

**POWERPROOF SUNSCREEN 100- homosalate, octinoxate, zinc oxide, 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.

Powerproof Sunscreen 100

Active ingredients

Homosalate (5%)

Octinoxate (5%)

Zinc Oxide (4%)

Titanium Dioxide (2.52%)

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 help prevent sunburn, not skin cancer or early skin aging.

For external use only

Do not use when skin is red, inflamed, irritated, or painful

When using this product do not apply on other parts of the body do not use on damaged or broken skin avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water do not apply directly to wound or open cut

Stop use and ask a doctor if Rash or irritation on skin develops and lasts

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- Apply the adequate amount onto the entire face at the last stage of your skin care routine. Re-apply frequently and generously to maintain protection. the palm of the hands and pat lightly with the fingertips.

- Apply liberally 15 minutes before sun exposure.

- Reapply at least every 2 hours.

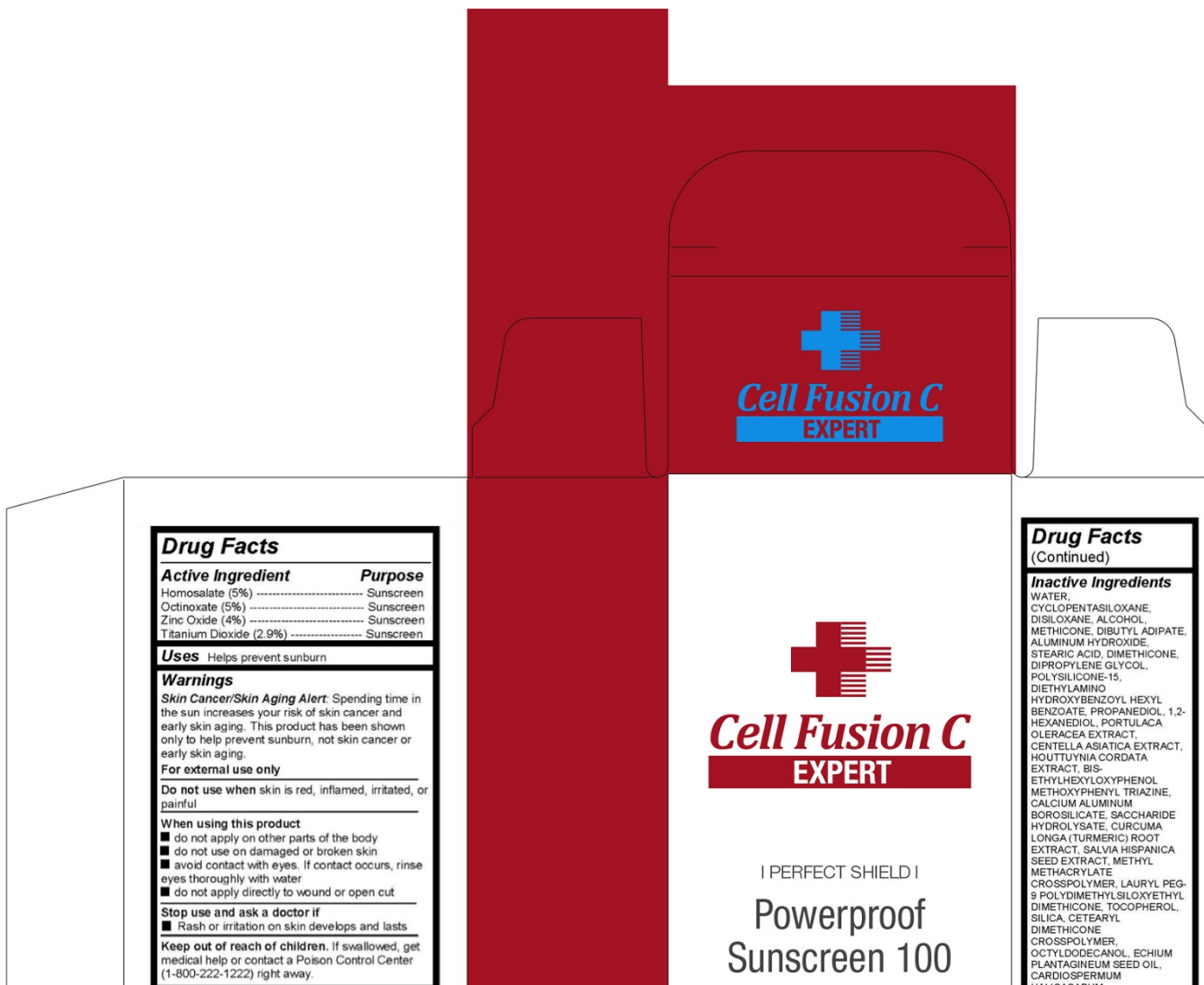
- Use a water-resistant sunscreen if swimming or sweating.

