

BABY BARE REPUBLIC MINERAL SUNSCREEN- zinc oxide lotion

COOLA, 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.

Baby Bare Republic Mineral Sunscreen

Baby Bare Republic Mineral Sunscreen

OPEN END

210

200

190

180

170

160

150

140

130

120

110

100

90

80

70

60

50

40

30

20

10

6.0 mm

124.0 mm

1.0 mm

FREE OF CHEMICAL SUNSCREEN ACTIVES

PEDIATRICIAN TESTED

SPF 50

BABY BARE REPUBLIC

MINERAL Sunscreen Lotion

Non-Nano Zinc Oxide

Broad Spectrum SPF 50

Water Resistant (80 Minutes)

Preserves Baby's Natural Skin Balance

Good Clean Fun For All Life's Adventures

Protect baby's delicate skin state with our gentle, love-infused formula that's free of chemical sunscreen actives.

Our mild, soothing formula combines protective non-nano Zinc Oxide with moisturizing Squalene, which has been clinically shown to support and prevent disruption to baby's natural skin balance. Infused with Calendula, Olive, and Avocado Oils, it helps keep baby's skin soft, soothed, and shielded.

#GOBAREOUTSIDE

- Hypoallergenic • Pediatrician Tested
- No Parabens, Phthalates, Dyes, or Fragrances

Shake well!

Drug Facts	
Active Ingredients	Purpose
Zinc Oxide 12.0%	Sunscreen
Uses • helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun	
Warnings	
For external use only	
Do not use on damaged or broken skin	
When using this product keep out of eyes. Rinse with water to remove.	
Stop use and ask doctor if skin rash occurs	
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
• Shake well. Apply liberally 15 minutes before sun exposure	
• reapply: • after 80 minutes of swimming or sweating	
• immediately after towel drying • at least every 2 hours	
• 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 a broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses • children under 6 months: Ask a doctor	
Inactive Ingredients	
1,2-Hexanediol, Allantoin, Butyltolyl Salicylate, G12-15 Alkyl Benzoate, Calendula Officinalis Flower Extract, Caprylyl Glycol, Dimethylsiloxane/Propylsilsesquioxane/Silica Crosspolymer, Glyceryl Stearate Sebacate, Glyceryl Stearate, Isocetyl Stearate, Isopropyl Isodecylate, Lecithin, Nonyl Alcohol, Octyl Stearate, Olive Squalene (Olive) Oil, Purosa Gravitaria (Avocado) Oil, Polyester-7, Polyethylene Glycol, Polychloroethylene, Propylalcohol, Silica Silylate, Sodium Chloride, Squalene, Triethanolamine, Triethyl Citrate, Water	
Other Information	
• protect this product from excessive heat and direct sun	
Questions or comments?	
Call 760-940-2125	

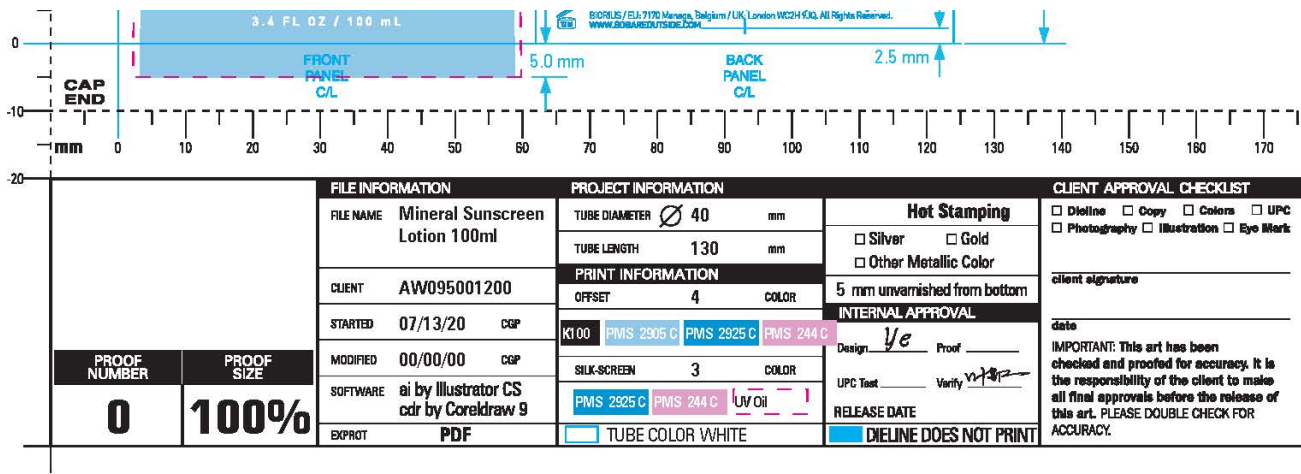
PARTIAL LARGE SIZE

V8

200%

130.0 mm

Made in USA with thoughtfully sourced global ingredients
 *Based on Reef Friendly Sunscreen Database & Certificate File
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BABY BARE REPUBLIC MINERAL SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SQUALANE (UNII: GW89575KF9)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
.ALPHA.-BISABOLOL, (-)-EPI- (UNII: 37VB7MC8L)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
ALLANTOIN (UNII: 344S277G0Z)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYESTER-7 (UNII: 0841698D2F)	
GLYCERYL BEHENATE/EICOSADIOATE (UNII: 73CJJ317SR)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISODECYL SALICYLATE (UNII: S7097PP4C)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T)	

1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-007-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	10/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/26/2020	

Labeler - COOLA, LLC (956990290)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(79753-007) , pack(79753-007)

Revised: 3/2023

COOLA, LLC