

ANEW ULTIMATE DAY MULTI-PERFORMANCE- homosalate, octinoxate, 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

Homosalate 8.0%.....

Octinoxate 5.0%.....

Oxybenzone 4.0%.....

Avobenzone 2.9%.....

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
- product may stain certain types of fabrics

Inactive ingredients:

water/eau, glycerin, dimethicone, butylene glycol, glycolic acid, behenyl alcohol, hydrogenated polyisobutene, trisiloxane, ethylhexyl isononanoate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, cetearyl alcohol, isohexadecane, phytol, thiodipropionic acid, PEG-100 stearate, ammonium hydroxide, parfum/fragrance, cetearyl glucoside, phenoxyethanol, dimethiconol, polysorbate 60, disodium EDTA, PEG-150 distearate, maltodextrin, tiliacora triandra leaf/vine extract, thiazolylalanine, saccharomyces ferment lysate filtrate, eclipta prostrata extract, saccharomyces/platinum ferment, isomalt, propylene glycol, SD alcohol 40-B, saccharomyces/copper ferment, saccharomyces/magnesium ferment, saccharomyces/malachite ferment, saccharomyces/tourmaline ferment, saccharomyces/zinc ferment, steareth-20, lecithin, vitis vinifera (grape) fruit cell extract, palmitoyl tetrapeptide-10, palmitoyl tetrapeptide-7, palmitoyl lysyl aminovaleroyl lysine, caramel, red 4/CI 14700.



DRUG FACTS / INFO DROGUE**Active Ingredients / Ingrédients actifs :**

Homosalate 8%.....	Sunscreen / Écran solaire
Octinoxate 5%.....	Sunscreen / Écran solaire
Oxybenzone 4%.....	Sunscreen / Écran solaire
Avobenzone 2.9%.....	Sunscreen / Écran solaire

Purpose / Propriété**Uses / Utilisations**

- Helps prevent sunburn / Aide à prévenir les coups de soleil.
- 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. / Si utilisé tel qu'indiqué avec d'autres mesures de protection solaire (voir le Mode d'emploi), permet de diminuer les risques de cancer de la peau et de vieillissement prématuré de la peau causés par le soleil.

Directions / Mode d'emploi

- Apply liberally and evenly 15 minutes before sun exposure. / Appliquer généreusement et uniformément 15 minutes avant l'exposition au soleil.
- Children under 6 months of age: ask a doctor. / Consulter un médecin avant d'utiliser sur les enfants de moins de six mois.
- Reapply at least every 2 hours. / Appliquer de nouveau au moins toutes les deux heures.
- Use a water-resistant sunscreen if swimming or sweating. / Utiliser un écran solaire résistant à l'eau pour nager ou en cas de transpiration.
- **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.
- **Mesures à prendre pour se protéger du soleil.** L'exposition au soleil augmente les risques de cancer de la peau et de vieillissement prématuré de la peau. Afin de diminuer ces risques, utiliser régulièrement un écran solaire à large spectre avec un FPS de 15 ou plus, ainsi que d'autres mesures de protection contre le soleil, dont :
 - Limiter l'exposition au soleil, surtout entre 10 h et 14 h.
 - Porter un chandail à manches longues, un pantalon, un chapeau et des lunettes de soleil.

Warnings / Avertissements

- For external use only. / Pour usage externe seulement.
- Do not use on damaged or broken skin. Keep out of eyes. Rinse with water to remove. / Ne pas utiliser sur la peau endommagée ou éraflée. Éviter tout contact avec les yeux. Rincer à l'eau pour enlever.
- Stop use and ask a doctor if rash occurs. / Cesser l'emploi et consulter un médecin en cas d'éruption cutanée.
- Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. / Garder hors de la portée des enfants. Si le produit est avalé, obtenir immédiatement de l'aide médicale ou contacter un centre antipoison.

Inactive Ingredients / Ingrédients inactifs

Water/eau, glycerin, dimethicone, butylene glycol, glycolic acid, behenyl alcohol, hydrogenated polyisobutene, trisiloxane, ethylhexyl isononanoate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, cetearyl alcohol, isohexadecane, phytol, thiodipropionic acid, peg-100 stearate, ammonium hydroxide, parfum/fragrance, cetearyl glucoside, phenoxyethanol, dimethiconol, polysorbate 60, disodium edta, peg-150 distearate, maltodextrin, tiliacora triandra leaf/vine extract, thiazolyalanine, saccharomyces ferment lysate filtrate, eclipia prostrata extract, saccharomyces/platinum ferment, isomalt, propylene glycol, sd alcohol 40-b, saccharomyces/copper ferment, saccharomyces/magnesium ferment, saccharomyces/malachite ferment, saccharomyces/tourmaline ferment, saccharomyces/zinc ferment, steareth-20, lecithin, vitis vinifera (grape) fruit cell extract, palmitoyl tetrapeptide-10, palmitoyl tetrapeptide-7, palmitoyl lysyl aminovaleroyl lysine, caramel, red 4/ci 14700.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71110-0013
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 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STEARETH-20 (UNII: L0Q8IK9E08)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
CARAMEL (UNII: T9D99G2B1R)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
THIODIPROPIONIC ACID (UNII: 3BBK323ED8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PHYTOL (UNII: 5BC2RZ81NG)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
THIAZOLYLALANINE (UNII: VTL1Y3S44B)	
ISOMALT (UNII: S870P55O2W)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71110-0013-1	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(71110-0013)