

SEI BELLA ADVANCED REVITAL R3 AGE DEFYING CREME- avobenzene, homosalate, octisalate, octocrylene, oxybenzone cream
Melaleuca, Inc.

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.

Sei Bella Advanced Revital R3 Age-Defying Creme - SPF 25 - Normal to Dry

Active ingredients

Avobenzene 1.8%, Homosalate 6%, Octisalate 3%, Octocrylene 1.86%, Oxybenzone 1.8%

Purpose

Sunscreen

Use

- provides moderate protection against sunburn

Warnings

For external use only

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash or irritation develops and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

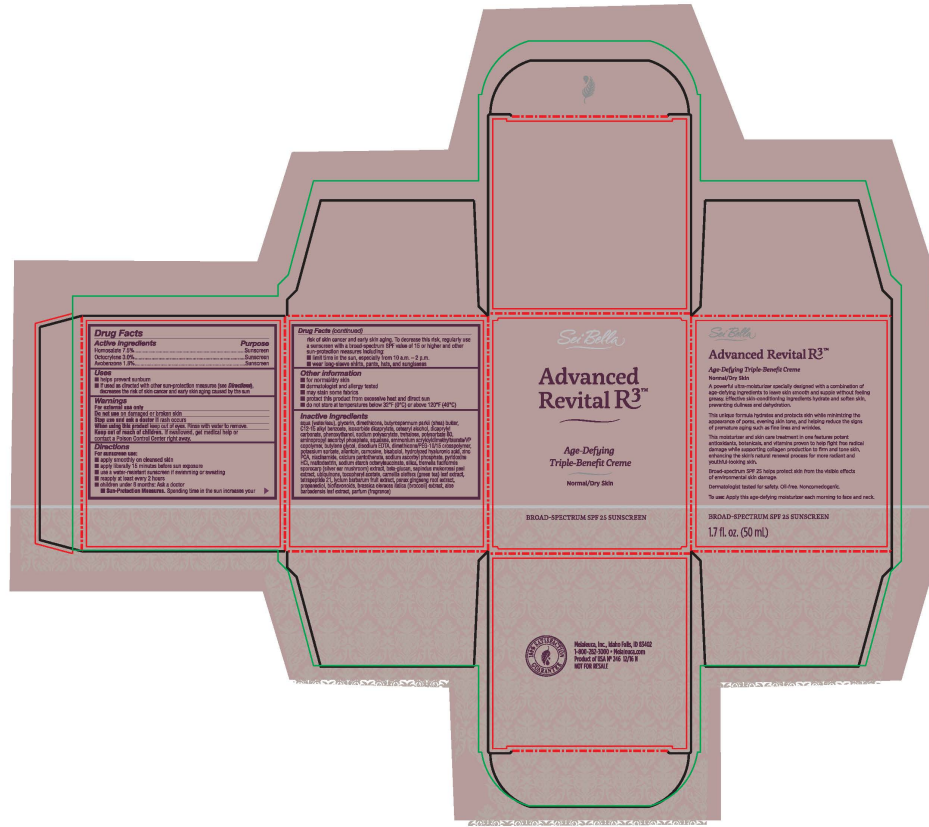
- apply smoothly on cleansed skin before sun exposure and as needed
- children under 6 months of age: ask a doctor

Other information

- dermatologist and allergy tested
- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun
- may stain some fabrics
- do not store at temperatures below 32°F (0°C) or above 120°F (49°C)

Inactive ingredients

aqua (water/eau), polyacrylate-15, polyacrylate-17, glycerin, cetyl palmitate, C20-22 alkyl phosphate, C20-22 alcohols, butyrospermum parkii (shea butter), C12-15 alkyl benzoate, trisloxane, dimethicone, cyclopentasiloxane, dimethicone crosspolymer, C14-22 alcohols, C12-20 alkyl glucoside, propylheptyl caprylate, caprylic/capric triglycerides, acetyl tetrapeptide-9, phenoxyethanol, cetyl alcohol, xanthan gum, triethanolamine, sodium polyacrylate, potassium sorbate, trisodium ethylenediamine disuccinate, parfum, bisabolol, panax ginseng root extract, camellia oleifera leaf extract, lycium barbarum fruit extract, aloe barbadensis leaf juice, ginkgo biloba leaf extract, butylene glycol, allantoin, tocopheryl acetate, linalool, hexyl cinnamal, benzyl salicylate, alpha isomethyl ionone



1. File name and Revision Date:	Age Defying Triple Benefit Creme Box 1216.ai
2. Part Number:	102000246
3. Color: Process, PMS (up to 8):	Metallic Pantone 525 and white
4. Label size:	10 x 11.406
5. Format:	Illustrator CC
6. Artwork contact. Name & Phone #:	Vanessa Rormell 208-535-2336
7. Last revised date:	13 December 2016

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-276
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.9 g in 50 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	3 g in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.93 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
PYRIDO XINE HYDRO CHLORIDE (UNII: 68 Y4CF58BV)	
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRAPEPTIDE-21 (UNII: 179JUC43HU)	
POLYSACCHARIDE-K (UNII: 3X48A86C8K)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
UBIDECARENONE (UNII: EJ27X76M46)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
TREHALOSE (UNII: B8WCK70T7I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOPROPYL ASCORBYL PHOSPHATE (UNII: 290O2PQ83R)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
SQUALANE (UNII: GW89575KF9)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
SHEA BUTTER (UNII: K49155WL9Y)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALLANTOIN (UNII: 344S277G0Z)	
CARNOSINE (UNII: 8HO6PVN24W)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
WATER (UNII: 059QF0KO0R)	
HYALURONIC ACID (UNII: S270N0TRQY)	
OCTENYLSUCCINIC ACID (UNII: 12UZE4X73L)	
ISOSORBIDE DICAPRYLATE (UNII: 0IK29C4889)	
SAPINDUS MUKOROSSIFRUIT RIND (UNII: 3D1P12PN9U)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
BROCCOLISPROUT (UNII: 128UH9LOAE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:54473-276-01	1 in 1 BOX	01/01/2018	
1	NDC:54473-276-50	50 mL in 1 JAR; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part352		01/01/2018	

Labeler - Melaleuca, Inc. (139760102)

Establishment			
Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		079711683	manufacture(54473-276)

Revised: 3/2020

Melaleuca, Inc.