

**SUN SPR SPF 50- avobenzone, octinoxate, octocrylene, oxybenzone, titanium dioxide spray**  
**AGEFARM SRL**

*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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**SUNSCREEN BODY SPF 50 SPRAY**

**ACTIVE INGREDIENTS**

AVOBENZONE

OCTINOXATE

OCTOCRYLENE

TITANIUM DIOXIDE

**PURPOSE**

Sunscreen

**USES**

helps prevent sunburn

use as directed with other sun protection measures (see Directions), decrease 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 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 Poison Control Center right away.

**DIRECTIONS**

<sup>1</sup>apply liberally 15 minutes before the sun exposure

reapply at least every 2 hours, immediately after towel drying

use a water-resistant sunscreen if swimming or sweating

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 the time in the sun, especially from 10 a.m. - 2p.m.

wear long-sleeved shirts, pants, hats, and sunglasses

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## INACTIVE INGREDIENTS

alcohol, BHT, bis-ethylhexyloxyphenol methoxyphenyl triazine, butyrospermum parkii butter extract, caprylic - capric triglyceride, carthamus tinctorius seed oil, cellulose gum, citronellol, coumarin, cyclomethicone, c12-15 alkyl benzoate, decyl glucose, diisopropyl sebacate, dimethicone, glycerin, hexyl cinnamal, coumarin, hydrolyzed soy protein, hydrolyzed wheat protein, lecithin, limnanthes alba seed oil, limonene, linalool, methylene bis-benzotriazolyl tetramethylbutyphenol (nano), methylisothiazolinone, menthyl lactate, microcrystalline cellulose, olea europaea oil unsonifiables, parfum, phenoxyethanol, potassium cetyl phosphate, propylene glycol, silica, tocopheryl acetate, tripeptide-1, vp-eicosene copolymer, water, xanthan gum

## STORAGE AND HANDLING

Protect this product from excessive heat and direct sun

## PRINCIPAL LABEL

Screen Cream Body SPF 50

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
AVOBENZONE 2%	Sunscreen
OCTINOXATE 2%	Sunscreen
OCTOCRYLENE 2%	Sunscreen
OXYBENZONE 2%	Sunscreen
TITANIUM DIOXIDE 2%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>helps prevent sunburn</li> <li>use as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li><b>For external use only</b></li> <li><b>Do not use</b> on damaged or broken skin</li> <li><b>Stop use and ask doctor</b> if rash occurs</li> <li><b>When using this product</b>, keep out of eyes. Rinse with water to remove</li> <li><b>Keep out of reach of children.</b> If swallowed, get medical help or contact Poison Control Center right away.</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply: at least every 2 hours, immediately after towel drying</li> <li>use a water-resistant sunscreen if swimming or sweating</li> <li>children under 6 months: Ask a doctor</li> <li><b>Sun Protection Measures.</b> 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 <b>broad spectrum</b> SPF value of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m. – 2 p.m.</li> <li>wear long-sleeved shirts, pants, hats, and sunglasses</li> </ul> </li> </ul>	
<b>Inactive Ingredients</b>	
alcohol, BHT, bis-ethylhexyloxyphenol methoxyphenyl triazine, butyrospermum parkii butter extract, caprylic/capric triglyceride, carthamus tinctorius seed oil, cellulose gum, citronellol, coumarin, cyclomethicone, c12-15 alkyl benzoate, decyl glucose, diisopropyl sebacate, dimethicone, glycerin, hexyl cinnamal, coumarin, hydrolyzed soy protein, hydrolyzed wheat protein, lecithin, limnanthes alba seed oil, limonene, linalool, methylene bis-benzotriazolyl tetramethylbutyphenol (nano), methylisothiazolinone, menthyl lactate, microcrystalline cellulose, olea europaea oil unsonifiables, parfum, phenoxyethanol, potassium cetyl phosphate, propylene glycol, silica, tocopheryl acetate, tripeptide-1, vp-eicosene copolymer, water, xanthan gum	
<b>Other information</b>	
Protect this product from excessive heat and direct sun	

SUNSCREEN 5033 BODY SPF50.jpg

## SUN SPR SPF 50

avobenzene, octinoxate, octocrylene, oxybenzone, titanium dioxide spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73310-5033
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1 mg in 5 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1 mg in 5 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1 mg in 5 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1 mg in 5 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1 mg in 5 mL

**Product Characteristics**

<b>Color</b>	white (CREAM)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73310-5033-3	150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/28/2019	

## *Drug Facts*

<i>Active Ingredient</i>	<i>Purpose</i>
AVOBENZONE 3%.....	Sunscreen
OCTINOXATE 5.5%.....	Sunscreen
OCTOCRYLENE 5%.....	Sunscreen
OXYBENZONE 2.5.....	Sunscreen
TITANIUM DIOXIDE 2.4%.....	Sunscreen

### *Uses*

- helps prevent sunburn
- use 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 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 Poison Control Center right away.

### *Directions*

- apply liberally 15 minutes before sun exposure
- reapply: at least every 2 hours, immediately after towel drying
- use a water-resistant sunscreen if swimming or sweating
- 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 sunglasses

### ***Inactive Ingredients***

ammonium acryloyldimethyltaurate-yp copolymer, bis-ethylhexyloxyphenol methoxyphenyl triazine, BHT, butyrospermum parkii butter extract, caprylic capric triglyceride, carbomer, carthamus, cetearyl alcohol, citronello, coumarin, diethylhexyl syringyldenemalonate, decyl glucoside, diisopropyl sebacate, dimethicone, dimethiconol behenate, c12-15 alkyl benzoate, glycerin, glyceryl stearate, hexyl cinnamal, hydrolyzed soy protein, hydrolyzed wheat protein, limnanthes alba seed oil, limonene, linalool, methylene bisbenzotriazolyl tetramethylbutylphenol (nano), menthyl lactate, methylisothiazolinone, olea europaea oil unaponifiables, parfum, peg-100 stearate, phenoxyethanol, pseudalteromonas ferment extract, propylene glycol, tocopherylacetate, triethanolamine, tripeptide-1, tripeptide-10 citrulline, yp-eicosene copolymer, water, xanthan gum

### ***Other Information***

Protect this product from excessive heat and direct sun

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/28/2019	

**Labeler** - AGEFARM SRL (439202467)

## **Establishment**

Name	Address	ID/FEI	Business Operations
COSMESIT SRL		339071951	manufacture(73310-5033)