ZINKA SPF 50 FACESTICK- homosalate, octinoxate, octisalate, octocrylene, zinc oxide stick
Zinka

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 ingredient

Homosalate (6.9%), Octinoxate (4.7%), Octisalate (4.0%), Octocrylene (3.4%), Zinc Oxide (5.0%)

Purpose

Sunscreen

Keep Out of Reach of Children

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

Uses

Helps prevent sunburn.

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early aging.

For external use only: Stop use and ask a doctor: if rash or irritation develops and lasts. Keep out of eyes. Rinse with water to remove.

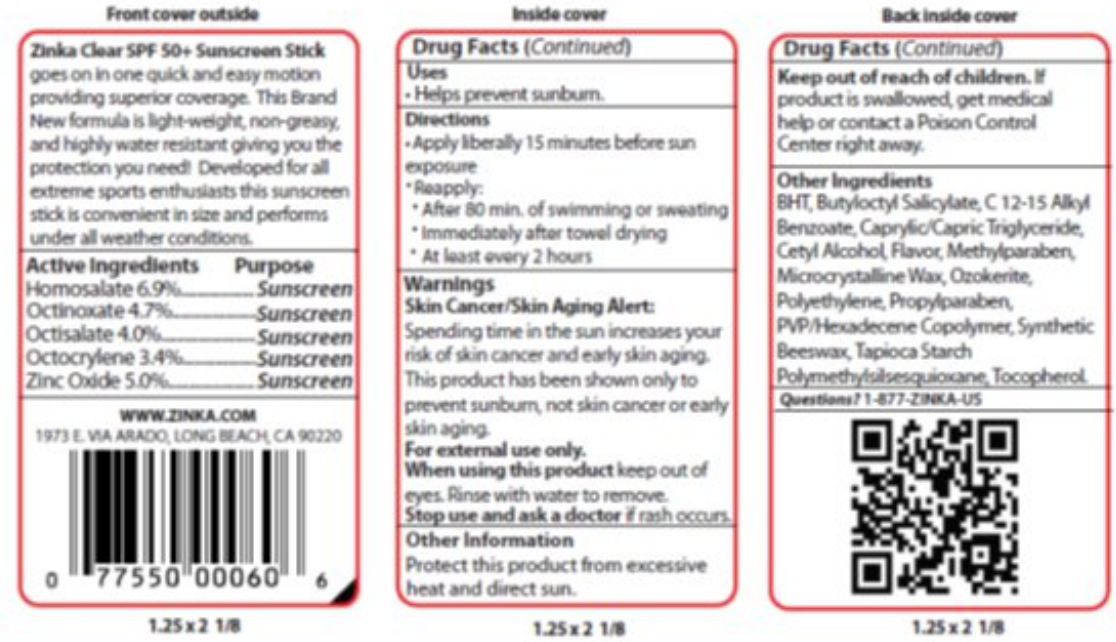
Directions

Apply liberally 15 minutes before sun exposure. Reapply: After 80 minutes of swimming or sweating. Immediately after towel drying. At least every 2 hours.

Inactive Ingredients

BHT, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Cetyl Alcohol, Flavor Methylparaben, Microcrystalline Wax, Ozokerite, Polyethylene, Propylparaben, PVP/Hexadecene Copolymer, Synthetic Beeswax, Tapioca Starch Polymethylsilsesquioxane, Tocopherol,.

Package/Label Principal Display Panel



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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52993-150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.7 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6.90 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3.40 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	10.50 mg in 1 g
CERESIN (UNII: Q1LS2UJO3A)	10.30 mg in 1 g
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	15.5 mg in 1 g
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	13 mg in 1 g
WHITE WAX (UNII: 7G1J5DA97F)	6.3 mg in 1 g

Product Characteristics

Color	WHITE	**Score**	

Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52993-150-03	1 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/09/2014	

Labeler - Zinka (153569595)

Registrant - Zinka (153569595)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(52993-150) , LABEL(52993-150)

Revised: 5/2014 Zinka