

**SPOMETICS GREEN NATURAL SUN- octocrylene, octinoxate, octisalate stick  
Spometrics Inc.**

*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.*

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**ACTIVE INGREDIENT**

Active ingredients: Octocrylene 8.0%, Ethylhexyl Methoxycinnamate 7.0%, Ethylhexyl Salicylate 4.5%

**INACTIVE INGREDIENT**

Inactive ingredients: Octyldodecanol, Diisostearyl Malate, Butylene Glycol Dicaprylate/Dicaprate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Silica Silylate, Dibutyl Lauroyl Glutamide, Dibutyl Ethylhexanoyl Glutamide, Pentylene Glycol, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Glycyrrhiza Glabra (Licorice) Root Extract, Adenosine, Niacinamide, Tocopheryl Acetate, Caprylic/Capric Triglyceride, Ligularia Fishceri Leaf Extract, Camellia Sinensis Leaf Extract, Echinacea Purpurea Leaf/Stem/Meristem Cell Culture Extract, Water, Butylene Glycol, Phellinus Linteus/Inonotus Obliquus (Mushroom) Extract Ferment Filtrate, Helianthus Annuus (Sunflower) Seed Oil, Morinda Citrifolia Leaf Cell Culture Extract, Acanthopanax Senticosus (Eleuthero) Root Extract, Acorus Calamus Root Extract, Actinidia Polygama Fruit Extract, Alpinia Officinarum Root Extract, Ampelopsis Japonica Root Extract, Ampelopsis Japonica Root Extract, Angelica Gigas Root Extract, Angelica Keiskei Extract, Artemisia Princeps Leaf Extract, Akebia Quinata Extract, Asparagus Cochinchinensis Root Extract, Dictamnus Dasycarpus Root Extract, Bambusa Vulgaris Extract, Albizia Julibrissin Bark Extract, Camellia Japonica Flower Extract, Carthamus Tinctorius (Safflower) Flower Extract, Centella Asiatica Extract, Chaenomeles Sinensis Fruit Extract, Chrysanthemum Indicum Flower Extract, Chrysanthemum Indicum Flower Extract, Allium Sativum (Garlic) Bulb Extract, Cnidium Monnieri Fruit Extract, Cnidium Officinale Root Extract, Coptis Japonica Root Extract, Cornus Officinalis Fruit Extract, Corydalis Turtschaninovii Root Extract, Crataegus Cuneata Fruit Extract, Anemarrhena Asphodeloides Root Extract, Curcuma Longa (Turmeric) Root Extract, Angelica Tenuissima Root Extract, Arctium Lappa Root Extract, Dioscorea Japonica Root Extract, Diospyros Kaki Leaf Extract, Astragalus Membranaceus Root Extract, Eclipta Prostrata Extract, Epimedium Koreanum Extract, Equisetum Arvense Extract, Eriobotrya Japonica Leaf Extract, Azadirachta Indica Leaf Extract, Belamcanda Chinensis Root Extract, Ginkgo Biloba Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Gynostemma Pentaphyllum Leaf/Stem Extract, Houltuyenia Cordata Extract, Hovenia Dulcis Fruit Extract, Lagerstroemia Indica Extract, Lentinus Edodes Extract, Leonurus Sibiricus Flower/Leaf/Stem Extract, Bupleurum Falcatum Root Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Lycium Chinense Fruit Extract, Capsicum Annuum Fruit Extract, Magnolia Kobus Bark Extract, Cassia Obtusifolia Seed Extract, Morus Alba Bark Extract, Nelumbo Nucifera Flower Extract, Ophiopogon Japonicus Root Extract, Orchid Extract, Paeonia Albiflora Root Extract, Paeonia Suffruticosa Root Extract, Panax Ginseng Root Extract, Panax Ginseng Root Extract, Perilla Frutescens Leaf Extract, Phellinus Linteus Extract, Phellodendron Amurense Bark Extract, Pinus Densiflora Leaf Extract, Plantago Asiatica Extract, Coix Lacryma-Jobi Ma-yuen Seed Extract, Pogostemon Cablin Leaf Extract, Polygonatum Officinale Rhizome/Root Extract, Polygonum Cuspidatum Root Extract, Polygonum Multiflorum Root Extract, Portulaca Oleracea Extract, Prunus Mume Flower Extract, Prunus Serrulata Flower Extract, Pueraria Lobata Root Extract, Rehmannia Glutinosa Root Extract, Rheum Undulatum Root/Stalk/Stem Extract, Rhodiola Rosea Root Extract, Chrysanthemum Zawadskii Extract, Rosa Multiflora Fruit Extract, Sapindus Mukurossi Peel Extract, Sasa Quelpaertensis Extract, Saururus Chinensis Leaf/Root Extract, Saussurea Involucrata Extract, Saxifraga Sarmetosa Extract, Ecklonia Cava Extract, Scutellaria Baicalensis Root Extract, Selaginella Tamariscina Extract, Sophora Flavescens Root Extract, Sophora Japonica Bud Extract, Cinnamomum

