

**SHIMMERSHADE BROAD SPECTRUM SPF 30 FIRST LIGHT- octisalate, zinc oxide cream
TAYLOR JAMES, LTD.**

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.

Shimmer Shade Broad Spectrum Sunscreen SPF 30 First Light

Active Ingredients Purpose

Octisalate 5% Sunscreen

Zinc Oxide 20% 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

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

Stop use and ask a doctor if rash occurs.

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.

Directions

- apply generously and evenly 15 minutes before sun exposure
- reapply at least every 2 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 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: Ask a doctor

Inactive Ingredients

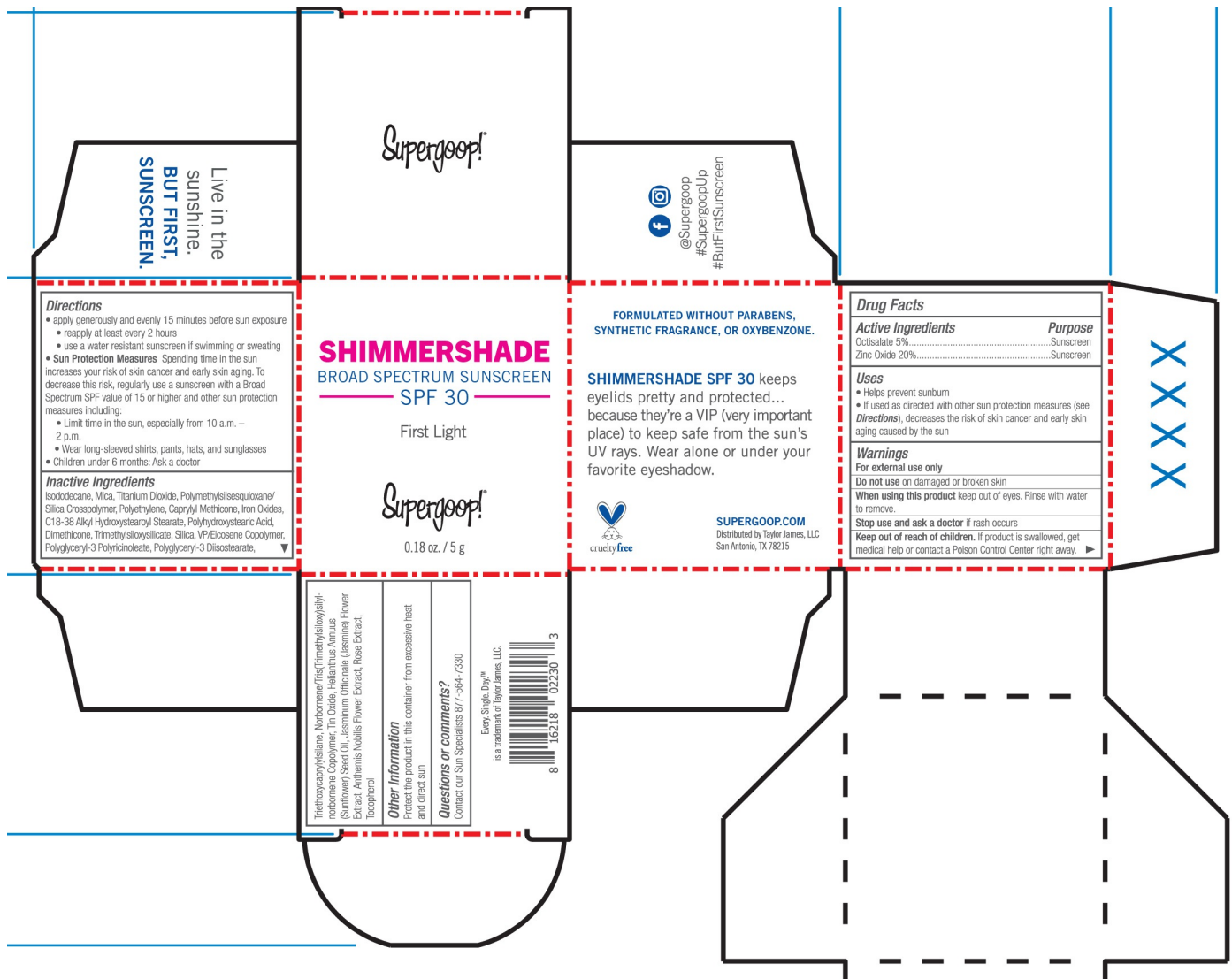
Isododecane, Mica, Titanium Dioxide, Polymethylsilsesquioxane/Silica Crosspolymer, Polyethylene, Caprylyl Methicone, Iron oxides, C18-38 Alkyl Hydroxystearoyl Stearate, Polyhydroxystearic Acid, Dimethicone, Trimethylsiloxysilicate, Silica, VP/Eicosene Copolymer, Polyglyceryl-3 Polyricinoleate, Polyglyceryl-3 Diisostearate, Triethoxycaprylylsilane, Norbornene/tris(trimethylsiloxy)silyl-norbornene Copolymer, Tin Oxide, Helianthus Annuus (Sunflower) Seed Oil, Jasminum Officinale (Jasmine) Flower Extract, Rose Extract, Tocopherol.

Shimmershade

Broad Spectrum Sunscreen SPF 30

First Light

0.18 oz. /5 g



Active Ingredient: Octisalate 5%, Zinc Oxide 20%
 Distributed by Taylor James, LLC, San Antonio, TX 78215
DRUG FACTS
 SEE OUTER BOX
 First Light
 0.18 oz. / 5 g

SHIMMERSHADE BROAD SPECTRUM SPF 30 FIRST LIGHT

octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75936-301	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	20 g in 100 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	5 g in 100 g	
Inactive Ingredients				
Ingredient Name				Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
JASMINUM OFFICINALE FLOWER (UNII: 0Q8K841432)				
ISODODECANE (UNII: A8289P68Y2)				
MICA (UNII: V8A1AW0880)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)				
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)				
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)				
VINYLPIRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)				
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)				
STANNIC OXIDE (UNII: KM7N50LOS6)				
.DELTA.-TOCOPHEROL (UNII: JU84X1IIN)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERROSFERRIC OXIDE (UNII: XM0M87F357)				
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-301-01	5 g in 1 JAR; Type 0: Not a Combination Product	01/24/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	01/23/2019		

Labeler - TAYLOR JAMES, LTD. (033381850)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 1/2019

TAYLOR JAMES, LTD.