

SOLEIL FORTE MULTI- octinoxate, octisalate, homosalate, avobenzone, octocrylene lotion
LINEX HEALTH & BEAUTY

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.

Linex (as PLD) - SOLEIL FORTE MULTI (67969-101)

ACTIVE INGREDIENT

OCTINOXATE 7.5%

OCTISALATE 5%

HOMOSALATE 5%

AVOBENZONE 3%

OCTOCRYLENE 2.75%

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

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

- APPLY LIBERALLY BEFORE 15 MINUTES SUN EXPOSURE.
- REAPPLY
- AFTER 40 MINUTES OF SWIMMING

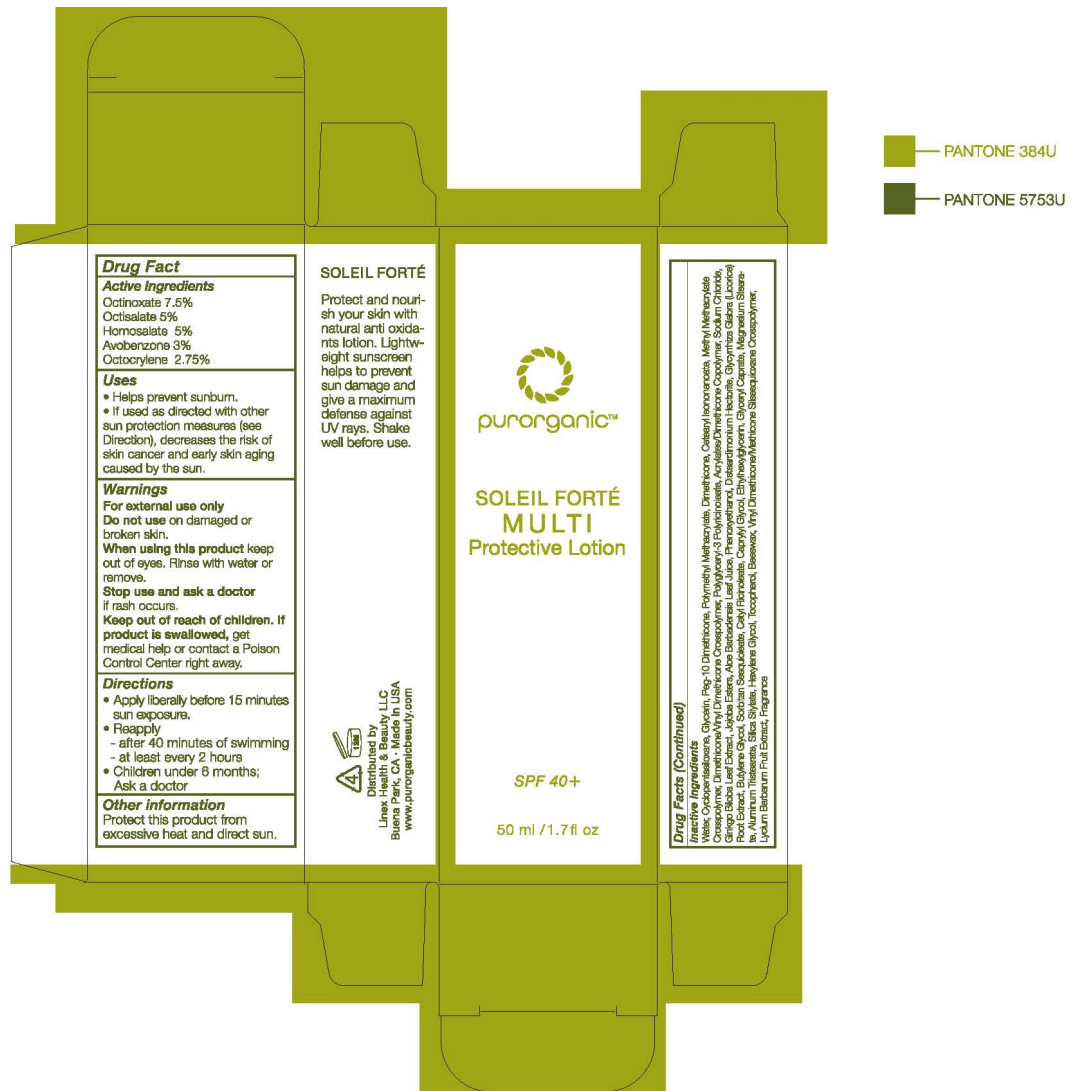
- AT LEAST EVERY 2 HOURS
- CHILDREN UNDER 6 MONTHS; ASK A DOCTOR.

OTHER INFORMATION

PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.

