Cosmetics