

**SAYUKI BROAD SPECTRUM SPF 30 ANTI-AGING DAILY MOISTURIZER SUNSCREEN-
avobenzone, octinoxate, octisalate, oxybenzone lotion**

Sayuki Custom Cosmetics

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.

Sayuki Broad Spectrum SPF 30 Anti-Aging Daily Moisturizer Sunscreen

Drug Facts

Purpose

Sunscreen

Active ingredients:

AVOBENZONE (3.0%)
OCTINOXATE (7.5%)
OCTISALATE (5.0%)
OXYBENZONE (4.0%)

Uses:

- helps prevent sunburn
- if used as directed with other sun protection measure (see Directions), decrease 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.

Stop use and ask a doctor

if rash occurs.

When using this product

keep out of eyes. Rinse with water to remove.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- apply liberally 15 minutes before sun exposure
- use a 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 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 measures including:

- limit time in the sun 10 AM to 2 PM
- wear long-sleeved shirts, pants, hats and sunglasses.

Inactive ingredients:

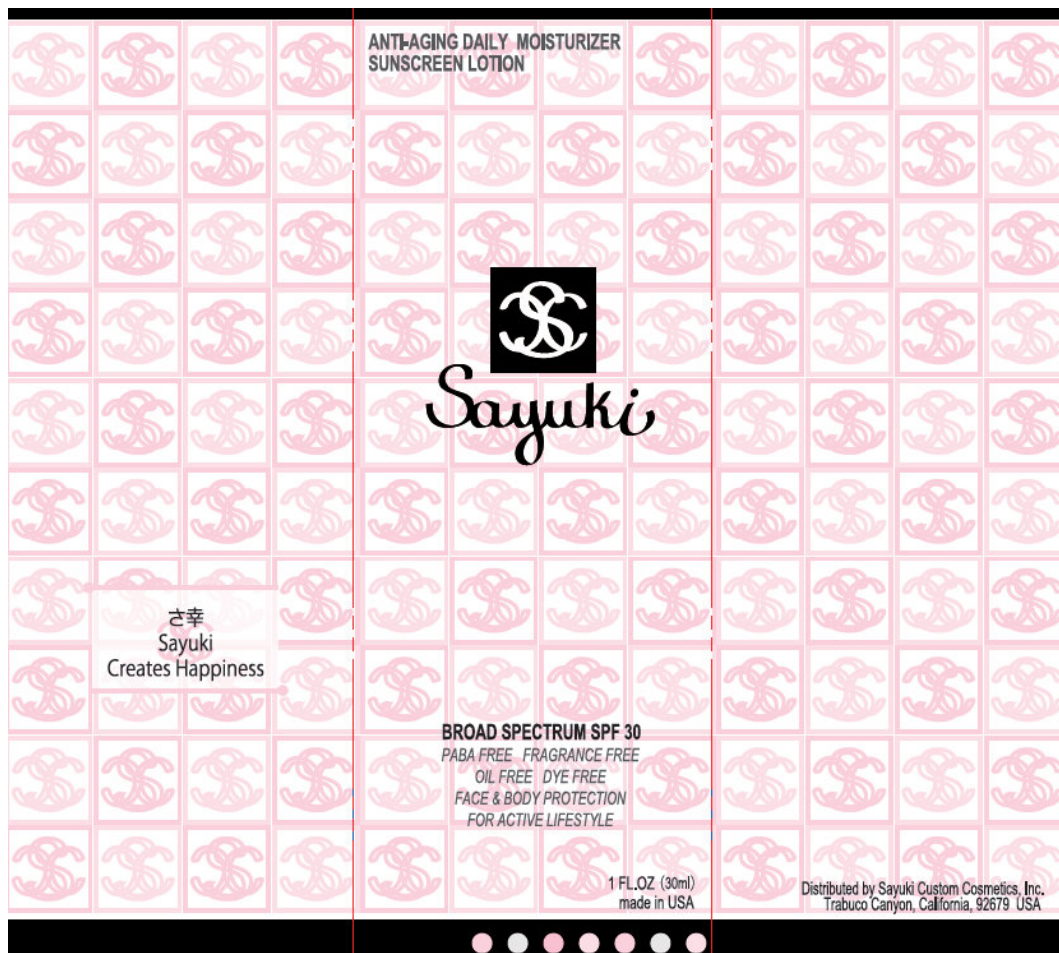
Water (Aqua), Isopropyl Palmitate, Isoeicosane, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Potassium Cetyl Phosphate, Glycerin, Cetyl Dimethicone, Ethylhexyl Methoxycrylene, Silica, Dimethicone, Polyglyceryl-3 Diisostearate, Cetearyl Alcohol, Hydroxyethylcellulose, Phenoxyethanol, Glyceryl Stearate, Peg-100 Stearate, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Butylene Glycol, Camelia Oleifera Leaf Extract, Punica Granatum Fruit Extract.

Other information:

- protect this product from excessive heat and direct sun.

Sayuki Anti-Aging Daily Moisturizer Sunscreen Lotion BROAD SPECTRUM SPF 30 PABA FREE FRAGRANCE FREE OIL FREE DYE FREE FACE AND BODY PROTECTION FOR ACTIVE LIFESTYLE 1 FL. OZ (30ml) made in USA Distributed by Sayuki Custom Cosmetics, Inc. Trabuco Canyon, California, 92679 USA Sayuki Creates Happiness

Sayuki Broad Spectrum SPF 30 Anti-Aging Daily Moisturizer Sunscreen Lotion 1oz/30ml (49517-0001-1)



Drug Facts

Active ingredients:	Purpose
AVOBENZONE (3.0%) OCTINOXATE (7.5%) OCTISALATE (5.0%) OXYBENZONE (4.0%)	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

Stop use and ask a doctor if rash occurs.

When using this products keep out of eyes. Rinse with water to remove.

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

Directions:

- apply liberally 15 minutes before sun exposure
- use a water-resistant sunscreen if swimming or sweating
- reapply at least two hours
- children under 6 months: Ask a doctor.

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 measures including:

- limit time in the sun 10 AM to 2 PM,
- wear long-sleeved shirts, pants, hats and sunglasses

Inactive ingredients:

water (aqua), isopropyl palmitate, isoeicosane, hydroxyethyl acrylate/sodium acrylyldimethyl laurate copolymer, potassium cetyl phosphate, glycerin, cetyl dimethicone, ethylhexyl methoxycrylene, silica, dimethicone, polyglyceryl-3 diisostearate, cetearyl alcohol, hydroxyethylcellulose, phenoxyethanol, glyceryl stearate, peg-100 stearate, caprylyl glycol, ethylhexylglycerin, hexylene glycol, tetrahexyldecyl ascorbate, tocopheryl acetate, butylene glycol, camelia oleifera leaf extract, punica granatum fruit extract

Other information:

- protect this product from excessive heat and direct sun.

SAYUKI BROAD SPECTRUM SPF 30 ANTI-AGING DAILY MOISTURIZER SUNSCREEN

avobenzone, octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49517-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
ISOEICOSANE (UNII: AR294KAG3T)	

SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
GLYCERIN (UNII: PDC6A3C0OX)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
DIMETHICONE (UNII: 92RU3N3Y1O)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
POMEGRANATE (UNII: 56687D1Z4D)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49517-0001-1	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/19/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/19/2012	

Labeler - Sayuki Custom Cosmetics (078441229)

Establishment

Name	Address	ID/FEI	Business Operations
Columbia Cosmetics Manufacturing, Inc.		068267863	manufacture(49517-0001)