INACTIVE INGREDIENTS

WATER, CYCLOPENTASILOXANE, GLYCERIN, PEG-10 DIMETHICONE, POLYMETHYL METHACRYLATE, DIMETHICONE, CETEARYL ISONONANOATE, METHYL METHACRYLATE CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, POLYGLYCERYL-3 POLYRICINOLEATE, ACRYLATES/DIMETHICONE COPOLYMER, SODIUM CHLORIDE, GINKGO BILOBA LEAF EXTRACT, JOJOBA ESTERS, ALOE BARBADENSIS LEAF JUICE, PHENOXYETHANOL, DISTEARDIMONIUM HECTORITE, GLYCYRRHIZA GLABRA (LICORICE) ROOT EXTRACT, BUTYLENE GLYCOL, SORBITAN SESQUIOLEATE, CETYL RICINOLEATE, CAPRYLYL GLYCOL, ETHYLHEXYLGLYCERIN, GLYCERYL CAPRATE, MAGNESIUM STEARATE, ALUMINUM TRISTEARATE, SILICA Silylate, HEXYLENE GLYCOL, TOCOPHEROL, BEESWAX, VINYL DIMETHICONE/METHICONE SESQUIOXANE CROSSPOLYMER, LYCIUM BARBARUM FRUIT EXTRACT, FRAGRANCE.



SOLEIL FORTE MULTI

octinoxate, octisalate, homosalate, avobenzene, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69769-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZENE (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)	AVOBENZENE	3 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.75 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
.ALPHA.,.BETA.'-DIGLYCERIN (UNII: LG6U99J4V1)	
POLYGLYCEROL POLYRICINOLEIC ACID (UNII: 3C96Y1D5T4)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GINKGO BILOBA WHOLE (UNII: 660486U6OI)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
CETYL RICINOLEATE (UNII: 1P677500YD)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL CAPRATE (UNII: 197M6VFC1W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ALUMINUM STEARATES (UNII: O4D7U3B46U)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
TOCOPHEROL (UNII: R0ZB2556P8)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	

CETEARYL ISONONANOATE (UNII: P5001U99NI)

METHYL METHACRYLATE (UNII: 196OC77688)

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69769-101-51	1 in 1 BOX	04/24/2015	
1	NDC:69769-101-11	50 mL in 1 TUBE; Type 0: Not a Combination Product		

Drug Fact

Active Ingredients

Octinoxate 7.5%
 Octisalate 5%
 Homosalate 5%
 Avobenzone 3%
 Octocrylene 2.75%

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see Direction), 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 or 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

- Apply liberally before 15 minutes sun exposure.
- Reapply - after 40 minutes of swimming - at least every 2 hours
- Children under 6 months; Ask a doctor

Other Information
 Protect this product from excessive heat and direct sun.

Inactive Ingredients Glycerin, Ethylhexyl Methacrylate, Dimethylsiloxane, Citrus Aurantium, Methyl Methacrylate, Polybutene-1, Bisphenol A Polycarbonate, Acrylate/Dimethylacrylate Copolymer, Sodium Chloride, Ginkgo Biloba Leaf Extract, Jobba Extract, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Disodium EDTA, Glycyrrhiza Glabra (Licorice) Root Extract, Butylene Glycol, Sorbitan Sebacate, Caprylyl Glycol, Ethylhexylglycerin, Glyceryl Caprylate, Magnesium Stearate, Hydroxyethyl Acrylate, Stearic Acid, Glyceryl Stearate, C12-15 Alkyl Benzenesulfonate, Polymethyl Methacrylate, Polymethyl Methacrylate Copolymer, Lyallium Borohum Phosphate, Fragrance.

Drug Facts (Continued)

Inactive Ingredients Glycerin, Ethylhexyl Methacrylate, Dimethylsiloxane, Citrus Aurantium, Methyl Methacrylate, Polybutene-1, Bisphenol A Polycarbonate, Acrylate/Dimethylacrylate Copolymer, Sodium Chloride, Ginkgo Biloba Leaf Extract, Jobba Extract, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Disodium EDTA, Glycyrrhiza Glabra (Licorice) Root Extract, Butylene Glycol, Sorbitan Sebacate, Caprylyl Glycol, Ethylhexylglycerin, Glyceryl Caprylate, Magnesium Stearate, Hydroxyethyl Acrylate, Stearic Acid, Glyceryl Stearate, C12-15 Alkyl Benzenesulfonate, Polymethyl Methacrylate, Polymethyl Methacrylate Copolymer, Lyallium Borohum Phosphate, Fragrance.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/24/2015	

Labeler - LINEX HEALTH & BEAUTY (050219996)

Revised: 12/2022

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