CELGEN MILD SUN- octinoxate, octisalate, bemotrizinol, titanium dioxide, ethylhexyl triazone, avobenzone cream BBHC CO., LTD

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.

76731-204

Active ingredient

Ethylhexyl Methoxycinnamate (6.50%)

Ethylhexyl Salicylate (4.50%)

Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine (4.00%)

Titanium Dioxide (2.125%)

Ethylhexyl Triazone (1.50%)

Butyl Methoxydibenzoylmethane (0.90%)

Purpose

Sunscreen

Use

Helps to 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 irritation occurs.

Keep out of reach of children

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

Directions

- Apply a proper amount evenly for the last step of skin care.
- Apply liberally 15 minutes before sun exposure.
- Reapply at least every two hours.
- Use a water resistant sunscreen if swim- ming or sweating.

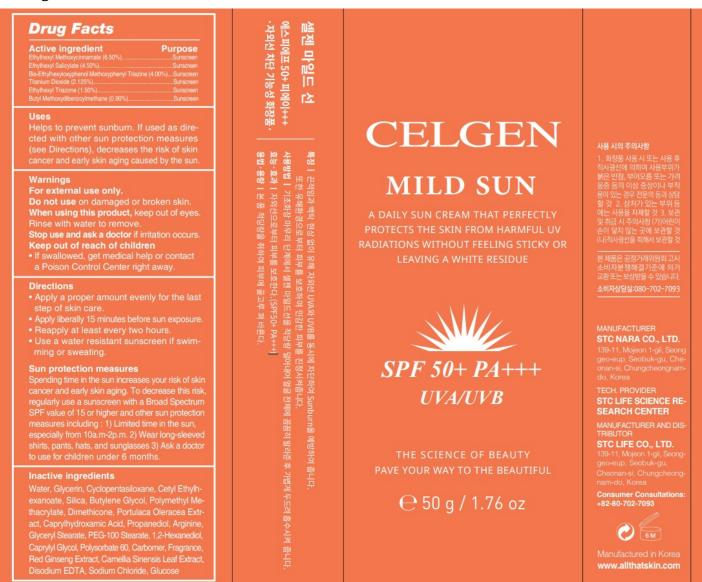
Sun protection measures.

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: 1) Limited time in the sun, especially from 10a.m-2p.m. 2) Wear long-sleeved shirts, pants, hats, and sunglasses 3) Ask a doctor to use for children under 6 months.

Inactive ingredients

Water, Glycerin, Cyclopentasiloxane, Cetyl Ethylhexanoate, Silica, Butylene Glycol, Polymethyl Methacrylate, Dimethicone, Portulaca Oleracea Extract, Caprylhydroxamic Acid, Propanediol, Arginine, Glyceryl Stearate, PEG-100 Stearate, 1,2-Hexanediol, Caprylyl Glycol, Polysorbate 60, Carbomer, Fragrance, Red Ginseng Extract, Camellia Sinensis Leaf Extract, Disodium EDTA, Sodium Chloride, Glucose

Package Label



CELGEN MILD SUN

octinoxate, octisalate, bemotrizinol, titanium dioxide, ethylhexyl triazone, avobenzone cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76731-204	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2.125 g in 100 g	
ETHYLHEXYL TRIAZONE (UNII: XQN8R9SAK4) (ETHYLHEXYL TRIAZONE - UNII:XQN8R9SAK4)	ETHYLHEXYL TRIAZONE	1.5 g in 100 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.9 g in 100 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 g in 100 g	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	4.5 g in 100 g	
BEMOTRIZINOL (UNII: PWZ1720CBH) (BEMOTRIZINOL - UNII:PWZ1720CBH)	BEMOTRIZINOL	4 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)				
DIMETHICO NE (UNII: 92RU3N3Y1O)				
CAPRYLHYDRO XAMIC ACID (UNII: UPY805K99W)				
PROPANEDIOL (UNII: 5965N8W85T)				
ARGININE (UNII: 94ZLA3W45F)				
POLYSORBATE 60 (UNII: CAL22UVI4M)				
GLYCERIN (UNII: PDC6A3C0OX)				
CETYL ETHYLHEXANO ATE (UNII: 134647WMX4)				
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)				
POLYOXYL 100 STEARATE (UNII: YD0 1N1999R)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				
PURSLANE (UNII: M6 S8 40 WXG5)				
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)				
1,2-HEXANEDIO L (UNII: TR046 Y3K1G)				
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)				
ASIAN GINSENG (UNII: CUQ3A77YXI)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
EDETATE DISODIUM ANHYDROUS (UNII: 8 NLQ36 F6 MM)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)				

Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:76731-204-01	50 g in 1 TUBE; Type 0: Not a Combination Product	09/03/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	09/03/2020		

Labeler - BBHC CO., LTD (689522401)

Registrant - STC Nara Co., Ltd (689135085)

Establishment				
Name	Address	ID/FEI	Business Operations	
STC Nara Co., Ltd		689135085	manufacture(76731-204)	

Revised: 9/2020 BBHC CO., LTD