

**CREAM- zinc oxide cream**  
**MONAT GLOBAL CORP**

*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.*

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**BB Cream SPF 40 Broad-Spectrum Moisturizer (Sand)**

**Active Ingredient**

Zinc Oxide 18.8%

**Purpose**

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.

**For external use only**

**Do not use** on damage or broken skin

**When using this product** keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor** if rash occurs

**Keep out of reach of children.** If product is swallowed, get medical help or contact a poison control center right away.

**Directions**

**Directions**

- Apply liberally 15 minutes before sun exposure
- Apply to all skin exposed to the sun
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- **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 value of 15 or higher and other sun protection measures including:
    - limit time in the sun, especially from 10am-2pm
    - wear a long-sleeved shirt, pants, hat, and sunglasses

**Inactive Ingredients**

Water/Eau, Dodecane, Coco-Caprylate, Tricaprylin, Brassica Napus Extract, Coconut Alkanes, Simmondsia Chinensis (Jojoba) Seed Oil, Stearalkonium Bentonite, Polyglyceryl-3 Polyricinoleate, Oryza sativa (Rice) Bran Extract, Propanediol, Caprylic/Capric Triglyceride, Glyceryl Caprylate, Coco-caprylate/Caprinate, Polyglyceryl-3 Diisostearate,

Polyhydroxystearic Acid, Magnesium Sulfate, Dimethicone, Cocos Nucifera (Coconut) Oil, Citrus Limon (Lemon) Peel Oil, Citrus Aurantifolia (Lime) Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Tremella Fuciformis Sporocarp Extract, Camellia Sinensis Leaf Extract, Linoleic Acid, Lecithin, Limnanthes Alba (Meadowfoam) Seed Oil, Crambe Abyssinica Seed Oil, Camellia Oleifera Seed Oil, Solanum Lycopersicum (Tomato) Seed Oil, Daucus Carota Sativa (Carrot) Seed Oil, Phytosteryl Canola Glycerides, Oleic Acid, Palmitic Acid, Stearic Acid, Triolein, Tocopherol, Adansonia Digitata Oil, Mauritia Flexuosa Fruit Oil, Gardenia Taitensis Flower Extract, Moringa Oleifera Seed Oil, Caryocar Brasiliense Fruit Oil, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Simmondsia Chinensis (Jojoba) Seed Extract, Triheptanoin, C9-12 Alkane, Dilinoleic Acid/Butanediol Copolymer, Castor Oil/IPDI Copolymer, Tocopherol Acetate, Ulva Lactuca Extract, Jojoba Esters, Polyglyceryl-6 Polyricinoleate, Silica, Triethyl Citrate, Glycerin, Betain, Glyceryl Undecylenate, Potassium Sorbate, Sodium Benzoate, Bentonite, May Contain: Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499).

### Other information

- Protect the product in this container from excessive heat and direct sun.

### Primary (Tube)

#### Tube-Primary

Printed Date: \_\_\_\_\_

**DO NOT SCALE DRAWING**

ART HISTORY AND NOTES

CREATED: 11/24/2021  
 LAST REVISED BY: 11/24/2021 NT: Created File  
 12/02/2021 NT: Copy edits  
 12/06/2021 NT: New design  
 12/10/2021 NT: Fill wt. & SPF 40  
 12/22/2021 NT: Broad-Spectrum  
 01/13/2022 NT: Broad-Spectrum moved to description  
 02/02/2022 NT: Moved window, How to use, Spectrum, warning  
 02/25/2022 NT: Rose gold finish, zipcode  
 03/08/2022 NT: Use and update Directions  
 03/10/2022 NT: Directions

MONAT GLOBAL CORP., DIST

ITEM NUMBER: MONAT US  
 XXXX BB CREAM SPF 40™  
 Tinted Moisturizer  
 35 ml e 1.18 fl. oz.

COLOR REQUIREMENTS:

- Rose Gold Hot Stamp
- Matte finish
- PANTONE Black 6 U

Tube Color: Natural

Print Process: 1C Offset Printing

- PANTONE Black 6 U

Print Process: 1C Silk Screen Printing

- Matte Varnish

Print Process: 1C Hot Stamping Printing

- Rose Gold Hot Stamp

Coating: Glossy

- Glossy Varnish

PO#: P2778

Name: \_\_\_\_\_

Code: \_\_\_\_\_

Spec: D25x108mm

03/17/2022

COLOR	1	2	3	4	5	6
PMS						

**wwp beauty** 15 Vreeland Rd. Ste. #4 Florham Park, NJ 07932

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS

LINEAR: .X = ±0.20 .XX = ±0.10

ANGULAR: ±0°30'

