

RITE AID ESSENTIAL DEFENSE SPF 45- avobenzone homosalate octisalate octocrylene oxybenzone lotion

RITE AID CORPORATION

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.

Drug Facts

Active Ingredients

Avobenzone 2.0 %

Homosalate 12.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 6.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- retains SPF after 80 minutes of activity in the water

Warnings

For external use only

When using this product

- keep out of eyes. Rinse with water to remove.

stop use and ask a doctor if

- rash or irritation develops and lasts

Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center right away.

Other Information

- may stain some materials

Directions

- shake well
- apply generously before sun exposure and as needed
- children under 6 months of age:ask a doctor
- reapply frequently and after towel drying, swimming or perspiring.

Inactive Ingredients

Water, Methylpropanediol, VP/Eicosene Copolymer, Sorbitan Isostearate, Cetyl Alcohol, Triethanolamine, Isostearic Acid, Stearic Acid, Cetyl Phosphate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Glycerin, Methylparaben, Chlorphenesin, Fragrance, Benzoic Acid, Phenoxyethanol, Disodium EDTA, Bisabolol, Retinyl Palmitate, Ascorbic Acid, Tocopheryl Acetate, PEG-8 Dimethicone, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Octyldodecanol, Silica.

Principal Display Panel

RITE

AID

Essential Defence

OIL FREE SUNSCREEN LOTION

SPF

45

Broad Spectrum Protection

RECOMMENDED

SKIN CANCER

FOUNDATION

won't clog pores

very water resistance

Vitamins A, C and E

4 FL. OZ. (118 mL)



Distributed by: Rite Aid Corporation
30 Hunter Lane, Camp Hill, PA 17011

0 11822 32243 0

THE SKIN CANCER FOUNDATION RECOMMENDS THIS PRODUCT AS AN EFFECTIVE UV SUNSCREEN Made in U.S.A. RA012-A

Drug Facts	
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Uses • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water	
Warnings For external use only When using this product • keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if • rash or irritation develops and lasts. Keep out of the reach of children. If swallowed get medical help or contact a Poison Control Center right away.	
Directions • shake well • apply generously and evenly before sun exposure and as needed • children under 6 months of age: ask a doctor • reapply frequently and after towel drying, swimming or perspiring	
Other information • may stain some materials Inactive ingredients Water, Methylpropanediol, VP/Eicosene Copolymer, Sorbitan Isostearate, Cetyl Alcohol, Triethanolamine, Isostearic Acid, Stearic Acid, Cetyl Phosphate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Glycerin, Methylparaben, Chlorphenesin, Fragrance, Benzoic Acid, Phenoxyethanol, Disodium EDTA, Bisabolol, Retinyl Palmitate, Ascorbic Acid, Tocopheryl Acetate, PEG-8 Dimethicone, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Octyldodecanol, Silica.	

RITE AID ESSENTIAL DEFENSE SPF 45

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Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11822-9004

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	12 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LEVOMENOL (UNII: 24WE03BX2T)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-9004-3	113 g in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/21/2012	

