

**ZINC FIVE-O ZINXATION KIDS SUNSCREEN SPF-50- zinc oxide lotion
ASTIVITA LIMITED**

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.

ZINC FIVE-O ZINXATION KIDS SUNSCREEN SPF-50

ACTIVE INGREDIENT

ZINC OXIDE 25%

PURPOSE

SUNSCREEN

USES

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreased 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.

DIRECTIONS:

- APPLY LIBERALLY AND EVENLY 20 MINUTES BEFORE SUN EXPOSURE
- REAPPLY:
 - AFTER 40 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 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
 - CHILDREN UNDER 6 MONTHS OF AGE: ASK A DOCTOR

OTHER INFORMATION

STORE AT TEMPERATURES BELOW 90°F (30°C). PROTECT THE PRODUCT IN THIS CONTAINER FROM EXCESSIVE HEAT AND DIRECT SUN.

INACTIVE INGREDIENTS

Water, Coco-caprylate/caprata, glycerine, coconut alkane, simmondsia chinensis (jojoba) seed oil, polyglyceryl-3-polyricinoleate, cera alba (beeswax), isostearic acid, polyhydroxy stearic acid, maltodextrin, phenylpropanol, propanediol, caprylyl glycol, tocopherol, ethylhexylglycerin, cetyl phosphate, sodium chloride, disodium EDTA, Vanilla Planifolia Bean Extract

QUESTIONS?

contactkids@zincfive0.com

ZINC FIVE-O

Safe for Kids, Safe for the Environment
No parabens, No silicones, No titanium dioxide
Natural Vanilla Fragrance

Drug Facts

Active Ingredient	Purpose
Zinc Oxide (25.0% w/w)	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 doctor if rash occurs

Directions

- apply liberally and evenly 20 minutes before sun exposure
- reapply:
 - After 40 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 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
- children under 6 months of age: ask a doctor

Other Information Store at temperatures below 90°F (30°C). Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Water, coco-caprylate/caprate, glycerine, coconut alkane, simmondsia chinensis (jojoba) seed oil, polyglyceryl-3- polyricinoleate, cera alba (beeswax), isostearic acid, polyhydroxy stearic acid, maltodextrin, phenylpropanol, propanediol, caprylyl glycol, tocopherol, ethylhexylglycerin, cetyl phosphate, sodium chloride, disodium EDTA, Vanilla Planifolia Bean Extract

Questions? contactkids@zincfive0.com

EcoCert  Approved Active Ingredient

www.zincfive0.com



X002E50CX5

Distributed by: AstiVita Ltd 1821 Ipswich Rd, Rocklea 4106, Queensland, Australia

ZINC FIVE-O



KIDS SUNSCREEN SPF 50

- Broad Spectrum SPF 50
- Sensitive Skin
- Water Resistant 40 minutes
- Natural Vanilla Fragrance

FORMULATED IN AUSTRALIA

AUSTL 316560

6.7 fl. oz. / 200 mL cream

REEF SAFE

ZINC FIVE-O ZINXATION KIDS SUNSCREEN SPF-50

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80982-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 g in 240 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
JOJOBA OIL (UNII: 724GKU717M)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
VANILLA BEAN (UNII: Q74T35078H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80982-004-39	240 g in 1 TUBE; Type 0: Not a Combination Product	11/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/02/2020	

Labeler - ASTIVITA LIMITED (742799513)

Establishment

Name	Address	ID/FEI	Business Operations
ASTIVITA LIMITED		742799513	label(80982-004)

Revised: 1/2022

ASTIVITA LIMITED