

LA MER THE BROAD SPECTRUM SPF 50 UV PROTECTING FLUID- avobenzene, homosalate, octisalate, octocrylene, and oxybenzone lotion
MAX HUBER RESEARCH 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.

LA MER THE BROAD SPECTRUM SPF 50 UV PROTECTING FLUID

Drug Facts

Active ingredients

AVOBENZONE 3.00%
HOMOSALATE 5.00%
OCTISALATE 5.00%
OCTOCRYLENE 2.70%
OXYBENZONE 3.00%

Purpose

Sunscreen

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

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

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply 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

Ingredients

WATER\AQUA\EAU • BUTYLOCTYL SALICYLATE • METHYL TRIMETHICONE • NEOPENTYL GLYCOL DIHEPTANOATE • ALEURITES MOLUCCANA (KUKUI) SEED OIL • LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • PEG 100 STEARATE • BUTYLENE GLYCOL • GLYCERYL STEARATE • DIPENTAERYTHRITYL TRIPOLYHYDROXYSTEARATE • POTASSIUM CETYL PHOSPHATE • ALGAE (SEAWEED) EXTRACT • SESAMUM INDICUM (SESAME) SEED OIL • MEDICAGO SATIVA (ALFALFA) SEED POWDER • HELIANTHUS ANNUUS (SUNFLOWER) SEEDCAKE • PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) SEED MEAL • EUCALYPTUS GLOBULUS (EUCALYPTUS) LEAF OIL • SODIUM GLUCONATE • COPPER GLUCONATE • CALCIUM GLUCONATE • MAGNESIUM GLUCONATE • ZINC GLUCONATE • TOCOPHERYL SUCCINATE • NIACIN • SESAMUM INDICUM (SESAME) SEED POWDER • LAMINARIA OCHROLEUCA EXTRACT • MALACHITE • CAFFEINE • SORBITOL • SODIUM HYALURONATE • CETYL ALCOHOL • STEARIC ACID • VP/EICOSENE COPOLYMER • ETHYLHEXYLGLYCERIN • SACCHARIDE ISOMERATE • CAPRYLIC/CAPRIC TRIGLYCERIDE • CAPRYLYL GLYCOL • AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER • DEHYDROXANTHAN GUM • SODIUM DEHYDROACETATE • CITRIC ACID • TOURMALINE • STYRENE/ACRYLATES COPOLYMER • SILICA • PEG-8 LAURATE • FRAGRANCE (PARFUM) • DISODIUM EDTA • PHENOXYETHANOL • LIMONENE • GERANIOL • HYDROXYCITRONELLAL • LINALOOL • CITRONELLOL • MICA • GREEN 5 (CI 61570) • TITANIUM DIOXIDE (CI 77891) <ILN40137>

Other information

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

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Carton

LA MER

the broad spectrum

spf 50 UV protecting fluid

1.7 fl. oz. liq./50 ml e

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65966-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.0312 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.052 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.052 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.02808 g in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0312 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
METHYL TRIMETHICONE (UNII: S73ZQ10GXM)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
PEG-100 STEARATE (UNII: YD01N1999R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SESAME OIL (UNII: QX10HYY4QV)	
ALFALFA SEED (UNII: 67PHZ58858)	
HELIANTHUS ANNUUS SEEDCAKE (UNII: 482WYF7XLC)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
COPPER GLUCONATE (UNII: RV823G6G67)	
CALCIUM GLUCONATE (UNII: SQE6VB453K)	
MAGNESIUM GLUCONATE (UNII: T42NAD2KHC)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE)	
NIACIN (UNII: 2679MF687A)	
SESAME SEED (UNII: 7Y1255HVXR)	
LAMINARIA OCHROLEUCA (UNII: 4R2124HE76)	
CAFFEINE (UNII: 3G6A5W338E)	
SORBITOL (UNII: 506T60A25R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	

SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
PEG-8 LAURATE (UNII: 762O8IWA10)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
GERANIOL (UNII: L837108USY)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65966-016-01	1 in 1 CARTON	05/05/2013	
1		50 mL in 1 BOTTLE; 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	05/05/2013	

Labeler - MAX HUBER RESEARCH LAB INC (926708694)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(65966-016) , REPACK(65966-016)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(65966-016)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(65966-016)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(65966-016)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(65966-016)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(65966-016) , REPACK(65966-016)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(65966-016) , REPACK(65966-016)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(65966-016)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(65966-016)

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