

**TRIENELLE SKINCARE DAILY RENEWAL CREME WITH TOCALLURE RESTORATION
COMPLEX BROAD SPECTRUM SPF 15- octinoxate 5%, oxybenzone 4.5%, avobenzone
3% cream**

NewMarket Health Products 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.

Trienelle Skincare Daily Renewal Creme

▯Drug Facts

▯Active Ingredient

▯Octinoxate 5.0%

Oxybenzone 4.5%

Avobenzone 3.0%▯

▯Purpose

▯Sunscreen

▯Uses

- ▯Helps prevent sunburn
- Higher SPF gives more sunburn protection

▯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 cream evenly twice daily to the face, neck, and other exposed areas before exposure to sun.
- Children under 6 months of age: 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 sunscreen with a Broad Spectrum SPF value 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
 - reapply at least every 2 hours
 - use a water resistant sunscreen if swimming or sweating. ▯

Inactive Ingredients

Water, Glycerin, C12-15 Alkyl Benzoate, Phenyl Trimethicone, Cyclomethicone, Tocotrienol, Dimethicone, PEG-100 Stearate, Glyceryl Stearate, Tocopherol, Cetearyl Alcohol, Cetyl Alcohol, Vaccinium Myrtillus Fruit and Leaf Extract, Chlorella Vulgaris Extract, Ganoderma Lucidum (Mushroom) Stem Extract, Trametes Versicolor Extract, Saccharum Officinarum Extract, Acer

Sacharinum Extract, Citrus Aurantium Dulcis Fruit Extract, Citrus Limon Extract, Palmitoyl Pentapeptide, Superoxide Dismutase, Stevia Rebaudiana Extract, Foeniculum Vulgare Extract, Hydrolyzed Algin, Applephenone, Salix Alba (Bark) Extract, Colostrum, Melatonin, Squalene, Elaeis Guineensis Oil, Phytosterols, Sea Water, Phospholipids, Butylene Glycol, Triacontanyl PVP, Phenoxyethanol, Xanthan Gum, Cetareath-20, Carbomer, Polysorbate-20, Methylparaben, Butylparaben, Propylparaben, Ethylparaben, Tetrasodium EDTA, Triethanolamine

Other Information

- Sun Alert: Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.
- Protect the product in this container from excessive heat and direct sun.

Distributed by

Trienelle Skincare, Inc.

