

VERTRA ELEMENTAL RESISTANCE WATER RESISTANT SUNSCREEN- octyl methoxycinnamate, oxybenzone, titanium dioxide, zinc oxide lotion
Vertra (Aust) Pty Ltd

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

Octyl Methoxycinnamate 6%
Oxybenzone 5%
Titanium Dioxide 6.3%
Zinc Oxide 9.9%

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 or irritation develops and lasts.

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

Directions

- apply liberally and evenly 15 minutes before sun exposure
- apply to all skin exposed to sun
- use a water resistant sunscreen if swimming or sweating
- 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 value 15 or higher and other sun protection measures including: limit time in the sun, especially from 10a.m.-2p.m., wear long-sleeve shirts, pants, hats, and sunglasses, children under 6 months of age: ask a doctor

Other information

- protect this product from excessive heat and direct sun

Inactive Ingredients

Acrylates copolymer, Ammonia, C12-15 alkyl benzoate, Cyclomethicone 5, Iodopropynyl butylcarbamate, Lauryl PEG/PPG-18/18 methicone, Methyl glucose dioleate, Methylchloroisothiazolinone, Methylisothiazolinone, Phenoxyethanol, Phenyl trimethicone, Polyhydroxystearic acid, Purified water, Silica dimethyl silylate, Silicone dioxide, Sodium chloride, Sodium dodecylbenzenesulfonate, Stearic acid, Triethoxycaprylylsilane, Xanthan gum

Questions or comments?

Vertra Inc - 875 Waimanu St. #614A Honolulu, HI 96813 - 1(808)593-8378 www.vertra.com

Vertra Elemental Resistance is proud to be the Official Suncare provider for the **Hawaiian Lifeguard Association**

Distributed by: Vertra Inc. Honolulu, HI 96813

Made in Australia

www.vertra.com

Principal Display Panel

Vertra Elemental Resistance

50+ **SUNPROTECTIONCREAM**

BROAD SPECTRUM SPF50+

UVA/UVB Protection

WATER RESISTANT (80 MINUTES) SUNSCREEN

Net. Wt. 2.8 oz (80 g)



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ELEMENTAL RESISTANCE

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BROAD SPECTRUM SPF 50+
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ELEMENTAL RESISTANCE

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Other information

• protect this product from excessive heat and direct sun

Inactive Ingredients

Acrylates copolymer • Avobenzone • C12-15 Alkyl benzoate • Cycloheximide 5 • Isopropyl myristate • Lauryl PEG-9/GM-38/18 methicone • Methyl glucose diacetate • Methylhexanediolacetate • Methylsiloxane • Phenyltrimethicone • Polyhydroxybutyric acid • Purified water • Silica dimethyl silicate • Silica dioxide • Sodium chloride • Sodium dodecylbenzenesulfonate • Stearic acid • Triethoxycaprylylsilane • Xanthan gum

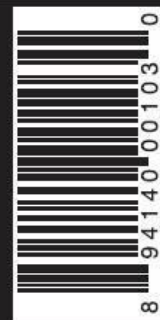
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69750-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.8 g in 80 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 80 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 80 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7.9 g in 80 g

Inactive Ingredients	
Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
WATER (UNII: 059QF0KO0R)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69750-001-80	1 in 1 BOTTLE		
1		80 g 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 not final	part352	05/18/2015	

Labeler - Vertra (Aust) Pty Ltd (743597064)

Establishment			
Name	Address	ID/FEI	Business Operations

Delta Laboratories Pty Limited		751231564	manufacture(69750-001)
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Revised: 5/2015

Vertra (Aust) Pty Ltd