Camphora (Camphor) Leaf Extract, Cinnamomum Cassia Bark Extract, Thuja Orientalis Extract, Citrus Junos Fruit Extract, Citrus Unshiu Peel Extract, Tricholoma Matsutake Extract, Trichosanthes Kirilowii Root Extract, Ulmus Davidiana Root Extract, Xanthium Strumarium Fruit Extract, Hizikia Fusiforme Extract, Acanthopanax Koreanum Extract, Achyranthes Japonica Extract, Acorus Gramineus Root/Stem Extract, Asarum Sieboldii Root Extract, Broussonetia Kazinoki Bark Extract, Actaea Heracleifolia Root Extract, Althaea Rosea Root Extract, Cudrania Tricuspidata Bark Extract, Angelica Dahurica Root Extract, Angelica Koreana Root Extract, Dendropanax Morbiferus Extract, Aralia Elata Branch/Leaf Extract, Atractylodes Japonica Rhizome Extract, Dryopteris Crassirhizoma Extract, Fraxinus Rhynchophylla Leaf Extract, Ganoderma Lucidum (Mushroom) Extract, Lespedeza Cuneata Extract, Machilus Odoratissima Bark Extract, Caragana Sinica Root Extract, Mallotus Japonicus Leaf Extract, Castanea Crenata (Chestnut) Shell Extract, Caulerpa Lentillifera Extract, Chelidonium Majus Extract, Rhododendron Brachycarpum Extract, Sorbus Alnifolia Branch/Leaf Extract, Taraxacum Platycarpum Extract, Cirsium Setidens Leaf Extract, Torreya Nucifera Extract, Tremella Fuciformis (Mushroom) Extract, Codonopsis Lanceolata Root Extract, Platycodon Grandiflorus Root Extract, Cordyceps Sinensis Extract, Cuscuta Australis Seed Extract, Cymbopogon Citratus Extract, Dicentra Spectabilis Flower Extract, Schisandra Chinensis Fruit Extract, Elaeagnus Glabra Extract, Eucommia Ulmoides Leaf Extract, Eugenia Caryophyllus (Clove) Bud Extract, Euphoria Longan Fruit Extract, Ficus Carica (Fig) Fruit Extract, Garcinia Mangostana Peel Extract, Gastrodia Elata Root Extract, Gleditsia Japonica Fruit Extract, Grifola Frondosa Extract, Hippophae Rhamnoides Fruit Extract, Ziziphus Jujuba Fruit Extract, Humulus Japonicus Extract, Illicium Verum (Anise) Fruit Extract, Imperata Cylindrica Root Extract, Isodonis Japonicus Leaf/Stalk Extract, Jasminum Officinale (Jasmine) Extract, Juglans Regia (Walnut) Seed Extract, Kalopanax Pictus Extract, Laminaria Japonica Extract, Ledebouriella Seseloides Root Extract, Ligustrum Japonicum Fruit Extract, Litchi Chinensis Fruit Extract, Lithospermum Erythrorhizon Root Extract, Luffa Cylindrica Fruit Extract, Momordica Charantia Fruit Extract, Moringa Oleifera Seed Extract, Nardostachys Chinensis Root Extract, Ocimum Sanctum Leaf Extract, Oldenlandia Diffusa Extract, Orostachys Japonica Extract, Oryza Sativa (Rice) Extract, Phaseolus Radiatus Seed Extract, Phyllanthus Emblica Fruit Extract, Phyllanthus Urinaria Extract, Pinus Koraiensis Seed Oil, Piper Longum Fruit Extract, Platycarya Strobilacea Extract, Polygala Tenuifolia Root Extract, Polygonum Fagopyrum (Buckwheat) Sprout Extract, Prunus Persica (Peach) Fruit Extract, Pueraria Mirifica Root Extract, Pulsatilla Koreana Root Extract, Punica Granatum Fruit Extract, Quercus Glauca Branch/Leaf Extract, Robinia Pseudoacacia Flower Extract, Rubus Coreanus Fruit Extract, Rumex Crispus Root Extract, Salvia Miltiorrhiza Root Extract, Sambucus Sieboldiana Leaf/Stem Extract, Sanguisorba Officinalis Root Extract, Santalum Album (Sandalwood) Extract, Schizonepeta Tenuifolia Extract, Scrophularia Buergeriana Root Extract, Sigesbeckia Glabrescens Extract, Smilax China Root Extract, Stewartia Koreana Leaf Extract, Terminalia Chebula Fruit Extract, Trachelospermum Asiaticum Flower/Leaf/Stem Extract, Tribulus Terrestris Fruit Extract, Viscum Album (Mistletoe) Extract, Withania Somnifera Root Extract, Zanthoxylum Piperitum Fruit Extract, Zea Mays (Corn) Silk Extract, Zingiber Officinale (Ginger) Root Extract, Abies Koreana Leaf Extract, Acer Tegmentosum Stem Extract, Actinidia Arguta Fruit Extract, Adonis Amurensis Extract, Agastache Rugosa Extract, Agrimonia Pilosa Extract, Alisma Orientale Tuber Extract, Allium Hookeri Extract, Allium Tuberosum Seed Extract, Alnus Japonica Extract, Anthriscus Sylvestris Extract, Aralia Cordata Extract, Artemisia Annuua Extract, Artemisia Capillaris Leaf Extract, Astilbe Chinensis Root Extract, Averrhoa Carambola Fruit Extract, Benincasa Cerifera Seed Extract, Betula Platyphylla Japonica Bark Extract, Boehmeria Nivea Root Extract, Caesalpinia Sappan Bark Extract, Cassia Mimosoides Extract, Celastrus Orbiculatus Branch/Leaf Extract, Citrus Aurantifolia (Lime) Fruit Extract, Cladosiphon Okamuranus Extract, Clematis Manshurica Extract, Clerodendrum Trichotomum Branch Extract, Cocos Nucifera (Coconut) Fruit Extract, Codium Fragile Extract, Cornus Walteri Extract, Cuminum Cuminum (Cumin) Seed Extract, Cynanchum Paniculatum Extract, Cyperus Rotundus Root Extract, Daemonorops Draco Extract, Dianthus Chinensis Extract, Elaeagnus Pungens Leaf Extract, Elettaria Cardamomum Seed Extract, Elsholtzia Splendens Extract, Enteromorpha Compressa Extract, Foeniculum Vulgare (Fennel) Fruit Extract, Forsythia Suspensa Fruit Extract, Geranium Thunbergii Extract, Glechoma Hederacea Extract, Hemerocallis Fulva Extract, Hericium Erinaceum (Mushroom) Extract, Hosta Longipes Extract, Hylocereus Undatus Fruit Extract, Inula Helenium Extract, Juniperus Communis Fruit Extract,

