

XXL SUN BLOCK SPF 50- octinoxate, octocrylene, octisalate, avobenzone, homosalate cream cream

Peer Pharma 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.

Gold Cosmetics XXL Sun Block SPF 50

GOLD cosmetics
Adj. & Skin Care Or.

XXL

SUN BLOCK

SPF 50

3.4fl. oz. e 100ml

Drug Facts

Active ingredient:
Homosalate(13%), Oxybenzone(7%), Octisalate(5%)
Octocrylene(4%), Avobenzon(3%)

Use: Helps prevent sunburn.

Warnings: For external use only. Do not use on damaged or broken skin. **Do not use** if you have known sensitivities to any one of the ingredients. **When using this product** avoid contacts with eyes. If contact occurs, rinse eyes thoroughly with water. **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 immediately. This cosmetic product should be used only for the purpose it was intended and according to its instructions. **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.

Directions for use: gently apply "gold" demi-makeup to face and neck 15 minutes before sun exposure for instant Coverage and correction as well as for protection. Reapply at least every 2 hours. Use a water-resistant sunscreen if swimming or sweating. Children under 6 months of age: ask a doctor.

Other information: protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Water(USP), Sorbitol, Dimethicone/Vinyl Dimethicone Crosspolymer, Aluminum Starch Octylsuccinate, Styrene/Acrylates Copolymer, Stearic acid, Behenyl Alcohol, Triethanolamine, Tricentany PVP, Potassium Cetyl Phosphate, Polyglyceryl-10 Pentastearate, Phenoxethanol, Fragrance, Sodium Stearoyl Lactylate, Carbomer, Dimethicone, Maris sal, C12-14 Pareth-12, Disodium EDTA, Triethylene glycol, Tocopheryl Acetate.

MADE IN IL
GOLD COSMETICS
& SKIN CARE
1118 AVE. J
BROOKLYN, NY 11230
TEL: 718-677 7711

907978

ITEM #8218

7290110808181

Oxybenzone 7%

Octocrylene 4%

Octisalate 5%

Avobenzone 3%

Homosalate 13%

Keep out of reach of children.

Provides SPF 50 protection

Directions for Use: Apply generously to face and body regularly before sun exposure and as needed.

Reapply: after 40 minutes before of or 80 minutes of swimming or sweating, immediately after towel drying, and at least every 2 hours.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69435-1905
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALMOND OIL (UNII: 66YXD4DKO9)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALLANTOIN (UNII: 344S277G0Z)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
SHEA BUTTER (UNII: K49155WL9Y)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SEA SALT (UNII: 87GE52P74G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0067Z)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
WATER (UNII: 059QF0K00R)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1905-1	100 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/06/2019	

Labeler - Peer Pharma Ltd. (514678390)

Registrant - Peer Pharma Ltd. (514678390)

Establishment

Name	Address	ID/FEI	Business Operations
Peer Pharma Ltd.		514678390	manufacture(69435-1905)

Revised: 9/2019

Peer Pharma Ltd.