

SOLEIL BROAD SPECTRUM SPF-30- octinoxate, octisalate, zinc oxide spray
The Soleil Group, LLC

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.

Soleil SPF-30

For external use only. Flammable: Do not use near heat, flame, or while smoking. 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 the product is swallowed, get medical help or contact a Poison Control Center immediately.

Keep out of reach of children

Octinoxate 5.0%, Octisalate
3.0%, Zinc Oxide 2.5%

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.

Sunscreen

Directions

Apply liberally 20 minutes prior to sun exposure. Do not spray onto face. Spray into hands and apply to face. Use in well-ventilated areas. Reapply: immediately after swimming, sweating or towel drying and 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.

Other Information

May stain or damage some fabrics or surfaces. Avoid long term storage above 40°C (120°F). Protect this product from excessive heat and direct sun.



BROAD SPECTRUM
SPF/30

MINERAL BASED
SUNSCREEN
ÉCRAN SOLAIRE
À BASE MINÉRAL

BODY • CORPS

1774 mL e 6.0 fl. oz

Protect your skin's DNA from damaging UV rays with this naturally based sunscreen. Moisturizes and nourishes skin. Fortified with potent antioxidants, vitamins and botanicals. Ultra convenient continuous mist works from any angle.



composed of red algae, vitamin C ester, vitamin E and bisabolol combined with other botanical extracts help reduce UV-induced DNA damage, hydrate and provide superior antioxidant protection.

• NO parabens, petrolatum, phthalates, propylene glycol, animal ingredients, synthetic colors or fragrances.

DRUG FACTS

Active Ingredients: Octinoxate 7.5%, Octisalate 4.0%, Zinc Oxide 1.7%, Avobenzone 1.0% 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.

Flammable: Do not use near heat, flame, or while smoking.

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 the product is swallowed, get medical help or contact a Poison Control Center immediately.

Directions: Apply liberally 20 minutes prior to sun exposure.

Do not spray onto face. Spray into hands and apply to face. Use in well-ventilated areas.

Reapply: immediately after swimming, sweating or towel drying and 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: acrylates copolymer, algae extract, aloe barbadensis leaf (aloe vera gel) juice, aqua (deionized water), artemisia pallens flower oil, bisabolol, camellia sinensis (green tea) leaf extract, caprylic/capric triglyceride, cetearyl alcohol, cetearyl olivate, citrus aurantifolia peel oil, citrus aurantium bergamia fruit extract, citrus limon peel oil, citrus nobilis flower oil, citrus sinensis peel oil, daucus carota sativa (carrot) extract, ethyl acetate, eucalyptus globulus oil, ferula galbaniflua resin oil, gamma undecalactone ethyl acetate, gluconolactone, glycerin, helianthus annuus (sunflower) oil, heliotropine, isoamyl acetate, isobutyl acetate, jasminum sambac oil, lecithin, opoponax oil, polysorbate-20, PPG-17/PDI/DMPA copolymer, salvia sclarea oil, sodium benzoate, sorbitan olivate, tetrahydroxydistearyl ascorbate (vitamin C), tocopherol acetate (vitamin E), zirconia (corn) propandiol.

Other Information: May stain or damage some fabrics or surfaces. Avoid long term storage above 40°C (104°F). Protect this product from excessive heat and direct sun.

DISTRIBUTED BY:

The Soleil Group, LLC.

Bronxville, NY 10708

Questions or comments?

Call 917-338-7291

www.soleil-du-midi.com



SOLEIL BROAD SPECTRUM SPF-30

octinoxate, octisalate, zinc oxide spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69630-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.4 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.7 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHACRYLATE/METHOXY PEG-10 MALEATE/STYRENE COPOLYMER (UNII: 39DK5WQ2PR)	
FUCUS VESICULOSUS (UNII: 535G2ABX9M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
water (UNII: 059QF0K00R)	
ARTEMISIA PALLENS WHOLE (UNII: 39JKR5L2G)	
LEVOMENOL (UNII: 24WE03BX2T)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE (UNII: U73D397055)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)	
CITRUS AURANTIUM FRUIT (UNII: DQD16J2B5O)	
CITRUS LIMON FRUIT OIL (UNII: 0HNC1J1YED)	
CITRUS NOBILIS (UNII: 8MFF77J91V)	
CITRUS SINENSIS FRUIT OIL (UNII: WV48LBL15Q)	
CARROT (UNII: L56Z1JK48B)	
ETHYL ACETOACETATE (UNII: IZP61H3TB1)	
EUCALYPTUS GLOBULUS WHOLE (UNII: S11P2XF3M3)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
PIPERONAL (UNII: KE109YAK00)	
ISOAMYL ACETATE (UNII: Z135787824)	
ISOBUTYL ACETATE (UNII: 7CR47FO6LF)	
JASMINUM SAMBAC WHOLE (UNII: 1Z81V275I0)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
OPOPANAX CHIRONIUM WHOLE (UNII: 0LGQ3H5EXR)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PEG/PPG-17/6 COPOLYMER (UNII: P5QZM4T259)	
SALVIA SCLAREA SEED OIL (UNII: JK0RP5O3HW)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69630-002-30	177.4 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/13/2015	

Labeler - The Soleil Group, LLC (079694651)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(69630-002)

Revised: 2/2015

The Soleil Group, LLC