702 Cathedral St.

Baltimore, MD 21201

1-800-539-5195

www.trienelle.com

Trienelle Skincare

Daily Renewal Creme

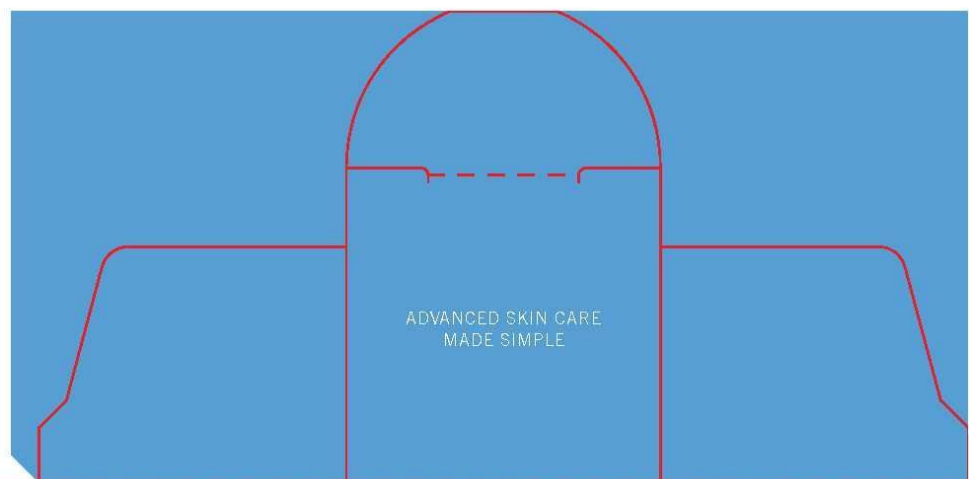
WITH TOCALLURE RESTORATION COMPLEX

Broad Spectrum SPF 15

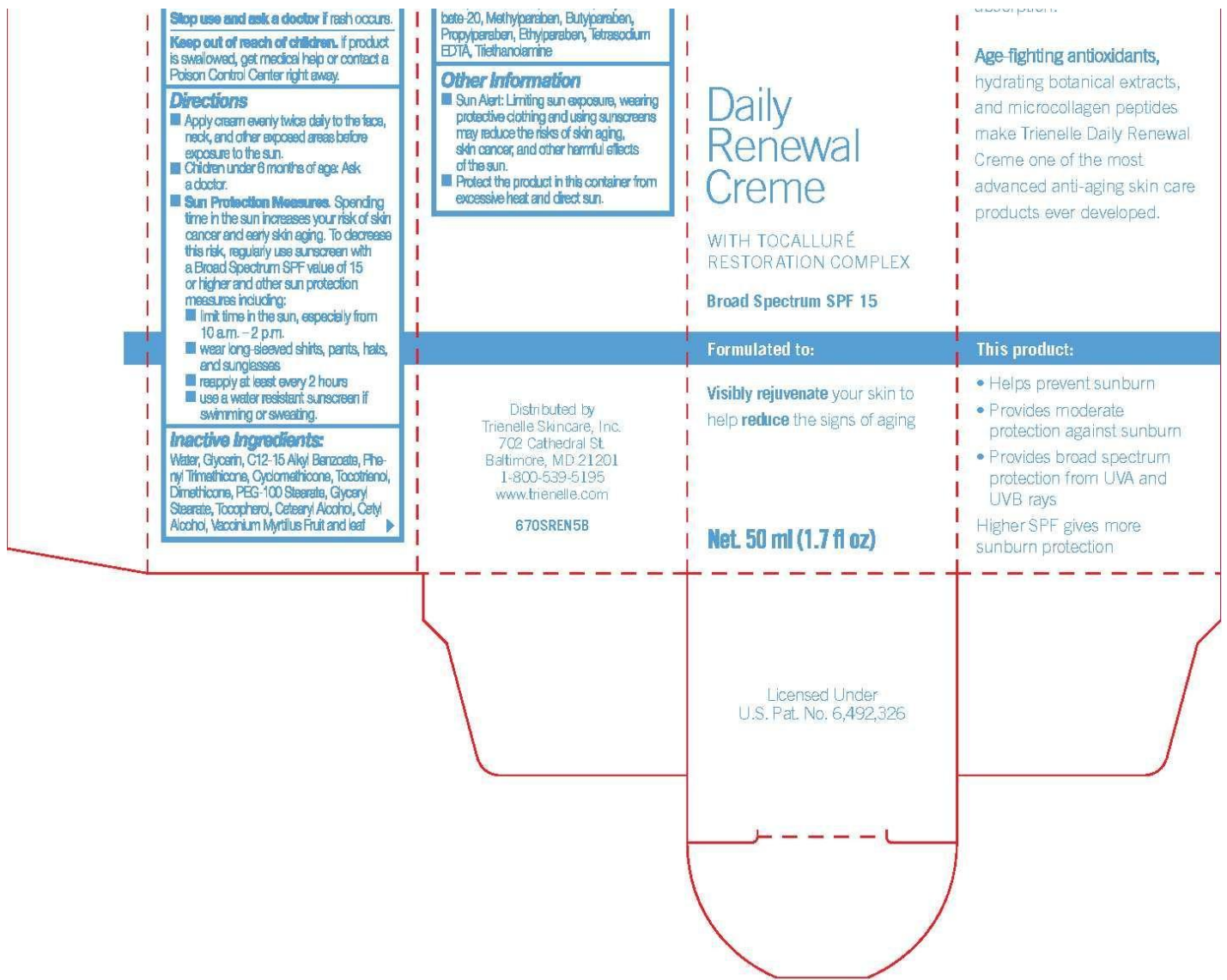
Formulated to:

