

**CLE CCC NEUTRAL DEEP- titanium dioxide, octinoxate, octisalate, avobenzone 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.

69231-036_CLE CCC Neutral Deep

Titanium Dioxide 0.93%

Ethylhexyl Methoxycinnamate 7.00%

Ethylhexyl Salicylate 2.00%

Avobenzone 0.52%

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, Butylene Glycol, Diphenylsiloxy Phenyl Trimethicone, C12-15 Alkyl Benzoate, CI 77492, Isoamyl p-Methoxycinnamate, Cetyl PEG/PPG-10/1 Dimethicone, CI 77499, Cyclohexasiloxane, CI 77491, Niacinamide, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Polymethyl Methacrylate, Sodium Chloride, Euphorbia Cerifera (Candelilla) Wax, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Sorbitan Olivatate, Synthetic Beeswax, Disteardimonium Hectorite, Triethoxycaprylylsilane, Trihydroxystearin, Dipropylene Glycol, Hydroxyacetophenone, Vegetable Oil, Chlorphenesin, Caprylyl Glycol, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Aurantium Dulcis (Orange) Oil, Propylene Carbonate, Dimethiconol, Adenosine, Cananga Odorata Flower Oil, Disodium EDTA, Dimethicone, 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, Dipotassium Glycyrrhizate, Malva Sylvestris (Mallow) Extract, Achillea Millefolium Extract, Alchemilla Vulgaris Extract, Alcohol, Primula Veris Extract, Mentha Piperita (Peppermint) Leaf Extract, Mica, Tocopherol, Polyester-1, Silica Dimethyl Silylate



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titanium dioxide, octinoxate, octisalate, avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69231-036
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	0.6 mg in 30 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.279 mg in 30 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.156 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
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)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
MICA (UNII: V8A1AW0880)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CANDELILLA WAX (UNII: WL0328HX19)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYESTER-10 (UNII: 212N9O2MMZ)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
CORN OIL (UNII: 8470G57WFM)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
ORANGE OIL (UNII: AKN3KSD11B)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
YLANG-YLANG OIL (UNII: 8YOY78GNNX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
LOWBUSH BLUEBERRY (UNII: G90PX41VP0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ADENOSINE (UNII: K72T3FS567)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
CHRYSANTHEMUM INDICUM FLOWER (UNII: I6OER6U04L)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ROSEMARY (UNII: IJ67X351P9)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
THYME (UNII: CW657OBU4N)	
JASMINUM OFFICINALE FLOWER (UNII: 0Q8K841432)	

GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
MALVA SYLVESTRIS FLOWERING TOP (UNII: X1U1U0N90J)	
ACHILLEA MILLEFOLIUM WHOLE (UNII: 2FXJ6SW4PK)	
ALCHEMILLA XANTHOCHLORA FLOWERING TOP (UNII: 9M289NKI69)	
ALCOHOL (UNII: 3K9958V90M)	
PRIMULA VERIS WHOLE (UNII: W6LFQ57E4M)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
TOCOPHEROL (UNII: ROZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69231-036-02	1 in 1 PACKAGE	11/09/2022	
1	NDC:69231-036-01	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	11/09/2022	

Labeler - KW ABSC, INC. (079548604)

Registrant - KW ABSC, INC. (079548604)

Establishment

Name	Address	ID/FEI	Business Operations
Cit Co., Ltd		690081646	manufacture(69231-036)

Revised: 11/2022

KW ABSC, INC.