

EXTREME PROTECT SPF 30- octinoxate, zinc oxide lotion
SCIENCE OF SKINCARE 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.

Active Ingredients

Octinoxate – 5.50%

Zinc Oxide – 4.12%

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 15 MINUTES BEFORE SUN EXPOSURE.
- Use a water resistant sunscreen if swimming or sweating
- Reapply 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:
 - o limit time in the sun, especially from 10 a.m.-2 p.m.
 - o wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

Other Information

PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.

Questions or Comments?

Call Customer Care at (888) 804-4447

Inactive Ingredients

Water, Polyacrylamide, Tocopherol, Ethylhexyl Palmitate, PPG-3 Myristyl Ether, Cetyl Alcohol, Glycol Stearate SE, VP/Hexadecene Copolymer, Olea Europaea (Olive) Leaf Extract, Aloe Barbadensis Leaf Juice, Asiaticoside, Asiatic Acid, Madecassic Acid, Sodium Dihydroxyethyl Phosphate, Ethyl Linoleate, Oleyl Alcohol, Glyceryl Stearate, Octyldodecyl Neopentanoate, Caprylyl Glycol, Hexylene Glycol, PEG-100 Stearate, C13-14 Isoparaffin, Laureth-7, Phenoxyethanol.

<p>EXTREME PROTECT SPF 30</p> <p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Octinoxate 5.50%</td><td>Sunscreen</td></tr><tr><td>Zinc oxide 4.12%</td><td>Sunscreen</td></tr></tbody></table> <p>Uses</p> <ul style="list-style-type: none">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. <p>Warnings</p> <ul style="list-style-type: none">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. <p>Directions</p> <ul style="list-style-type: none">Apply liberally 15 minutes before sun exposure.Use a water resistant sunscreen if swimming or sweating.Reapply 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:<ul style="list-style-type: none">o limit time in the sun, especially from 10 a.m.-2 p.m.o wear long-sleeve shirts, pants, hats, and sunglassesChildren under 6 months: Ask a doctor <p>Other information</p> <p>Protect this product from excessive heat and direct sun.</p> <p>Questions or comments?</p> <p>Call Customer Care at (888) 804-4447</p> <p>Inactive Ingredients</p> <p>Water, Polyacrylamide, Tocopherol, Ethylhexyl Palmitate, PPG-3 Myristyl Ether, Cetyl Alcohol, Glycol Stearate SE, VP/Hexadecene Copolymer, Olea Europaea (Olive) Leaf Extract, Aloe Barbadensis Leaf Juice, Asiaticoside, Asiatic Acid, Madecassic Acid, Sodium Dihydroxyethyl Phosphate, Ethyl Linoleate, Oleyl Alcohol, Glyceryl Stearate, Octyldodecyl Neopentanoate, Caprylyl Glycol, Hexylene Glycol, PEG-100 Stearate, C13-14 Isoparaffin, Laureth-7, Phenoxyethanol.</p>	Active ingredients	Purpose	Octinoxate 5.50%	Sunscreen	Zinc oxide 4.12%	Sunscreen	<p>UTILISATION: Aide à prévenir les coups de soleil. Si le produit est utilisé conformément aux instructions avec d'autres mesures de protection solaire (voir Mode d'emploi), il réduit le risque que le soleil cause un cancer de la peau ou un vieillissement précoce de la peau.</p> <p>PRECAUTIONS D'EMPLOI: Réserve à un usage externe. Ne pas utiliser ce produit sur une peau endommagée ni sur une plaie. Faire attention que le produit n'entre pas en contact avec les yeux. En cas de contact, rincer sous l'eau. En cas d'irritation, cesser l'utilisation du produit et consulter un médecin. Garder hors de la portée des enfants. Si le produit est ingéré, contacter immédiatement un médecin ou un centre antipoison.</p> <p>MODE D'EMPLOI: Appliquer généreusement 15 minutes avant l'exposition au soleil. En cas de transpiration abondante ou d'exposition à l'eau, utiliser un écran solaire résistant à l'eau, réappliquer au moins toutes les deux heures. Mesures de protection solaire: Une exposition prolongée au soleil augmente le risque de vieillissement prématuré de la peau et de cancer de la peau. Pour réduire ce risque, il est recommandé d'utiliser un écran solaire avec un facteur de protection (SPF) de 15 ou plus et d'utiliser d'autres mesures de protection contre le soleil, notamment: Éviter de rester longtemps au soleil, particulièrement entre 10h00 et 14h00. Porter des vêtements à manches longues et couvrant les jambes, ainsi qu'un chapeau et des lunettes de soleil. Enfants de moins de 6 mois: Consulter un médecin.</p> <p>PLUS D'INFORMATION: Protéger ce produit contre la chaleur excessive et éviter de l'exposer directement au soleil.</p> <p>INGREDIENTS(NON-US):Water/Aqua/Eau, Ethylhexyl Methoxycinnamate, Zinc Oxide, Polyacrylamide, Tocopherol, Ethylhexyl Palmitate, PPG-3 Myristyl Ether, Cetyl Alcohol, Glycol Stearate SE, VP/Hexadecene Copolymer, Olea Europaea (Olive) Leaf Extract, Aloe Barbadensis Leaf Juice, Asiaticoside, Asiatic Acid, Madecassic Acid, Sodium Dihydroxyethyl Phosphate, Ethyl Linoleate, Oleyl Alcohol, Glyceryl Stearate, Octyldodecyl Neopentanoate, Caprylyl Glycol, Hexylene Glycol, PEG-100 Stearate, C13-14 Isoparaffin, Laureth-7, Phenoxyethanol.</p>	 <p>is CLINICAL®</p> <p>EXTREME PROTECT</p> <p>SPF 30</p> <p>Broad Spectrum Sunscreen Crème</p>  <p>100 g e Net wt. 3.5 oz.</p> <p>COSMECEUTICALS</p>	<p>HYDRATING RESTORATIVE ULTIMATE PROTECTION</p> <p>EXTREME PROTECT SPF 30 provides extraordinary protection by combining broad-spectrum UVA/UVB protection and powerful antioxidants to mitigate oxidative solar damage. Featuring micro-fine zinc oxide and micro-encapsulated organic active sunscreens, EXTREME PROTECT SPF 30 offers advanced sun protection.</p> <p>HYDRATANT RÉPARATEUR PROTECTION ULTIME</p> <p>EXTREME PROTECT SPF 30 offre une protection extraordinaire, grâce à la protection à large spectre contre les UVA/UVB combinée à des antioxydants puissants, qui permettent d'atténuer l'oxydation dommageable créée par le soleil. Fait d'oxyde de zinc très fin et d'un écran solaire biologique micro-encapsulé, EXTREME PROTECT SPF 30 offre une protection solaire évoluée.</p>  <p>INNOVATIVE SKINCARE® Distributed by/Distribué par: Scinco Of Skincare® PO Box 464 Beverly Hills, CA 90213 RP, MS, & S. NB, UK Made in the U.S.A. Fabriqué aux États-Unis.</p> <p>www.isclinical.com ITEM# 1351.100</p>
Active ingredients	Purpose								
Octinoxate 5.50%	Sunscreen								
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iS CLINICAL®

