

SPF 30 SUNSCREEN TOTTLE - avobenzene, oxybenzone, homosalate, octinoxate, octisalate lotion
INNOVATION SPECIALTIES

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

Avobenzene 1%

Oxybenzone 3%

Homosalate 5 %

Octinoxate 7.5 %

Octisalate 5 %

Purpose

Sunscreen

Keep out of reach of children, If swallowed get medical help or contact a Poison Control Center.

Directions

Apply liberally (or generously) and every 15 minutes before sun exposure. Children under 6 months of age ask a doctor. 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. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. Reapply after 80 min. of swimming or sweating. Immediately after towel drying.

Warnings:

For external use only. Do not use on damaged or broken skin. when using this product keep out of eyes. In case of contact rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children, if swallowed get medical help or contact a Poison Control Center.

Dosage and Administration

Apply liberally (or generously)15 minutes before sun exposure, and reapply as needed.

Inactive Ingredients

Water, Dimethyl Capramide, Dimethicone, C12-15 Alkyl Benzoate, Aloe Barbadosis Leaf Juice, Tocopheryl Acetate, Symphytum Officinale Leaf Extract, Tocopherol, Nasturium Officinale Extract, Chamomile Recutita Extract, Calendula Officinalis Flower Extract, Triethanolamine, Propylparaben, Phenoxyethanol, Glyceryl Stearate, Methylparaben, Ethylparaben, Butylparaben, Peg-100 Stearate, Isobutylparaben, Tetrasodium Edta, Carbomer, Acrylates, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance.



Drug Facts

Active Ingredients	Purpose
Avobenzone 1%	Sunscreen
Benzophenone-3 3%	Sunscreen
Homosalate 5%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5%	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.

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1.5 FL. OZ. / 44 ml

Questions Call 1-855-755-5346

Made in USA for Innovation Line

Culver City, CA 90230

SPF 30 Sunscreen

Rev. No. 71600-1

SPF 30 SUNSCREEN TOTTLE

avobenzone, oxybenzone, homosalate, octinoxate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76138-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
COMFREY LEAF (UNII: DG4F8T839X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPII3FV8)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CARBOMER HOMOPOLYMER TYPE A (UNII: F68VH75CJC)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76138-201-04	44 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2009	

Labeler - INNOVATION SPECIALTIES (030837314)

Establishment

Name	Address	ID/FEI	Business Operations
CORETEX PRODUCTS INC		061944620	manufacture(76138-201)