SHISEIDO ULTIMATE SUN PROTECTION- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray
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 ULTIMATE SUN PROTECTION SPRAY

Drug Facts

Active ingredients	Purpose
AVOBENZONE 3.0%	Sunscreen
HOMOSALATE 15.0%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OCTOCRYLENE 2.5%	Sunscreen
OXYBENZONE 5.0%	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.

When using this product keep away from face to avoid breathing it.

Flammable

Do not use near heat, flame, or while smoking

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
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face
- do not apply in windy conditions
- use in a well-ventilated area

Inactive Ingredients

SD ALCOHOL 40-B, DIMETHICONE, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, BUTYLENE GLYCOL, XYLITOL, SYZYGIUM JAMBOS LEAF EXTRACT, PEG/PPG-14/7 DIMETHYL ETHER, ACRYLATES/OCTYLACRYLAMIDE COPOLYMER, WATER, FRAGRANCE,

Other information

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

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 150 mL Bottle Carton

SHI SEIDO

Anti-Aging Suncare

50+

Ultimate
Sun Protection Spray

BROAD SPECTRUM
SPF 50+

For Face/Body

WATER RESISTANT
(80 MINUTES)

SUNSCREEN

150mL 5 FL. OZ.

RECOMMENDED
SKIN CANCER FOUNDATION
ACTIVE

Ultimate
Sun Protection Spray
BROAD SPECTRUM
SPF 50+
For Face/Body

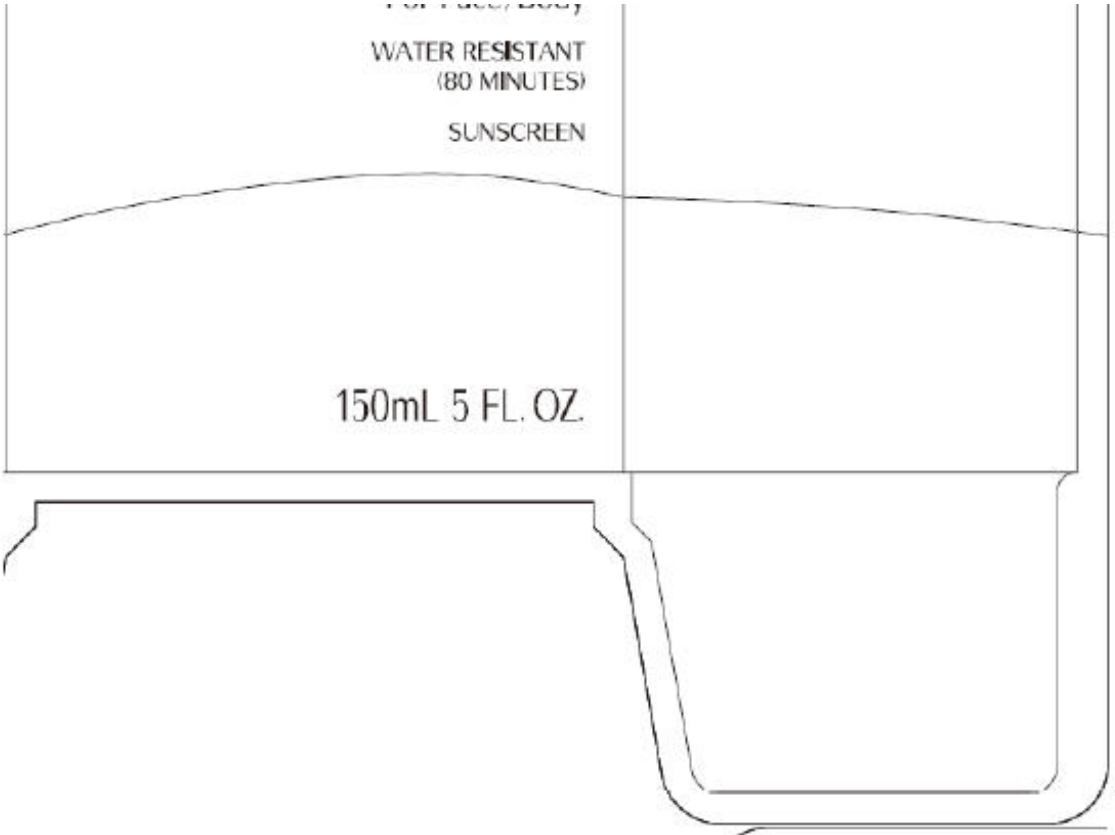
360°

SHISEIDO

Anti-Aging Suncare

50+

Ultimate
Sun Protection Spray
BROAD SPECTRUM
SPF 50+
For Face/Body



SHISEIDO

ULTIMATE SUN PROTECTION SPRAY

BROAD SPECTRUM

SPF 50+

FOR FACE/BODY

Multi-Environment Defense. Multi-Faceted Skin Protection.

A convenient spray-type sunscreen that allows quick, easy application over large areas of skin, especially hard-to-reach areas such as the back. It protects skin against powerful UV rays, while skincare ingredients maintain skin's beauty. With its light texture, it feels comfortable, with no stickiness.

