

**OP DARK TANNING XTREME OIL AMPLIFIER SPF4 - octinoxate, octisalate spray**  
**Sun & Skin Care Research, 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.*

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**DRUG FACTS**

**Active Ingredients**

Octinoxate 3.0%

Octisalate 2.0%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn

**Warnings**

**Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

**For external use only. Do not use** on damaged or broken skin. **Stop use and ask a doctor if** rash occurs. **When using this product** keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or call a poison control center right away.

**Directions**

- apply evenly and liberally to all exposed areas 15 minutes before sun exposure. Ensure skin is completely covered with product.
- reapply after 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours
- children under 6 months: Ask a doctor

**Other Information**

- protect this product from excessive heat and direct sun
- for use on skin only
- avoid contact with fabric

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### When using this product

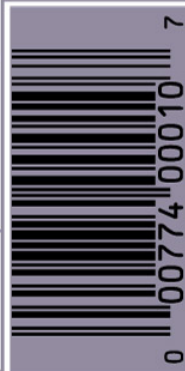
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  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
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**Inactive Ingredients** Aloe Barbadensis Leaf Extract, C12-15 Alkyl Benzoate, Citrus Aurantium Dulcis (Orange) Peel Oil, Cocos Nucifera (Coconut) Oil, Daucus Carota Sativa (Carrot) Root Extract, Daucus Carota Sativa (Carrot) Seed Oil, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Laureth-4, Olea Europaea (Olive) Fruit Oil, Polysorbate 80, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E)



### Other Information

- protect this product from excessive heat and direct sun
- for use on skin only. Avoid contact with fabric

Manufactured and Distributed by

**Sun & Skin Care Research, Inc.**

851 Greensboro Rd., Cocoa, FL 32926

Made in U.S.A. [www.oceanpotion.com](http://www.oceanpotion.com)

1-800-715-3485



Dark Tanning  
**XTREME**  
**oil**  
**AMPLIFIER**

with **Carrot & Coconut Oils**

8.5 FL OZ  
 (251mL)

**SPF 4**  
**4**

Black Silk screen white  
 PMS300 PMS Yellow PMS1375  
 PMS 133 (opaque silk screen)  
 die line

## OP DARK TANNING XTREME OIL AMPLIFIER SPF4

octinoxate, octisalate spray

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:62802-010

<b>Route of Administration</b>	TOPICAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CARROT (UNII: L56Z1JK48B)	
ORANGE OIL (UNII: AKN3KSD11B)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LAURETH-4 (UNII: 6HQ855798J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALMOND OIL (UNII: 66YXD4DKO9)	
CARROT SEED OIL (UNII: 595AO13F11)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-010-85	251 mL in 1 BOTTLE, SPRAY		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2012	

**Labeler** - Sun & Skin Care Research, LLC (849772207)

**Establishment**

Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture