

DR.JART PREMIUM BEAUTY BALM 03 DEEP- 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.

49404-136_Deactivation

Octinoxate 6.79%

Octisalate 4.50%

Sunscreen

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

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours.
- 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 am - 2 pm

– Wear long-sleeved shirts, pants, hats and sunglasses

- Children under 6 months: 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

TITANIUM DIOXIDE

ZINC OXIDE

GLYCERIN

TALC

PEG-10 DIMETHICONE

IRON OXIDES

C12-15 ALKYL BENZOATE

NIACINAMIDE

DIPHENYLSILOXY PHENYL TRIMETHICONE

DIPROPYLENE GLYCOL

HEXYL LAURATE

DISTEARDIMONIUM HECTORITE
MAGNESIUM SULFATE
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER
DIMETHICONE
TRIETHOXYCAPRYLYLSILANE
PHENOXYETHANOL
METHICONE
POLYGLYCERYL-6 POLYRICINOLEATE
ETHYLHEXYLGLYCERIN
TRIHYDROXYSTEARIN
CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL
ADENOSINE
PINUS SYLVESTRIS LEAF OIL
CITRUS AURANTIFOLIA (LIME) OIL
BHT
EUCALYPTUS GLOBULUS LEAF OIL
CITRUS LIMON (LEMON) PEEL OIL
CITRUS AURANTIUM BERGAMIA (BERGAMOT) FRUIT OIL
ALLANTOIN
GLYCERYL POLYMETHACRYLATE
PROPYLENE GLYCOL
1,2-HEXANEDIOL
PLATINUM POWDER
PALMITOYL TRIPEPTIDE-1
POLYSORBATE 80

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

You may report a serious adverse event from use of this product to: Report Reaction, LLC PO Box 22
Plainsboro, NJ 08536-0222

Dr.Jart+

What is 'BB' Beauty Balm?

BB is your skincare regimen in one tube, created by Dr.Jart. It moisturizes, protects, and corrects. No foundation needed, BB is your moisturizer, sunscreen and treatment serum, while hiding uneven skintone so well that it minimizes the need for foundation or concealer. Skin looks smooth, perfect and natural. Dr.Jart BB is Asia's 'wonder' beauty product.

Drug Facts (Continued)

Inactive ingredients

Water, Cyclopentasiloxane, Cyclohexasiloxane, Titanium Dioxide, Zinc Oxide, Glycerin, Talc, PEG-10 Dimethicone, Iron Oxides, C12-15 Alkyl Benzoate, Niacinamide, Diphenylsiloxy Phenyl Trimethicone, Dipropylene Glycol, Hexyl Laurate, Distearidimonium Hectorite, Magnesium Sulfate, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethicone, Triethoxycaprylylsilane, Phenoxethanol, Methicone, Polyglyceryl-6 Polyricinoleate, Ethylhexylglycerin, Trihydroxystearin, Citrus Aurantium Dulcis (Orange) Peel Oil, Adenosine, Pinus Sylvestris Leaf Oil, Citrus Aurantifolia (Lime) Oil, BHT, Eucalyptus Globulus Leaf Oil, Citrus Limon (Lemon) Peel Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Allantoin, Glycerol Polymethacrylate, Propylene Glycol, Platinum Powder, Palmitoyl Tripeptide-1, Polysorbate 8

Questions & Comments?

Call 1-855-869-0362

HAVE&BE USA, INC.
168 Fifth Avenue, New York, NY 10010 USA
US.DR.JART.COM

Dr.Jart+
PREMIUM

BB
Beauty Balm

**Multi-Action Skincare +
Make up**

- + Firming moisture technology
- + Sunscreen & Antioxidants
- + Brightens & Conceals uneven skintone

Broad Spectrum
SPF 45
40 mL / 1.4 fl. oz.

Dr. Jart



US HAVE&BE Co.,LTD.

03 DEEP

Dr.Jart
Premium Beauty Balm
닥터자르트 프리미엄 뷰티 밤

**MULTI ACTION FORMULA
SPF 45 SUNSCREEN**

Perfect and protect skin instantly with this all-in-one multifunctional Beauty Balm. Premium BB's natural-looking coverage evens skin tone and minimizes the appearance of imperfections. Infused with a serum of advanced brightening and anti-aging properties to firm and hydrate. Antioxidant bio-peptides and adenosine help restore skin back to supple elasticity. Lightweight with mineral sunscreens, creating an ideal base makeup application.

PRODUCT DESCRIPTION

Sunscreen
Skin Brightening
Flawless Coverage

CONTAINS

- + Sunscreen : protects
- + Bio-Peptide Complex : promotes natural collagen
- + Adenosine : known to improve elasticity and firm skin
- + Neutralizing pigments

DERMATOLOGIST
TESTED

SAFETY
FORMULA

DR.JART
GLOBAL PRODUCT

Drug Facts

Active ingredients Purpose

Octinoxate 6.79% Sunscreen
Octisalate 4.50% 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- **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: Ask a doctor

Other information

- Protect the product in this container from excessive heat and direct sunlight.
- You may report a serious adverse event from use of this product to: Report Reaction, LLC PO Box 22 Plainsboro, NJ 08536-0222

2017.12. HAVE&BE Co.,LTD.



DR.JART PREMIUM BEAUTY BALM 03 DEEP

octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49404-136
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.71 mg in 40 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	1.8 mg in 40 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
TALC (UNII: 7SEV7J4R1U)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
ORANGE OIL (UNII: AKN3KSD11B)	
ADENOSINE (UNII: K72T3FS567)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
LIME OIL (UNII: UZH29XGA8G)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LEMON OIL (UNII: I9GRO824LL)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
ALLANTOIN (UNII: 344S277G0Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PLATINUM (UNII: 49DFR088MY)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49404-136-02	1 in 1 CARTON	01/08/2018	03/27/2020
1	NDC:49404-136-01	40 mL in 1 CONTAINER; 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	01/08/2018	03/27/2020

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(49404-136)

Revised: 3/2020

Have & Be Co., Ltd.