

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.

BB Cream SPF 40 Broad-Spectrum Moisturizer (Porcelain)

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,

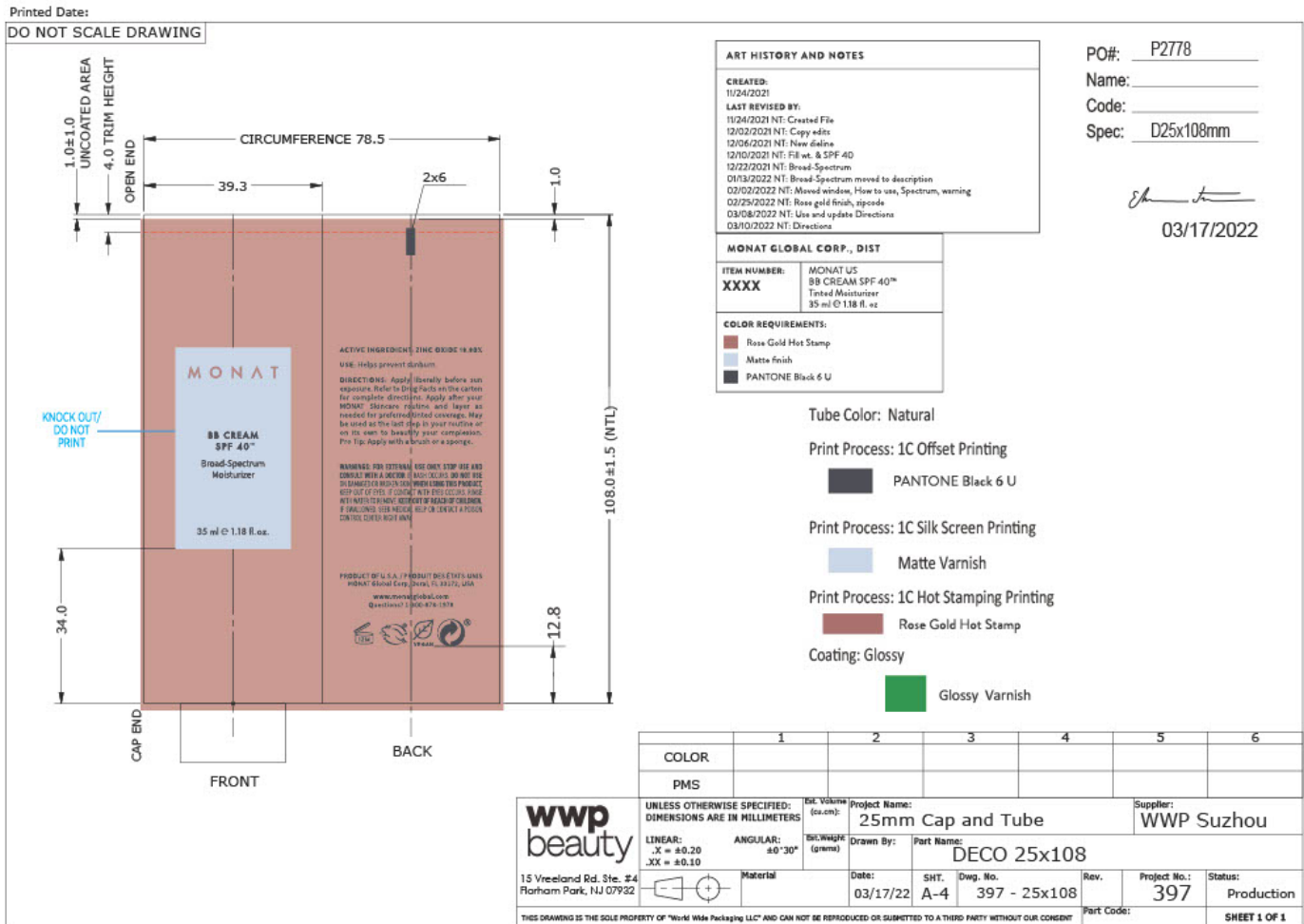
Polyhydroxystearic Acid, Magnesium Sulfate, Dimethicone, Cocos Nucifera (Coconut) Oil, Citrus Limon (Lemon) Peel Oil, Citrus Aurantifolia (Lime) Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Tremella Fuciformis Sporocarp Extract, Camellia Sinensis Leaf Extract, Linoleic Acid, Lecithin, Limnanthes 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.

