

ELEVEN UNRIVALED SERUM- zinc oxide lotion

Eco Chic, LLC

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.

ELEVEN UNRIVALED SERUM

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SPECS

CLIENT: ELEVEN

Date: 01/23/22

Product: Unrivald Sun Serum
Secondary Packaging - Outer box

Colors: 2

Organic ink if possible

- Black
- PMS 102 C

Stock: 18pt. Neenah Eggshell Folding Board 100% PCW White



ELEVEN UNRIVALED SERUM

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79163-399
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	110 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENYLPROPANOL (UNII: 0F897O3O4M)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
ALLANTOIN (UNII: 344S277G0Z)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
VANILLA PLANIFOLIA WHOLE (UNII: BOS0R5Y21O)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)	
HEDYCHIUM SPICATUM WHOLE (UNII: V88105URGI)	
SHEA BUTTER ETHYL ESTERS (UNII: V2CI786FPG)	
PROPANEDIOL (UNII: 5965N8W85T)	
CITRUS NOBILIS (UNII: 8MFF77J91V)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
RUTIN (UNII: 5G06TVY3R7)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHEROL (UNII: ROZB2556P8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCO-CAPRYLATE (UNII: 4828G836N6)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79163-399-02	1 in 1 CARTON	11/01/2022	
1	NDC:79163-399-01	28 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:79163-399-03	8 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2022	

Labeler - Eco Chic, LLC (097807096)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(79163-399)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(79163-399) , manufacture(79163-399)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(79163-399) , pack(79163-399)

Revised: 3/2023

Eco Chic, LLC