

SHISEIDO CLEAR STICK UV PROTECTOR- avobenzone, homosalate, octinoxate, octisalate, octocrylene, and oxybenzone cream

SHISEIDO AMERICAS CORPORATION

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.

SHISEIDO CLEAR STICK UV PROTECTOR

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
AVOBENZONE 2.5%	Sunscreen
HOMOSALATE 10.0%	Sunscreen
OCTINOXATE 4.9%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OCTOCRYLENE 5.0%	Sunscreen
OXYBENZONE 3.0%	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

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - 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

DIPHENYLSILOXY PHENYL TRIMETHICONE·TRIETHYLHEXANOIN·MINERAL OIL·HYDROXYSTEARIC ACID·DIBUTYL LAUROYL GLUTAMIDE·POLYAMIDE-8·PEG/PPG-14/7 DIMETHYL ETHER·LECITHIN·GLYCYRRHIZA GLABRA (LICORICE) ROOT EXTRACT·PPG-17·SILICA DIMETHYL SILYLATE·BHT·TOCOPHEROL·PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE·FRAGRANCE·

Other information

- protect this product in this container from excessive heat and direct sun.
- avoid contact with clothing and other textiles-may stain.

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

SHI SEIDO
GINZA TOKYO

Clear Stick
UV Protector

50+
WetForce

BROAD SPECTRUM
SPF 50+

For Face/Body

WATER RESISTANT
(80 MINUTES)

SUNSCREEN

15g NET WT. .52 OZ.



Clear Stick UV Protector



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Drug Facts (continued)

Inactive ingredients

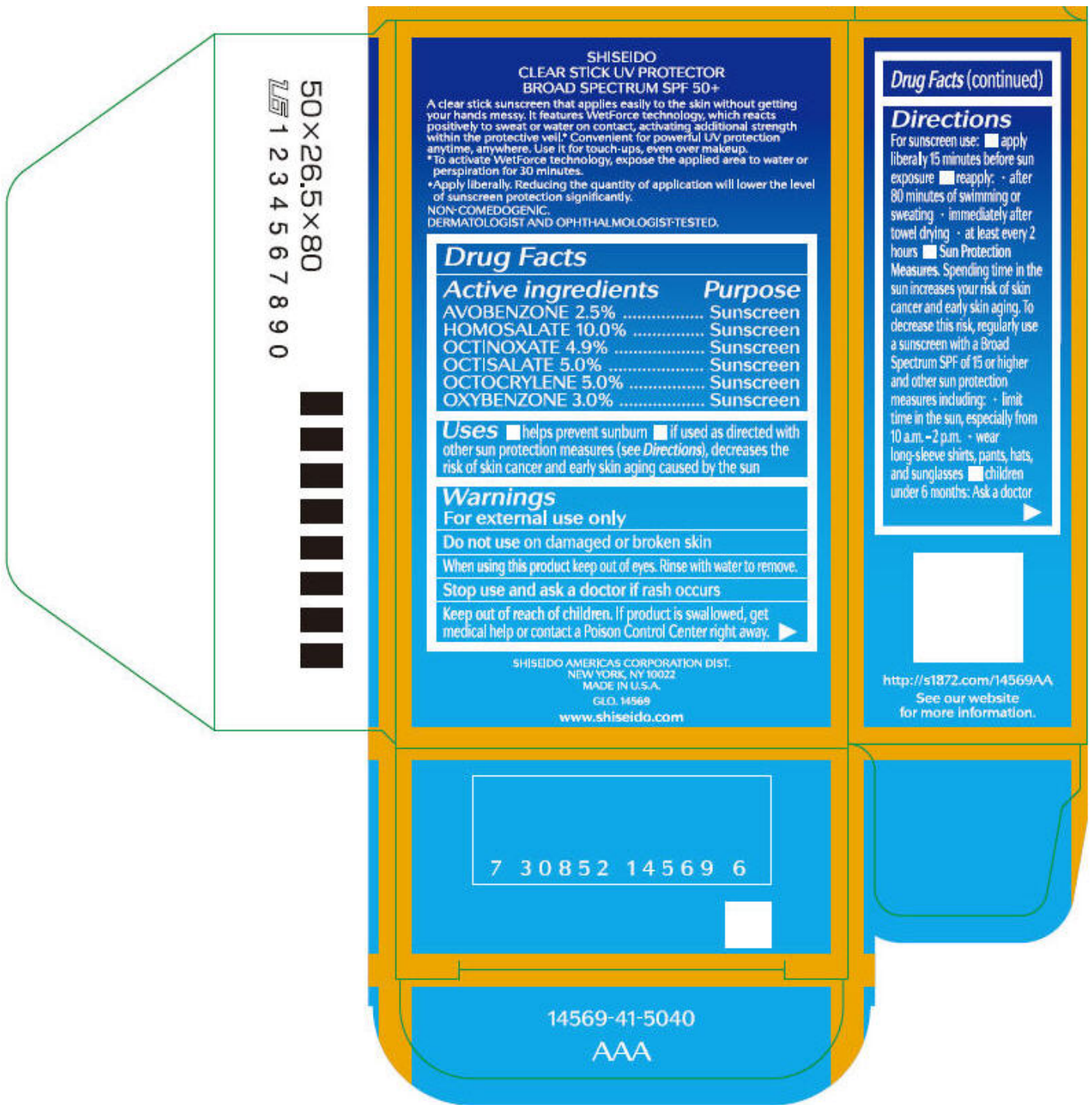
DIPHENYLSILOXY PHENYL
TRIMETHICONE •
TRIETHYLHEXANOIN •
MINERAL OIL •
HYDROXYSTEARIC ACID •
DIBUTYL LAUROYL GLUTAMIDE •
POLYAMIDE-8 •
PEG/PPG-14/7 DIMETHYL ETHER •
LECITHIN •
GLYCYPHIZA GLABRA (LICORICE)
ROOT EXTRACT •
PPG-17 •
SILICA DIMETHYL SILYLATE •
BHT • TOCOPHEROL •
PENTAERYTHRITYL
TETRA-DI-T-BUTYL
HYDROXYHYDROCINNAMATE •
FRAGRANCE •

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-365
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	375 mg in 15 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	1500 mg in 15 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	735 mg in 15 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	750 mg in 15 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	750 mg in 15 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	450 mg in 15 g

Inactive Ingredients

Ingredient Name	Strength
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
MINERAL OIL (UNII: T5L8T28FGP)	
12-HYDROXYSTEARIC ACID (UNII: 933ANU3H2S)	
DIBUTYL LAUROYL GLUTAMIDE (UNII: 3V7K3IA58X)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
PPG-17 (UNII: OV0Q322E0U)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-365-40	1 in 1 CARTON	02/01/2018	
1		15 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	02/01/2018	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-365) , analysis(58411-365)