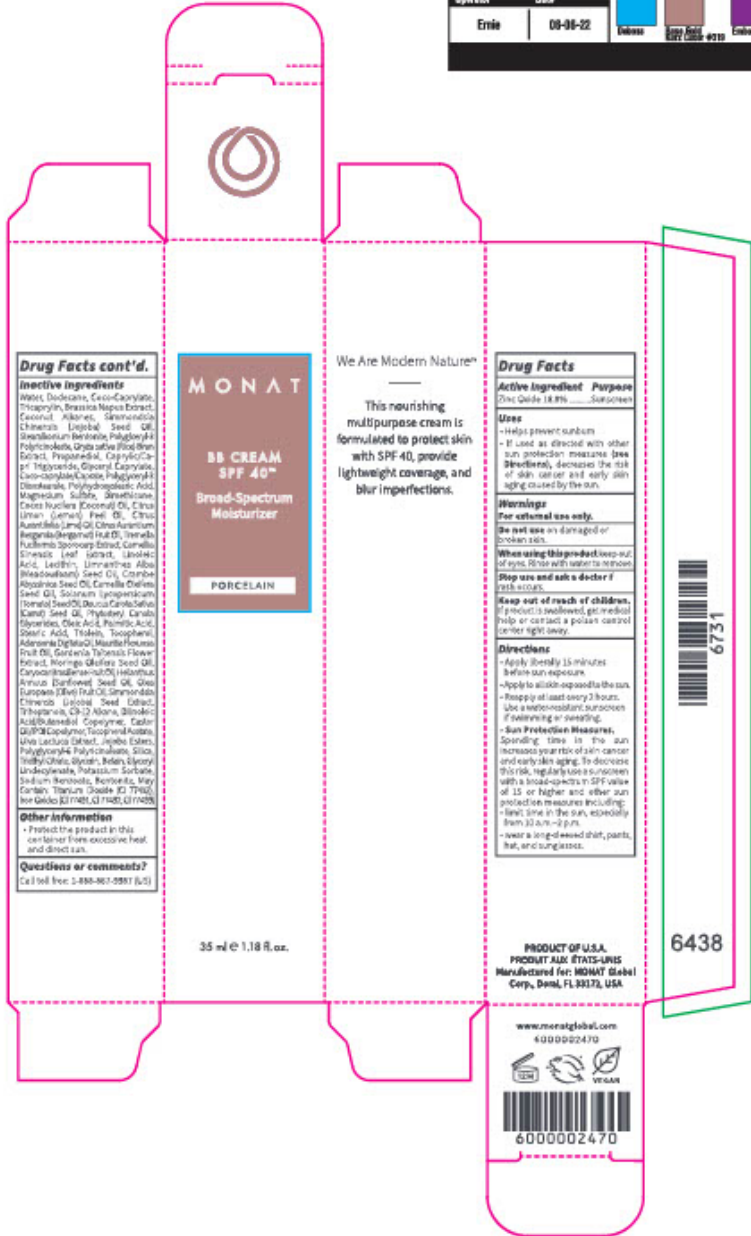
Primary Package(Tube)

Tube



Outer Package(Carton)

Customer	Process Colors		
Need		This Product Order Accrues For: <input checked="" type="checkbox"/> Order Breaks <input checked="" type="checkbox"/> Process Color <input type="checkbox"/> Reduced price with indicated changes required. *See website for complete order approval process.	Form Index / SCD
Project Name / Description			6701
US - Porcelain	Spot Colors	APPROVED FOR COPY	DIGITALLY APPROVED FOR COPY
Dimensions	Stock #		
1.1343 x 1.1343 x 5.375	Full, Emboss, Spot UV, Varnish		
Operator	Date	 06/13/2022 Title	Customer Digital Signature
Ernie	06-06-22		
			



Carton- Outer Package

CREAM

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78518-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78518-007-01	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(78518-007)

Revised: 8/2023

MONAT GLOBAL CORP