

**SKIN REJUVENATING DAILY MOISTURIZER BROAD SPECTRUM SPF 30  
SUNSCREEN- octinoxate and zinc oxide cream  
Dermaset, 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.*

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**SKIN REJUVENATING DAILY MOISTURIZER BROAD SPECTRUM SPF 30  
SUNSCREEN**

**DRUG FACTS:**

**ACTIVE INGREDIENTS**

Octinoxate 7.5%, Zinc Oxide 10.0%.

**Purpose**

Sunscreen

**WARNINGS**

**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 Reach of Children

**DIRECTIONS**

Apply to all skin exposed to the sun. \*Apply liberally and evenly 15 minutes before sun exposure. \*Reapply at least every 2 hours. \*Use a water-resistant sunscreen if swimming or sweating. \*For children under 6 months of age:

Ask a doctor.

**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 value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses.

**INACTIVE INGREDIENTS**

Water (Aqua), Butyloctyl Salicylate, Glycerin, Dimethicone, Styrene/Acrylates Copolymer, Coco-Caprylate/Caprates, Caprylic/Capric Triglyceride, VP/Eicosene Copolymer, Carthamus Tinctorius Oleosomes, Elettaria Cardamomum Seed Extract, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Perilla Frutescens Extract, Pyrus Malus

(Apple) Fruit Extract, Rose Extract, Santalum Album Extract, Camellia Sinensis Leaf Extract, Anthemis Nobilis Flower Extract, Cananga Odorata Flower Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Cucumis Melo (Melon) Fruit Extract, Cucumis Sativus Fruit Extract, Jasminum Officinale Flower/Leaf Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Rubus Idaeus (Raspberry) Fruit Extract, Polygonum Aviculare Extract, Vitis Vinifera Fruit Cell Extract, Propanediol, Cetearyl Alcohol, Pentylene Glycol, Arachidyl Alcohol, Polyhydroxystearic Acid, Coco-Glucoside, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Behenyl Alcohol, Xanthan Gum, Triethoxycaprylylsilane, Arachidyl Glucoside, Phenethyl Alcohol, Caprylyl Glycol.

## **OTHER INFORMATION**

Protect the product in this container from excessive heat and direct sun.

## **PRINCIPAL DISPLAY PANEL - 29g Tube Label**

DermaSet™  
HOLLYWOOD SKINCARE

SPF  
30

SKIN REJUVENATING

DAILY MOISTURIZER  
BROAD SPECTRUM SPF 30 SUNSCREEN

For Face & Neck

29g - Net Wt. 1 Oz

DermaSet™  
HOLLYWOOD SKINCARE



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octinoxate and zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80873-100
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (500000 MW)</b> (UNII: 5Z4DPO246A)	
<b>COCOYL CAPRYLOCAPRATE</b> (UNII: 8D9H4QU99H)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CARTHAMUS TINCTORIUS SEED OLEOSOMES</b> (UNII: 9S60Q72309)	
<b>CARDAMOM</b> (UNII: 8BC4CUT4JL)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PERILLA FRUTESCENS SEED</b> (UNII: 8M62PUD356)	
<b>APPLE</b> (UNII: B423VGH5S9)	
<b>SANTALUM ALBUM SEED</b> (UNII: 7RZT0U509Y)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CHAMAEMELUM NOBILE FLOWER</b> (UNII: O2T154T6OG)	
<b>CANANGA ODORATA FLOWER</b> (UNII: 76GTF6Z97M)	
<b>ORANGE PEEL</b> (UNII: T19T76XD44)	
<b>MUSKMELON</b> (UNII: ZV095H5633)	
<b>JASMINUM OFFICINALE FLOWER</b> (UNII: 0Q8K841432)	
<b>LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP</b> (UNII: 9YT4B71U8P)	
<b>RASPBERRY</b> (UNII: 4N14V5R27W)	
<b>POLYGONUM AVICULARE TOP</b> (UNII: ZCD6009IUF)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>ARACHIDYL GLUCOSIDE</b> (UNII: 6JVV35J0OJ)	
<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80873-100-01	29 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	10/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	10/30/2020	

**Labeler** - Dermaset, Inc. (117655065)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Solutions		807907928	MANUFACTURE(80873-100)

Revised: 1/2022

Dermaset, Inc.