

CREAM- zinc oxide cream
Oxygen Development 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.

MONAT BB CREAM SPF 40 Broad-Spectrum Moisturizer

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

Warnings

For external use only

Do not use

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 a doctor

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

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 the 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 10 a.m. - 2 p.m.

wear a long-sleeved shirt, pants, hat, and sunglasses

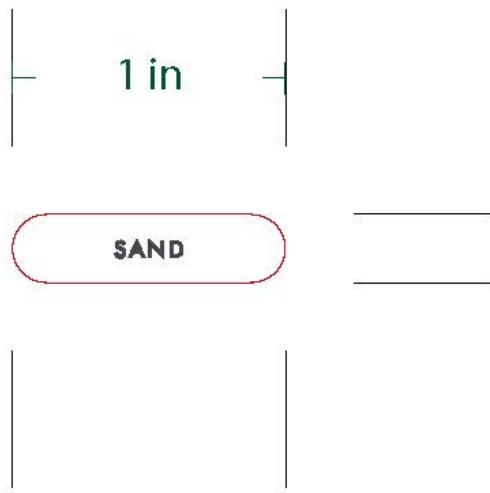
Inactive Ingredient

Water, 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, Camelia Sinensis Leaf Extract, Linoleic Acid, Lecithin, Limnanther Alba (Meadowfoam) Seed Oil, Crambe Abyssinica Seed Oil, Camelia 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, Maurita Flexuosa Fruit Oil, Gardenia Taitensis Flower Extract, Moringa Oleifera Seed Oil, Caryocar Brasiliense Fruit Oil, Helianthus Annuus (Sunflower) Seed Oil, Olea Europea (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 77492), Iron Oxides (CI 77491, CI 77492, CI 77499)

