

TATCHA THE SILK SUNSCREEN- 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.

TATCHA® THE SILK SUNSCREEN

Drug Facts

Active Ingredient

Zinc Oxide (10%)

Purpose

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

- Shake well.
- 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.

Inactive Ingredients

AQUA/WATER/EAU, C12-15 ALKYL BENZOATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, LAURYL PEG-8 DIMETHICONE, DIMETHICONE, ISODODECANE, TRIDECYL SALICYLATE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, PROPANEDIOL, CAPRYLYL METHICONE, POLYMETHYLSILSESQUIOXANE, NIACINAMIDE, SACCHAROMYCES/RICE FERMENT FILTRATE, SILICA, SQUALANE, CAMELLIA SINENSIS LEAF EXTRACT, CLADOSIPHON OKAMURANUS EXTRACT, HYDROLYZED SILK, BISABOLOL, ALLANTOIN, TOCOPHEROL, THEOBROMA CACAO (COCOA) SEED EXTRACT, ARCTIUM LAPPA ROOT EXTRACT, KAPPAPHYCUS ALVAREZII EXTRACT, SODIUM HYALURONATE, LECITHIN, CAESALPINIA SPINOSA FRUIT EXTRACT, LACTOBACILLUS, MALTODEXTRIN, CAPRYLYL GLYCOL, DIMETHICONE CROSSPOLYMER, HYDROGENATED LECITHIN, TETRASODIUM GLUTAMATE DIACETATE, PEG-10, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, PROPYLENE GLYCOL, LAURYL PEG-10 TRIS(TRIMETHYLSILOXY)SILYLETHYL DIMETHICONE, POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE, BUTYLENE GLYCOL, PHOSPHORIC ACID, SODIUM HYDROXIDE, SODIUM CHLORIDE, HEXYLENE GLYCOL, ETHYLHEXYLGLYCERIN, PHENOXYETHANOL, IRON OXIDES (CI 77491, 77492, 77499)

Questions?

Call toll-free (877) 322-8633

broad spectrum SPF 50

PA +++++

HYDRATING MINERAL SHIELD

10% zinc oxide protects against UVA/UVB rays. Natural plant extracts and red algae cocoon skin from pollution and blue light. Silk primes skin, hyaluronic acid hydrates, and niacinamide evens tone. Leaves a healthy glow, never a white cast.

BEAUTIFUL FACES, BEAUTIFUL FUTURES

Your purchase supports education equality

www.tatcha.com/giving-back

MADE IN USA

DIST. TATCHA LLC

SAN FRANCISCO, CA 94123 USA

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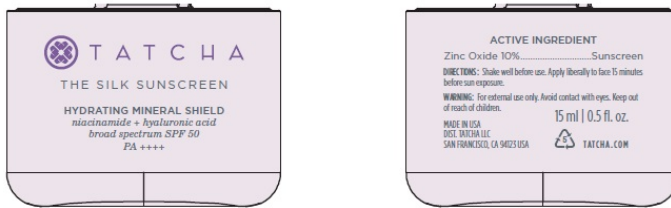
TATCHA.COM

