

**SUDDEN CHANGE DERMA RENEWAL COMPLEX- octinoxate, zinc oxide cream
CCA Industries 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.

Sudden Change Derma Renewal Complex

Drug Facts

Active Ingredient

Octinoxate 6.00%

Zinc oxide 2.00%

Purpose

Sunscreen

Uses:

Helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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 use and ask a doctor

if rash occurs.

Keep out of the reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- For sunscreen use: 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: ask a doctor.

Other Information

- Protect this product from excessive heat and direct sun.

Inactive Ingredients

WATER (AQUA), BUTYLENE GLYCOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, SIMMONDSIA, CHINENSIS (JOJOBA) SEED OIL, GLYCERIN, DIMETHICONE, CETEARYL OLIVATE, HYDROGENATED OLIVE OIL, UNSAPONIFIABLES, CETYL ALCOHOL, SORBITAN OLIVATE, ALOE BARBADENSIS LEAF EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, TOCOPHERYL ACETATE, TETRAHEXYLDECYL ASCORBATE, SODIUM HYALURONATE, C12-15 ALKYL BENZOATE, TRIBEHENIN, CERAMIDE NG, PEG-10 RAPESEED STEROL, PALMITOYL HEXAPEPTIDE-12, XANTHAN GUM, ALLANTOIN, TRIETHOXYCAPRYLYLSILANE, PHENOXYETHANOL, CAPRYLYL GLYCOL, POTASSIUM SORBATE, HEXYLENE GLYCOL, BISABOLOL, FRAGRANCE, CITRUS AURANTIUM (NEROLI) FLOWER OIL

Questions or Comments?

Call 1-800-595-6230

Report any issues associated with this product to the telephone number or address listed on this package.

Package Labeling:

SUDDEN CHANGE

#6041



REPAIR +

SUDDEN CHANGE
ESSENTIAL SKINCARE

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Sudden Change Essential Skincare products
**CLEANSE • DETOX
REPAIR • RESTORE**
your skin making it softer smoother, and more radiant.

CLEANSE:

- **Sudden Change Hydra Cleansing Crème:** Natural Fruit Extracts gently exfoliate dead skin cells, and remove makeup and impurities while tightening pores. Perfect for daily use.

DETOX:

- **Sudden Change 3 in 1 Clay Mask:** A proprietary combination of Charcoal, Eucalyptus and Red Algae absorb oils and impurities, exfoliate, and tighten pores for softer, smoother skin. It is like an "instant face lift".
- **Sudden Change Green Tea Facial Mask:** A therapeutic mask containing Green Tea Antioxidants that instantly cool and accelerates the visibility of smoother, firmer skin after use.

REPAIR:

- **Sudden Change Derma Renewal Complex:** This exclusive formula, with Oligopeptides, Ceramides, Jojoba and Antioxidants absorbs on contact to moisturize, condition your skin and help reverse signs of sun damage. Daily protection with SPF 10.
- **Sudden Change Revitalizing Night Cream:** A complex of essential nutrients and moisturizers that penetrate below the skin's surface to ensure long-lasting hydration, increase elasticity and reveal softer, smoother skin.

RESTORE:

- **Sudden Change Under-Eye Firming Serum:** This serum utilizes a unique technology that forms an invisible micro-layer over the skin. In only 3 minutes, the appearance of wrinkles, fine lines, bags, puffiness and dark circles disappear. The effect lasts for hours so you can look great all day.

SUDDEN CHANGE
ESSENTIAL SKINCARE

Derma Renewal Complex



SPF10 SUNSCREEN

Daily Moisturizing Treatment

Oligopeptides
Ceramides
Antioxidants

1 FL OZ (30 ML)

Sudden Change Derma Renewal Complex has been exclusively formulated to help repair visible signs of sun damage, including sun spots and uneven skin tone. It works below the surface of the skin to dramatically improve the look and feel of your skin like nothing else you have ever tried. This formula absorbs on contact to quickly begin repairing the skin's natural dermal barrier.

What makes this formula special:

- Oligopeptides and Hyaluronic Acid help reduce the appearance of visible signs of sun damage.
- Super antioxidants are known to neutralize free radicals and help speed natural skin repair.
- Ceramides and Jojoba Oil are known to help restore skin's natural defense barrier.
- Sunscreen with zinc oxide helps shield and protect skin.

cca core care AMERICA
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SUDDEN CHANGE DERMA RENEWAL COMPLEX

octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61543-0003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
HYDROGENATED OLIVE OIL (UNII: 53839415GI)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
CERAMIDE NG (UNII: C04977SRJ5)	
PEG-10 RAPESEED STEROL (UNII: 258O76T85M)	
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALLANTOIN (UNII: 344S277G0Z)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
LEVOMENOL (UNII: 24WE03BX2T)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE91OXH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61543-0003-0	1 in 1 BOX	04/01/2018	
1		30 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	04/01/2018	

Labeler - CCA Industries Inc. (106771041)

Revised: 9/2021

CCA Industries Inc.