

**SUN PROTECTION EMULSION FACE LA PRAIRIE- avobenzene, homosalate, octisalate, octocrylene, oxybenzone cream  
Juvena 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.*

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**Sun Protection Emulsion Face SPF 30**

Active Ingredients	Purpose
Avobenzene 3.0%	sunscreen
Homosalate 10.0%	sunscreen
Octisalate 2.6%	sunscreen
octocrylene 2.4%	sunscreen
Oxybenzone 5.0%	sunscreen

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

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 face and throat.

Apply evenly before sun exposure.

Reapply as needed or after towel drying, swimming or perspiring.

Water (Aqua), Caprylyl Methicone, Hexyldecanol, Dimethicone, Polyglyceryl-3 Methylglucose Distearate, Undercrylene Dimethicone, Aluminum Starch Octenylsuccinate, Steareth-21, Octyldodecyl Oliviate, Cetyl Alcohol, Silica, Glycerin, Glycoproteins, Panax Ginseng Root Extract\*, Equisetum Arvense (Horsetail) Extract\*, Sodium Hyaluronate, Corallina Officinalis Extract, Sea Water ( Maris Aqua), Algae Extract, Aloe Barbadensis Leaf Juice, Steareth-2, Ethylhexyl Glycerin, Disodium EDTA, Benzylidene Dimethoxydimethylindanone, sodium hydroxide, porphyra Umbilicalis Extract, Squalane, Carbomer, Potassium Sorbate, Hydroxyethyl acrylate/ Sodium Acryloyldimethyl Taurate Copolymer, Palmaria Pakmata Extract, Tocopheryl Acetate, Diethylhexyl Syringyldenemalonate, Pelvetia Canaliculata Extract, Polysorbate 60, Lecithin, Caprylic/ Capric Triglyceride, Sodium Lactate, Caprylyl Glycol, Alcohol, Benzyl Alcohol, Fragrance ( parfum), Phenoxyethanol, Chlorphenesin, Sodium Benzoate, Methylparaben, Ethylparaben, Propylparaben

## Drug Facts

### Active Ingredients Purpose

Avobenzone 3.0 %.....	Sunscreen
Homosalate 10.0%.....	
Octisalate 2.6%.....	
Octocrylene 2.4%.....	
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 face & throat
- apply evenly before sun exposure
- reapply as needed or after towel drying, swimming or perspiring

### Inactive Ingredients

Water (Aqua), Caprylyl Methicone, Hexyldecanol, Dimethicone, Polyglyceryl-3 Methylglucose Distearate, Undecylenedimethicone, Aluminum Starch Octylsuccinate, Steareth-21, Octyldodecyl Olivate, Cetyl Alcohol, Silica, Glycerin, Glycoproteins\*, Panax Ginseng Root Extract\*, Equisetum Arvense (Horse-tail) Extract\*, Sodium Hyaluronate, Corallina Officinalis Extract, Sea Water (Maris Aqua), Algae Extract, Aloe Barbadiensis Leaf Juice, Steareth-2, Ethylhexyl Glycolin, Disodium EDTA, Benzylidene Dimethoxydimethyldianone, Sodium Hydroxide, Porphyra Umbilicalis Extract, Squalane, Carbomer, Potassium Sorbate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Palmaria Palmata Extract, Tocopheryl Acetate, Diethylhexyl Syringidenemalonate, Palvetia Canaliculata Extract, Polysorbate 60, Lecithin, Caprylic/Capric Triglyceride, Sodium Lactate, Caprylyl Glycol, Alcohol, Benzyl Alcohol, Fragrance (Parfum), Phenoxyethanol, Chlorphenesin, Sodium Benzoate, Methylparaben, Ethylparaben, Propylparaben (J71)

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

Sun protection emulsion face SPF 30

125mL/ 4.2 FL. OZ.



**SUN PROTECTION EMULSION FACE LA PRAIRIE**

avobenzone, homosalate, octisalate, octocrylene, oxybenzone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59614-221
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	3 mL in 100 mL

<b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	10 mL in 100 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (octisalate - UNII:4X49Y0596W)	Octisalate	2.5 mL in 100 mL
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	2.4 mL in 100 mL
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	5 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Hexyldecanol</b> (UNII: 151Z7P1317)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>STEARETH-2</b> (UNII: V56DFE46J5)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>squalane</b> (UNII: GW89575KF9)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>alcohol</b> (UNII: 3K9958V90M)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>ETHYL PARABEN</b> (UNII: 14255EXE39)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59614-221-11	0.088 mL in 1 DRUM		
2	NDC:59614-221-02	1 in 1 BOX		
2	NDC:59614-221-01	125 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/14/2011	

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**Registrant** - Juvena GMBH (315053785)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Temmentec Ag		480586411	manufacture

Revised: 2/2011

Juvena GMBH