

**CLE CCC COOL MEDIUM DEEP- titanium dioxide, octinoxate, octisalate cream
KW ABSC, INC.**

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.

69231-031_CLE CCC Cool Medium Deep

Titanium Dioxide 8.45%

Ethylhexyl Methoxycinnamate 7.00%

Ethylhexyl Salicylate 3.00%

Sunscreen

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure. Reapply at least every two 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 of 15 or higher and other sun protection measures including: 1) Limited time in the sun, especially from 10 am to 2 pm. 2) Wear long-sleeve shirts, pants, hats, and sunglasses

Ask a doctor to use for children under 6 months

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, C12-15 Alkyl Benzoate, Butylene Glycol, CI 77492, Isoamyl p-Methoxycinnamate, Cyclohexasiloxane, Cetyl PEG/PPG-10/1 Dimethicone, Niacinamide, Dicaprylyl Carbonate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Ceresin, Mica, CI 77491, Diisostearyl Malate, Sodium Chloride, CI 77499, Disteardimonium Hectorite, Sorbitan Sesquioleate, Synthetic Wax, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Sorbitan Olivatate, Polyester-1, Silica Dimethyl Silylate, Dipropylene Glycol, Hydroxyacetophenone, Chlorphenesin, Propylene Carbonate, Vegetable Oil, Dimethicone, Caprylyl Glycol, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Aurantium Dulcis (Orange) Oil, Triethoxycaprylylsilane, Adenosine, Cananga Odorata Flower Oil, Disodium EDTA, Natto Gum, Saussurea Involucrata Extract, Vaccinium Angustifolium (Blueberry) Fruit Extract, Tocopheryl Acetate, Hydrolyzed Hyaluronic Acid, Glycerin, Melissa Officinalis Leaf Extract, Chrysanthemum Indicum Flower Extract, Camellia Sinensis Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Aspalathus Linearis Leaf Extract, Thymus Vulgaris (Thyme) Flower/Leaf Extract, Jasminum Officinale (Jasmine) Flower Water, Veronica Officinalis Extract, Malva Sylvestris (Mallow) Extract, Achillea Millefolium Extract, Alchemilla Vulgaris Extract, Alcohol, Primula Veris Extract, Mentha Piperita (Peppermint) Leaf Extract, Dipotassium Glycyrrhizate, Tocopherol

COOL
MEDIUM
DEEP

DRUG FACTS

ACTIVE INGREDIENTS-PURPOSES

TITANIUM DIOXIDE 8.45% SUNSCREEN
OCTINOXATE 7% SUNSCREEN
OCTISALATE 3% SUNSCREEN

USES

HELP PREVENT SUNBURN

DIRECTIONS

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 OF 15 OR HIGHER AND OTHER SUN PROTECTION MEASURES INCLUDING: 1) LIMITED TIME IN THE SUN, ESPECIALLY FROM 10 AM TO 2 PM. 2) WEAR LONG-SLEEVE SHIRTS, PANTS, HATS, AND SUN GLASSES
- ASK A DOCTOR TO USE FOR CHILDREN UNDER 6 MONTHS

INACTIVE INGREDIENTS

WATER, CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, BUTYLENE GLYCOL, CI 77492, ISOAMYL P-METHOXYCINNAMATE, CYCLOHEXASILOXANE, CETYL PEG/PPG-10/1 DIMETHICONE, NIACINAMIDE, Dicaprylyl Carbonate, Bis-Ethylhexyloxyphenol, Methoxyphenyl Triazine, CERESIN, MICA, CI 77491, DIISOSTEARYL MALATE, SODIUM CHLORIDE, CI 77499, DISTEARDIMONIUM HECTORITE, SORBITAN SESQUIOLEATE, SYNTHETIC WAX, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, SORBITAN OLIVATE, POLYESTER-1, SILICA DIMETHYL SILYLATE, DIPROPYLENE GLYCOL, HYDROXYACETOPHENONE, CHLORPHENESIN, PROPYLENE CARBONATE, VEGETABLE OIL, DIMETHICONE, CAPRYLYL GLYCOL, CITRUS AURANTIUM BERGAMIA (BERGAMOT) FRUIT OIL, CITRUS AURANTIUM DULCIS (ORANGE) OIL, TRIETHOXYCAPRYLYLSILANE, ADENOSINE, CANANGA ODORATA FLOWER OIL, DISODIUM EDTA, NATTO GUM, SAUSSUREA INVOLUCRATA EXTRACT, VACCINIUM ANGUSTIFOLIUM (BLUEBERRY) FRUIT EXTRACT, TOCOPHERYL ACETATE, HYDROLYZED HYALURONIC ACID, GLYCERIN, MELISSA OFFICINALIS LEAF EXTRACT, CHRYSANTHEMUM INDIICUM FLOWER EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, ASPALATHUS LINEARIS LEAF EXTRACT, THYMUS VULGARIS (THYME) FLOWER/LEAF EXTRACT,

