

FACE AND BODY SPF 30- avobenzone, octinoxate, octocrylene, oxybenzone, titanium dioxide, zinc oxide 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.

SUNSCREEN SPF 30

ACTIVE INGREDIENTS

AVOBENZONE

OCTINOXATE

OCTOCRYLENE

OXYBENZONE

ZINC OXIDE

TITANIUM DIOXIDE

PURPOSE

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 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 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 vp copolymer, bixa orellana seed extract, benzyl alcohol, bis-ethylhexyloxyphenol methoxyphenyl triazine, caprylic-capric triglyceride, cetaryl alcohol, citronellol, coumarin, c12-15 alkyl benzoate, decyl glucose, diisopropyl sebacate, dimethicone, dimethiconol behenate, ethylhexylglycerin, glycerin, glyceryl stearate, hexyl cinnamal, hydrolyzed soy protein, hydrolyzed wheat protein, limonene, linalool, menthylene bis-benzotriazolyl tetramethylbutylphenol (nano), parfum, peg-100 stearate, propylene glycol, menthyl lactate, silica, tocopheryl acetate, tocopherol, tripeptide-1, vp-eicosene copolymer, water, xanthan gum

OTHER INFORMATION

Protect this product from excessive heat and direct sun

SUNSCREEN LABEL

SPF 30 Face and Body

Drug Facts	
Active Ingredient	Purpose
AVOBENZONE 2%.....	Sunscreen
OCTINOXATE 2%.....	Sunscreen
OCTOCRYLENE 2%.....	Sunscreen
OXYBENZONE 2%.....	Sunscreen
ZINC OXIDE 2%.....	Sunscreen
TITANIUM DIOXIDE 2%.....	Sunscreen
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 vp copolymer, bixa orellana seed extract, benzyl alcohol, bis-ethylhexyloxyphenol methoxyphenyl triazine, caprylic-capric triglyceride, cetaryl alcohol, citronellol, coumarin, c12-15 alkyl benzoate, decyl glucose, diisopropyl sebacate, dimethicone, dimethiconol behenate, ethylhexylglycerin, glycerin, glyceryl stearate, hexyl cinnamal, hydrolyzed soy protein, hydrolyzed wheat protein, limonene, linalool, methylene bis-benzotriazolyl tetramethylbutylphenol (nano), parfum, peg-100 stearate, propylene glycol, menthyl lactate, silica, tocopheryl acetate, tocopherol, tripeptide-1, vp-eicosene copolymer, water, xanthan gum	
Other information	
Protect this product from excessive heat and direct sun	

SUNSCREEN 22 SPF 30.jpg

FACE AND BODY SPF 30

avobenzone, octinoxate, octocrylene, oxybenzone, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73310-3022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1 mg in 5 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1 mg in 5 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1 mg in 5 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1 mg in 5 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 mg in 5 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
PEG-100 STEARATE (UNII: YD01N1999R)	1 mg in 5 mL

Product Characteristics

Color	white (Cream)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73310-3022-3	150 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

Inertive Ingredients

ammonium acryloyldimethyltaurate-yp copolymer, bis-ethylhexyloxyphenol methoxyphenyl triazine, BHT, butyrospermum parkii butter extract, caprylic capric triglyceride, carbomer, carthamus, cetearyl alcohol, citronellol, coumarin, diethylhexyl syringylidenemalonate, decyl glucooside, 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 (nanol), menthyl lactate, methylisothiazolinone, olea europaea oil unascorbifiables, 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

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(73310-3022)