Visibly rejuvenate your skin to help reduce the signs of aging

Net. 50 ml (1.7 fl oz)



<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> <tr> <td>Octinoxate 5.0%</td> <td rowspan="3">Sunscreen</td> </tr> <tr> <td>Oxybenzone 4.5%</td> </tr> <tr> <td>Avobenzone 3.0%</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> Helps prevent sunburn Higher SPF gives more sunburn protection <p>Warnings</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p>	Active Ingredient	Purpose	Octinoxate 5.0%	Sunscreen	Oxybenzone 4.5%	Avobenzone 3.0%	<p>Drug Facts (continued)</p> <p>Inactive Ingredients:</p> <p>Extract, Chlorella Vulgaris Extract, Ganoderma Lucidum (Mushroom) Stem Extract, Trametes Versicolor Extract, Saccharum Officinarium Extract, Acer Sacharinum Extract, Citrus Aurantium Dulcis Fruit Extract, Citrus Limon Extract, Palmitoyl Pentapeptide, Superoxide Dismutase, Stevia Rebaudiana Extract, Foeniculum Vulgare Extract, Hydrolyzed Algin, Pyrus Malus (Apple) Fruit Extract, Salix Alba (Bark) Extract, Colostrum, Melatonin, Squalene, Elaeis Guineensis Oil, Phytosterols, Sea Water, Phospholipids, Butylene Glycol, Triacontanyl PVP, Phenoxyethanol, Xanthan Gum, Cetareath-20, Carbomer, Polysor-</p>		<p>Trienelle Daily Renewal Creme is a comprehensive, one-step solution for brighter, younger-looking skin. The exclusive Tocallurè Restoration Complex brings you the rejuvenating benefits of tocotrienols, a high-potency form of vitamin E, in an advanced liposomal delivery system for better absorption.</p>
Active Ingredient	Purpose								
Octinoxate 5.0%	Sunscreen								
Oxybenzone 4.5%									
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TRIENELLE SKINCARE DAILY RENEWAL CREME WITH TOCALLURE RESTORATION COMPLEX BROAD SPECTRUM SPF 15

octinoxate 5%, oxybenzone 4.5%, avobenzone 3% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50972-736
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 mg in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	4.5 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
TOCOTRIENOLS (UNII: KP2MW85SSQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VACCINIUM MYRTILLUS FRUITING TOP (UNII: QT6362QVN8)	
VACCINIUM MYRTILLUS LEAF (UNII: Y4U591OU70)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
GANODERMA LUCIDUM STEM (UNII: U8PA41532G)	
TRAMETES VERSICOLOR FRUITING BODY (UNII: 4C900477MT)	
SUGARCANE (UNII: 81H2R5AOH3)	
ACER SACCHARINUM WHOLE (UNII: 3PIN4S77JQ)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON (UNII: 24RS0A988O)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
SUPEROXIDE DISMUTASE (CU-ZN) SACCHAROMYCES CEREVISIAE (UNII: ZQP6EKT6WD)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
FOENICULUM VULGARE WHOLE (UNII: J1UK54JBGH)	
LAMINARIA DIGITATA HYDROLYZED ALGINIC ACID (UNII: 9E3P882579)	
APPLE (UNII: B423VGH5S9)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
BOS TAURUS COLOSTRUM (UNII: S256WJ3OFQ)	
MELATONIN (UNII: JL5DK93RCL)	
SQUALENE (UNII: 7QWM220FJH)	
PALM OIL (UNII: 5QUO05548Z)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCINE MAX WHOLE (UNII: NID9NUV93F)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ETHYLPARABEN (UNII: 14255EXE39)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TROLAMINE (UNII: 9O3K93S3TK)	

Product Characteristics

Color	white (off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50972-736-01	1 in 1 BOX		
1		50 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/29/2014	

Labeler - NewMarket Health Products LLC (828825989)**Establishment**

Name	Address	ID/FEI	Business Operations
Bio genesis Labs		069117328	manufacture(50972-736)

Revised: 9/2014

NewMarket Health Products LLC