

**CANCER COUNCIL PROTECT AND HYDRATE RADIANCE SPF50 PLUS-
avobenzene, homosalate, octisalate, octocrylene lotion
Vitality US Co.**

Cancer Council Protect and Hydrate Radiance SPF50 Plus

Drug Facts

Active Ingredients

Avobenzene 3%

Homosalate 10%

Octisalate 5%

Octocrylene 8%

Purpose

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

Directions

- apply liberally 15 minutes before sun exposure
- apply to all skin exposed to the sun
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **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 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-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive ingredients

Water, Beeswax, Cyclomethicone, Cetearyl Alcohol, Isopropyl Palmitate, Cetareth-20, Fragrance, Benzyl Alcohol, Hydroxyacetophenone, Carbomer, Phenoxyethanol, Triethanolamine, Sodium Stearoyl Glutamate, Mica, Iron Oxides, Tocopheryl Acetate, Titanium Dioxide, Maltodextrin, Aloe Barbadensis Leaf Juice, Citric Acid

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

info@vitalityusco.com

Product Packaging



CANCER COUNCIL PROTECT AND HYDRATE RADIANCE SPF50 PLUS

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84258-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84258-002-01	1 in 1 CARTON	09/19/2024	
1		148 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/19/2024	

Labeler - Vitality US Co. (119152224)

Revised: 4/2024

Vitality US Co.