**EXTREME PROTECT®
SPF 30**
*Broad Spectrum
Sunscreen Crème*



3.1250



HYDRATING RESTORATIVE ULTIMATE PROTECTION

EXTREME PROTECT SPF 30 provides extraordinary protection by combining broad-spectrum UVA/UVB protection and powerful antioxidants to mitigate oxidative solar damage. Featuring micro-fine zinc oxide and micro-encapsulated organic active sunscreens, EXTREME PROTECT SPF 30 offers advanced sun protection.

DIRECTIONS: Apply generously and evenly prior to sun exposure. Reapply as needed or after swimming, towel drying, perspiring heavily, or washing.

ACTIVE INGREDIENTS: Octinoxate 5.50%, Zinc oxide 4.12%

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.

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ITEM# 1351.100
LBL.1351.100.1747



100 g e Net wt. 3.5 oz.

INNOVATIVE SKINCARE®

EXTREME PROTECT SPF 30

octinoxate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69219-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	4.12 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PPG-3 MYRISTYL ETHER (UNII: 7913J43WZ5)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCOL STEARATE SE (UNII: 6YLY96TQL6)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
OLEA EUROPAEA LEAF (UNII: MJ95C30H47)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASIATICOSIDE (UNII: PK039VY215)	

ASIATIC ACID (UNII: 9PA5A687X5)
MADECASSIC ACID (UNII: M7O1N24J82)
SODIUM DIHYDROXYCETYL PHOSPHATE (UNII: YWI33EV595)
ETHYL LINOLEATE (UNII: MJ2YTT4J8M)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
PEG-100 STEARATE (UNII: YD01N1999R)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
LAURETH-7 (UNII: Z95S6G8201)
PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69219-103-51	1 in 1 BOX	10/01/2014	
1	NDC:69219-103-13	100 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:69219-103-55	1 in 1 BOX	10/01/2014	
2	NDC:69219-103-15	5 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
3	NDC:69219-103-28	240 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/01/2014	

Labeler - SCIENCE OF SKINCARE LLC (006251958)

Revised: 1/2018

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