MULTI PROTECTION UV BOUNCER- octinoxate, octocrylene, octisalate cream Codecosme International 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.

ACTIVE INGREDIENT

Active ingredients: Ethylhexyl Methoxycinnamate 7.00%, Octocrylene 5.00%, Ethylhexyl Salicylate 4.50%

INACTIVE INGREDIENT

Inactive ingredients: Water, Alcohol Denat., Butylene Glycol, Butyl Methoxydibenzoylmethane, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Silica, Methyl Methacrylate Crosspolymer, Dimethicone, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Acrylates/C10-30 Alkyl Acrylate, Crosspolymer, Fragrance, Isohexadecane, Caprylyl Glycol, Potassium Hydroxide, Polysorbate 80, Phenoxyethanol, 1,2-Hexanediol, Ethylhexylglycerin, BHT, Citrus Aurantifolia (Lime) Oil, Disodium EDTA, Buddleja Axillaris Leaf Extract, Phyllostachis Bambusoides Juice, Malpighia Emarginata (Acerola) Fruit Extract, Propylene Glycol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Salvia Officinalis (Sage) Leaf Extract, Cucumis Sativus (Cucumber) Fruit Extract, Sorbaria Sorbifolia Bark/Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Carex Humillis Root Extract, Nelumbo Nucifera Flower Extract, Lilium Candidum Bulb Extract, Alcohol, Syringa Vulgaris (Lilac) Extract, Glycine, Serine, Glutamic Acid, Saussurea Involucrata Extract, Aspartic acid, Leucine, Camellia Sinensis Leaf Extract, Alanine, Lysine, Arginine, Tyrosine, Phenylalanine, Threonine, Proline, Valine, Isoleucine, Aloe Barbadensis Leaf Extract, Psidium Guajava Leaf Extract, Abronia Villosa Leaf Extract, Cinchona Succirubra Bark Extract, Chenopodium Quinoa Seed Extract, Histidine, Methionine, Cysteine, Rhodiola Rosea Root Extract, Oxygen

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: 1. If any of the following symptoms occur when using the product, stop using immediately and consult a dermatologist. a) red spots, swelling, itchy rashes other skin irritations, etc. b) if a) occurs after applying and being exposed to sunlight. 2. Do not use on wounds, inflamed skin, itchy areas, or other infected areas. 3. Storage and handling: a) must close cap after use. b) Keep out of reach of children. c) keep away from extreme heat, cold and direct sunlight. d) Avoid contact with eyes. In case of contact with eyes, rinse thoroughly with water. 4. For external use only.

DESCRIPTION

Uses: A cooling and moisturizing UV protector/makeup primer. When applied, it protects the skin from UV rays and leaves a beautiful sheen. Contains internationally renowned Korean Jeju hypoxic water and British Harrogate sparkling water.

Directions: Pump appropriate amount of the product onto your hands and apply on the entire face in outward strokes using a sponge or fingertips. If required, reapply it on areas that are vulnerable to sunlight such as cheekbones, nasal bridge, and forehead. Close cap after use.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MULTI PROTECTION UV BOUNCER

octinoxate, octocrylene, octisalate cream

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71786-010 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | Octinoxate | 3.5 g in 50 mL | |
| Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | Octocrylene | 2.5 g in 50 mL | |
| Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | Octisalate | 2.25 g in 50 mL | |

| Inactive Ingredients | | | |
|------------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| Water (UNII: 059QF0KO0R) | | | |
| Butylene Glycol (UNII: 3XUS85K0RA) | | | |

| | Packaging | | | |
|---|--------------------|--|-----------------------------|--------------------|
| ı | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 NDC:71786-010-02 | 1 in 1 CARTON | 10 /0 1/20 17 | |
| ı | 1 NDC:71786-010-01 | 50 mL in 1 TUBE; 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 | 10/01/2017 | |
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Labeler - Codecosme International Co., Ltd. (689846614)

Registrant - Codecosme International Co., Ltd. (689846614)

| Establishment | | | | |
|--------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Cosmecca Korea Co., Ltd. | | 688830827 | manufacture(71786-010) | |

Revised: 10/2017 Codecosme International Co., Ltd.