- Broad spectrum UV protection helps reduce signs of photo-aging, with SuperVeil-UV 360™ technology.
- Rose Apple Leaf Extract counteracts oxidation*, the process which accelerates skin aging, and helps prevent DNA damage* caused by UV rays.
- Formulated with Xylitol to help keep skin soft and healthy-looking.
- Spray mist spreads evenly and easily, veiling the body with a layer of protection.
- A comfortably light, non-sticky texture.
- Water resistant (80 minutes)
- Sand-proof
- NON-COMEDOGENIC
- DERMATOLOGIST AND

Drug Facts (continued)

Warnings

Flammable

Do not use near heat, flame, or while smoking

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  - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a

61×46×173

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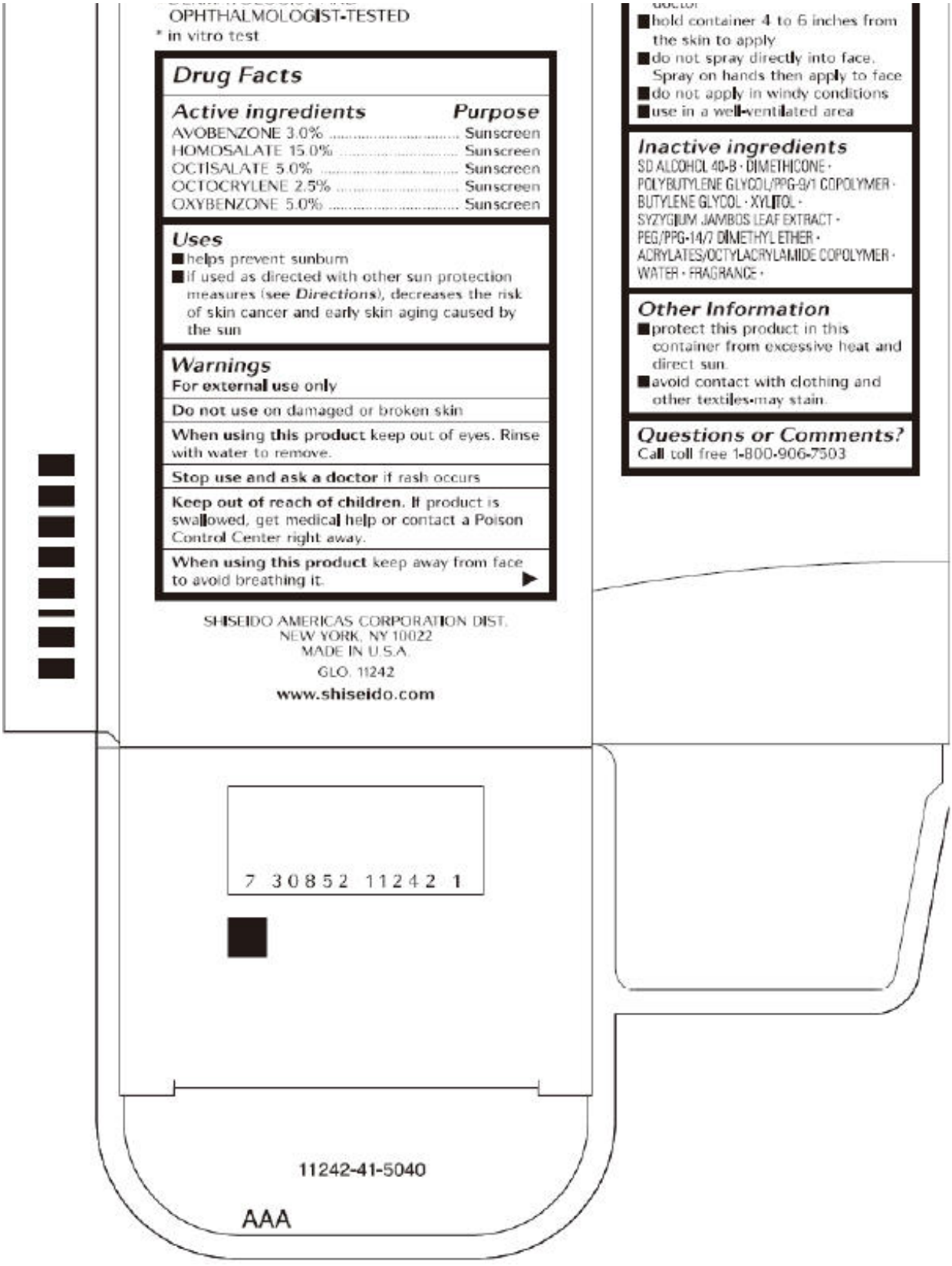

SHISEIDO ULTIMATE SUN PROTECTION

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58411-142

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.98 mg in 132.6 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	19.89 mg in 132.6 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	6.63 mg in 132.6 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3.32 mg in 132.6 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6.63 mg in 132.6 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
XYLITOL (UNII: VCQ006KQ1E)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-142-80	1 in 1 CARTON	04/01/2014	
1		132.6 g in 1 BOTTLE, SPRAY; 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	04/01/2014	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-142) , analysis(58411-142)

Revised: 12/2018 SHISEIDO AMERICAS CORPORATION