- Children under 6 months of age: ask a doctor

Inactive ingredients

WATER, CYCLOPENTASILOXANE, DISILOXANE, ALCOHOL, METHICONE, DIBUTYL ADIPATE, ALUMINUM HYDROXIDE, STEARIC ACID, DIMETHICONE, DIPROPYLENE GLYCOL, POLYSILICONE-15, DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE, PROPANEDIOL, 1,2-HEXANEDIOL, PORTULACA OLERACEA EXTRACT, CENTELLA ASIATICA EXTRACT, HOUTTUYNIA CORDATA EXTRACT, BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE, CALCIUM ALUMINUM BOROSILICATE, SACCHARIDE HYDROLYSATE, CURCUMA LONGA (TURMERIC) ROOT EXTRACT, SALVIA HISPANICA SEED EXTRACT, METHYL METHACRYLATE CROSSPOLYMER, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, TOCOPHEROL, SILICA, CETEARYL DIMETHICONE CROSSPOLYMER, OCTYLDODECANOL, ECHIUM PLANTAGINEUM SEED OIL, CARDIOSPERMUM HALICACABUM FLOWER/LEAF/VINE EXTRACT, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL UNSAPONIFIABLES, POLYMETHYLSILSESQUIOXANE, POLYGLYCERYL-6 POLYRICINOLEATE, PEG-10 DIMETHICONE, PANTHENOL, SODIUM CHLORIDE, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, ROSE FLOWER OIL, JUNIPERUS MEXICANA OIL, HYDROGENATED LECITHIN, CERAMIDE 3 (CERAMIDE NP), SUCROSE STEARATE, CHOLESTEROL, PALMITIC ACID, CHOLESTERYL MACADAMIATE, SACCHARIDE ISOMERATE, HYDROLYZED LUPINE PROTEIN, SODIUM HYALURONATE

Powerproof Sunscreen 100





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POWERPROOF SUNSCREEN 100

homosalate, octinoxate, zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52554-1112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	2.5 g in 50 mL
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	2.5 in 50 mL
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	2 g in 50 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	1.45 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
HEXAMETHYLDISILOXANE (UNII: D7M4659BPU)	
ALCOHOL (UNII: 3K9958V90M)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

STEARIC ACID (UNII: 4ELV7Z65AP)
DIMETHICONE (UNII: 92RU3N3Y1O)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
POLYSILICONE-15 (UNII: F8DRP5BB29)
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)
PROPANEDIOL (UNII: 5965N8W85T)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
PURSLANE (UNII: M6S840WXG5)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
HOUTTUYNIA CORDATA FLOWERING TOP (UNII: RH041UUZ22)
BEMOTRIZINOL (UNII: PWZ1720CBH)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
INVERT SUGAR (UNII: ED959S6ACY)
TURMERIC (UNII: 856YO1Z64F)
CHIA SEED (UNII: NU0OLX06F8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52554-1112-2	1 in 1 PACKAGE	11/01/2017	
1	NDC:52554-1112-1	50 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	11/01/2017	

Labeler - CMS LAB Inc. (557795012)

Registrant - CMS LAB Inc. (557795012)

Establishment

Name	Address	ID/FEI	Business Operations
CMS LAB Inc.		557795012	relabel(52554-1112)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd.		689512611	manufacture(52554-1112)

Revised: 11/2017

CMS LAB Inc.