EST. Volume (cc/cm): \_\_\_\_\_

Part Name: 25mm Cap and Tube

Supplier: WWP Suzhou

Material: \_\_\_\_\_

Date: 03/17/22

SHT. A-4

Dwg. No. 397 - 25x108

Rev. \_\_\_\_\_

Project No.: 397

Status: Production

Part Code: \_\_\_\_\_

SHEET 1 OF 1

### Outer-Carton



# CREAM

zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78518-008
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	18.8 mg in 100 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CITRUS AURANTIIFOLIA FRUIT OIL</b> (UNII: 7937R189CB)	
<b>LINOLEIC ACID</b> (UNII: 9KJL21T0QJ)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>LIMNANTHES ALBA WHOLE</b> (UNII: DKY81513ER)	
<b>CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL</b> (UNII: 0QW9S92J3K)	
<b>GLYCERYL CAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DODECANE</b> (UNII: 11A386X1QH)	
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>COCOS NUCIFERA WHOLE</b> (UNII: 245J88W96L)	
<b>CITRUS LIMON SEED OIL</b> (UNII: T78Z8273XO)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS)</b> (UNII: CH428W5O62)	
<b>COCO-CAPRYLATE</b> (UNII: 4828G836N6)	
<b>DILINOLEIC ACID/BUTANEDIOL COPOLYMER</b> (UNII: 1F2S8T535O)	
<b>ULVA LACTUCA</b> (UNII: PHR3P25W6Y)	
<b>POLYGLYCERYL-6 POLYRICINOLEATE</b> (UNII: YPM0ZOC2HR)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	0.111 mg in 100 mg
<b>CITRUS AURANTIUM FRUIT OIL</b> (UNII: 59JDQ5VT0T)	
<b>TREMELLA FUCIFORMIS WHOLE</b> (UNII: 4938BNS0GU)	
<b>CAMELLIA SINENSIS WHOLE</b> (UNII: C5M4585ZBZ)	
<b>OLEIC ACID</b> (UNII: 2UMI9U37CP)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>GLYCERYL TRIOLEATE</b> (UNII: O05EC62663)	
<b>PHYTOSTERYL MACADAMIATE</b> (UNII: 233VSF903M)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>CARYOCAR BRASILIENSE FRUIT OIL</b> (UNII: WDI9AGC94F)	
<b>TRHEPTANOIN</b> (UNII: 2P6O7CFW5K)	
<b>SOLANUM LYCOPERSICUM</b> (UNII: 0243Q4990L)	
<b>DAUCUS CAROTA SUBSP. SATIVUS SEED</b> (UNII: 9M6AAX381U)	
<b>MAURITIA FLEXUOSA FRUIT OIL</b> (UNII: 48H19MS04L)	
<b>MORINGA OLEIFERA SEED OIL</b> (UNII: REM6A5QMC0)	

<b>HELIANTHUS ANNUUS WHOLE</b> (UNII: 17S27ZT6KR)
<b>OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES</b> (UNII: XO45V955LT)
<b>BRASSICA NAPUS WHOLE</b> (UNII: NFP6814VZ4)
<b>COCONUT ALKANES</b> (UNII: 1E5KJY107T)
<b>POLYGLYCERYL-5 POLYRICINOLEATE</b> (UNII: FT3MR7CR64)
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>SIMMONDSIA CHINENSIS SEED</b> (UNII: D24K2Q1F6H)
<b>ORYZA SATIVA WHOLE</b> (UNII: 84IVV0906Z)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>CAMELLIA OLEIFERA SEED</b> (UNII: 59ED29FM2J)
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)
<b>ADANSONIA DIGITATA SEED OIL</b> (UNII: 77MKL7AR5I)
<b>GARDENIA TAITENSIS FLOWER</b> (UNII: T0OCU8201Y)
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>GLYCERYL 1-UNDECYLENATE</b> (UNII: B68LJT9544)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>BENTONITE</b> (UNII: A3N5ZCN45C)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)
<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)
<b>BETAINE</b> (UNII: 3SCV180C9W)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>TRICAPRYLIN</b> (UNII: 6P92858988)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78518-008-01	1 in 1 CARTON	09/12/2022	
1		35 mg in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/12/2022	

**Labeler** - MONAT GLOBAL CORP (027036949)

**Establishment**

Name	Address	ID/FEI	Business Operations
OXYGEN DEVELOPMENT, LLC		137098492	manufacture(78518-008)

Revised: 8/2023

MONAT GLOBAL CORP