

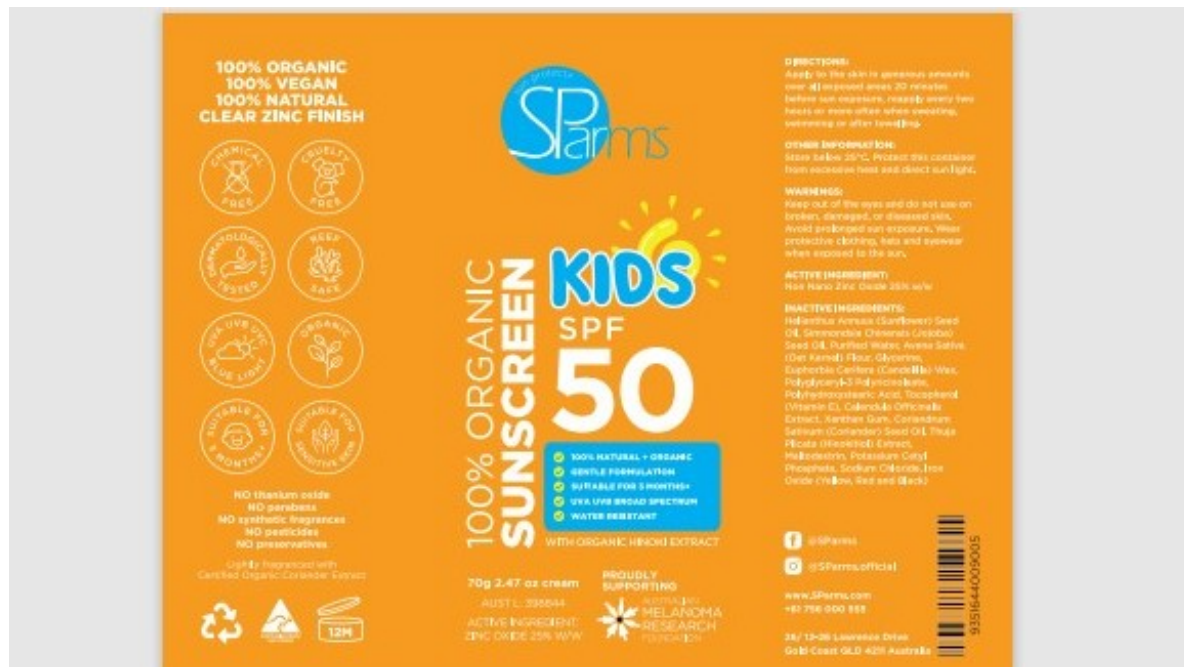
SPARMS ORGANIC KIDS SUNSCREEN- zinc oxide cream

Veganic SKN 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.

SParms Organic Kids Sunscreen

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SPARMS ORGANIC KIDS SUNSCREEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83252-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 kg in 100 kg

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
JOJOBA OIL (UNII: 724GKU717M)	

CALENDULA OFFICINALIS WHOLE (UNII: PFR03EBU0H)
CORIANDER OIL (UNII: 7626GC95E5)
SUNFLOWER OIL (UNII: 3W1JG795YI)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
GLYCERIN (UNII: PDC6A3C0OX)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
WATER (UNII: 059QF0KO0R)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SODIUM HINOKITIOL (UNII: 5MPS47D679)
TOCOPHEROL (UNII: R0ZB2556P8)
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
CANDELILLA WAX (UNII: WL0328HX19)
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83252-003-00	0.07 kg in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/06/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/06/2023	

Labeler - Veganic SKN Limited (743536682)

Establishment

Name	Address	ID/FEI	Business Operations
Veganic SKN Limited		743536682	manufacture(83252-003) , pack(83252-003) , label(83252-003)

Revised: 2/2023

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