

AVON NUTRA EFFECTS HYDRATION DAY CREAM- octinoxate, homosalate, avonbenzone, oxybenzone 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 5.5%.....

Homosalate 5.0%....

Avonbenzone 2.9%.....

Oxybenzone 1.0%.....

Purpose

.....Sunscreen

.....Sunscreen

.....Sunscreen

.....Sunscreen

Uses

Helps prevent sunburn.

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 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,
- Product may stain fabrics.

Inactive ingredients

WATER/EAU, GLYCERIN, PROPANEDIOL, DIMETHICONE, HYDROGENATED POLYISOBUTENE, HYDROXYETHYL UREA, LAURYL LACTATE, CETEARYL ALCOHOL, SILICA, PEG-100 STEARATE, PENTYLENE GLYCOL, FRAGRANCE/PARFUM, PHENOXYETHANOL, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, CETEARETH-20, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, CARBOMER, CHLORPHENESIN, DISODIUM EDTA, ISOHEXADECANE, ETHYLENE/PROPYLENE/STYRENE COPOLYMER, UREA, CHOLESTEROL, DILAURYL THIODIPROPIONATE, DIMETHICONE CROSSPOLYMER, PHYTOL, SODIUM HYDROXIDE, XANTHAN GUM, SODIUM DEHYDROACETATE, SODIUM PCA, POLYSORBATE 60, PANTHENOL, BORON NITRIDE, SODIUM HYALURONATE, TOCOPHERYL ACETATE, BUTYROSPERMUM PARKII (SHEA) BUTTER, BUTYLENE/ETHYLENE/STYRENE COPOLYMER,

HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT, CEREUS GRANDIFLORUS (CACTUS) FLOWER EXTRACT, SALVIA HISPANICA SEED EXTRACT, MALTODEXTRIN, POUZOLZIA PENTANDRA EXTRACT, PELVETIA CANALICULATA EXTRACT.



DRUG FACTS

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Inactive Ingredients

Water/eau, glycerin, propanediol, dimethicone, hydrogenated polyisobutene, hydroxyethyl urea, lauryl lactate, cetearyl alcohol, silica, peg-100 stearate, pentylene glycol, fragrance/parfum, phenoxethanol, acrylates/c10-30 alkyl acrylate copolymer, ceteareth-20, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, carbomer, chlorphenesin, disodium edta, isohexadecane, ethylene/propylene/styrene copolymer, urea, cholesterol, dilauryl thiodipropionate, dimethicone copolymer, phytol, sodium hydroxide, xanthan gum, sodium dihydroacetate, sodium pca, polysorbate 60, panthenol, boron nitride, sodium hyaluronate, tocopheryl acetate, butyrospermum parkii (shea) butter, butylene/ethylene/styrene copolymer, helianthus annuus (sunflower) seed extract, cereus grandiflorus (cactus) flower extract, salvia hispanica seed extract, maltodextrin, pouzolida pentandra extract, pelvetia canaliculata extract.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71110-0012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	55 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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DILAURYL THIODIPROPIONATE (UNII: V51YH1B080)
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)
POLYSORBATE 60 (UNII: CAL22UVI4M)
BORON NITRIDE (UNII: 2U4T60A6YD)
WATER (UNII: 059QF0K00R)
GLYCERIN (UNII: PDC6A3C0OX)
PROPANEDIOL (UNII: 5965N8W85T)
ISOHEXADECANE (UNII: 918X1OUF1E)
CHOLESTEROL (UNII: 97C5T2UQ7J)
PANTHENOL (UNII: WV9CM0O67Z)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
PHYTOL (UNII: 5BC2RZ81NG)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
XANTHAN GUM (UNII: TTV12P4NEE)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
DIMETHICONE (UNII: 92RU3N3Y1O)
HYDROXYETHYL UREA (UNII: MBQ7DDQ7AR)
LAURYL LACTATE (UNII: G5SU0BFK7O)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CHLORPHENESIN (UNII: I670DAL4SZ)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71110-0012-1	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(71110-0012)