Saccharomyces/Kaempferia Parviflora Rhizome Ferment Extract Filtrate, Kochia Scoparia Fruit Extract, Lepidium Apetalum Seed Extract, Linum Usitatissimum (Linseed) Seed Extract, Magnolia Liliflora Bud Extract, Mangifera Indica (Mango) Fruit Extract, Morinda Citrifolia Fruit Extract, Myristica Fragrans (Nutmeg) Extract, Oenanthe Javanica Extract, Oenothera Biennis (Evening Primrose) Seed Extract, Panax Notoginseng Root Extract, Passiflora Edulis Fruit Extract, Patrinia Villosa Extract, Persicaria Hydropiper Extract, Petasites Japonicus Root Extract, Peucedanum Japonicum Extract, Phaseolus Angularis Seed Extract, Phoenix Dactylifera (Date) Fruit Extract, Phragmites Communis Extract, Physalis Alkekengi Fruit Extract, Pinellia Ternata Root Extract, Polygonum Aviculare Extract, Poncirus Trifoliata Fruit Extract, Poria Cocos Extract, Potentilla Chinensis Extract, Prunella Vulgaris Extract, Prunus Armeniaca (Apricot) Kernel Extract, Prunus Amygdalus Dulcis (Sweet Almond) Seed Extract, Psidium Guajava Leaf Extract, Psoralea Corylifolia Fruit Extract, Quercus Acutissima Fruit Extract, Rhus Semialata Gall Extract, Rosa Rugosa Root Extract, Salicornia Herbacea Extract, Sargassum Fulvellum Extract, Sedum Sarmentosum Extract, Sorbus Commixta Extract, Spirodela Polyrhiza Extract, Suaeda Asparagoides Extract, Swertia Japonica Extract, Trametes Versicolor Extract, Trapa Japonica Fruit Extract, Trigonella Foenum-Graecum Seed Extract, Tussilago Farfara (Coltsfoot) Leaf Extract, Uncaria Gambir Extract, Undaria Pinnatifida Extract, Verbena Officinalis Leaf Extract, Viola Mandshurica Flower Extract, Vitex Trifolia Fruit Extract, Zingiber Mioga Extract, Fragrance