Packaging

15 mL - OUTER PACKAGE LABEL

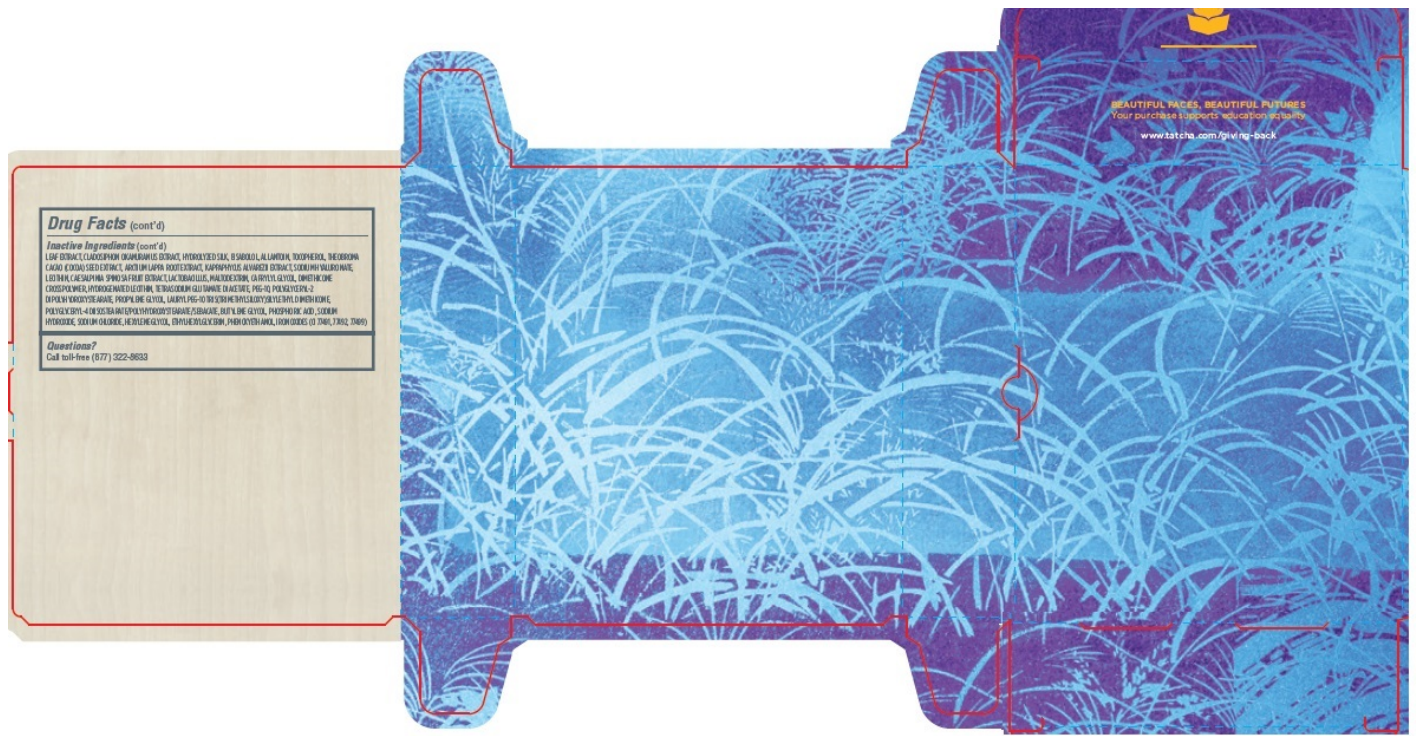


15 mL - INNER PACKAGE LABEL



50 mL - OUTER PACKAGE LABEL





50 mL - INNER PACKAGE LABEL



DRUG FACTS LABEL

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide (10%)	Sunscreen
Uses	
<ul style="list-style-type: none"> Helps prevent sunburn. If used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun. 	
Warnings	
For external use only.	
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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	
<ul style="list-style-type: none"> Shake well. 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. 	

Drug Facts (cont'd)
Inactive Ingredients (cont'd)
LEAF EXTRACT, CLADOSIPHON OKAMURANUS EXTRACT, HYDROLYZED SILK, BISABOLOL, ALLANTOIN, TOCOPHEROL, THEOBROMA CACAO (COCOA) SEED EXTRACT, ARCTIUM LAPPA ROOT EXTRACT, KAPPA PHYCUS ALVAREZII EXTRACT, SODIUM HYALLURONATE, LECITHIN, CAESALPINIA SPINOSA FRUIT EXTRACT, LACTOBIACILLUS, MALTODEXTRIN, CAPRYLYL GLYCOL, DIMETHICONE COPOLYMER, HYDROGENATED LECITHIN, TETRASODIUM GLUTAMATE DIACETATE, PEG-10, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, PROPYLENE GLYCOL, LAURYL PEG-10 TRIS(trimethylsiloxy)silylethyl dimethicone, POLYGLYCERYL-4 DISOOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE, BUTYLENE GLYCOL, PHOSPHORIC ACID, SODIUM HYDROXIDE, SODIUM CHLORIDE, HEXYLENE GLYCOL, ETHYLHEXYLGLYCERIN, PHENOXETHANOL, IRON OXIDES (CI 77491, 77492, 77499)
Questions?
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TATCHA THE SILK SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69417-130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LAURYL PEG-8 DIMETHICONE (300 CPS) (UNII: ELL2U7K8T8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
NIACINAMIDE (UNII: 25X51I8RD4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SQUALANE (UNII: GW89575KF9)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CLADOSIPHON OKAMURANUS (UNII: 2IJE0CH09J)	
SILK, BASE HYDROLYZED (1000 MW) (UNII: UMQ31C11AY)	
LEVOMENOL (UNII: 24WE03BX2T)	
ALLANTOIN (UNII: 344S277G0Z)	
TOCOPHEROL (UNII: R0ZB2556P8)	
COCOA (UNII: D9108TZ9KG)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
KAPPAPHYCUS ALVAREZII (UNII: T479H08K2O)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

CAESALPINIA SPINOSA FRUIT POD (UNII: EXY4496LWD)
LACTOBACILLUS FERMENTUM (UNII: 2C1F12C6AP)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)
POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PHOSPHORIC ACID (UNII: E4GA8884NN)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69417-130-05	1 in 1 BOX	03/08/2022	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69417-130-17	1 in 1 BOX	03/08/2022	
2		50 mL in 1 BOTTLE; 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	03/08/2022	

Labeler - TATCHA INC. (006811461)