

**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 TRI-POLYHYDROXYSTEARATE • 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 ACRYLOYLDIMETHYLAURATE/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	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
METHYL TRIMETHICONE (UNII: S73ZQIOGXM)	
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 DEHYDROACETATE (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 final	M020	05/05/2013	

Labeler - MAX HUBER RESEARCH LAB INC (926708694)

Registrant - Estee Lauder Companies Inc. (790802086)

Establishment			
Name	Address	ID/FEI	Business Operations
PALC		078364654	label(65966-016) , pack(65966-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Ltd.		204132062	pack(65966-016) , label(65966-016)

Establishment			
Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture(65966-016) , pack(65966-016) , label(65966-016)

Establishment			
Name	Address	ID/FEI	Business Operations

Estee Lauder N.V.		370151326	manufacture(65966-016) , pack(65966-016) , label(65966-016)
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Establishment

Name	Address	ID/FEI	Business Operations
The Estee Lauder Inc		802599436	manufacture(65966-016) , pack(65966-016) , label(65966-016)

Establishment

Name	Address	ID/FEI	Business Operations
Northtec LLC		943871157	pack(65966-016) , label(65966-016)

Establishment

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

Revised: 4/2023

MAX HUBER RESEARCH LAB INC