

SUN PROTECTION BODY SPF 30- avobenzone, homosalate, octisalate, oxybenzone lotion
Juvena Produits de Beaute GMBH

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.

Sun Protection Lotion Body SPF 30

Active ingredients	Purpose
Avobenzone 3.0%	sunscreen
Homosalate 7.0%	sunscreen
Octisalate 5.0 %	sunscreen
oxybenzone 5.0 %	sunscreen

Keep out of reach of children
Do not use on infants under 6 months of age.

- Stop use and ask a doctor if rash or irritation develops and lasts.
when using this product keep out of eyes. Rinse with water to remove.
- Apply daily after cleansing and toning
 - smooth over body
 - apply evenly before sun exposure
 - reapply as needed or after towel drying, swimming or perspiring

Water (Aqua), Butyloctyl Salicylate, Undecrylene Dimethicon, Polyester-8, Caprylyl Methicone, Polyglyceryl-3 Methylglucose Distearate, Octyldodecyl Olivat, Pentylene Glycol, Steareth-21, Glycoproteins, Panax Ginseng Root Extract, Equisetum Arvense (Horsetail) Extract, Sodium Hyaluronate, Allantoin, Porphyras Umbilicalis Extract, Tocopheryl Acetate, Benzylidene Dimethoxydimethylindanone, Sea Water (Maris Aqua) Diethylhexy Syringyldenemalonate, Polyacrylamide, Potassium Sorbate, Xanthan Gum , Pelvetia Canaliculate Extract, Lecithin, Caprylic/ Capric Triglyceride, Palmmaria Palmate Extract, Ethylhexyl Glycerin, Algae Extract, Steareth-2, Disodium EDTA, Hydroxypropyl Starch Phosphate, Alcohol. C13-14 Isoparaffin, Sodium Lactate, Cetyl Alcohol, Dipropylene Glycol, Laureth-7, Fragrance (Parfum), Benzyl Alcohol, Sodium Benzoate, Phenoxyethanol, Chlorphenesin, Methylparaben, Propylparaben

Drug Facts

Active Ingredients	Purpose
Avobenzone 3.0 %.....	Sunscreen
Homosalate 7.0%	
Octisalate 5.0 %.....	
Oxybenzone 5.0 %.....	

Uses

- helps prevent sunburn
- for skin that burns easily
- provides moderate protection against sunburn
- higher SPF gives more sunburn protection

Warnings

For 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.

Keep out of reach of children. • **Do not use** on infants under 6 months of age.

Directions

- apply daily after cleansing and toning
- smooth over body
- apply evenly before sun exposure
- reapply as needed or after towel drying, swimming or perspiring

Inactive Ingredients

Water (Aqua), Butyloctyl Salicylate, Undecylene Dimethicone, Polyester-8, Caprylyl Methicone, Polyglyceryl-3 Methylglucose Distearate, Octyldodecyl Olivate, Pentylene Glycol, Steareth-21, Glycoproteins*, Panax Ginseng Root Extract*, Equisetum Arvense (Horsetail) Extract*, Sodium Hyaluronate, Allantoin, Porphyra Umbilicalis Extract, Tocopheryl Acetate, Benzylidene Dimethoxydimethylindanone, Sea Water (Maris Aqua), Diethylhexyl Syringidenemalonate, Polyacrylamide, Potassium Sorbate, Xanthan Gum, Pelvetia Canaliculata Extract, Lecithin, Caprylic/Capric Triglyceride, Palmaria Palmata Extract, Ethylhexyl Glycerin, Algae Extract, Steareth-2, Disodium EDTA, Hydroxypropyl Starch Phosphate, Alcohol, C13-14 Isoparaffin, Sodium Lactate, Cetyl Alcohol, Dipropylene Glycol, Laureth-7, Fragrance (Parfum), Benzyl Alcohol, Sodium Benzoate, Phenoxyethanol, Chlorophanesin, Methylparaben, Propylparaben (I71)

* La Prairie's exclusive Cellular Complex
US Patent 5,840,309

Sun Protection lotion body SPF 30

180mL/ 6.0 FL.OZ



SUN PROTECTION BODY SPF 30

avobenzone, homosalate, octislate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59614-511	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	3 mL in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	7 mL in 100 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)		OCTISALATE	5 mL in 100 mL	
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)		OXYBENZONE	5 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)				
HYALURONATE SODIUM (UNII: YSE9PPT4TH)				
ALLANTOIN (UNII: 344S277G0Z)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
DIPROPYLENE GLYCOL (UNII: E107L85C40)				
LAURETH-7 (UNII: Z95S6G8201)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59614-511-02	1 in 1 BOX		
1	NDC:59614-511-01	180 mL in 1 BOTTLE		
2	NDC:59614-511-11	0.09 mL in 1 DRUM		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	02/14/2011		

Labeler - Juvena Produits de Beaute GMBH (315053785)

Registrant - Temmentec Ag (480586411)

Establishment

Name	Address	ID/FEI	Business Operations
Temmentec Ag		480586411	manufacture

