

**GLO SKIN BEAUTY SOLAR SHADE SPF 50- glo skin beauty solar shade spf 50 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.*

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**DRUG FACTS**

**Active Ingredients**

Titanium Dioxide 6.5%

Zinc Oxide 8.6%

**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 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**

- apply generously 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

**Inactive ingredients**

Aqua/Water/Eau, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Dimethicone, Cyclotetrasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Aluminum Hydroxide, Stearic Acid, Dimethicone/PEG-10/15 Crosspolymer, Glycerin, Sodium Chloride, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Cetearyl Oliviate, Sorbitan Oliviate, Cyclohexasiloxane, Hexyl Laurate, Sodium Hyaluronate, Tocopherol, Tocopheryl Acetate, PEG/PPG-18/18 Dimethicone, Dimethicone/Polyglycerin-3 Crosspolymer, Ascorbyl Palmitate, Dimethicone/Vinyl Dimethicone Crosspolymer, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Ethylhexyl Palmitate, Silica Dimethyl Silylate, Butylene Glycol, Ascorbic Acid, Citric Acid, Phenoxyethanol, Caprylyl

Glycol, Ethylhexylglycerin, Hexylene Glycol, PEG-8

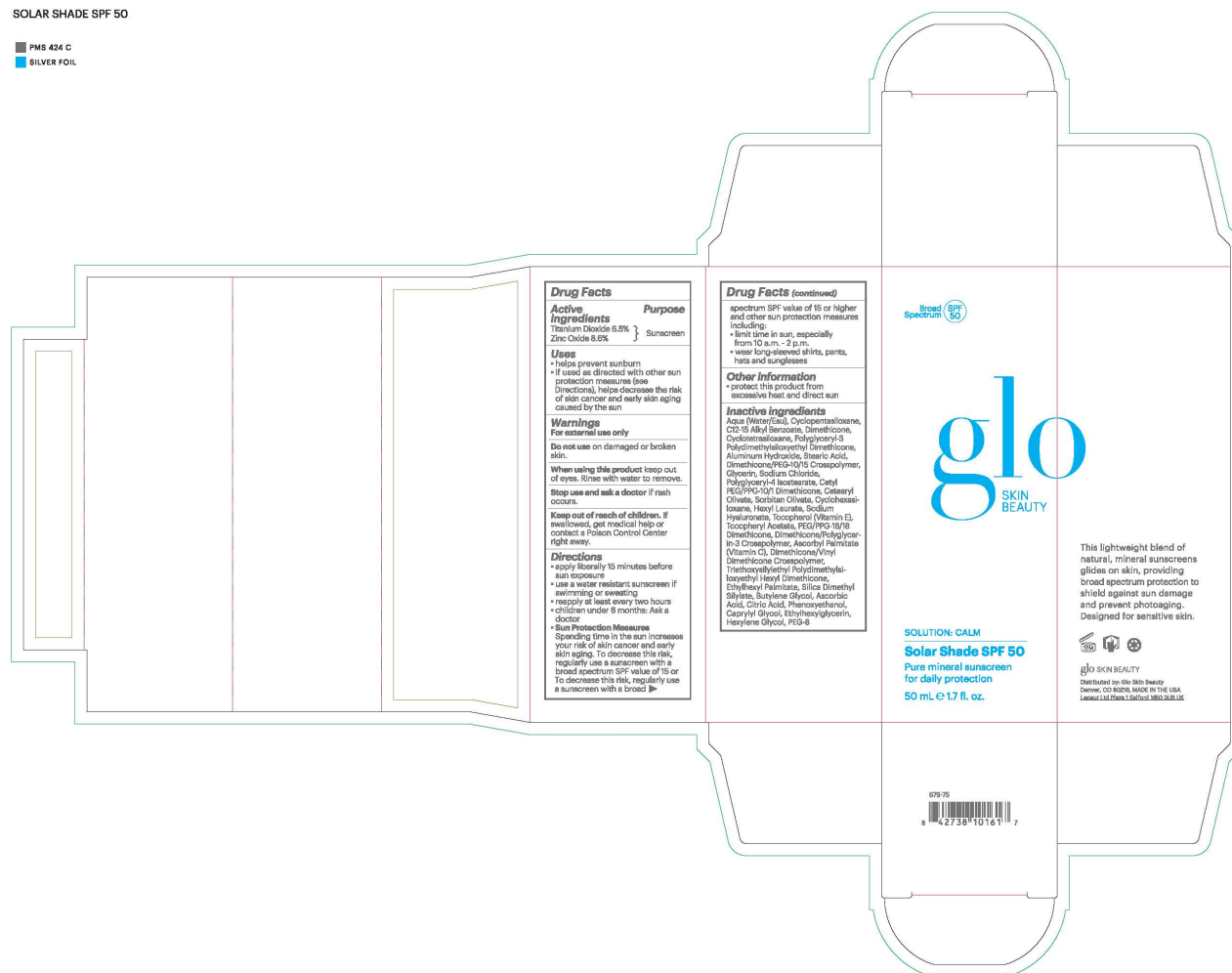
## Other Information

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

## Principal Display Panel

SOLAR SHADE SPF 50

■ PMS 424 C  
■ SILVER FOIL



## GLO SKIN BEAUTY SOLAR SHADE SPF 50

glo skin beauty solar shade spf 50 lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60541-1200
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	6.5 g in 1 g

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	8.6 g in 1 g
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### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
C12-15 ALCOHOLS (UNII: 2C8M6XLB5C)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PEG-12 DIMETHICONE/PPG-20 CROSSPOLYMER (UNII: 965K72OQXO)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60541-1200-5	1 in 1 CARTON	12/31/2017	
1		50 g 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	12/31/2017	

**Labeler** - Hayden Caleel LLC (011367468)

