

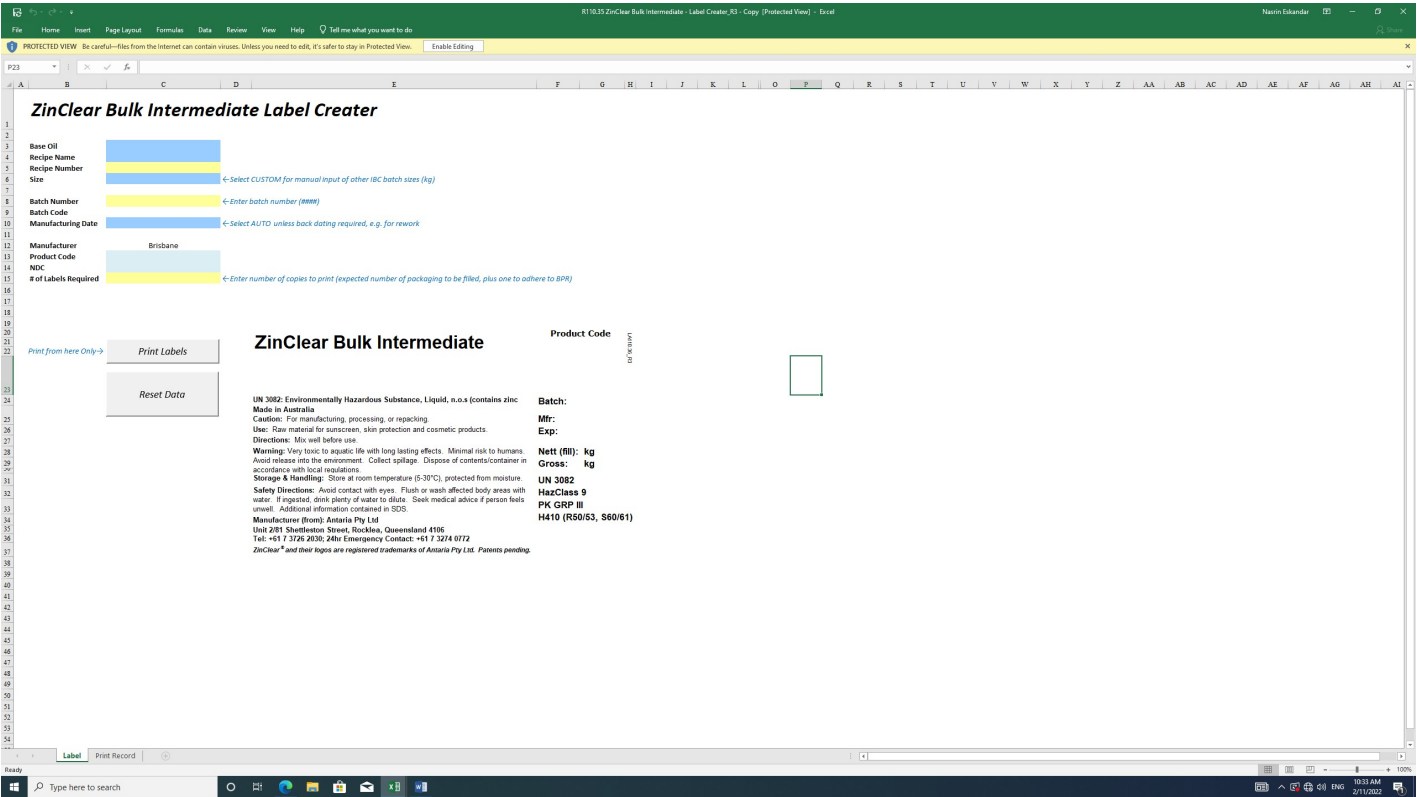
ZINXATION BULK SUNSCREEN- zinc oxide cream

Advance ZincTek 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.

Zinxation Sunscreen

Zinxation Bulk Sunscreen Label



IBC Label

ZINXATION BULK SUNSCREEN			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60396-5555
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	
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)				
CANDELILLA WAX (UNII: WL0328HX19)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
ISOSTEARIC ACID (UNII: X33R8U0062)				
JOJOBA OIL (UNII: 724GKU717M)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)				
GLYCERIN (UNII: PDC6A3C0OX)				
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)				
WATER (UNII: 059QF0KO0R)				
ETHYLENEDIAMINE TETRAETHANOL (UNII: K5APE098Z1)				
ETHYLHEXYL PALMITATE (UNII: 2865993309)				
SODIUM HINOKITOL (UNII: 5MPS47D679)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60396-5555-1	1000 kg in 1 CONTAINER; Type 0: Not a Combination Product	11/02/2022	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part352	11/02/2022	

Labeler - Advance ZincTek Limited (743874997)

Establishment			
Name	Address	ID/FEI	Business Operations
Antaria Pty Ltd		743874997	manufacture(60396-5555)

Revised: 11/2022

Advance ZincTek Limited