

**DERMAPROT HELIOPROT AB SPF 30- octinoxate,titanium dioxide,oxybenzone,avobenzone lotion**  
**SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS**

*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.*

**DERMAPROT HELIOPROT LOCION ANTISOLAR SPF 30**

ETHYLHEXYL METHOXYCINNAMATE, TITANIUM DIOXIDE, BUTYL METHOXYDIBENZOYLMETHANE, BENZOPHENONE-3, are a set of physical and chemical filters that provide SPF 30

Sunscreen lotion from wide spectrum sunscreen SPF 30

Keep out of reach of children

Provides moderate protection against sun. This product is for topical application.

Avoid the contact with eyes, rinse with water to remove.

Do not apply this product on under six months aged children

Rub to cover the area to be protected and wait for its full absorption

Solar protector UVA UVB has an aqueous base where we deposited all the active ingredients to guarantee a wide range of the sun protection; rehydrates the skin tissues maintaining cellular bioactivity without the inconvenient of the oily foundations.



IMAGE OF THE CARTON LABEL

<b>DERMAPROT HELIOPROT AB SPF 30</b>			
octinoxate,titanium dioxide,oxybenzone,avobenzone lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66854-026
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.5 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	3 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	2.5 mL in 100 mL

OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	1.5 mL in 100 mL
<b>Inactive Ingredients</b>		
Ingredient Name		Strength
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
GLYCERIN (UNII: PDC6A3C0OX)		
ALUMINUM OXIDE (UNII: LM26O6933)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CHAMOMILE (UNII: FGL3685T2X)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)		
OCTYLDODECANOL (UNII: 461N1O614Y)		
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)		
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)		
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
METHYL PARABEN (UNII: A218C7H9T)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
PROPYL PARABEN (UNII: Z8IX2SC1OH)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66854-026-01	10 mL in 1 BOTTLE		
2	NDC:66854-026-02	45 mL in 1 BOTTLE		
3	NDC:66854-026-03	70 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/30/2012	

**Labeler** - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

**Registrant** - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Establishment			
Name	Address	ID/FEI	Business Operations

SPAI-SONS PHARMACEUTICAL  
INTERNATIONAL COSMETICS

880172184

analysis(66854-026) , manufacture(66854-026) ,  
label(66854-026) , pack(66854-026)

Revised: 6/2012

SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS