

**LA MER THE REPARATIVE FACE SUN BROAD SPECTRUM SPF 30- avobenzone, 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.*

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**LA MER THE REPARATIVE FACE SUN LOTION**  
**Broad Spectrum SPF 30**

***Drug Facts***

**Active ingredients**

Avobenzone 3.00%  
Homosalate 5.00%  
Octisalate 5.00%  
Octocrylene 2.70%  
Oxybenzone 2.50%

**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

### **Inactive ingredients**

water/aqua/eau • dimethicone • butyloctyl salicylate • neopentyl glycol diheptanoate • butylene glycol • peg-100 stearate • dipentaerythrityl tri-polyhydroxystearate • silica • lauryl peg-9 polydimethylsiloxylethyl dimethicone • butyrospermum parkii (shea butter) • methyl trimethicone • phenyl trimethicone • trisiloxane • glyceryl stearate • 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 • rosmarinus officinalis (rosemary) extract • citrus aurantifolia (lime) peel extract • cucumis sativus (cucumber) fruit extract • pyrus malus (apple) fruit extract • scutellaria baicalensis root extract • plankton extract • laurdimonium hydroxypropyl hydrolyzed soy protein • malachite • acetyl hexapeptide-8 • caffeine • arginine ferulate • lecithin • cholesterol • yeast extract/faex/extrait de levure • sorbitol • glycerin • trehalose • phytosphingosine • polyquaternium-51 • styrene/acrylates copolymer • cetyl alcohol • vp/eicosene copolymer • polysilicone-11 • sucrose • urea • caprylyl glycol • ethylhexylglycerin • saccharide isomerate • caprylic/capric triglyceride • ammonium acryloyldimethyltaurate/vp copolymer • sodium pca • sodium hyaluronate • dehydroxanthan gum • peg-8 laurate • tocopheryl acetate • citric acid • tourmaline • propyl gallate • xanthan gum • ascorbyl tocopheryl maleate • stearic acid • nordihydroguaiaretic acid • alcohol denat. • fragrance (parfum) • hexylene glycol • disodium edta • sodium dehydroacetate • phenoxyethanol • hydroxycitronellal • linalool • hexyl cinnamal • amyl cinnamal • benzyl benzoate • coumarin • limonene • citronellol • geraniol • citral • mica <iln39596>

### **Other information**

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

MAX HUBER RESEARCH LABS INC., DIST.  
NEW YORK, N.Y. 10022

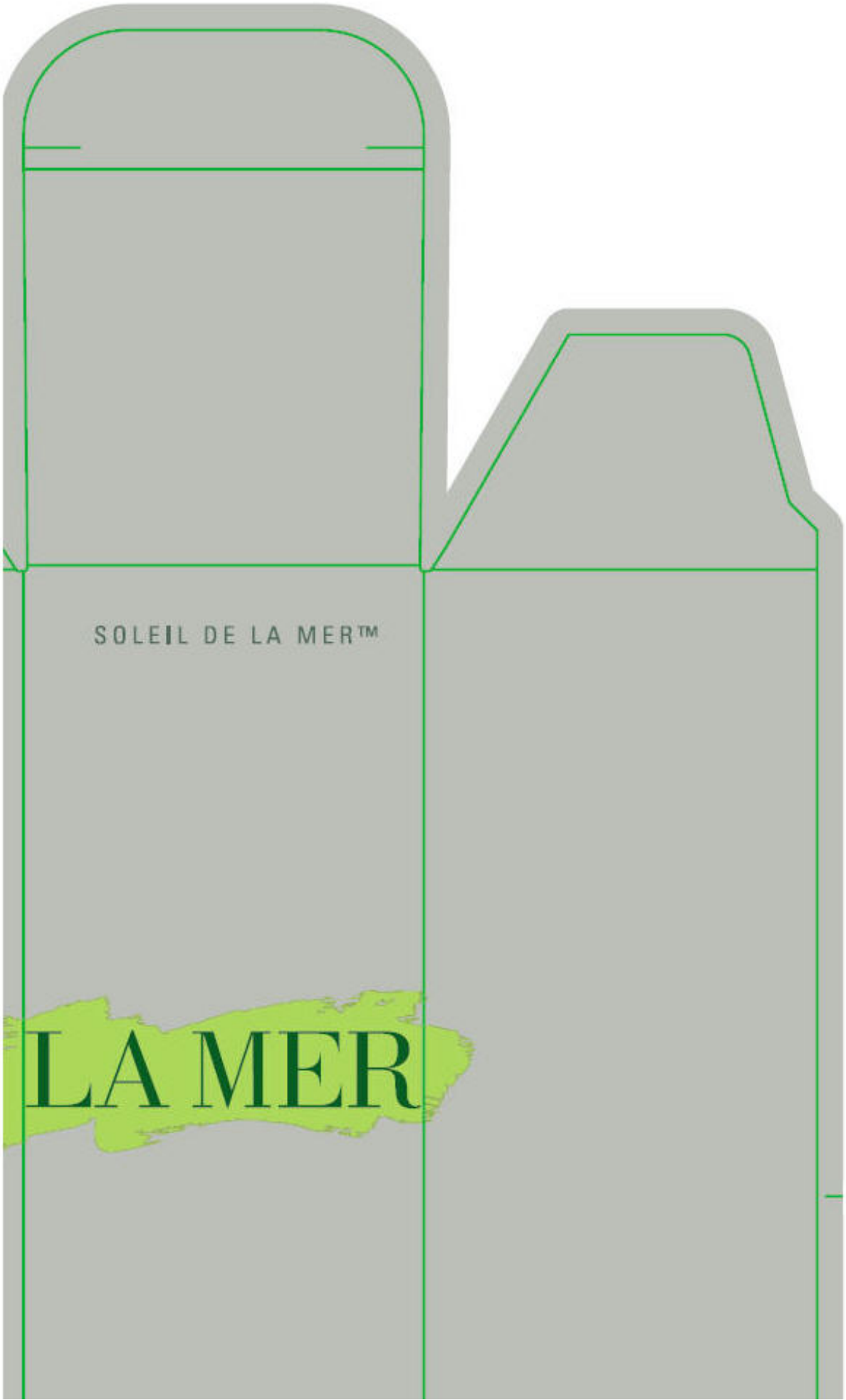
### **PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton**

SOLEIL DE LA MER™

**LA MER**

the reparative face sun lotion  
broad spectrum spf 30

1.7 fl. oz./oz. liq./50 ml e



SOLEIL DE LA MER™

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1.7 fl. oz./oz. liq./50 ml e

S.3 ©

53EP-01-1111

**The Reparative Face Sun Lotion SPF 30** This luxurious, deeply hydrating sun lotion harnesses the power of the sea to help protect the skin from the sun. It absorbs quickly and offers skin broad spectrum UVA/UVB protection and powerful anti-aging benefits to help repair the appearance of existing damage and prevent the formation of new lines, wrinkles and age spots. Sea-born ingredients and the nutrient-rich Miracle Broth™, heart of La Mer's profound powers of transformation, help rejuvenate, rehydrate and soothe. Skin looks youthfully radiant.

### Drug Facts

Active ingredients	Purpose
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### Drug Facts (continued)

#### Inactive ingredients

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**Other information**

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

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0321941500

0321941907 85842



MAX HUBER RESEARCH LABS INC., DIST.  
NEW YORK, N.Y. 10022  
LONDON W1K 3BQ • PARIS • MILANO  
MADE IN UK 53EP  
www.LaMer.com



