

FACE AND BODY SPF 15- octinoxate, oxybenzone, avobenzone 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.

AGESKIN Sunscreen SPF 15 Face and Body

ACTIVE INGREDIENTS

Octinoxate

Oxybenzone

Avobenzone

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

WARNING

For external use only.

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If product swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Apply liberally, 15 minutes before sun exposure

Reapply: at least every 2 hours

Use a water-resistant sunscreen if swimming or sweating

SUN PROTECTION MEASURES. Spending time in the sun increases your risk of skin cancer and early skin aging.

To decrease this risk, regular 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

Children under 6 months. Ask a doctor

INACTIVE INGREDIENTS

water, C12-15 alkyl benzoate, disopropyl sebacate, isononyl isononanoate, squalane, glyceril stearate, cocos nucifera oil, cetearyl alcohol, propylene glycol, peg-100 stearate, glycerin, dimethicone, vp/eicosene copolymer, calendula officinalis flower extract, ammonium acryloyldimethyltaurate, vp/copolymer, bixia orellana seed extract, hydrolyzed wheat protein, hydrolyzed soy protein, tocopherol, tocopheryl acetate, tripeptide-10 citrulline, caprylic/capric triglyceride, xanthan gum, pseudoalteromonas ferment extract, tripeptide-1, lecithin, carbomer, triethanolamine, benzyl alcohol, dimethiconol behenate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, diethylhexyl syringylidenemalonate, parfum, hexyl cinnamal, coumarin, limonene, linalool, citronellol, menthyl lactate, ethylhexylglycerin, polysorbate 60

STORAGE

Protect this container from heat and sun

SUNSCREEN LABEL

SPF 15 Face and Body Label



Drug Facts	
Active Ingredient	Purpose
AVOBENZONE 2%.....	Sunscreen
OCTINOXATE 2%.....	Sunscreen
OXYBENZONE 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 <u>broad spectrum</u> 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	
ammonia acryloyldimethyl taurate w/p copolymer, benzyl alcohol, bixa orellana seed extract, c12-15 alkyl benzoate, calendula officinalis flower extract, caprylic/capric triglyceride, carbomer, cetaryl alcohol, citronellol, cocos nucifera oil, coumarin, diethylhexyl syringylidenemalonate, diisopropyl sebacate, dimethicone, dimethiconol behenate, ethylhexylglycerin, glycerin, glyceryl stearate, hexyl cinnamal, hydrolyzed soy protein, hydrolyzed wheat protein, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isononyl isonanoate, lecithin, linalool, limonene, menthyl lactate, parfum, peg-100 stearate, polysorbate 60, propylene glycol, pseudoalteromonas ferment extract, squalene, tocopherol, tocopheryl acetate, triethanolamine, tripeptide-1, tripeptide-10 citrulline, w/p eicosane copolymer, water, xanthan gum	
Other information	
Protect this product from excessive heat and direct sun	

SCREEN 1510 SPF 15

FACE AND BODY SPF 15

octinoxate, oxybenzone, avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73310-1522
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1 mg in 5 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 mg in 5 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	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:73310-1522-3	150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/28/2019	

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
AVOBENZONE 1.5%.....	Sunscreen
OCTINOXATE 6%.....	Sunscreen
OXYBENZONE 2.7%.....	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

ammonia acryloyldimethyl taurate w/p copolymer, benzyl alcohol, bixa
Orellana seed extract, c12-15 alkyl benzoate, calendula officinalis
flower extract, caprylic/capric triglyceride, carbomer, cetearyl alcohol,
citronellol, cocos nucifera oil, coumarin, diethylhexyl
syringylidenemalonate, diisopropyl sebacate, dimethicone,
dimethiconol behenate, ethylhexylglycerin, glycerin, glyceryl stearate,
hexyl cinnamal, hydrolyzed soy protein, hydrolyzed wheat protein,
hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer,
isononyl isononanoate, lecithin, linalool, limonene, menthyl lactate,
parfum, peg-100 stearate, polysorbate 60, propylene glycol,
pseudalteromonas ferment extract, squalene, tocopherol, tocopheryl
acetate, triethanolamine, tripeptide-1, tripeptide-10 citrulline, w/p
eicosane 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(73310-1522)