

**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 (Nude)**

**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/Caprates, 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 Package (Tube)

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 edit  
12/04/2021 NT: New die line  
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: Revised artwork, How to use, Spectrum, warning  
02/25/2022 NT: Rose gold finish, stripes  
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						

**wpp beauty**

15 Vreeland Rd. Ste. #4  
Raritan Park, NJ 07922

UNLESS OTHERWISE SPECIFIED:  
DIMENSIONS ARE IN MILLIMETERS

LINEAR: .X = ±0.20  
.XX = ±0.10

ANGULAR: ±0° 30'

Vol. Volume (cc/cm)  
Part Name: 25mm Cap and Tube  
Supplier: WWP Suzhou

Mat. Weight (grams)  
Drawn By: \_\_\_\_\_  
Part Name: DECO 25x108

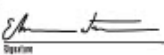

Date: 03/17/22  
SHT. A-4  
Dwg. No. 397 - 25x108  
Rev. \_\_\_\_\_  
Project No.: 397  
Status: Production

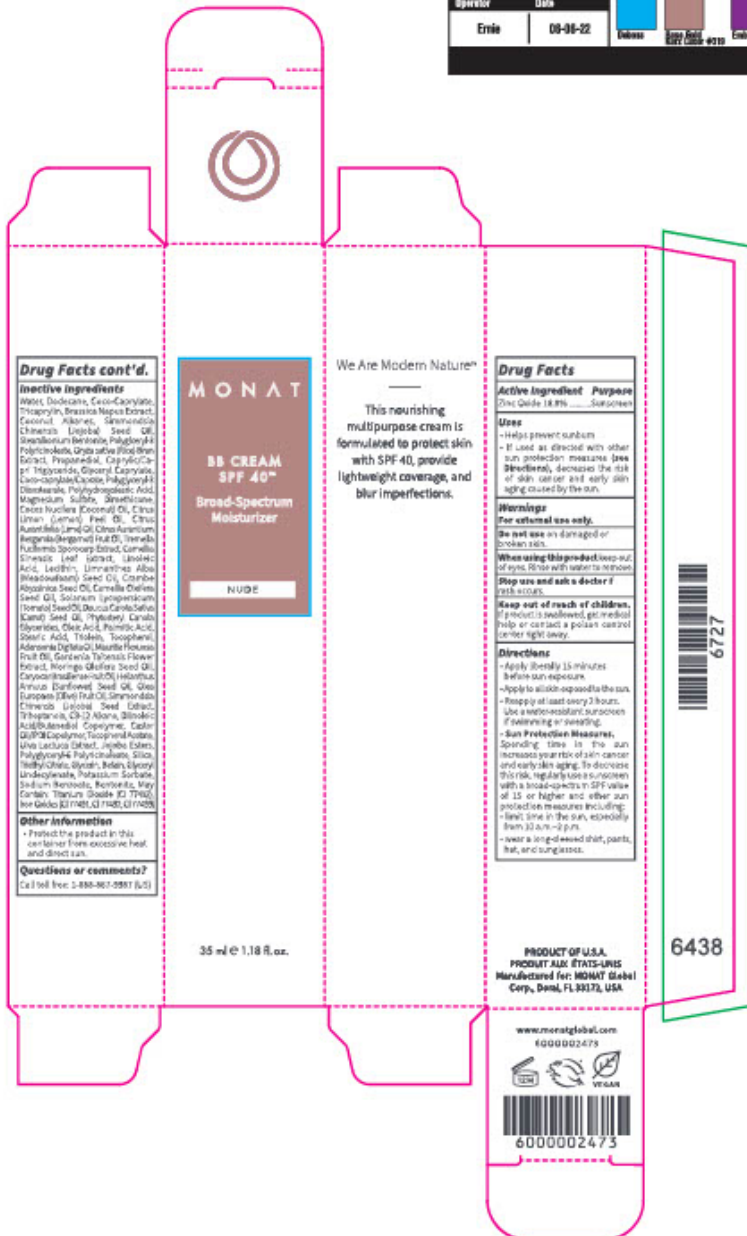
THIS DRAWING IS THE SOLE PROPERTY OF "World Wide Packaging LLC" AND CAN NOT BE REPRODUCED OR SUBMITTED TO A THIRD PARTY WITHOUT OUR CONSENT

Part Code: \_\_\_\_\_  
SHEET 1 OF 1

### Outer Package(Carton)

Carton

Customer		Process Colors			
<b>Need</b>					
<b>Project Name / Description</b>				This Print is Color Accurate For: <input checked="" type="checkbox"/> Color Proof <input checked="" type="checkbox"/> Process Color	<b>Form Index / SID</b>
<b>US - Rate</b>		<b>Spot Colors</b>		<input type="checkbox"/> Revised proof with indicated changes required. <i>Star vehicle will require a new signed proof</i>	<b>6727</b>
<b>Dimensions</b>		<b>Stock #</b>		<b>APPROVED FOR COPY</b>	
1.1343 x 1.1343 x 5.375		<b>Foil, Emboss, Spot UV, Varnish</b>		<b>DIGITALLY APPROVED FOR COPY</b>	
<b>Specialty</b>	<b>Date</b>				<b>06/13/2022</b>
<b>Erie</b>	<b>06-06-22</b>			<b>Printed</b>	<b>Site</b>
					<b>Customer Digital Signature</b>



zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78518-006
<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: 834K0W0S5G)	
<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: 059QF0K00R)	
<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: R0ZB2556P8)	
<b>CARYOCAR BRASILIENSE FRUIT OIL</b> (UNII: WDI9AGC94F)	
<b>TRiheptanoIn</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:78518-006-01	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
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OXYGEN DEVELOPMENT, LLC

137098492

manufacture(78518-006)

Revised: 8/2023

MONAT GLOBAL CORP