

SILKEN PORE PERFECTING SUNSCREEN BROAD SPECTRUM SPF 35- octisalate, zinc oxide lotion
TATCHA INC.

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

Octisalate 5.00%

Zinc Oxide 15.00%

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

When using this product • keep out of eyes • rinse with water to remove • do not use on damaged or broken skin

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.

For external use only

Directions

- Apply liberally 15 minutes before sun exposure
- Use water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: ask a doctor
- Sun Protection Measures: Spending time in the sun decreases risk of skin cancer and early 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 10:00 am - 2:00 pm. Wear long sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients

WATER, ISODODECANE, CYCLOPENTASILOXANE, PROPANEDIOL, HDI/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER, GLYCERIN, DIMETHICONE, OCTYLDODECYL NEOPENTANOATE, BEHENYL ALCOHOL, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, ROSA MULTIFLORA FRUIT EXTRACT, ERIOBOTRYA JAPONICA LEAF EXTRACT, STEARYL GLYCYRRHETINATE (LICORICE EXTRACT), GLYCYRRHIZA INFLATA (LICORICE) ROOT EXTRACT, CAMELLIA SINENSIS (GREEN TEA) LEAF EXTRACT, PISTACIA LENTISCUS (MASTIC) GUM, SERICIN (SILK EXTRACT), ALGAE EXTRACT, LECITHIN, INOSITOL (RICE EXTRACT), POLYHYDROXYSTEARIC ACID, SORBITAN TRISTEARATE, SODIUM DILAURAMIDOGLUTAMIDE LYSINE, SILICA,

POTASSIUM SORBATE, BEHENETH-20, SODIUM ACRYLATE/ACRYLOYLDIMETHYLTAURATE/DIMETHYLACRYLAMIDE CROSSPOLYMER, POLYMETHYLSILSESQUIOXANE, TITANIUM DIOXIDE, METHICONE, TRIMETHYLSILOXYSILICATE, DIMETHICONOL, DISODIUM EDTA, IRON OXIDES (CI77491), TIN OXIDE, MICA, FRAGRANCE (NATURAL), ETHYLHEXYLGLYCERIN, ALCOHOL, PHENOXYETHANOL.

Other Information

- Protect this product from excessive heat and direct sun.

TATCHA

SILKEN

pore perfecting sunscreen


broad spectrum SPF 35

PA +++

Japanese wild rose and silk extracts

and Hadasei-3™ Complex

10 ml | 0.34 fl. oz.

<p>ACTIVE INGREDIENTS</p> <p>Octisalate (5%).....Sunscreen Zinc Oxide (15%).....Sunscreen</p> <p>WARNINGS</p> <p>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 product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>DIRECTIONS</p> <p>Apply liberally 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 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-sleeve shirts, pants, hats, and sunglasses Children under 6 months: Ask a doctor.</p> <p>Questions? Call toll free (888) 739-2932 ext. 1</p> <p>FORMULATED IN JAPAN MADE IN USA DIST. TATCHA LLC, SAN FRANCISCO, CA 94123 USA TATCHA.COM</p> <p>10 ml 0.34 fl. oz.</p>	<p>SILKEN</p> <p>pore perfecting sunscreen broad spectrum SPF35 PA+++</p> <p>TATCHA</p> 

Drug Facts

Active Ingredients **Purpose**
Octisalate 5%.....Sunscreen
Zinc Oxide 15%.....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 use and ask a doctor if rash occurs.

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

Directions
■ Apply liberally 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 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-sleeve shirts, pants, hats, and sunglasses.

← **Drug Facts** (continued)



TATCHA

SILKEN
pore perfecting sunscreen
broad spectrum SPF 35
PA+++

Japanese wild rose and silk extracts
and Hadasei-3™ Complex

10 ml | 0.34 fl. oz.

Formulated without parabens, synthetic fragrances, mineral oil, sulfate detergents, phthalates, urea, DEA or TEA.

Non-comedogenic.
Non-irritating.
Non-sensitizing.
Dermatologist tested.

SILKEN
pore perfecting sunscreen
broad spectrum SPF 35
PA+++

Inspired by the geisha's skin-perfecting and sun-protecting rituals, this weightless, anti-aging sunscreen features Japanese Wild Rose, Loquat Leaf, Licorice and Silk extracts to reduce the appearance of pores, leaving skin glowing while providing elegant and effective sun protection.

Tatcha's proprietary Hadasei-3™ Complex offers antioxidant protection and additional nourishment to the skin, while protecting it from damaging UV rays.

FORMULATED IN JAPAN
MADE IN U.S.A.
DIST. TATCHA LLC
SAN FRANCISCO, CA 94123 USA
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TATCHA.COM



SILKEN PORE PERFECTING SUNSCREEN BROAD SPECTRUM SPF 35

octisalate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69417-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15 in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ISODODECANE (UNII: A8289P68Y2)	
DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
PROPANEDIOL (UNII: 5965N8W85T)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4C00W6C5)	
ROSA MULTIFLORA FRUIT (UNII: EZ5DSL4T27)	
ERIOBOTRYA JAPONICA LEAF (UNII: Z02066SV11)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	

GLYCYRRHIZA ECHINATA ROOT (UNII: V6E722P1VB)
CAMELLIA JAPONICA LEAF (UNII: 4E3VE6KTLY)
PISTACIA LENTISCUS RESIN (UNII: 7446H202QW)
SILK SERICIN (UNII: 0N1VMU8G9W)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
INOSITOL (UNII: 4L6452S749)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
SORBITAN TRISTEARATE (UNII: 6LUM696811)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
BEHENETH-20 (UNII: BJ4GP2IFLN)
SODIUM ACRYLATE (UNII: 7C98FKB43H)
POLYMETHYLSILSESQUOXANE (11 MICRONS) (UNII: Z570VEV8XK)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
METHICONE (20 CST) (UNII: 6777U11MKT)
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)
BROWN IRON OXIDE (UNII: 1N032N7MFO)
MICA (UNII: V8A1AW0880)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
ALCOHOL (UNII: 3K9958V90M)
PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69417-110-03	1 in 1 CARTON	06/01/2015	
1		10 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 not final	part352	06/01/2015	

Labeler - TATCHA INC. (006811461)