PRO-TECT SUNSCREEN FOR PROFESSIONALS- meradimate, octinoxate, octisalate, oxybenzone 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.

Active ingredients

Meradimate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 5.0%

Purpose

Sunscreen

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

Directions

•apply liberally 15 minutes before sun exposure
•reapply:
•after 80 minutes of swimming or sweating
•immediately after towel drying
•at least every 2 hours
•children under 6 months: 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 sun-glasses

Other Information

• Daily usage of Pro-Tect® SPF 30+ may help reduce the chance of premature aging of the skin due to overexposure to the sun. • This product provides more than 30 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.

Inactive Ingredients

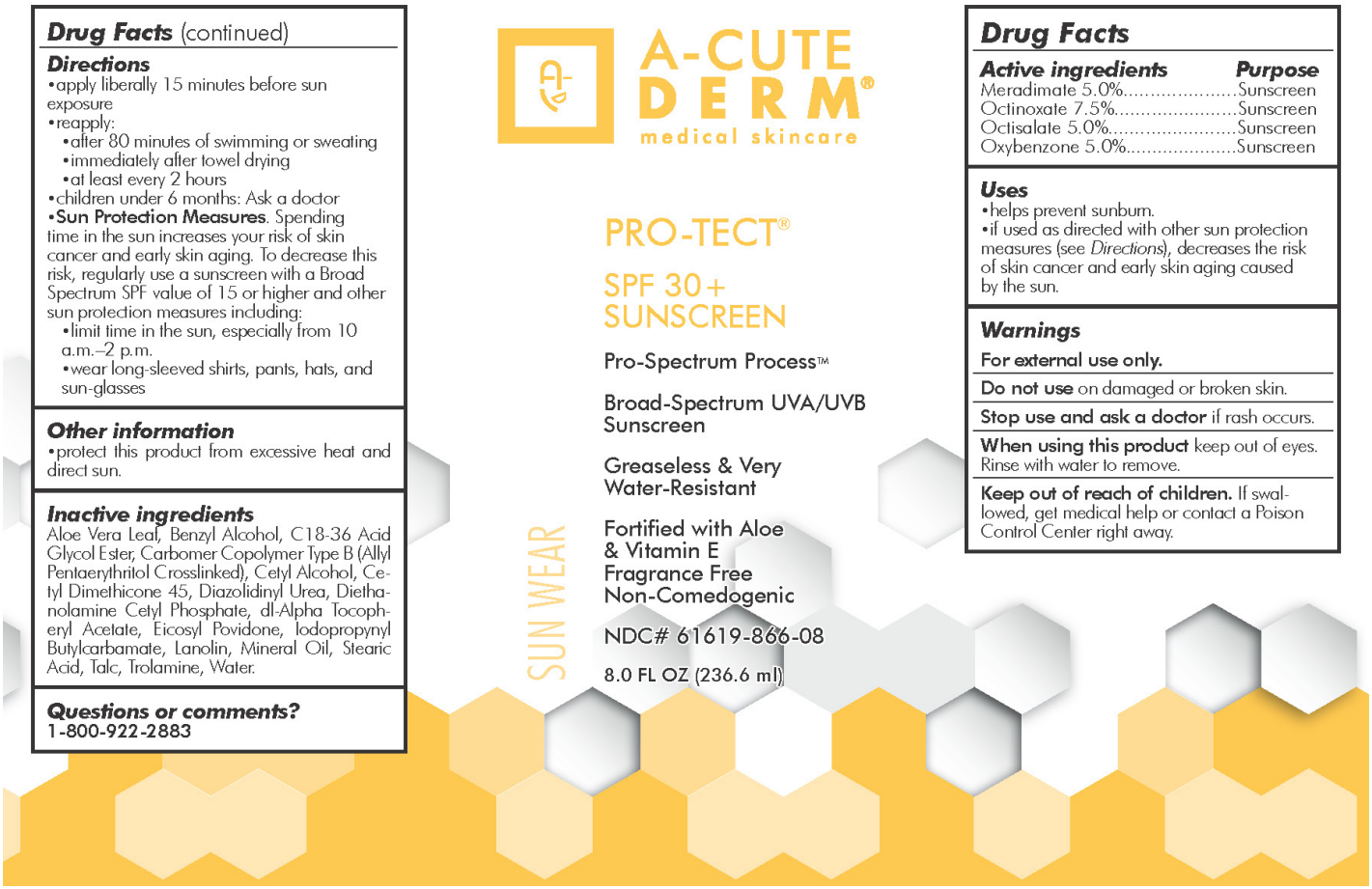
Aloe Vera Leaf, Benzyl Alcohol, C18-36 Acid Glycol Ester, Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked), Cetyl Alcohol, Cetyl Dimethicone 45, Diazolidinyl Urea, Diethanolamine Cetyl Phosphate, dl-Alpha Tocopheryl Acetate, Eicosyl Povidone, Iodopropynyl Butylcarbamate, Lanolin, Mineral Oil, Stearic Acid, Talc, Trolamine, Water.

Questions or Comments

1-800-922-2883

Package label

NDC# 61619-866-08



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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61619-866
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LANOLIN (UNII: 7EV65EAW6H)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

MINERAL OIL (UNII: T5L8T28FGP)	
TALC (UNII: 7SEV7J4R1U)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL DIMETHICONE 45 (UNII: IK315POC44)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61619-866-32	946.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2016	
2	NDC:61619-866-01	29.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2016	
3	NDC:61619-866-02	59.1 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2016	
4	NDC:61619-866-04	118.3 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2016	
5	NDC:61619-866-08	236.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/08/2016	

Labeler - A-Cute Derm, Incorporated (809845803)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(61619-866)

Revised: 12/2020 A-Cute Derm, Incorporated