

**AVON NUTRA EFFECTS BALANCE 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.

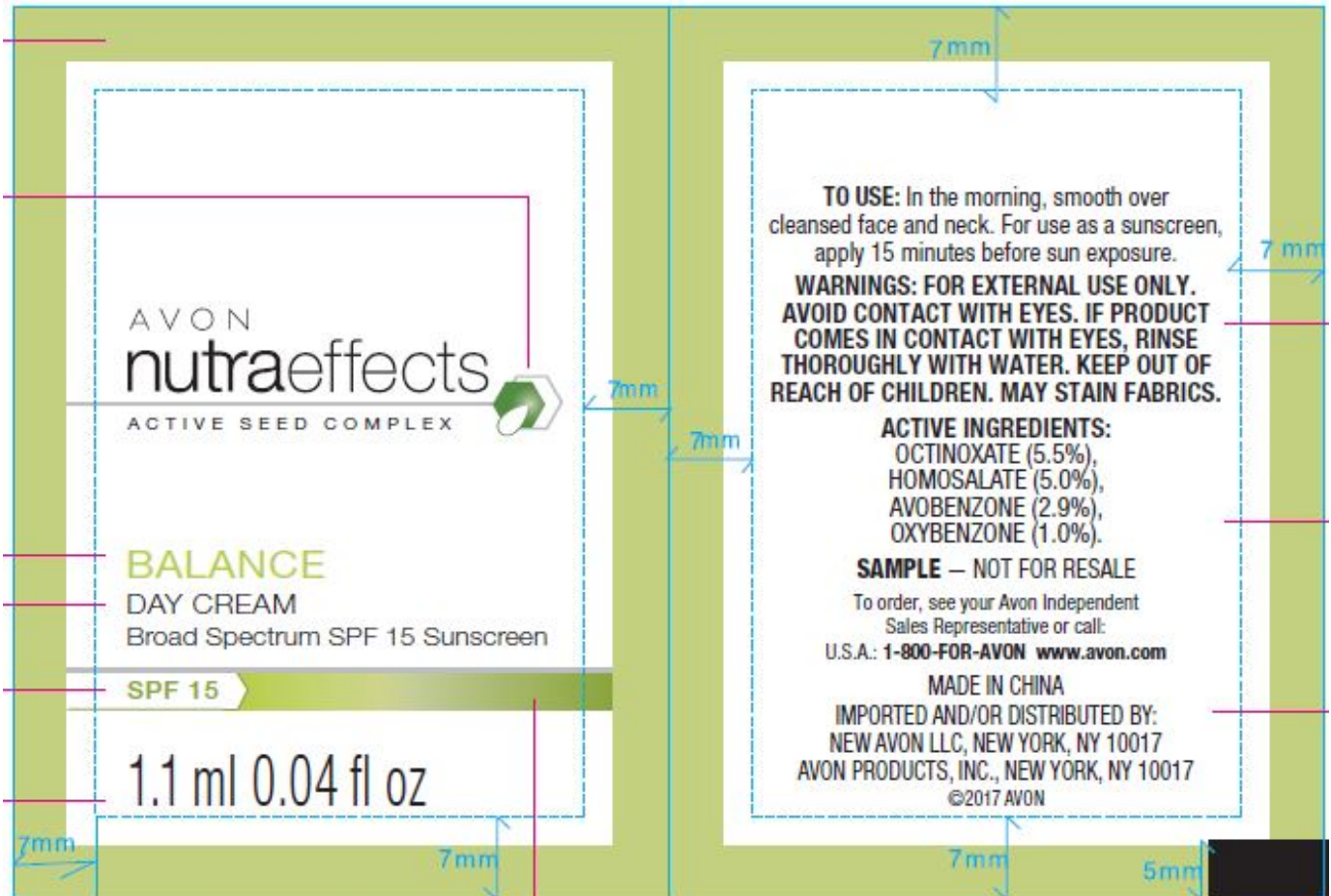
Wear long-sleeved shirts, pants, hats and sunglasses.

***Other Information***

- Protect the product in this container from excessive heat and direct sun,
- Product may stain fabrics.

***Inactive ingredients***

WATER/EAU, BUTYLENE GLYCOL, DIMETHICONE, ETHYLHEXYL ISONONANOATE, PEG-8, SILICA, GLYCERIN, POLYSILICONE-11, CAPRYLYL GLYCOL, PARFUM/FRAGRANCE, GLYCERYL STEARATE, HYDROGENATED LECITHIN, PHENOXYETHANOL, BEHENYL ALCOHOL, CETYL ALCOHOL, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, CARBOMER, DISODIUM EDTA, PANTHENOL, TALC, CHOLETH-24, ISOHEXADECANE, SODIUM HYDROXIDE, HEXYLENE GLYCOL, CETETH-24, POLYGLYCERYL-3 DIISOSTEARATE, PYRIDOXINE HCL, POLYSORBATE 60, LAURETH-12, TOCOPHERYL ACETATE, HELIANTHUS ANNUUS (SUNFLOWER) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, PHYTOL, ISOMALT, MALTODEXTRIN, POUZOLZIA PENTANDRA EXTRACT, SALVIA HISPANICA SEED EXTRACT, LECITHIN, VITIS VINIFERA (GRAPE) FRUIT CELL EXTRACT.



## DRUG FACTS

Active Ingredients:	Purpose
Octinoxate 5.5%.....	Sunscreen
Homosalate 5.0%.....	Sunscreen
Avobenzone 2.9%.....	Sunscreen
Oxybenzone 1.0%.....	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, butylene glycol, dimethicone, ethylhexyl isononanoate, peg-8, silica, glycerin, polysilicone-11, caprylyl glycol, parfum/fragrance, glyceryl stearate, hydrogenated lecithin, phenoxyethanol, behenyl alcohol, cetyl alcohol, vinyl dimethicone/methicone silsesquioxane crosspolymer, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, acrylates/c10-30 alkyl acrylate crosspolymer, carbomer, disodium edta, panthenol, talc, choleth-24, isohexadecane, sodium hydroxide, hexylene glycol, ceteth-24, polyglyceryl-3 diisostearate, pyridoxine hcl, polysorbate 60, laureth-12, tocopheryl acetate, helianthus annuus (sunflower) seed extract, camellia sinensis leaf extract, phytol, isomalt, maltodextrin, pouzolzia pentandra extract, salvia hispanica seed extract, lecithin, vitis vinifera (grape) fruit cell extract.

## AVON NUTRA EFFECTS BALANCE DAY CREAM

octinoxate, homosalate, avobenzone, oxybenzone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71110-0015
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: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	10 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
TALC (UNII: 7SEV7J4R1U)	
CHOLETH-24 (UNII: 5UE7I54O43)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CETETH-24 (UNII: 0EV3Z43Y2I)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PANTHENOL (UNII: WV9CM0O67Z)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PHYTOL (UNII: 5BC2RZ81NG)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
ISOMALT (UNII: S870P55O2W)	
LAURETH-12 (UNII: OAH19558U1)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71110-0015-1	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(71110-0015)