

PRO-TECT EVERYDAY SUNSCREEN SPF 15- octinoxate, octisalate, padimate o lotion
Bio-Medical & Pharmaceutical Manufacturing Corporation

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.

Pro-Tect Everyday Sunscreen SPF 15

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 Phospate, 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 -
Pro-Tect Everyday Sunscreen
SPF 15
190 grams
NDC:37945-868-65**

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PRO-TECT EVERYDAY SUNSCREEN SPF 15

octinoxate, octisalate, padimate o lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37945-868
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20 mg in 1 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	50 mg in 1 g

Inactive Ingredients

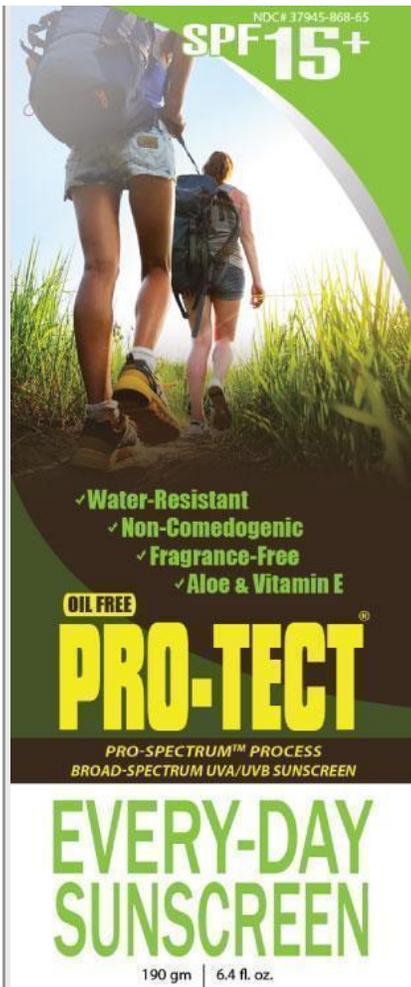
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
.ALPHA.-TOCOPHEROL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

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37945-868-06	207.7 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/1987	02/05/2015
2	NDC:37945-868-65	190 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2015	



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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/1987	

Labeler - Bio-Medical & Pharmaceutical Manufacturing Corporation (072186356)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(37945-868)

Revised: 2/2015

Bio-Medical & Pharmaceutical Manufacturing Corporation