## **PURPOSE**

Purpose: Sunscreen

## **WARNINGS**

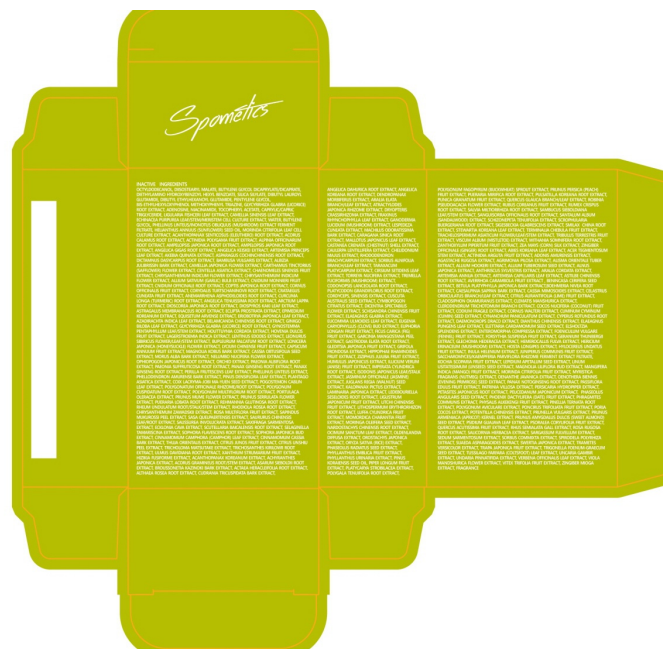
Warnings: • For external use only • Do not use on damaged or broken skin • When using this product keep out of eyes. Rinse with water to remove. • Stop use and ask a doctor if rash occurs • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

## **DESCRIPTION**

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.

Directions: • apply generously 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 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 • children under 6 months of age: Ask a doctor

## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



## SPOMETICS GREEN NATURAL SUN

octocrylene, octinoxate, octisalate stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:719 11-0 10
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octocrylene</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	Octocrylene	1.84 g in 23 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	1.61 g in 23 g
<b>Octisalate</b> (UNII: 4X49 Y0 596 W) (OCTISALATE - UNII:4X49 Y0 596 W)	Octisalate	1.03 g in 23 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Octyldodecanol</b> (UNII: 46 1N106 14Y)	
<b>Diisostearyl Malate</b> (UNII: QBS8 A3XZGQ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:719 11-0 10-0 2	1 in 1 CARTON	12/0 1/20 17	
1	NDC:719 11-0 10-0 1	23 g in 1 CONTAINER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part352	12/01/2017	
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**Labeler** - Spometrics Inc. (694798423)

**Registrant** - Spometrics Inc. (694798423)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Hankook Cosmetics Manufacturing Co.,Ltd_Eumseong Factory		688235645	manufacture(71911-010)

Revised: 12/2017

Spometrics Inc.