

CELL FUSION C LASER SUNSCREEN- zinc oxide, homosalate, octisalate, titanium dioxide cream

CMS LAB 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.

Active ingredients

Active ingredients:

ZINC OXIDE 12.70%

HOMOSALATE 7.50%

ETHYLHEXYL SALICYLATE 4.50%

TITANIUM DIOXIDE 2.20%

Purpose

Sunscreen

Uses

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

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

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming 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:
 - limit time in the sun, especially from 10a.m.-2p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

■ children under 6 months of age : Ask a doctor

Inactive ingredients

Inactive ingredients

Water, Cyclopentasiloxane, Dipropylene Glycol, Disiloxane, Lauryl Peg-10
Tris(trimethylsiloxy)silylethyl Dimethicone, Glycerin, Butyloctyl Salicylate, Silica, Dimethicone,
Disteardimonium Hectorite, Magnesium Sulfate, Methyl Methacrylate Crosspolymer, 1,2-Hexanediol,
Triethoxycaprylylsilane, Stearic Acid, Aluminum Hydroxide, Sorbitan Caprylate, Dimethicone/Peg-
10/15 Crosspolymer, Lavandula Angustifolia (Lavender) Oil, Dimethicone/Vinyl Dimethicone
Crosspolymer, Glyceryl Caprylate, Ethylhexylglycerin, Sodium Citrate, Hydroxydecyl Ubiquinone,
Hydrolyzed Collagen, Tocopherol, Hydrogenated Lecithin, Ceramide Np, Sucrose Stearate,
Cholesterol, Cholesteryl Macadamiate, Palmitic Acid,
Biosaccharide Gum-4, Saccharide Isomerate, Hydrolyzed Lupine Protein

Other Information

Other Information

protect the product in this container from excessive heat and direct sun

Questions

Questions?

+82 080-447-1820;

Outside US, dial collect 212-804-7608

www.cellfusionc.co.kr

Dist. by Dkcos

20 W 33rd St New York, NY 10001

www.dkcos.com

CMS LAB Inc.

Made in Korea

www.cellfusionc.co.kr

Package Label: Cell Fusion C Laser Sunscreen SPF50+ 10mL

Drug Facts

Active Ingredients	Purpose
Zinc Oxide (12.7%)	Sunscreen
Homosalate (7.5%)	Sunscreen
Ethylhexyl Salicylate (4.5%)	Sunscreen
Titanium Dioxide (2.2%)	Sunscreen

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Cell Fusion C

Dermatological Laboratory

LASER SUNSCREEN Broad Spectrum SPF 50+

Effective UV Protection
Improves Overall
Skin Condition

WATER RESISTANT
(80 minutes)
10ML / 0.33 FL.OZ.

Drug Facts (Continued)

Inactive Ingredients

Water, Cyclopentasiloxane, Dipropylene Glycol, Disiloxane, Lauryl Peg-10 Tris(trimethylsilyloxy)Silylethyl Dimethicone, Glycerin, Butyloctyl Salicylate, Silica, Dimethicone, Disteardimonium Hectorite, Magnesium Sulfate, Methyl Methacrylate Cross polymer, 1,2-Hexanediol, Triethoxycaprylylsilane, Stearic Acid, Aluminum Hydroxide, Sorbitan Caprylate, Dimethicone/Peg-10/15 Cross polymer, Lavandula Angustifolia (Lavender) Oil, Dimethicone/Vinyl Dimethicone Crosspolymer, Glyceryl Caprylate, Ethylhexylglycerin, Sodium Citrate, Hydroxydeyl Ubiquinone, Hydrolyzed Collagen, Tocopherol, Hydrogenated Lecithin, Ceramide Np, Sucrose Stearate, Cholesterol, Cholesteryl Myristate, Palmitic Acid, Biosaccharide Gum-4, Saccharide Isomerate, Hydrolyzed Lupine Protein

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Package Label: Cell Fusion C Laser Sunscreen SPF50+ 50mL

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Cell Fusion C
Dermatological Laboratory

**LASER
SUNSCREEN**
Broad Spectrum SPF 50+
Effective UV Protection
Improves Overall
Skin Condition

WATER RESISTANT
(80 minutes)
50ML / 1.69 FL.OZ.



Drug Facts (Continued)

Inactive Ingredients

Water, Cyclopentasiloxane, Dipropylene Glycol, Disiloxane, Lauryl Peg-10 Tris(trimethylsiloxy)Silylethyl Dimethicone, Glycerin, Butyloctyl Salicylate, Silica, Dimethicone, Disteardimonium Hecto rite, Magnesium Sulfate, Methyl Methacrylate Crosspolymer, 1,2-Hexanediol, Triethoxycaprylsilane, Stearic Acid, Aluminum Hydroxide, Sorbitan Caprylate, Dimethicone/Peg-10/15 Crosspolymer, Lavandula Angustifolia (Lavender) Oil, Dimethi cone/Vinyl Dimethicone Crosspolymer, Glyceryl Caprylate, Ethylhexylgly cerin, Sodium Citrate, Hydroxydecyl Ubiquinone, Hydrolyzed Collagen, Tocopherol, Hydrogenated Lecithin, Ceramide Np, Sucrose Stearate, Cholesterol, Cholesteryl Macadamiate, Palmitic Acid, Biosaccharide Gum-4, Saccharide Isomerate, Hydrolyzed Lupine Protein

CELL FUSION C LASER SUNSCREEN

zinc oxide, homosalate, octisalate, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52554-1200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	12.70 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.50 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.50 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.20 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
Dipropylene Glycol (UNII: E107L85C40)	
HEXAMETHYLDISILOXANE (UNII: D7M4659BPU)	
Glycerin (UNII: PDC6A3C0OX)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
Triethoxycaprylsilane (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SORBITAN MONOCAPRYLATE (UNII: 1VTA8DCP5Q)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Glyceryl Caprylate (UNII: TM2TZD4G4A)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
IDEBENONE (UNII: HB6PN45W4J)	
Tocopherol (UNII: R0ZB2556P8)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
Ceramide Np (UNII: 4370DF050B)	
Sucrose Stearate (UNII: 274KW0O50M)	
Cholesterol (UNII: 97C5T2UQ7J)	
Cholesteryl Macadamiate (UNII: DFP79OD7KP)	
Palmitic Acid (UNII: 2V16EO95H1)	
BIOSACCHARIDE GUM-4 (UNII: 9XRL057X90)	
Saccharide Isomerate (UNII: W8K377W98I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52554-1200-1	10 mL in 1 CARTON; Type 0: Not a Combination Product	05/01/2020	
2	NDC:52554-1200-2	50 mL in 1 CARTON; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2020	

Labeler - CMS LAB Inc. (557795012)

Registrant - CMS LAB Inc. (557795012)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co.,LTD. Gwanjeong Factory		689512611	manufacture(52554-1200)

Revised: 5/2020

CMS LAB Inc.