

**MDSOLARSCIENCES SPF40 ULTRA-SPORT - meradimate and octisalate and octocrylene and titanium dioxide and zinc oxide stick**

**Ecometics, 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.*

-----

**Drug Facts**

**Active Ingredients**

Meradimate 3.50% ..... Sunscreen

Octisalate 3.50% ..... Sunscreen

Octocrylene 10.00% ..... Sunscreen

Titanium Dioxide 1.35% ..... Sunscreen

Zinc Oxide 10.25% ..... Sunscreen

**Uses**

Helps prevent sunburn

Higher SPF gives more sunburn protection

Retains SPF after 80 minutes of activity in the water or sweating

**Warnings**

For external uses only.

When using this product  
keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if  
rash or irritation develops and lasts.

Keep out of reach of children.

If swallowed,  
get medical help or contact a Poison Control  
Center right away

**Other Information**

Sun alert: Limiting sun exposure, wearing  
protective clothing, and using sunscreen may  
reduce the risk of skin aging, skin cancer, and  
other harmful effects of the sun.

May stain  
clothing. You may report serious adverse  
reactions to Report Reactions, LLC,  
PO Box 22, Plainsboro, NJ 08536-0222

**Inactive Ingredients**

Caprylyl Methicone, Cyclopentasiloxane, Butyrospermum Parkii (Shea Butter), Petrolatum, Beeswax, Polyethylene, C12-15 Alkyl Benzoate, Paraffin Wax, Simmondsia Chinensis (Jojoba) Butter, Copernicia Cerifera (Carnauba) Wax, Polyester-8, Hydrogenated Soybean Oil, Stearic Acid, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Triethoxysilyl ethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Microcrystalline Wax, BHT, Aluminum Hydroxide, Tetrahexyldecyl Ascorbate

### **Directions**

Apply liberally and uniformly to all exposed areas 15-20 minutes before sun exposure. Reapply often (every 2 hours) and after swimming, excessive perspiration and washing. Effective sun protection for children under 2 years of age is strongly recommended.

### **Principle Display Panel**



**MDSolarSciences**

**SPF 40**

**Broad Spectrum  
UVA-UVB Sunscreen**

**Ultra-Sport**  
**STICK**

**LIGHT & MOISTURIZING**

**Very Water Resistant**

**No Fragrance**

***For Adults and Children***

**10 g - .35 Oz.**

MDSolarSciences  
 SPF 40  
 Broad Spectrum  
 UVA-UVB Sunscreen  
 Ultra-Sport  
 Stick  
 LIGHT and MOISTURIZING  
 Very Water Resistant  
 No Fragrance  
 For Adults and Children  
 10 g - .35 Oz

**Drug Facts**

<b>Active ingredients:</b>	<b>Purpose</b>
Meradimate 3.5% .....	Sunscreen
Ocilsalate 3.5% .....	Sunscreen
Octocrylene 10% .....	Sunscreen
Titanium Dioxide 1.35% .....	Sunscreen
Zinc Oxide 10.25% .....	Sunscreen

**Uses**

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Retains SPF after 80 minutes of activity in the water or sweating

**Warnings**

**For external use only**

**When using this product**

- Keep out of eyes. Rinse with water to remove

**Stop use and ask a doctor if**

- Rash or irritation develops and lasts

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Other information**

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun • May stain clothing • You may report serious adverse reactions to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536-0222 ▶

**Drug Facts  
(continued)**

**Directions**

Apply liberally and uniformly to all exposed areas 15-20 minutes before sun exposure. Reapply often (every 2 hours) and after swimming, excessive perspiration and washing • Effective sun protection for children under 2 years of age is strongly recommended. ▶



**MDSolarSciences**

**SPF 40**  
 Broad Spectrum  
 UVA-UVB Sunscreen

**Ultra-Sport**  
 STICK

**LIGHT & MOISTURIZING**  
**Very Water Resistant**

**No Fragrance**

**For Adults and Children**

10 g - .35 Oz.

MDSolarSciences Corp  
 40 Richards Avenue  
 3rd Floor  
 Norwalk, CT 06854  
 www.mdsolarsciences.com  
 Patent Pending

**Drug Facts  
(continued)**

**Inactive ingredients**

Caprylyl Methicone, Cyclopentasiloxane, Butyrospermum Parkii (Shea Butter), Petrolatum, Beeswax, Polyethylene, C12-15 Alkyl Benzoate, Paraffin Wax, Simmondsia Chinensis (Jojoba) Butter, Copernicia Cerifera (Carnauba) Wax, Polyester-8, Hydrogenated Soybean Oil, Stearic Acid, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Microcrystalline Wax, BHT, Aluminum Hydroxide, Tetrahexyldecyl Ascorbate



### Additional Carton Labeling

MDSolarSciences Corp  
40 Richards Avenue, 3rd Floor, Norwalk, CT 06854

www.mdsolarsciences.com  
Patent Pending

UPC 8 55488 00204 2

## MDSOLARSCIENCES SPF40 ULTRA-SPORT

meradimate and octisalate and octocrylene and titanium dioxide and zinc oxide stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17452-360
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Meradimate</b> (UNII: J9QGD60OUZ) (Meradimate - UNII:J9QGD60OUZ)	Meradimate	0.35 g in 10 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.35 g in 10 g
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	1 g in 10 g
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.135 g in 10 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	1.025 g in 10 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	

<b>Carnauba Wax</b> (UNII: R12CBM0EIZ)	
<b>POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED)</b> (UNII: T9296U138P)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17452-360-01	10 g in 1 CONTAINER		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2010	

**Labeler** - Ecometics, Inc (064843923)

**Registrant** - Ecometics, Inc (064843923)

### Establishment

Name	Address	ID/FEI	Business Operations
Ecometics, Inc		064843923	manufacture

Revised: 10/2010

Ecometics, Inc