DRUG FACTS (CONTINUED)

JASMINUM OFFICINALE (JASMINE) FLOWER WATER, VERONICA OFFICINALIS EXTRACT, MALVA SYLVESTRIS (MALLOW) EXTRACT, ACHILLEA MILLEFOLIUM EXTRACT, ALCHEMILLA VULGARIS EXTRACT, ALCOHOL, PRIMULA VERIS EXTRACT, MENTHA PERITATA (PEPPERMINT) LEAF EXTRACT, DIPOTASSIUM GLYCYRRHIZATE, TOCOPHEROL

WARNINGS

FOR EXTERNAL USE ONLY. DO NOT USE ON DAMAGED OR BROKEN SKIN. STOP USING 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 PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

OTHER INFORMATION

PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUNLIGHT.

MANUFACTURED FOR CLE LIFESTYLE CORPORATION 18655 BISHOP AVENUE CARSON, CALIFORNIA USA 90746

EU RESPONSIBLE PERSON BIORIUS EU: WAVRE, BE / LONDON WC2H 9JQ, UK

MADE IN KOREA

WWW.CLECOSMETICS.COM



COOL MEDIUM DEEP 306

PLEASE RECYCLED FOR ENVIRONMENTAL PRESERVATION PURPOSE. PLEASE FOLLOW THE INSTRUCTIONS AND CAUTION INFORMATION BEFORE USE.



CLE COSMETICS

OUR MULTI-FUNCTIONAL ESSENTIALS EDIT OUT THE EXCESS TO BRING YOU HERO PRODUCTS MADE TO MATCH THE PACE OF MODERN LIFE. FLEXIBLE, YET COMPREHENSIVE, EACH OF OUR PRODUCTS CAN SEAMLESSLY COMPLIMENT A MULTI-STEP SELF CARE RITUAL OR STAND ALONE AS A SINGLE, GO-TO PRODUCT.

CCC CREAM IS COMPOSED OF CC AND BB CREAM, UTILIZING MICRO CAPSULE TECHNOLOGY – AN EFFECTIVE TECHNIQUE TO ENSURE THE ESSENCE, TINT AND SUN PROTECTION ARE RELEASED INSTANTLY.

RADIANT SKIN
CCC CREAM

MICRO CAPSULE TECHNOLOGY
SPF 50

e 30 ML 1FL.OZ

CLE CCC COOL MEDIUM DEEP

titanium dioxide, octinoxate, octisalate cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69231-031 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-------------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 2.1 mg in 30 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 0.9 mg in 30 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 2.535 mg in 30 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| CYCLOMETHICONE 6 (UNII: XHK3U310BA) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| AMILOXATE (UNII: 376KTP06K8) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X) | |
| NIACINAMIDE (UNII: 25X51I8RD4) | |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA) | |
| MICA (UNII: V8A1AW0880) | |
| BEMOTRIZINOL (UNII: PWZ1720CBH) | |
| CERESIN (UNII: Q1LS2UJO3A) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| POLYESTER-10 (UNII: 212N9O2MMZ) | |
| SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A) | |
| SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099) | |
| LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA) | |
| SORBITAN OLIVATE (UNII: MDL271E3GR) | |
| CORN OIL (UNII: 8470G57WFM) | |
| CHLORPHENESIN (UNII: I670DAL4SZ) | |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) | |
| BERGAMOT OIL (UNII: 39W1PKE3JI) | |
| ORANGE OIL (UNII: AKN3KSD11B) | |
| PROPYLENE CARBONATE (UNII: 8D08K3S51E) | |

| | |
|--|--|
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G) | |
| HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| CANANGA OIL (UNII: 8YOY78GNNX) | |
| DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | |
| ADENOSINE (UNII: K72T3FS567) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69231-031-02 | 1 in 1 PACKAGE | 10/24/2022 | |
| 1 | NDC:69231-031-01 | 30 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 | 10/24/2022 | |

Labeler - KW ABSC, INC. (079548604)

Registrant - KW ABSC, INC. (079548604)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| Cit Co., Ltd | | 690081646 | manufacture(69231-031) |

Revised: 10/2022

KW ABSC, INC.