

GLOWELL SPF 30 TINTED MINERAL SUNSCREEN LIGHT- zinc oxide and titanium dioxide cream

GLOWELL SPF 30 TINTED MINERAL SUNSCREEN MEDIUM- zinc oxide and titanium dioxide cream

GLOWELL SPF 30 TINTED MINERAL SUNSCREEN TAN- zinc oxide and titanium dioxide cream

GLOWELL SPF 30 TINTED MINERAL SUNSCREEN DEEP- zinc oxide and titanium dioxide cream

GLOWELL, 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.

Glowell® SPF 30 Tinted Mineral Sunscreen

Drug Facts

Active ingredients	Purpose
Zinc Oxide 14.20%	Sunscreen
Titanium Dioxide 0.5%	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

- **For external use only**
- **Do not use** on damaged or broken skin
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop and ask a doctor** if a rash occurs.

- **Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away. May stain some fabrics.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 80 minutes of swimming or sweating.
 - Immediately after towel drying.
 - at least every two hours.
- **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 am – 2pm.
- Wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor.

Inactive Ingredients

- Deionized Water, Isododecane, C12-15 Alkyl Benzoate, Iron Oxide, Butylene Glycol, Polyglyceryl-3 Diisostearate, Mica, Cocos Nucifera (Coconut) Oil, Quaternium-90 Bentonite, VP/Eicosene Copolymer, Butyrospermum Parkii (Shea) Butter, Polyhydroxystearic Acid, Gluconolactone (and) Sodium Benzoate, Fragrance, Propylene Carbonate, Bismuth Oxochloride, Triethoxycaprylylsilane, Tocopherol, Titanium Dioxide (CI77891), Ethyl Ferulate.

Other Information

- Protect this product from excessive heat and direct sun. Wash with soap to remove from skin.

Questions or Comments?

Call **1-833-GLOW-SPF**

**Distributed by: Glowell, LLC.
South Plainfield, NJ 07080.**

PRINCIPAL DISPLAY PANEL - 147 mL Tube Label - Light

GLO
WELL®

SPF30

TINTED
MINERAL
SUNSCREEN

ADAPTS TO SKIN TONE
WITH A BUILDABLE
GLOWING FINISH

FOR
LIGHT SKIN
TONES

UVA/UVB BROAD SPECTRUM SPF 30
WATER RESISTANT 80 MINUTES
5FL OZ. (147mL)

GLOW WELL®

SPF30

TINTED MINERAL SUNSCREEN

ADAPTS TO SKIN TONE
WITH A BUILDABLE
GLOWING FINISH

FOR
LIGHT SKIN
TONES

UVA/UVB BROAD SPECTRUM SPF 30
WATER RESISTANT 80 MINUTES
5 FL OZ. (147mL)



PROTECT, ENHANCE AND
ILLUMINATE SKIN FROM SUN
UP TO SUN DOWN. THIS IS
SPF WITH YOU FACTOR.

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SEE HOW



IT WORKS



PRINCIPAL DISPLAY PANEL - 147 mL Tube Label - Medium

GLO
WELL®

SPF30

TINTED
MINERAL
SUNSCREEN

ADAPTS TO SKIN TONE
WITH A BUILDABLE
GLOWING FINISH

FOR
MEDIUM SKIN
TONES

UVA/UVB BROAD SPECTRUM SPF 30
WATER RESISTANT 80 MINUTES
5FL OZ. (147mL)

GLOW WELL®

SPF30

TINTED MINERAL SUNSCREEN

ADAPTS TO SKIN TONE
WITH A BUILDABLE
GLOWING FINISH

FOR
MEDIUM SKIN
TONES

UVA/UVB BROAD SPECTRUM SPF 30
WATER RESISTANT 80 MINUTES
5FL OZ. (147mL)



PROTECT, ENHANCE AND
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SEE HOW



