

**PRO-TECT EVERYDAY SUNSCREEN SPF 15- octinoxate, octisalate, padimate o lotion  
A-Cute Derm, Incorporated**

*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**

Pro-Tect® SPF 15+ Sunscreen Broad-Spectrum UVA/UVB Protection & Moisturizing Lotion

**Active Ingredients**

Octinoxate.....	7.5%
Oxybenzone.....	2.0%
Padimate O.....	5.0%

**Purpose**

Sunscreen

**Uses**

•Pro-Tect® SPF 15+ Broad-Spectrum UVA & UVB protection. •Helps prevent sunburn. •Retains a SPF of 15+ after 80 minutes of activity in water of perspiring. •Provides high protection against sunburn and tanning. •For skin highly sensitive to sunburn.

**Warnings**

•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. •Do not use if sensitive to any of the ingredients of their related compounds.

**KEEP OUT OF REACH OF CHILDREN**

**Directions**

•Apply liberally and evenly on all exposed areas 20-30 minutes before exposure to the sun and as needed.  
•Children under 6 months of age: ask a doctor.

**Inactive ingredients**

Aloe Vera Leaf, Benzyl Alcohol, Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked), Cetyl Alcohol, Diazolidinyl Urea, Diethanolamine Cetyl Phosphate, dl-Alpha Tocopheryl Acetate, Iodopropynyl Butylcarbamate, Trolamine, Water.

**Other Information**

•Daily usage of Pro-Tect SPF15+ may help reduce the chance of premature aging of the skin due to overexposure to the sun. •This product provides more than 15 times your natural protection against sunburn. •Very Water Resistant UVA & UVB Broad-Spectrum Protection. •This product may stain light colored fabrics if washed with bleach. Wash clothing without bleach to remove safely.

### Questions or Comments

Bio-Medical & Pharm. Mfg. Corp.  
 4311 South Dr.  
 Houston, TX 77053-4820  
 281-835-8051  
 M-F 8AM-5PM  
 www.bio-medicalmanufacturing.com

### Principal Display Panel

<p><b>Inactive Ingredients</b>          Aloe Vera Leaf, Benzyl Alcohol, Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked), Cetyl Alcohol, Diazolidinyl Urea, Diethanolamine Cetyl Phosphate, dl-Alpha Tocopheryl Acetate, Iodopropynyl Butylcarbamate, Trolamine, Water.</p>
<p><b>Other Information</b>          •Daily usage of Pro-Tect® SPF 15 may help reduce the chance of premature aging of the skin due to overexposure to the sun. •This product provides more than 15 times your natural protection against sunburn. •Very Water Resistant UVA &amp; UVB Broad-Spectrum Protection.</p>
<p><b>Questions or Comments</b>          A-Cute Derm, Inc.          1810 Cravens Road          Stafford, TX 77477          800.922.2883          M-F 8:30am-5:30pm          info@a-cutederm.com          www.a-cutederm.com</p>



## PRO-TECT® SPF 15 SUNSCREEN

Pro-Spectrum Process™  
 Broad-Spectrum UVA/UVB Sunscreen  
 Greaseless & Very Water-Resistant

Fortified with Aloe & Vitamin E  
 Fragrance Free  
 Non-Comedogenic

NDC# 61619-868-08  
 8.0 FL OZ (236.6 gm)

SUN WEAR

<p><b>Drug Facts</b>          Pro-Tect® SPF 15 Sunscreen Broad-Spectrum UVA/UVB Protection &amp; Moisturizing Lotion.</p>												
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Marketed by  
 A-Cute Derm, Inc. Stafford, TX 77477  
 Item 86018 • V. 082615  
 Animal Cruelty Free • Made in U.S.A.



Pro-Tect  
 SPF 15  
 Sunscreen  
 8.0 FL. OZ 236.6 gram  
 NDC:61619-868-08

# PRO-TECT EVERYDAY SUNSCREEN SPF 15

octinoxate, octisalate, padimate o lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61619-868
<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	75 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20 mg in 1 g
<b>PADIMATE O</b> (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	50 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 809Y72KV36)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>DIETHANOLAMINE CETYL PHOSPHATE</b> (UNII: 4UG0316V9S)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61619-868-08	236.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/03/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/03/2015	

**Labeler** - A-Cute Derm, Incorporated (809845803)

## Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(61619-868)

