ANEW VITALE DAY- homosalate, octinoxate, oxybenzone, avobenzone lotion
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

Homosalate 8%.....

Octinoxate 5%.....

Oxybenzone 4%.....

Avobenzone 2.85%.....

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.

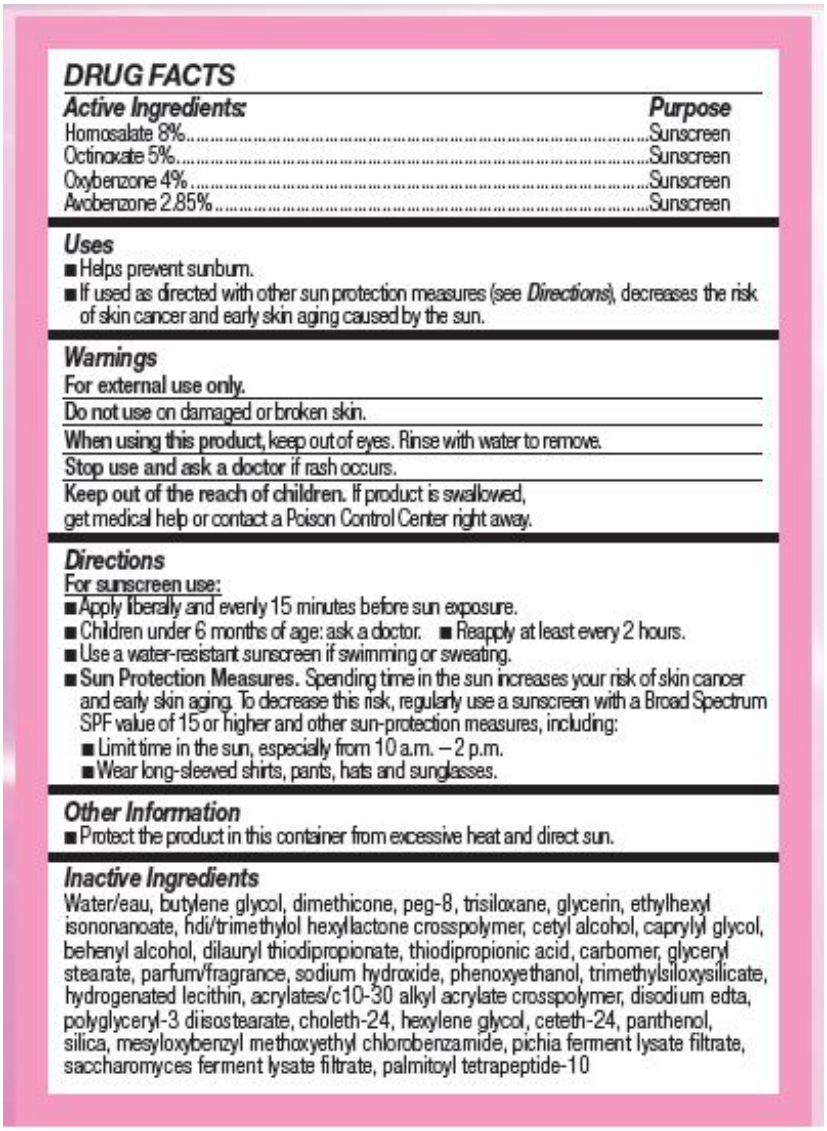
  • wear long-sleeved shirts, pants, hats, and sunglasses

Other Information

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

Inactive ingredients:

water/eau, butylene glycol, dimethicone, PEG-8, trisiloxane, glycerin, ethylhexyl isononanoate, HDI/trimethylol hexyllactone crosspolymer, cetyl alcohol, caprylyl glycol, behenyl alcohol, dilauryl thiodipropionate, thiodipropionic acid, carbomer, glyceryl stearate, parfum/fragrance, sodium hydroxide, phenoxyethanol, trimethylsiloxysilicate, hydrogenated lecithin, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, polyglyceryl-3 diisostearate, choleth-24, hexylene glycol, ceteth-24, panthenol, silica, mesyloxybenzyl methoxyethyl chlorobenzamide, pichia ferment lysate filtrate, saccharomyces ferment lysate filtrate, palmitoyl tetrapeptide-10.



DRUG FACTS

Active Ingredients:	Purpose
Homosalate 8%	Sunscreen
Octinoxate 5%	Sunscreen
Oxybenzone 4%	Sunscreen
Avobenzone 2.85%	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

For sunscreen use:

- 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, butylene glycol, dimethicone, peg-8, trisiloxane, glycerin, ethylhexyl isononanoate, hdi/trimethylol hexyllactone crosspolymer, cetyl alcohol, caprylyl glycol, behenyl alcohol, dilauryl thiodipropionate, thiodipropionic acid, carbomer, glyceryl stearate, parfum/fragrance, sodium hydroxide, phenoxyethanol, trimethylsiloxysilicate, hydrogenated lecithin, acrylates/c10-30 alkyl acrylate crosspolymer, disodium edta, polyglyceryl-3 diisostearate, choleth-24, hexylene glycol, ceteth-24, panthenol, silica, mesyloxybenzyl methoxyethyl chlorobenzamide, pichia ferment lysate filtrate, saccharomyces ferment lysate filtrate, palmitoyl tetrapeptide-10

ANEW VITALE DAY

homosalate, octinoxate, oxybenzone, avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71110-0017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength

PANTHENOL (UNII: WV9CM0O67Z)	
MESYLOXYBENZYL METHOXYETHYL CHLOROBENZAMIDE (UNII: 3HB4C300XB)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DILAURYL THIODIPROPIONATE (UNII: V51YH1B080)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
THIODIPROPIONIC ACID (UNII: 3BBK323ED8)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CHOLETH-24 (UNII: 5UE7I54O43)	
CETETH-24 (UNII: 0EV3Z43Y2I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71110-0017-1	1.1 mL in 1 PACKET; Type 0: Not a Combination Product	12/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/19/2014	

Labeler - Avon Products, Inc. (001468693)

Establishment

Name	Address	ID/FEI	Business Operations
Avon Manufacturing (Guangzhou) Ltd		544863277	manufacture(71110-0017)

Revised: 12/2018 Avon Products, Inc.