

**FACE SPF 50- avobenzene, octinoxate, octocrylene, oxybenzone, titanium dioxide cream**  
**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 Face SPF 50**

**Drug Facts**

**Active ingredients**

AVOBENZONE 2%

OCTINOXATE 2%

OCTOCRYLENE 2%

OXYBENZONE 2%

TITANIUM DIOXIDE 2%

**PURPOSE**

SUNSCREEN

**USES**

helps prevent sunburn

use as directed with other sun protection measures (see Direction), 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 put 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, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:

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

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

### **INACTIVE INGREDIENTS**

ammonium acryloyldimethyltaurate-vp copolymer, bis-ethylhexyloxyphenol methoxyphenyl triazine, BHT, butyrospermum parkii butter extract, caprylic capric triglyceride, carbomer, carthamus, cetearyl alcohol, citronellol, coumarin, diethylhexylsyringylidenemalonate, 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 unsonifiables, parfum, peg-100 stearate, phenoxyethanol, pseudoalteromonas ferment extract, propylene glycol, tocopherylacetate, triethanolamine, tripeptide-1, tripeptide-10 citrulline, vp-eicosene copolymer, water, xanthan gum

### **OTHER INFORMATION**

Protect this product from excessive heat and direct sun

### **SUNSCREEN LABEL**

## Screen Cream Face 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 <u>broad spectrum</u> 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>	
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<b>Other information</b>	
Protect this product from excessive heat and direct sun	

SUNSCREEN FACE SPF 50 SPRAY 5022

### FACE SPF 50

avobenzone, octinoxate, octocrylene, oxybenzone, titanium dioxide cream

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73310-5022
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	1 mg in 5 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	1 mg in 5 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 mg in 5 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1 mg in 5 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	1 mg in 5 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	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**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73310-5022-2	50 mL in 1 CONTAINER; 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

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### ***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(73310-5022)