

NUTRASCREEN COLOR BALANCED- zinc oxide lotion DMK - Danne Montague King

Nutrascreen Color Balanced SPF 30

DRUG FACTS	PURPOSE
Active Ingredients: Zinc Oxide (20.2%).....	Sunscreen

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Uses: Helps prevent sunburn. If used as directed, it reduces the risk of skin cancer and early skin aging caused by the sun.

Warnings: (For external use only) - Do not use it on damaged or broken skin. Keep out of your eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops. Keep out of reach of children. Get medical help or contact a Poison Control Center right away if swallowed.

DMK

Danné Montague-King®

NUTRASCREE® COLOR BALANCED

NOURISHING DAY CREAM
WITH SPF 30

50 ml (1.7 fl oz)

Directions:

- apply generously 15 minutes before sun exposure.
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours

Inactive Ingredients: Water/Aqua/Eau, Dicaprylyl Carbonate, Cyclopentasiloxane, Polyhydroxystearic Acid, Polyglyceryl-4-Oleate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Cyclohexasiloxane, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Phenoxyethanol, Dimethicone/Vinyl Dimethicone Crosspolymer, Caprylic/Capric Triglyceride, Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer, Pentylene Glycol, Butylene Glycol, Isohexadecane, Hydrolyzed Rice Protein, Polysorbate 80, PEG-10 Dimethicone, Spiraea Ulmaria Extract, Ethylhexylglycerin, Galactoarabinan, Glycerin, Polysilicone-11, Polygonum Aviculare Extract, Alteromonas Ferment Extract, Potassium Sorbate, Sodium Benzoate. May Contain: Titanium Dioxide/CI 77891, Iron Oxide/CI 77492, Iron Oxide/CI 77491.

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Questions or comments? Call toll free 1-888-DANNE-4-U

Other Information Exclusive formula provides increased dermal hydration and improves the skin's overall appearance. Keep product from excessive heat and away from direct sun.

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- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures, including:
 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses.
 - children under six months of age. Ask a doctor.

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EU/UK Responsible Persons: MSL, BL9 5NB, UK
MSL, STE 5385, 27 UPPER
PEMBROKE ST, DUBLIN, IE

Made in USA
Danné Montague-King Co.
Los Angeles, CA 90670
www.dannemking.com
CPNP# 3821630



NUTRASCREEN COLOR BALANCED

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81537-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.24 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	5.56 g in 100 mL
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	0.78 g in 100 mL
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	0.05 g in 100 mL
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	0.4875 g in 100 mL
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	0.19 g in 100 mL
POLYGONUM AVICULARE WHOLE (UNII: M990N03611)	0.01 g in 100 mL
POLYGLYCERYL-4 OLEATE (UNII: 15B05TY4GX)	3.75 g in 100 mL
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	2 g in 100 mL
ALTEROMONAS MACLEODII POLYSACCHARIDES (UNII: AP6XG2GR8Z)	0.0025 g in 100 mL
FERRIC OXIDE RED (UNII: 1K09F3G675)	0.1463 g in 100 mL
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	0.325 g in 100 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.002 g in 100 mL
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	2.3 g in 100 mL
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	1.3 g in 100 mL
WATER (UNII: 059QF0KO0R)	37.8875 g in 100 mL
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	0.975 g in 100 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.002 g in 100 mL
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	9 g in 100 mL
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	4 g in 100 mL
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)	1.9 g in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	1.125 g in 100 mL
PENTYLENE GLYCOL (UNII: 50C1307PZG)	0.75 g in 100 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.67 g in 100 mL
ISOHEXADECANE (UNII: 918X1OUF1E)	0.65 g in 100 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.52 g in 100 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.125 g in 100 mL
GALACTOARABINAN (UNII: SL4SX1O487)	0.1037 g in 100 mL

GLYCERIN (UNII: PDC6A3C0OX)	0.111 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	3.4125 g in 100 mL

Product Characteristics

Color	brown (Opaque Orange-Brown Lotion)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81537-104-02	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/15/2022	

Labeler - DMK - Danne Montague King (624242264)

Registrant - DMK - Danne Montague King (624242264)

Establishment

Name	Address	ID/FEI	Business Operations
DMK - Danne Montague King		624242264	label(81537-104) , pack(81537-104)

Establishment

Name	Address	ID/FEI	Business Operations
Creative Essences, Inc.		079120182	manufacture(81537-104)

Revised: 10/2023

DMK - Danne Montague King