

ORGANYS DERMA MADE- zinc oxide lotion
Organys Beauty

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zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83612-0330
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	132 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEHOA3F75J)	
GLYCERIN (UNII: PDC6A3C00X)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
ISODODECANE (UNII: A8289P68Y2)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83612-0330-1	45 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/29/2021	01/31/2024
2	NDC:83612-0330-2	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/21/2023	
3	NDC:83612-0330-3	45 mL in 1 TUBE; Type 0: Not a Combination Product	01/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/29/2021	

Labeler - Organys Beauty (077820778)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83612-0330)

Establishment

Name	Address	ID/FEI	Business Operations
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Nanophase Technologies Corporation		118812921	manufacture(83612-0330) , pack(83612-0330)
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Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83612-0330) , manufacture(83612-0330)

Revised: 2/2024

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