

DR.JART PREMIUM BEAUTY BALM FAIR-LIGHT- zinc oxide, titanium dioxide, octinoxate, octisalate cream
Have & Be Co., 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.

49404-148 Dr.Jart+ Premium Beauty Balm Fair-Light

OCTINOXATE 6.8%
OCTISALATE 4.5%
TITANIUM DIOXIDE 4.8%
ZINC OXIDE 5.0%

Sunscreen

Helps prevent sunburn

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two 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 long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

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 using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

WATER, CYCLOPENTASILOXANE, CYCLOHEXASILOXANE, GLYCERIN, TITANIUM DIOXIDE(CI 77891), PEG-10 DIMETHICONE, TALC, C12-15 ALKYL BENZOATE, HEXYL LAURATE, DIPHENYLSILOXY PHENYL TRIMETHICONE, NIACINAMIDE, DIPROPYLENE GLYCOL, DISTEARDIMONIUM HECTORITE, MAGNESIUM SULFATE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, DIMETHICONE, IRON OXIDES(CI 77492), TRIETHOXYCAPRYLYLSILANE, PHENOXYETHANOL, IRON OXIDES(CI 77491), METHICONE, IRON OXIDES(CI 77499), POLYGLYCERYL-6 POLYRICINOLEATE, TRIHYDROXYSTEARIN, ETHYLHEXYLGLYCERIN, ADENOSINE, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, CITRUS AURANTIFOLIA (LIME) OIL, PINUS SYLVESTRIS LEAF OIL, BHT, EUCALYPTUS GLOBULUS LEAF OIL, CITRUS AURANTIUM BERGAMIA (BERGAMOT) FRUIT OIL, CITRUS LIMON (LEMON) PEEL OIL, TOCOPHEROL, ALLANTOIN, 1,2-HEXANEDIOL, PALMITOYL TRIPEPTIDE-5, POLYSORBATE 80, PLATINUM POWDER,

PALMITOYL HEXAPEPTIDE-12

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



DR.JART PREMIUM BEAUTY BALM FAIR-LIGHT

zinc oxide, titanium dioxide, octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49404-148
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.8 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	5 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.8 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TALC (UNII: 7SEV7J4R1U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYGLYCERYL-6 POLYRICINOLEATE (UNII: YPM0ZOC2HR)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ADENOSINE (UNII: K72T3FS567)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
LIME OIL, COLD PRESSED (UNII: UZH29XGA8G)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

BERGAMOT OIL (UNII: 39W1PKE3JI)	
LEMON OIL, COLD PRESSED (UNII: I9GRO824LL)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALLANTOIN (UNII: 344S277G0Z)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PLATINUM (UNII: 49DFR088MY)	
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49404-148-02	1 in 1 CARTON	04/25/2022	
1	NDC:49404-148-01	40 mL in 1 BOTTLE, PUMP; 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	04/25/2022	

Labeler - Have & Be Co., Ltd. (690400408)

Registrant - Have & Be Co., Ltd. (690400408)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd.		689512611	manufacture(49404-148)

Revised: 4/2022

Have & Be Co., Ltd.