

**GUARD SUNSCREEN BROAD SPECTRUM SPF 30- octinoxate, avobenzone lotion
COSMETIC ENTERPRISES 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.

Guard Sunscreen High Definition Protection SPF 30

Active ingredients Purpose

Ethylhexylmethoxycinnamate (Octinoxate) 2.0% Sunscreen

ButylMethoxydibenzoylmethane (avobenzone) .5% Sunscreen

Uses

Helps Prevent Sunburn

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs.

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.

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 10 a.m. -2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months of age: Ask a doctor

Inactive ingredients: Water, Carthamus Tinctorius (Safflower) Oleosomes, C12-15 Alkyl Benzoate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Phospholipids, Retinyl Palmitate (Vitamin A), Ascorbyl Palmitate (Vitamin C), Tocopheryl Nicotinate, Beta Glucan, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Disodium EDTA, Vanilla Planifolia Fruit Extract

Guard Sunscreen

High Definition Protection

Ecran Solaire Total

Haute Definition

SPF 30

Broad Spectrum UVA/UVB

Anti-age

1.5fl oz/ 44ml

embossed

1 29/32"

1 1/16"

5 19/32"

27/32"

UN PROTECTANT

Drug Facts	
Active ingredients Ethylhexyl Methoxycinnamate (Octinoxate), 2.0%	Purpose Sunscreen
Butyl Methoxydibenzoylmethane (Avobenzone), 0.5%	Sunscreen
Uses Helps prevent sunburn	
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.	
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Directions For sunscreen use: • Apply liberally 15 minutes before sun exposure • Reapply at least every two 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 10 a.m.-2 p.m. • Wear long-sleeved shirts, pants, hats and sunglasses • Children under 6 months of age: Ask a doctor	
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Other Information Protect product from excessive heat and direct sun.	
Questions or comments? Call 323-866-1800	

EMK SYNERCELL[®] and HYDRAPEARL HYBRID[™] release vitamins and antioxidants to the dermis to prevent sunburn, wrinkles, discolorations, and loss of firmness from UV damage. Clinically proven HD-SHIELD[™] full UV protection reflects light for a perfected skin finish, ideal for photo shoots with flashlights. Good for all skin types, including Fitzpatrick II through IV, it is vital after professional treatments and cosmetic surgery. Photo stable in sunlight for up to 24h.

To Use: After your daily skin care routine, apply over any area to be exposed to sunlight.

Superb for all skin types • Dermatologist tested • Hypoallergenic
OIL FREE • FRAGRANCE FREE • PARABEN FREE • COLORANT FREE • ANTI-POLLUTION

EMK SYNERCELL[®] et HYDRAPEARL HYBRID[™] aident à libérer vitamines et antioxydants en quantité idéales pour nourrir le derme pendant l'exposition. La peau est protégée contre les coups de soleil, la formation des rides, la décoloration, et la perte de fermeté. Avec le complexe HD-SHIELD[™], les UVs sont réfléchis de la surface de la peau sans créer de brillance, pour une finition parfaite et un teint naturel, même sous les flashes des projecteurs. Cet écran fonctionne sur tout type de peau, et est stable pendant plus de 24h.

Utilisation: Après vos soins habituels, appliquer Guard Sunscreen[™] sur toutes les zones exposées au soleil. Idéal pour tout type de peau • Testé sur peau sensible sous contrôle dermatologue • Hypoallergénique

EMK[®]

BEVERLY HILLS

GUARD SUNSCREEN[™]

High Definition Protection

Ecran Solaire Total Haute Définition

SPF 30 Broad Spectrum UVA/UVB

ANTI-AGE

1.5 fl oz / 44 ml

Distributed by EMK Skin Care
BEVERLY HILLS, CA 90210
BRUSSELS, Avenue Hamoir 12, 1180
PARIS, Saint-Honoré 75008

Made in USA

MIX Board
FSC FSC® C103164

12M

7 107577 101214

GUARD SUNSCREEN BROAD SPECTRUM SPF 30

octinoxate, avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56 152-5008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
TOCOPHERYL NICOTINATE, D-.ALPHA. (UNII: WI1J5UCY5C)	
VANILLA (UNII: Q74T35078H)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K00R)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56152-5008-1	44 mL in 1 CARTON; Type 0: Not a Combination Product	12/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/20/2018	

Labeler - COSMETIC ENTERPRISES LTD (017701475)

Registrant - COSMETIC ENTERPRISES LTD (017701475)

Establishment

Name	Address	ID/FEI	Business Operations
COSMETIC ENTERPRISES LTD		017701475	manufacture(56152-5008)