CLE CCC NEUTRAL MEDIUM LIGHT- 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.

69231-029_CLE CCC Neutral Medium Light

Titanium Dioxide 9.03%

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 of 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, Cyclohexasiloxane, Butylene Glycol, Isoamyl p-Methoxycinnamate, Cetyl PEG/PPG-10/1 Dimethicone, Niacinamide, Dicaprylyl Carbonate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Ceresin, Diisostearyl Malate, Sodium Chloride, Iron Oxides (CI 77492), Disteardimonium Hectorite, Sorbitan Sesquioleate, Synthetic Wax, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Sorbitan Olivate, Mica (CI 77019), Iron Oxides (CI 77491), Chlorphenesin, Dipropylene Glycol, Dimethicone, Polyester-1, Propylene Carbonate, 1,2-Hexanediol, Hydroxyacetophenone, Iron Oxides (CI 77499), Vegetable Oil, Silica Dimethyl Silylate, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Aurantium Dulcis (Orange) Oil, Phenyl Trimethicone, Dimethicone Crosspolymer, Adenosine, Cananga Odorata Flower Oil, Disodium EDTA, Natto Gum, Saussurea Involucrata Extract, Bambusa Vulgaris Leaf/Stem Extract, Vaccinium Angustifolium (Blueberry) Fruit Extract, Cocos Nucifera (Coconut) Oil, 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, Tocopherol



CLE CCC NEUTRAL MEDIUM LIGHT

titanium dioxide, octinoxate, octisalate cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:69231-029

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	2.7096 mg in 30 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
AMILOXATE (UNII: 376KTP06K8)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
NIACINAMIDE (UNII: 25X5118RD4)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
BEMOTRIZINOL (UNII: PWZ 1720CBH)	
CERESIN (UNII: Q1LS2UJO3A)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
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)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYESTER-10 (UNII: 212N9O2MMZ)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

CORN OIL (UNII: 8470G57WFM)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
ORANGE OIL (UNII: AKN3KSD11B)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ADENOSINE (UNII: K72T3FS567)	
CANANGA OIL (UNII: 8YOY78GNNX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

ı	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:69231- 029-02	1 in 1 PACKAGE	10/18/2022		
:	NDC:69231- 029-01	30 mL in 1 CONTAINER; Type 0: Not a Combination Product			

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
rt352	10/18/2022		
	Citation	Citation Date	

Labeler - KW ABSC, INC. (079548604)

Registrant - KW ABSC, INC. (079548604)

Establishment					
Name	Address	ID/FEI	Business Operations		
Cit Co., Ltd		690081646	manufacture(69231-029)		

Revised: 10/2022 KW ABSC, INC.