

BALI BODY TINTED SUPER SERUM TAN SPF 30- octisalate, octocrylene, titanium dioxide, zinc oxide lotion

BALI BODY TINTED SUPER SERUM NATURAL SPF 30- octisalate, octocrylene, titanium dioxide, zinc oxide lotion

Bali Body Pty Ltd

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.

Bali Body Tinted Super Serum SPF 30

Drug Facts

Active ingredients:- Natural Shade

Octisalate 3.1%

Octocrylene 8.1%

Titanium Dioxide 3.2%

Zinc Oxide 5.9%

Active ingredients - Tan Shade

Octisalate 4.9%

Octocrylene 7.8%

Titanium Dioxide 3.1%

Zinc Oxide 5.6%

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 ageing 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.

Please refer to balibodyco.com for further sun safety instructions.

Directions

- Apply liberally 15 mins before sun exposure.
- Shake well to activate.
- Apply 2-3 drops onto your fingertips & blend evenly all over the face & neck.
- 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 ageing. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10am - 2pm
- Wear long sleeve shirts, pants, hats and sunglasses
- Children under 6 months: Ask a doctor.

Inactive ingredients - Natural Shade

Caprylyl Methicone, Water (Aqua), C12-15 Alkyl Benzoate, Lauryl PEG/PPG-18/18 Methicone, Dimethicone, Caprylic/Capric Triglyceride, Pentylene Glycol, Cyclopentasiloxane, Methyl Methacrylate Crosspolymer, Dimethiconol, Sodium Chloride, Polyhydroxystearic Acid, Jojoba Esters, Silica, Mica, Polyglyceryl-3 Beeswax, Triethoxycaprylylsilane, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, PEG/PPG-18/18 Dimethicone, Sodium Stearoyl Glutamate, Citrus Aurantium Dulcis (Orange) Peel Oil, Boswellia Carterii Oil, Hydrogen Dimethicone, Tin Oxide, Limonene, Caprylyl Glycol, Glycerin, Hyaluronic Acid, Phenoxyethanol, Tocopheryl Acetate, Ethylhexylglycerin, Diaminopropionoyl Tripeptide-33, Glycine, Glutamic Acid, Serine, Aspartic Acid, Leucine, Alanine, Lysine, Arginine, Phenylalanine, Tyrosine, Isoleucine, Proline, Threonine, Valine, Histidine, Titanium Dioxide (CI 77891), Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499)

Inactive ingredients - Tan Shade

Water (Aqua), Caprylyl Methicone, C12-15 Alkyl Benzoate, Lauryl PEG/PPG-18/18 Methicone, Dimethicone, Caprylic/Capric Triglyceride, Cyclopentasiloxane, Pentylene Glycol, Methyl Methacrylate Crosspolymer, Polyhydroxystearic Acid, Sodium Chloride,

Dimethiconol, Jojoba Esters, Silica, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Mica, PEG/PPG-18/18 Dimethicone, Polyglyceryl-3 Beeswax, Triethoxycaprylylsilane, Sodium Stearoyl Glutamate, Hydrogen Dimethicone, Citrus Aurantium Dulcis (Orange) Peel Oil, Boswellia Carterii Oil, Tin Oxide, Limonene, Caprylyl Glycol, Hyaluronic Acid, Glycerin, Tocopheryl Acetate, Phenoxyethanol, Diaminopropionoyl Tripeptide-33, Ethylhexylglycerin, Glycine, Glutamic Acid, Serine, Aspartic Acid, Leucine, Alanine, Lysine, Arginine, Phenylalanine, Tyrosine, Isoleucine, Proline, Threonine, Valine, Histidine, Titanium Dioxide (CI 77891), Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499)

Other information

- Protect this product from excessive heat and direct sun.
- Keep out of direct sunlight or other sources of strong light.
- Product to be stored between 5-28C/41-82F.
- Report serious adverse events to: AMS Fulfillment, 29010 Commerce Centre Drive, Valencia CA, 1935

Product Packaging - Natural Shade



BALI BODY TINTED SUPER SERUM TAN SPF 30

octisalate, octocrylene, titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	78 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	31 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	56 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
ORANGE OIL (UNII: AKN3KSD11B)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLUTAMIC ACID (UNII: 3KX376GY7L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
HYALURONIC ACID (UNII: S270N0TRQY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ASPARTIC ACID (UNII: 30KYC7MIAI)	
LEUCINE (UNII: GMW67QNF9C)	
LYSINE (UNII: K3Z4F929H6)	
PHENYLALANINE (UNII: 47E5O17Y3R)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
MICA (UNII: V8A1AW0880)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
STANNOUS OXIDE (UNII: JB2MV9I3LS)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCINE (UNII: TE7660XO1C)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
WATER (UNII: 059QF0KO0R)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ALANINE (UNII: OF5P57N2ZX)	
TYROSINE (UNII: 42HK56048U)	
PROLINE (UNII: 9DLQ4CIU6V)	
ARGININE (UNII: 94ZLA3W45F)	

ISOLEUCINE (UNII: 04Y7590D77)
THREONINE (UNII: 2ZD004190S)
VALINE (UNII: HG18B9YRS7)
HISTIDINE (UNII: 4QD397987E)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SERINE (UNII: 452VLY9402)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0032-1	1 in 1 BOX	07/31/2023	
1		30 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 final	M020	07/31/2023	

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octisalate, octocrylene, titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	81 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	31 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	32 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	59 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
ORANGE OIL (UNII: AKN3KSD11B)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
GLUTAMIC ACID (UNII: 3KX376GY7L)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
HYALURONIC ACID (UNII: S270N0TRQY)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
ASPARTIC ACID (UNII: 30KYC7MIAI)
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FERROSO FERRIC OXIDE (UNII: XM0M87F357)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
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OTC monograph final	M020		07/31/2023	

Labeler - Bali Body Pty Ltd (757840223)

Revised: 3/2023

Bali Body Pty Ltd