

ANEW VITALE DAY- octinoxate, octisalate, oxybenzone, avobenzone cream
Avon Products, Inc.

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.

Active Ingredients

Octinoxate 7.0%.....

Octisalate 4.5%.....

Oxybenzone 4.0%.....

Avobenzone 2.8%.....

Purpose

..... Sunscreen

..... Sunscreen

..... Sunscreen

..... Sunscreen

Uses

- helps prevent sunburn
- if used 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

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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- children under 6 month of age:ask a doctor
- 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, 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

Other Information

- protect the product in this container from excessive heat and direct sun.

Inactive ingredients:

water/eau, dimethicone, glycerin, PEG-8, butyloctyl salicylate, ceteryl alcohol, trisiloxane, dilauryl thiodipropionate, phytol, behenyl alcohol,

thiodipropionic acid, panthenol, mesyloxybenzyl methoxyethyl chlorobenzamide, pichia ferment lysate filtrate, saccharomyces ferment lysate filtrate, palmitoyl tetrapeptide-10, kaempferia galanga root extract, polysorbate 60, cetareth-20, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, dimethicone crosspolymer, isohexadecane, carbomer, sodium hydroxide, disodium EDTA, caprylyl glycol, 1,2-hexanediol, parfum/fragrance.



DRUG FACTS

Active Ingredients:

	Purpose
Octinoxate 7%.....	Sunscreen
Octisalate 4.5%.....	Sunscreen
Oxybenzone 4%.....	Sunscreen
Avobenzone 2.8%.....	Sunscreen

Uses

- Helps prevent sunburn.
- If used 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.

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Children under 6 months of age: ask a doctor. ■ 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, 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.

Other Information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Water/eau, dimethicone, glycerin, PEG-8, butyloctyl salicylate, cetearyl alcohol, trisiloxane, dilauryl thiodipropionate, phytol, behenyl alcohol, thiodipropionic acid, panthenol, mesyloxybenzyl methoxyethyl chlorobenzamide, pichia ferment lysate filtrate, saccharomyces ferment lysate filtrate, palmitoyl tetrapeptide-10, kaempferia galanga root extract, polysorbate 60, cetearth-20, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, dimethicone crosspolymer, isohexadecane, carbomer, sodium hydroxide, disodium EDTA, caprylyl glycol, 1,2-hexanediol, parfum/fragrance

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71110-0008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	45 mg in 1 g
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	40 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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POLYSORBATE 60 (UNII: CAL22UVI4M)
ISOHEXADECANE (UNII: 918X1OUF1E)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
GLYCERIN (UNII: PDC6A3C0OX)
THIODIPROPIONIC ACID (UNII: 3BBK323ED8)
WATER (UNII: 059QF0KO0R)
DIMETHICONE (UNII: 92RU3N3Y1O)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
PANTHENOL (UNII: WV9CM0O67Z)
TRISILOXANE (UNII: 9G1ZW13R0G)
DILAURYL THIODIPROPIONATE (UNII: V51YH1B080)
PHYTOL (UNII: 5BC2RZ81NG)
MESYLOXYBENZYL METHOXYETHYL CHLOROBENZAMIDE (UNII: 3HB4C300XB)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71110-0008-1	1.1 g in 1 PACKET; Type 0: Not a Combination Product	03/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2016	

Labeler - Avon Products, Inc. (001468693)

Establishment

Name	Address	ID/FEI	Business Operations
Avon Manufacturing (Guangzhou) Ltd.		544863277	manufacture(71110-0008)

Revised: 6/2018

Avon Products, Inc.