IT WORKS



PRINCIPAL DISPLAY PANEL - 147 mL Tube Label - Tan

GLO
WELL®

SPF30

TINTED
MINERAL
SUNSCREEN

ADAPTS TO SKIN TONE
WITH A BUILDABLE
GLOWING FINISH

FOR
TAN SKIN
TONES

UVA/UVB BROAD SPECTRUM SPF 30
WATER RESISTANT 80 MINUTES
5FL OZ. (147mL)

GLOW WELL®

SPF30

TINTED MINERAL SUNSCREEN

ADAPTS TO SKIN TONE
WITH A BUILDABLE
GLOWING FINISH

FOR
TAN SKIN
TONES

UVA/UVB BROAD SPECTRUM SPF 30
WATER RESISTANT 80 MINUTES
5 FL OZ. (147mL)



PROTECT, ENHANCE AND
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SEE HOW



IT WORKS



PRINCIPAL DISPLAY PANEL - 147 mL Tube Label - Deep

GLO
WELL®

SPF30

TINTED
MINERAL
SUNSCREEN

ADAPTS TO SKIN TONE
WITH A BUILDABLE
GLOWING FINISH

FOR
DEEP SKIN
TONES

UVA/UVB BROAD SPECTRUM SPF 30
WATER RESISTANT 80 MINUTES
5FL OZ. (147mL)

GLOW WELL®

SPF30

TINTED MINERAL SUNSCREEN

ADAPTS TO SKIN TONE
WITH A BUILDABLE
GLOWING FINISH

FOR
DEEP SKIN
TONES

UVA/UVB BROAD SPECTRUM SPF 30
WATER RESISTANT 80 MINUTES
5 FL OZ. (147mL)



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SEE HOW



IT WORKS



GLOWELL SPF 30 TINTED MINERAL SUNSCREEN LIGHT

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83495-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.142 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.005 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BUTYLENE GLYCOL (UNII: 3XUS85KORA)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
MICA (UNII: V8A1AW0880)	
COCONUT OIL (UNII: Q9L0O73W7L)	
QUATERNIUM-90 BENTONITE (UNII: 97K5YEF88C)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYL FERULATE (UNII: 5B8915UELW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83495-101-01	147 mL in 1 TUBE; Type 0: Not a Combination Product	07/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/05/2023	

GLOWELL SPF 30 TINTED MINERAL SUNSCREEN MEDIUM

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83495-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.142 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.005 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KOOR)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
MICA (UNII: V8A1AW0880)	
COCONUT OIL (UNII: Q9L0O73W7L)	
QUATERNIUM-90 BENTONITE (UNII: 97K5YEF88C)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYL FERULATE (UNII: 5B8915UELW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83495-102-01	147 mL in 1 TUBE; Type 0: Not a Combination Product	07/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/05/2023	

GLOWELL SPF 30 TINTED MINERAL SUNSCREEN TAN

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83495-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.142 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.005 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
MICA (UNII: V8A1AW0880)	
COCONUT OIL (UNII: Q9L0O73W7L)	
QUATERNIUM-90 BENTONITE (UNII: 97K5YEF88C)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
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PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYL FERULATE (UNII: 5B8915UELW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83495-103-01	147 mL in 1 TUBE; Type 0: Not a Combination Product	07/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/05/2023	

GLOWELL SPF 30 TINTED MINERAL SUNSCREEN DEEP

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83495-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.142 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.005 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
MICA (UNII: V8A1AW0880)	
COCONUT OIL (UNII: Q9L0O73W7L)	
QUATERNIUM-90 BENTONITE (UNII: 97K5YEF88C)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYL FERULATE (UNII: 5B8915UELW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83495-104-01	147 mL in 1 TUBE; Type 0: Not a Combination Product	07/05/2023	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part352	07/05/2023	

Labeler - GLOWELL, LLC. (117700937)

Revised: 6/2023

GLOWELL, LLC.