

DEAR SUN TONE PERFECTING SPF CUSHION- homosalate, octisalate, octocrylene, zinc oxide cream
RBGROUP Co., Ltd

84326-001_Dear Sun Tone Perfecting SPF Cushion

Homosalate 10.00%

Octisalate 3.00%

Octocrylene 2.00%

Zinc Oxide 13.30%

Sunscreen

Helps prevent sunburn

If used as directed with other sun protection measure (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.

■ children under 6 months of age: ask a doctor

■ **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

■ **For external use only**

■ **Do not use** on demaged or broken skin.

■ **Stop use and ask a doctor** if rash occurs.

■ **When using this product** keep out of eyes. Rinse with water to remove.

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

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

Water, Butyloctyl Salicylate, Glycerin, Cetyl PEG/PPG-10/1 Dimethicone, C12-15 Alkyl Benzoate, Niacinamide, Cyclopentasiloxane, Silica, Sodium Chloride, Polyhydroxystearic Acid, 1,2-Hexanediol, Triethoxycaprylylsilane, Disteardimonium Hectorite, Ceresin, Fragrance, Propylene Carbonate, Trihydroxystearin, Ethylhexylglycerin, Caprylyl Glycol, Butylene Glycol, Caprylic/Capric Triglyceride, Hydrogenated Phosphatidylcholine, Centella Asiatica Extract, Sucrose Stearate, Iron Oxides (CI 77492), Cetearyl Alcohol, Iron Oxides (CI 77491), Tocopherol, Madecassoside, Madecassic Acid, Asiaticoside, Asiatic Acid

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



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84326-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	13.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8I02K35FA)	

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
NIACINAMIDE (UNII: 25X51I8RD4)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CERESIN (UNII: Q1LS2UJO3A)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)
SUCROSE STEARATE (UNII: 274KW0050M)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TOCOPHEROL (UNII: ROZB2556P8)
MADECASSOSIDE (UNII: CQ2F5O6YIY)
MADECASSIC ACID (UNII: M7O1N24J82)
ASIATICOSIDE (UNII: PKO39VY215)
ASIATIC ACID (UNII: 9PA5A687X5)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84326-001-02	1 in 1 CARTON	10/01/2024	
1	NDC:84326-001-01	15 g 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 Drug	M020	10/01/2024	

Labeler - RBGROUP Co., Ltd (987610097)

Registrant - RBGROUP Co., Ltd (987610097)

Establishment

Name	Address	ID/FEI	Business Operations
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690081646

manufacture(84326-001)

Revised: 10/2024

RBGROUP Co., Ltd