

**SLMD MOISTURIZER WITH SPF- sunscreen lotion**  
**Owen Biosciences, 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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**SLMD Moisturizer with SPF**

**Active Ingredients**

|            |       |
|------------|-------|
| Octinoxate | 7.50% |
| Oxybenzone | 3.50% |
| Avobenzone | 2.50% |
| Octisalate | 1.50% |

**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.

skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

**Keep out of reach of children.**

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

**Directions**

- apply liberally and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating:
- immediately after towel drying
- at least every two hours
- 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 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

sunscreen

topical sunscreen

### **Other information**

- protect this product in this container from excessive heat and direct sun
- may stain some fabrics

### **Inactive ingredients**

Water

Emulsifying Wax NF

Cetyl Alcohol

Glycerin

DEA-Cetyl Phosphate

Dimethicone

Behentrimonium Methosulfate

Cetearyl Alcohol

Myristoyl Pentapeptide-17

Myristoyl Tetrapeptide-13

Ascorbyl Linoleate

Retinyl Linoleate

Lysophosphatidic acid

Panthenol

Allantoin

Arginine

Beta-Glucan

Sodium Carboxymethyl Beta-Glucan

Ethyl Macadamiate

Borago Officinalis Seed Oil

Triticum Vulgare (Wheat) Germ Oil

Tocopheryl Acetate

Retinyl Palmitate

Citrus Paradisi (Grapefruit) Fruit Extract

Camellia Sinensis Leaf Extract

Rosa Canina Fruit Extract

Hamamelis Virginiana (Witch Hazel) Extract

Polyglyceryl-3 Polyricinoleate

Polyglyceryl 5 Oleate

PPG-2 Myristyl Ether Propionate

Pentaerythrityl Tetracaprylate/Tetracaprate

Disodium EDTA

Caprylyl Glycol  
Phenoxyethanol

**Do not use**

- on damaged or broken skin

**Stop us and ask a doctor if**

irritation becomes severe

**Daily Moisturizer Back.jpg**

Daily Moisturizer Back.jpg



Stop use and ask a doctor if rash appears

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

### ***Directions***

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- reapply at least every 2 hours
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  - at least every 2 hours
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### ***Other information*** ▶

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## **SLMD MOISTURIZER WITH SPF**

sunscreen lotion

### **Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:59958-403 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength       |
|---|-------------------|----------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 7.5 g in 100 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 3.5 g in 100 g |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE        | 2.5 g in 100 g |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE        | 1.5 g in 100 g |

## Inactive Ingredients

| Ingredient Name                                       | Strength          |
|---|-------------------|
| <b>WATER</b> (UNII: 059QF0KO0R)                       | 60.628 g in 100 g |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)               | 2.5 g in 100 g    |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                    | 2 g in 100 g      |
| <b>CETYL PHOSPHATE</b> (UNII: VT07D6X67O)             | 2 g in 100 g      |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                 | 2 g in 100 g      |
| <b>BEHENTRIMONIUM METHOSULFATE</b> (UNII: 5SHP745C61) | 1 g in 100 g      |

## Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:59958-403-01 | 1 in 1 PACKAGE  | 04/05/2017           |                    |
| 1 |                  | 60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352                                  | 04/05/2017           |                    |

**Labeler** - Owen Biosciences, Inc. (790003045)

**Registrant** - Owen Biosciences, Inc. (790003045)

## Establishment

| Name                   | Address | ID/FEI    | Business Operations    |
|------------------------|---------|-----------|------------------------|
| Owen Biosciences, Inc. |         | 790003045 | manufacture(59958-403) |