Other Information

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

0.25 in



ART HISTORY AND NOTES

CREATED:
06/15/2022
LAST REVISED BY:
06/15/2022 NT: Created File













MONAT GLOBAL CORP., DIST

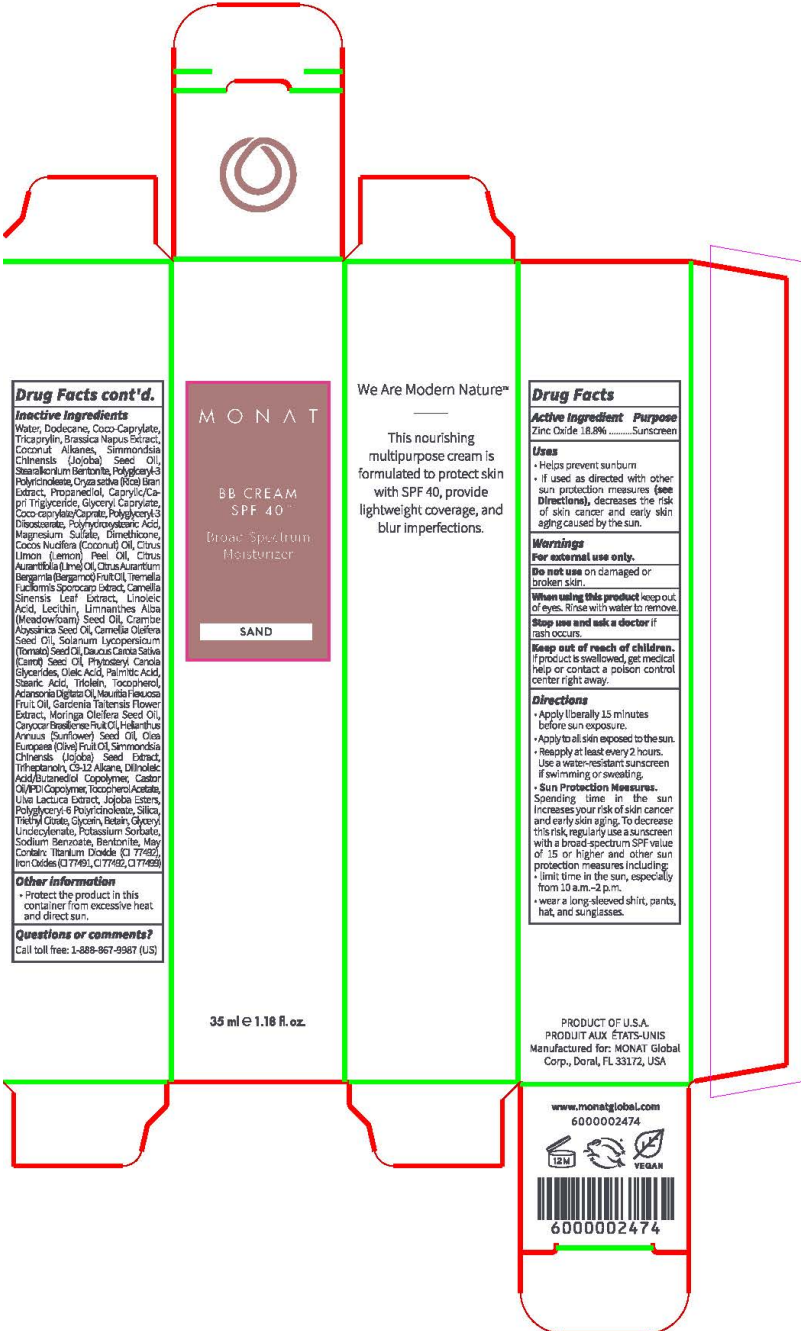
BB CREAM
SHADE LABEL
Sand

COLOR REQUIREMENTS:
■ PANTONE Black 6 U

SAND

ART HISTORY AND NOTES
<p>CREATED: 04/29/2022</p> <p>LAST REVISED BY: 04/29/2022 NT: Created File 05/06/2022 NT: Copy edits 05/11/2022 NT: Copy edits from new brief 05/12/2022 NT: Copy edits 05/20/2022 NT: Shade and barcode on each carton 05/25/2022 NT: Remove Shade color 06/02/2022 NT: Thickness of name 06/03/2022 NT: Font thickness/sizes on front panel</p>

MONAT GLOBAL CORP., DIST					
<p>ITEM NUMBER: 600002474</p>	<p>US. CARTON BB CREAM SPF 40™ Tinted Moisturizer 35 ml e 1.18 fl. oz</p>				
<p>COLOR REQUIREMENTS:</p> <table border="0"> <tr> <td> PANTONE Black 6 U</td> <td> Bevel/Deboss</td> </tr> <tr> <td> Rose Gold Hot Stamp</td> <td> Embossing</td> </tr> </table>		 PANTONE Black 6 U	 Bevel/Deboss	 Rose Gold Hot Stamp	 Embossing
 PANTONE Black 6 U	 Bevel/Deboss				
 Rose Gold Hot Stamp	 Embossing				



Drug Facts cont'd.

Inactive Ingredients

Water, Dodecane, Coco-Caprylate, Tricaprylin, Brassica Napus Extract, Coconut Allene, Simmondsia Chinensis (Jojoba) Seed Oil, Stearalkonium Bentonite, Polyglyceryl-3 Polyricinoleate, Crysaline (Rice) Stem Extract, Propenediol, Caprylic/Capric Triglyceride, Glycerin Caprylate, Coco-caprylate/Caprate, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Magnesium Sulfate, Dimethicone, Cocos Nucifera (Coconut) Oil, Citrus Limon (Lemon) Peel Oil, Citrus Aurantiobloa (Lime) Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Terminalia Fuldum's Sporocarp Extract, Camellia Sinensis Leaf Extract, Linoleic Acid, Lecithin, Limnanthes Alba (Meadowfoam) Seed Oil, Camboe Abyssinica Seed Oil, Camellia Oleifera Seed Oil, Solanum Lycopersicum (Tomato) Seed Oil, Daucus Carota Sativa (Carrot) Seed Oil, Phytosecy Carota Glycosides, Oleic Acid, Palmitic Acid, Stearic Acid, Trifolium Tocopherol, Acarozona Diglucosyl, Neulitia Heulocosa Fruit Oil, Garcinia Tallensis Flower Extract, Moringa Oleifera Seed Oil, Canyaca Brasiliensis Fruit Oil, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Simmondsia Chinensis (Jojoba) Seed Extract, Trifolium, C5-12 Alkane, Dihydrolic Acid/Buzanedol Copolymer, Cadzor OI/PI Copolymer, Tocopherol Acetate, Uvae Ursaria Extract, Jojoba Esters, Polyglyceryl-6 Polyricinoleate, Silica, Triethyl Citrate, Glycerin, Betaine, Glycerol Undecylate, Potassium Sorbate, Sodium Benzoate, Bentonite, May Contain: Barium Dioxide (CI 77067), Iron Oxides (CI 77491, CI 77492, CI 77499)

Other information

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

Questions or comments?

Call toll free: 1-888-967-9967 (US)

MONAT

BB CREAM
SPF 40™

Broad Spectrum
Moisturizer

SAND

We Are Modern Nature™

—

This nourishing
multipurpose cream is
formulated to protect skin
with SPF 40, provide
lightweight coverage, and
blur imperfections.

Drug Facts

Active ingredient Purpose

Zinc Oxide 1.8.9% _____ 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 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

• 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 10 a.m.–2 p.m.,
• wear a long-sleeved shirt, pants, hat, and sunglasses.

