EVERYDAY SUNSCREEN SPF 50- avobenzone, homosalate, octinoxate, octisalate cream Taylor James

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.

Everyday Sunscreen SPF 50

Active Ingredients Purpose

Avobenzone 3% Sunscreen

Homosalate 10% Sunscreen

Octinoxate 7.5% Sunscreen

Octisalate 5% Sunscree

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

Keep out of reach of children.

Stop use and ask a doctor if rash occurs

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

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

Directions

• 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 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-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

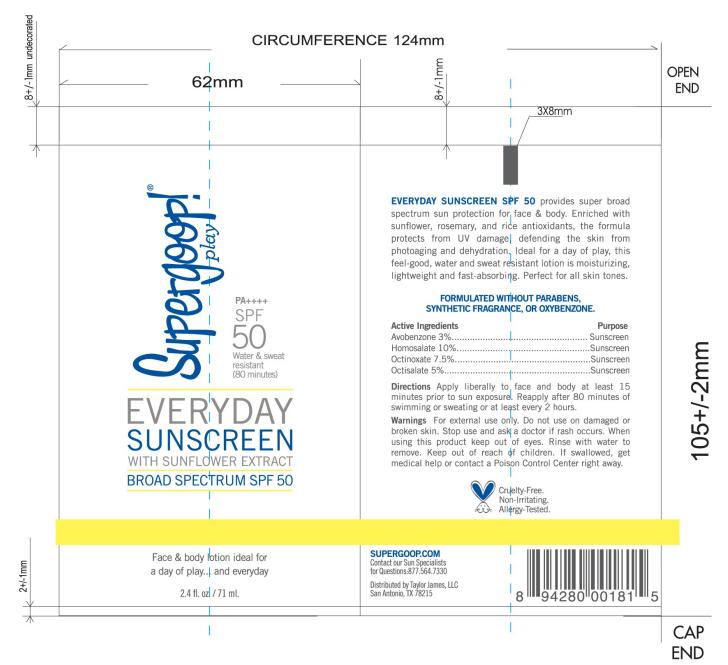
Water, Isododecane, Polyester-8, Glycerin, Cetyl Alcohol, Potassium Cetyl Phosphate, Acrylates Copolymer, Oryza Sativa (Rice) Bran Extract, Diisopropyl Sebacate, Isodecyl Neopentanoate, Lauryl Lactate, Cetearyl Olivate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Hydroxyacetophenone, Sorbitan Olivate, Diethylhexyl Syringylidenemalonate, Aniba Rosaeodora (Rosewood) Wood Oil, Chlorphenesin, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Limon (Lemon) Peel Oil, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Ocimum Bascilicum (Basil) Flower/Leaf Extract, Pelargonium Graveolens Flower Oil, Pogostemon Cablin Oil, 1,2-hexanediol, Caprylyl Glycol, Xanthan Gum, Helianthus Annuus (Sunflower) Extract, Behenic Acid, Cetyl Behenate, Isostearyl Isostearate, Pentylene Glycol, Trisodium Ethylenediamene Disuccinate, Tocopheryl, Allantoin, Rosmarinus

