

**COLORESCIENCE TOTAL PROTECTION NO SHOW MINERAL SUNSCREEN- zinc
oxide lotion
Colorescience**

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.

Colorescience Total Protection No Show Mineral Sunscreen

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FILE NAME: CG22029-B01-Carton
 DESIGNER: Voytek Janusz
 SALESPERSON: Chris Gustafson
 PROJECT MGR:
 DATE: 08/10/2022
 LAYOUT SIZE: 0 x 0
 STOCK TYPE: .018 SBS ReMagine C1S
 NOTES:

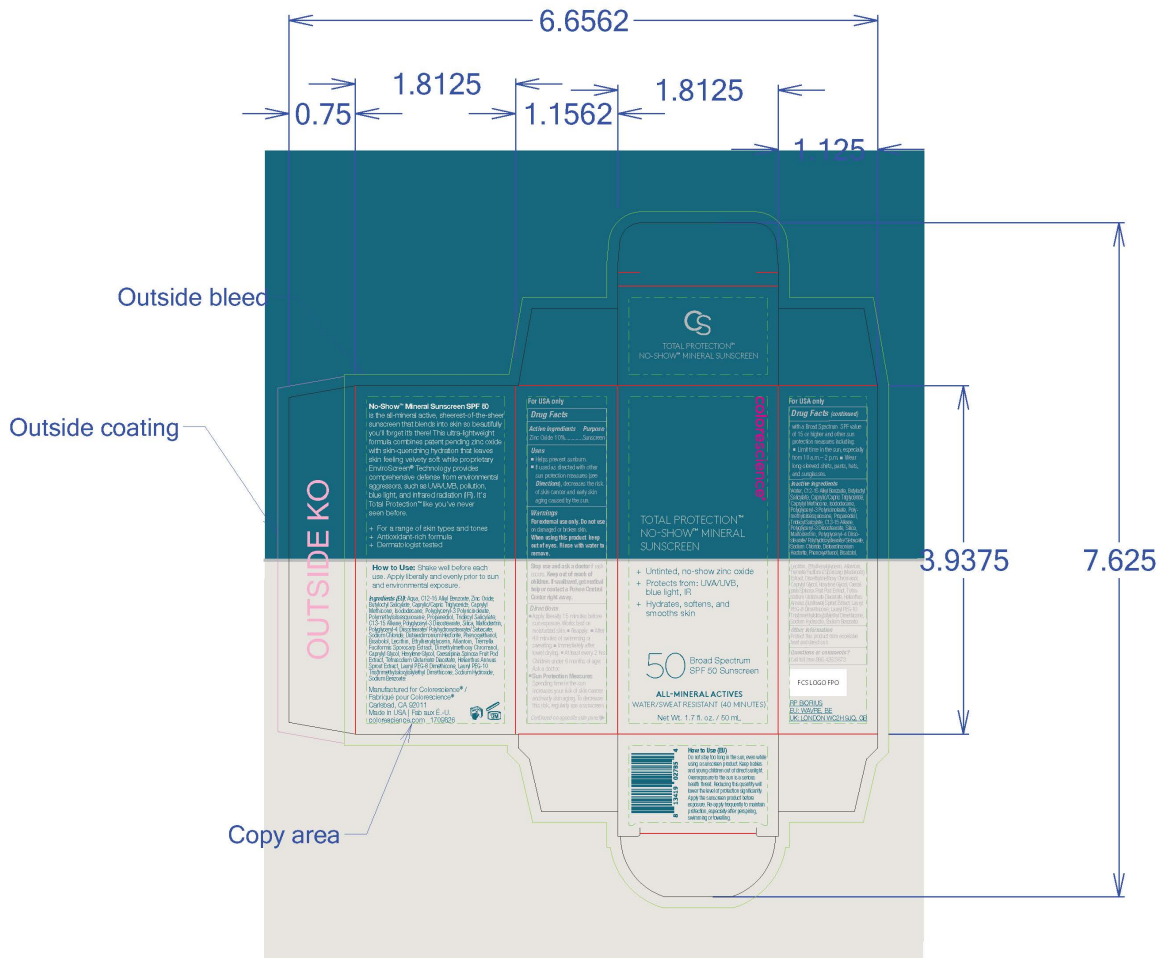
SHEET SIZE: 0 x (0)
 GRAIN OR FLUTE: (horizontal)
 SHEET WASTE: 0%
 INCHES OF RULE: 64.62
 REVISION: 0
 DESIGN VIEW: outside

CUT
 CREASE
 PARTIAL CUT
 PERF
 EDGE OF SHEET
 ANNOTATION
 GLUE/TAPE
 OUTSIDE KO
 INSIDE KO
 BLEED
 SAFETY/COPY
 GLUE ASSISTS
 STRIPPING
 DIEBOARD

SEE CORRESPONDING "DESIGN REQUEST FORM" & SUPPORTING DOCUMENTS FOR ADDITIONAL ACCEPTANCE CRITERIA

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No Show 50ML Tottle - CS Code 1709826



COLORESCIENCE TOTAL PROTECTION NO SHOW MINERAL SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-066
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	107 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
LAURYL PEG-8 DIMETHICONE (300 CPS) (UNII: ELL2U7K8T8)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHYLMETHOXY CHROMANOL (UNII: XBH432G01F)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALLANTOIN (UNII: 344S277G0Z)	
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAESALPINIA SPINOSA FRUIT POD (UNII: EXY4496LWD)	
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISODODECANE (UNII: A8289P68Y2)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68078-066			

1	NDC:68078-066-02	1 in 1 CARTON	03/20/2023	
1	NDC:68078-066-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68078-066-04	1 in 1 CARTON	03/20/2023	
2	NDC:68078-066-03	78 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/20/2023	

Labeler - Colorescience (128731929)

Revised: 7/2023

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