PRODUCT OF U.S.A.
PRODUIT AUX ETATS-UNIS
Manufactured for: MONAT Global Corp., Doral, FL 33172, USA

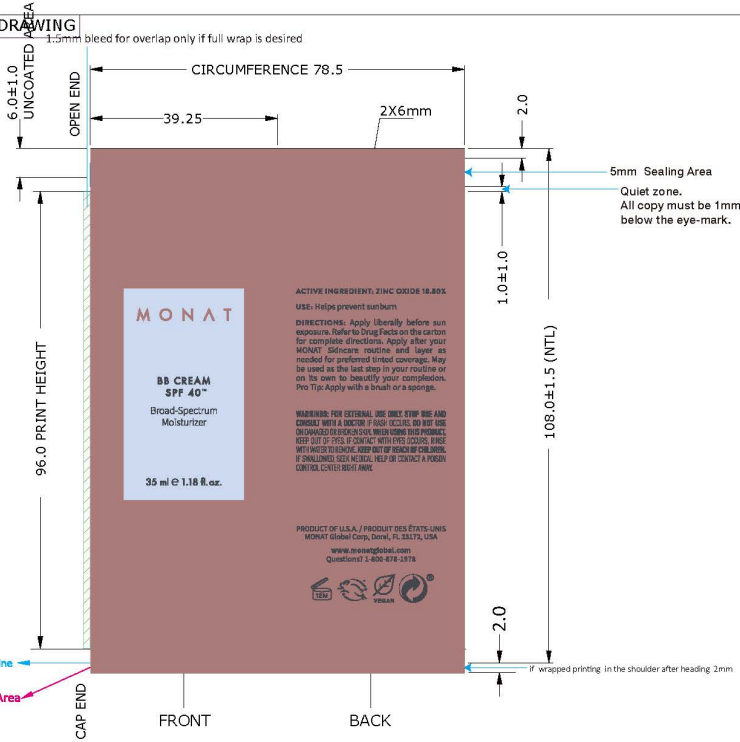
www.monatglobal.com
600002474



35 ml e 1.18 fl. oz.

Printed Date:

DO NOT SCALE DRAWING



PO#: _____
 Name: _____
 Code: _____
 Spec: D25x108mm

ART HISTORY AND NOTES	
CREATED:	11/24/2021
LAST REVISED BY:	11/24/2021 NT: Created File
	12/02/2021 NT: Copy edit
	12/06/2021 NT: New dieline
	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
	03/10/2022 NT: Use end 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

	1	2	3	4	5	6
COLOR						
PMS						

<p>15 Vreeland Rd. Ste. #4 Florham Park, NJ 07932</p>	<p>UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS TOLERANCES: PRECISION:</p> <p>LINEAR: ±0.15 X = ±0.1 ANGULAR: ±0°30' XX = ±0.05</p>	<p>Est. Volume (cc/in) Test Weight (grams)</p>	<p>Project Name: 25mm Cap and Tube</p> <p>Supplier: WWP Suzhou</p>
	<p>Material</p>	<p>Drawn By: A-4</p> <p>Date: 12/03/21</p>	<p>Part Name: DECO 25x108</p> <p>SHT. Dwg. No. D25x108</p>
<p>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</p>			<p>Part Code:</p> <p>SHEET 1 OF 1</p>

CREAM

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-111
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
TRICAPRYLIN (UNII: 6P92858988)	7 mg in 100 mg
JOJOBA OIL (UNII: 724GKU717M)	2.73 mg in 100 mg
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	2.04 mg in 100 mg
RICE BRAN (UNII: R60QEP13IC)	2 mg in 100 mg
COCO-CAPRYLATE (UNII: 4828G836N6)	1.99 mg in 100 mg
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	1.04 mg in 100 mg

DIMETHICONE (UNII: 92RU3N3Y1O)	1 mg in 100 mg
TRHEPTANOIN (UNII: 2P6O7CFW5K)	0.91 mg in 100 mg
WATER (UNII: 059QF0KO0R)	27.96 mg in 100 mg
STEARALKONIUM ION (UNII: UMO7T7E1XN)	2.6 mg in 100 mg
BENTONITE (UNII: A3N5ZCN45C)	0.93 mg in 100 mg
DODECANE (UNII: 11A386X1QH)	11.96 mg in 100 mg
BRASSICA NAPUS WHOLE (UNII: NFP6814VZ4)	3.5 mg in 100 mg
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	1.33 mg in 100 mg
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	1 mg in 100 mg
PROPANEDIOL (UNII: 5965N8W85T)	2 mg in 100 mg
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	1.2 mg in 100 mg
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	1.5 mg in 100 mg
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	1.32 mg in 100 mg
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	0.52 mg in 100 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	2.39 mg in 100 mg
FERRIC OXIDE RED (UNII: 1K09F3G675)	1.18 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-111-01	1 in 1 CARTON	07/06/2023	
1		100 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	07/06/2023	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-111)

Revised: 7/2023

Oxygen Development LLC