53EP-01-1111



# LA MER THE REPARATIVE FACE SUN BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65966-011
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0KO0R)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>butyloctyl salicylate</b> (UNII: 2EH13UN8D3)	
<b>neopentyl glycol diheptanoate</b> (UNII: 5LKW3C543X)	
<b>butylene glycol</b> (UNII: 3XUS85K0RA)	
<b>peg-100 stearate</b> (UNII: YD01N1999R)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>methyl trimethicone</b> (UNII: S73ZQI0GXM)	
<b>phenyl trimethicone</b> (UNII: DR0K5NOJ4R)	
<b>trisiloxane</b> (UNII: 9G1ZW13R0G)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)	
<b>sesame oil</b> (UNII: QX10HYY4QV)	
<b>alfalfa seed</b> (UNII: 67PHZ58858)	
<b>helianthus annuus seedcake</b> (UNII: 482WYF7XLC)	
<b>eucalyptus oil</b> (UNII: 2R04ONI662)	
<b>sodium gluconate</b> (UNII: R6Q3791S76)	
<b>copper gluconate</b> (UNII: RV823G6G67)	
<b>calcium gluconate</b> (UNII: SQE6VB453K)	
<b>magnesium gluconate</b> (UNII: T42NAD2KHC)	
<b>zinc gluconate</b> (UNII: U6WSN5SQ1Z)	
<b>.alpha.-tocopherol succinate, d-</b> (UNII: LU4B53JYVE)	
<b>niacin</b> (UNII: 2679MF687A)	
<b>sesame seed</b> (UNII: 7Y1255HVXR)	
<b>laminaria ochroleuca</b> (UNII: 4R2124HE76)	

<b>rosemary</b> (UNII: IJ67X351P9)	
<b>lime peel</b> (UNII: 544EQK5Q0W)	
<b>cucumber</b> (UNII: YY7C30VXJT)	
<b>apple</b> (UNII: B423VGH5S9)	
<b>scutellaria baicalensis root</b> (UNII: 7J95K7ID2S)	
<b>acetyl hexapeptide-8</b> (UNII: L4EL31FWIL)	
<b>caffeine</b> (UNII: 3G6A5W338E)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>trehalose</b> (UNII: B8WCK70T7I)	
<b>phytosphingosine</b> (UNII: GIN46U9Q2Q)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>urea</b> (UNII: 8W8T17847W)	
<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
<b>ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>saccharide isomerate</b> (UNII: W8K377W98I)	
<b>medium-chain triglycerides</b> (UNII: C9H2L21V7U)	
<b>ammonium acryloyldimethyltaurate/vp copolymer</b> (UNII: W59H9296ZG)	
<b>sodium pyrrolidone carboxylate</b> (UNII: 469OTG57A2)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>peg-8 laurate</b> (UNII: 762O8IWA10)	
<b>.alpha.-tocopherol acetate</b> (UNII: 9E8X80D2L0)	
<b>citric acid monohydrate</b> (UNII: 2968PHW8QP)	
<b>propyl gallate</b> (UNII: 8D4SNN7V92)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>ascorbyl tocopheryl maleate</b> (UNII: D2G6259XR5)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>masoprocol</b> (UNII: 7BO8G1BYQU)	
<b>hexylene glycol</b> (UNII: KEH0A3F75J)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>sodium dehydroacetate</b> (UNII: 8W46YN971G)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>hydroxycitronellal</b> (UNII: 8SQ0VA4YUR)	
<b>.alpha.-hexylcinnamaldehyde</b> (UNII: 7X6O37OK2I)	
<b>.alpha.-amylcinnamaldehyde</b> (UNII: WC51CA3418)	
<b>benzyl benzoate</b> (UNII: N863NB338G)	
<b>coumarin</b> (UNII: A4VZ22K1WT)	
<b>.beta.-citronellol, (r)-</b> (UNII: P01OUT964K)	
<b>geraniol</b> (UNII: L837108USY)	
<b>citral</b> (UNII: T7EU009VPP)	
<b>mica</b> (UNII: V8A1AW0880)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65966-011-01	1 in 1 CARTON	11/11/2012	
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	11/11/2012	

**Labeler** - MAX HUBER RESEARCH LAB INC (926708694)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(65966-011) , REPACK(65966-011)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(65966-011)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(65966-011)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(65966-011)

## Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(65966-011)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(65966-011) , REPACK(65966-011)

## Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(65966-011) , REPACK(65966-011)

## Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(65966-011)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(65966-011)



