DEFENSE ZONE KIDS BROAD SPECTRUM SPF 50 SUNSCREEN- homosalate, octinoxate, octisalate, titanium dioxide lotion
Prime Enterprises 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.

Defense Zone Kids Broad Spectrum SPF 50 Sunscreen

Active Ingredients

Homosalate 15%

Octinoxate 7.5%

Octisalate 5%

Titanium Dioxide 2.4%

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
- 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Fragrance (Parfum), Hydroxypropyl Methylcellulose, Methylisothiazolinone, Methylparaben, Polyethylene, Polyhydroxystearic Acid, Polysorbate 20, Propylene Glycol, Propylparaben, Sorbitan Oleate, Styrene/Acrylates Copolymer, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water (Aqua)

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments?

Call toll free 1-855-LIV-GOLD (548-4653)

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0233
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75.8 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	151.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.5 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	24.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCOA BUTTER (UNII: 512OYT1CRR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0233-4	235 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/09/2016	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0233) , manufacture(58443-0233) , label(58443-0233) , analysis(58443-0233)

Revised: 1/2020 Prime Enterprises Inc.