

ADVANCED REVITAL- avobenzene, homosalate, octocrylene lotion
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 Lotion SPF 25 Normal to Oily

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

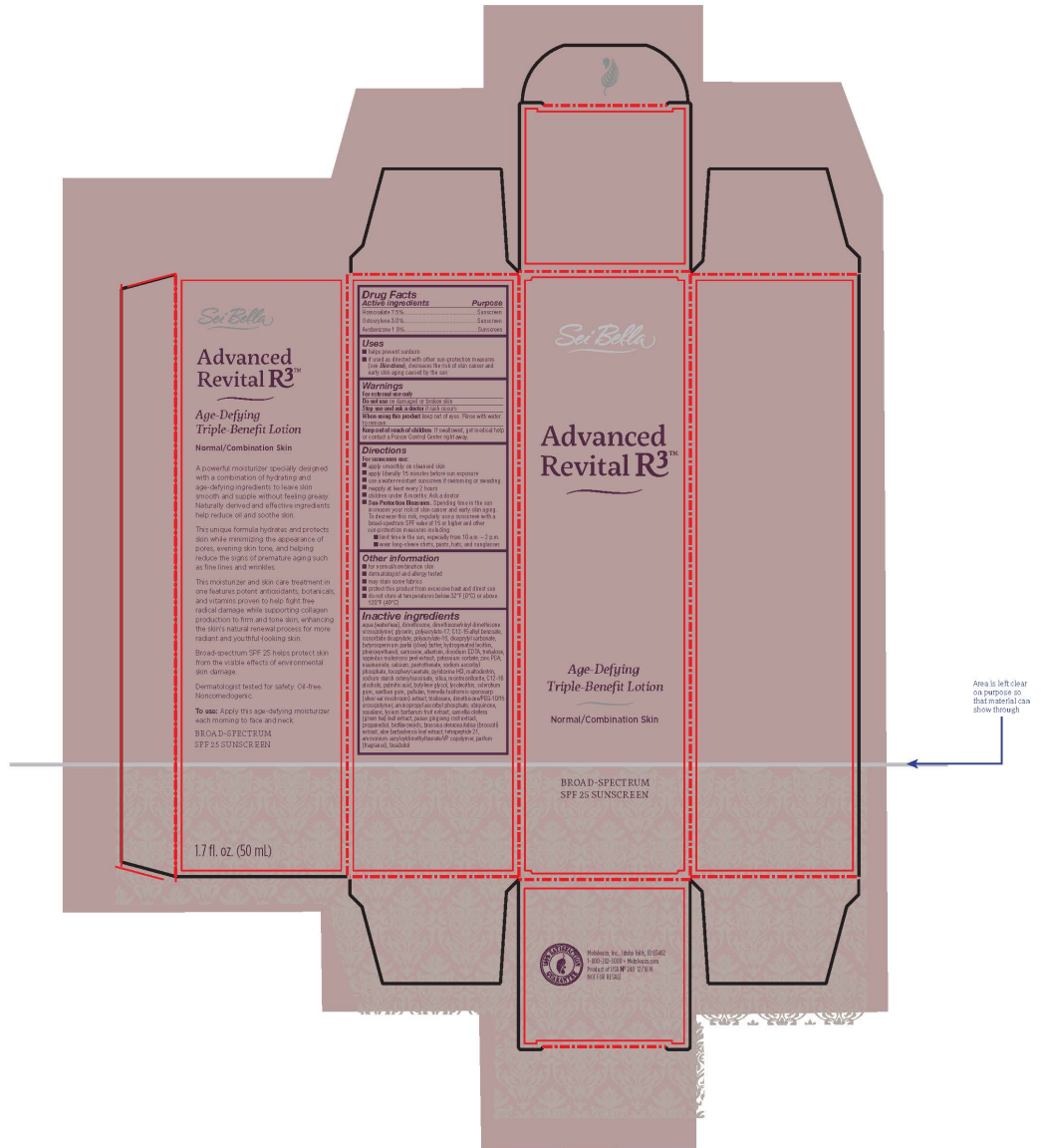
- apply smoothly on cleansed skin before sun exposure and as needed
- children under six months of age: ask a doctor

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, C20-22 alkyl phosphate, C20-22 alcohols, trisiloxane, dimethicone, cyclopentasiloxane, dimethicone crosspolymer, cetyl palmitate, glycerin, butyrospermum parkii (shea butter), C12-15 alkyl benzoate, dicaprylyl carbonate, C14-22 alcohols, C12-20 alkyl glucoside, propylheptyl caprylate, acetyl tetrapeptide-9, phenoxyethanol, cetyl alcohol, caprylyl glycol, 1,2 hexanediol, triethanolamine, xanthan gum, trisodium ethylenediamine disuccinate, parfum, bisabolol, panax ginseng root extract, lycium barbarum fruit extract, aloe barbadensis leaf juice, camellia oleifera leaf extract, butylene glycol, allantoin, tocopheryl acetate, limonene, butylphenyl methylpropional



Melaleuca
The Wellness Company

- File name and Revision Date: Age Defying Triple Benefit Lotion 1216.ai
- Part Number: 102000248
- Color; Process, PMS (up to 5): Metallic Pantone 5125 and white
- Label size: 10.97x 7.656
- Format: Illustrator CC
- Artwork contact, Name & Phone #: Vanessa Romell 208-535-2336
- Last revised date: 13 December 2016

Sei Bella Pink/Visual 18pt brushed aluminum UV Dull Varnish 7/14/2016	PANTONE 5115 C
Sei Bella Pink/Visual 18pt brushed aluminum UV Gloss Varnish 11/17/2016	
Emboss Silver Hot Foil Stamp	
Silver Hot Foil Stamp	

DIE LINE	Flood coat of 5115 C on the inside of the box
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-277
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNOSINE (UNII: 8HO6PVN24W)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
SAPINDUS MUKOROSSIFRUIT RIND (UNII: 3D1P12PN9U)	
NIACINAMIDE (UNII: 25X51I8RD4)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
UBIDECARENONE (UNII: EJ27X76M46)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LEVOMENOL (UNII: 24WE03BX2T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
TETRAPEPTIDE-21 (UNII: 179JUC43HU)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ISOSORBIDE DICAPRYLATE (UNII: 0IK29C4889)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
AMINOPROPYL ASCORBYL PHOSPHATE (UNII: 290O2PQ83R)	
C12-16 ALCOHOLS (UNII: S4827SZE3L)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TREHALOSE (UNII: B8WCK70T7I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
SQUALANE (UNII: GW89575KF9)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
SHEA BUTTER (UNII: K49155WL9Y)
TRISILOXANE (UNII: 9G1ZW13R0G)
MALTO DEXTRIN (UNII: 7CVR7L4A2D)
PROPANEDIOL (UNII: 5965N8W85T)
WATER (UNII: 059QF0KO0R)
XANTHAN GUM (UNII: TTV12P4NEE)
PULLULAN (UNII: 8ZQ0AYU1TT)
MONTMORILLONITE (UNII: A585MN1H2L)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)
BROCCOLI SPROUT (UNII: 128UH9LOAE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-277-01	1 in 1 BOX	01/01/2018	
1		50 mL in 1 BOTTLE; 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	05/01/2017	

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		079711683	manufacture(54473-277)