

FIRMING DAY SPF 30- zinc oxide octinoxate cream
CEN BEAUTY LLC

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.

ACTIVE INGREDIENT

ZINC OXIDE 15%

OCTINOXATE 6%

PURPOSE

SUNSCREEN

USES

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

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. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- Apply on to clean and dry face morning and night, avoiding the delicate eye area.
- Apply 15 minutes before sun exposure. May be used daily.
- Consult your physician before use.

Other Information

- STORE AT 15-30°C (59-86°F)
- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.

INGREDIENTS

aqua (water), cyclopentasiloxane, PEG-10 dimethicone, dimethicone, butylene glycol, cyclohexasiloxane, glycerin, carollina officinalis extract, algae extract, avena sativa (oat) kernel extract, angelica sinensis extract, 10-hydroxydecanoic acid, sebacic acid, 1,10-decanediol acid, betaine, dimethicone/vinyl dimethicone crosspolymer, lauryl PEG-9 polydimethylsiloxyethyl dimethicone, lecithin, dimethicone/PEG-10/15 crosspolymer, triethoxycaprylylsilane, decamethylcyclopentasiloxane, trifluoromethyl C1-C4 alkyl dimethicone, quaternium-90, bentonite, butylene glycol, sodium chloride, sodium citrate, ethylhexylglycerin, propylene carbonate, propylene glycol, potassium sorbate, methylisothiazolinone, iodopropynyl butylcarbamate, phenoxyethanol

<p>Drug Facts</p> <hr/> <p>Active ingredient</p> <p>Zinc Oxide 15%.....Sunscreen Oxinate 6%.....Sunscreen</p>	<p>Drug Facts (continued)</p> <hr/> <p>Directions</p> <ul style="list-style-type: none"> Apply on to clean and dry face morning and night, avoiding the delicate eye area. Apply 15 minutes before sun exposure. May be used daily. Consult your physician before use.
<p>Uses</p> <ul style="list-style-type: none"> Helps prevent sunburn If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun 	<p>Other Information</p> <ul style="list-style-type: none"> Store at 15-30°C (59-86°F) Protect this product from excessive heat and direct sun.
<p>Warnings</p> <p>For external use only</p> <hr/> <p>Do not use</p> <ul style="list-style-type: none"> On damaged or broken skin <hr/> <p>When using this product</p> <ul style="list-style-type: none"> Keep out of eyes. Rinse with water to remove <hr/> <p>Stop use and ask a doctor if rash occurs</p> <hr/> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Inactive Ingredients aqua (water), cyclopentasiloxane, PEG-10 dimethicone, dimethicone, butylene glycol, cyclohexasiloxane, glycerin, carollina officinalis extract, algae extract, avena sativa (oat), kernel extract, angelica sinensis extract, 10-hydroxydecanoic acid, sebacic, 1,10-decanediol acid, betaine, dimethicone/vinyl dimethicone, crosspolymer, lauryl PEG-9 polydimethylsiloxyethyl dimethicone, avena sativa (oat) kernel extract, angelica sinensis extract, lecithin, dimethicone/PEG-10/15 crosspolymer dimethicone/vinyl dimethicone, crosspolymer, triethoxycaprylylsilane, decamethylcyclopentasiloxane, trifluoromethyl C1-C4alkyl dimethicone, quaternium-90 bentonite, butylene glycol, sodium chloride, sodium citrate, ethylhexylglycerin, propylene carbonate, propylene glycol, potassium sorbate, methylisothiazolinone, iodopropynyl butylcarbamate, phenoxyethanol</p>



FIRMING DAY SPF 30

zinc oxide octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54272-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
GLYCERIN (UNII: PDC6A3C0OX)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
OAT (UNII: Z6J799EAJK)	
ANGELICA SINENSIS WHOLE (UNII: 697D19QDBN)	
10-HYDROXYDECANOIC ACID (UNII: NP03XO416B)	
SEBACIC ACID (UNII: 97AN39ICTC)	
1,10-DECANEDIOL (UNII: 5I577UDK52)	
BETAINE (UNII: 3SCV180C9W)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
DIMETHICONE PEG-10 PHOSPHATE (UNII: O7Q5NJ7X88)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DODECAMETHYLPENTASILOXANE (UNII: 0QDQ2VQ5YJ)	
2,2,2-TRIFLUOROACETOPHENONE (UNII: 6T7L1UPY09)	
QUATERNIUM-91 (UNII: 00J8H295NB)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54272-202-11	30 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/21/2013	

Labeler - CEN BEAUTY LLC (078664118)

Registrant - CEN BEAUTY LLC (078664118)

Revised: 3/2013

CEN BEAUTY LLC