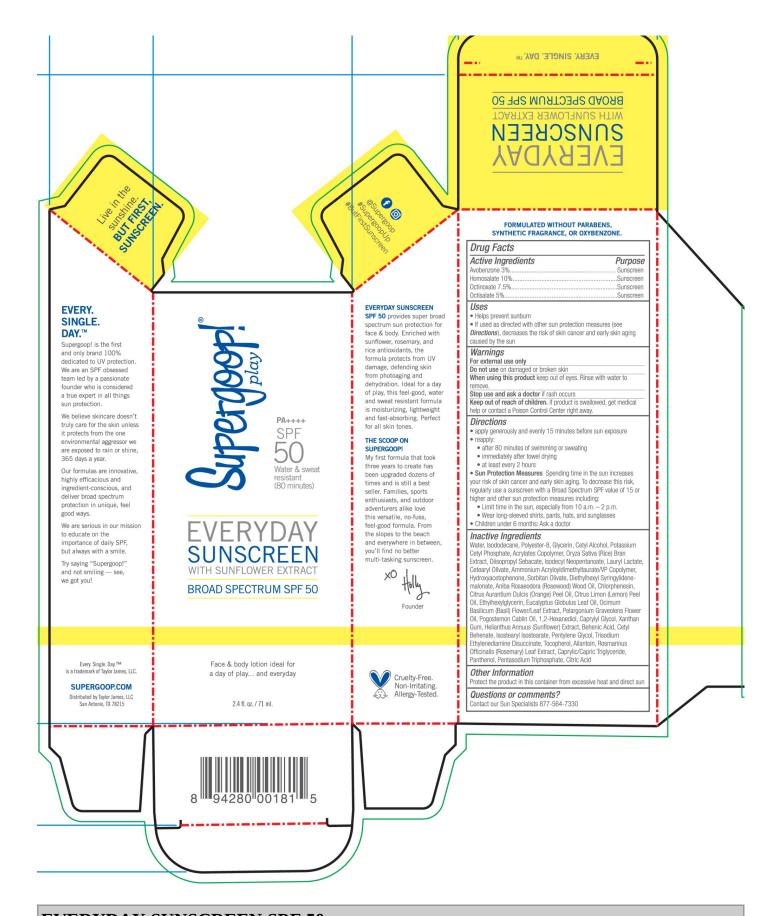
Officinalis (Rosemary) Leaf Extract, Caprylic/Capric Triglyceride, Panthenol, Pentasodium Triphosphate, Citric Acid

Everyday Sunscreen with Sunflower Extract

Broad Spectrum SPF 50

2.4 fl. oz./ 71 ml





EVERYDAY SUNSCREEN SPF 50

avobenzone, homosalate, octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75936-235
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	10 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ROSEMARY (UNII: IJ67X351P9)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
BEHENIC ACID (UNII: H390488X0A)	
CETYL BEHENATE (UNII: WFM51TRO3E)	
ISOSTEARYL ISOSTEARATE (UNII: IV0Z586Z4Y)	
PENTYLENE GLYCOL (UNII: 50 C130 7 PZG)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PANTHENOL (UNII: WV9CM0O67Z)	
ISODODECANE (UNII: A8289P68Y2)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
AMMO NIUM ACRYLO YLDIMETHYLTAURATE/VP CO PO LYMER (UNII: W59 H9 29 6 ZG)	
DIETHYLHEXYL SYRINGYLIDENEMALO NATE (UNII: 3V5U97P248)	
ROSEWOOD OIL (UNII: F2522O5L7B)	
CHLORPHENESIN (UNII: I670 DAL4SZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
O CIMUM BASILICUM FLO WERING TOP (UNII: 7SAB275FP2)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
ISODECYL NEOPENTANO ATE (UNII: W60 VYE24XC)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
HYDRO XYACETO PHENO NE (UNII: G1L3HT4CMH)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
ORANGE OIL (UNII: AKN3KSD11B)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PATCHOULI OIL (UNII: F3IN55X5PO)	
1,2-HEXANEDIO L (UNII: TR0 46 Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALLANTO IN (UNII: 344S277G0Z)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296 U138 P)	
RICE BRAN (UNII: R60 QEP13IC)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
LEMON OIL (UNII: 19 GRO 8 24LL)	

PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
POTASSIUM CETYL PHO SPHATE (UNII: 03KCY6P7UT)	
TRISO DIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9 SW4PFD2FZ)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75936-235-01	71 mL in 1 TUBE; Type 0: Not a Combination Product	07/06/2018		
2	NDC:75936-235-03	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/06/2018		
3	NDC:75936-235-04	532 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2018		
4	NDC:75936-235-05	222 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2018		
5	NDC:75936-235-06	3 mL in 1 PACKET; Type 0: Not a Combination Product	07/06/2018		
6	NDC:75936-235-07	10 mL in 1 TUBE; Type 0: Not a Combination Product	07/06/2018		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	07/06/2018		

Labeler - Taylor James (033381850)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cosway Company, Inc.		620899877	manufacture(75936-235)	

Revised: 7/2018 Taylor James