

LA MER THE RADIANT SKINTINT BROAD SPECTRUM SPF 30- octinoxate, octisalate, and titanium dioxide cream

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 RADIANT SKINTINT BROAD SPECTRUM SPF 30

Drug Facts

Active Ingredients

OCTINOXATE 7.5%

OCTISALATE 2.0%

TITANIUM DIOXIDE 5.3%

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 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

Inactive Ingredients

WATER\AQUA\EAU • BUTYLENE GLYCOL • OCTYLDODECYL NEOPENTANOATE • CETYL ALCOHOL • LAURETH-4 • ASCORBYL GLUCOSIDE • NEOPENTYL GLYCOL DIHEPTANOATE • 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 • POLYETHYLENE • HELICHRYSUM ARENARIUM (EVERLASTING) EXTRACT • CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT • PEG-100 STEARATE • HYDROGENATED LECITHIN • CORALLINA OFFICINALIS EXTRACT • GELIDIUM CARTILAGINEUM EXTRACT • SACCHAROMYCES LYSATE EXTRACT • MENTHA VIRIDIS (SPEARMINT) • PELARGONIUM GRAVEOLENS (GERANIUM) FLOWER OIL • LAMINARIA SACCHARINA EXTRACT • CITRUS GRANDIS (GRAPEFRUIT) PEEL OIL • LAMINARIA DIGITATA EXTRACT • METHYLDIHYDROJASMONATE • SIGESBECKIA ORIENTALIS (ST. PAUL'S WORT) EXTRACT • ACETYL HEXAPEPTIDE-8 • SUCROSE • GLYCERIN • GLYCYRRHETINIC ACID • CAFFEINE • PROPYLENE GLYCOL DIETHYLHEXANOATE • LECITHIN • ISOHEXADECANE • POLYGLYCERYL-3 BEESWAX • WHEY PROTEIN\LACTIS PROTEIN\PROTEINE DU PETIT-LAIT • DIMETHOXYTOLYL PROPYLRESORCINOL • CITRUS AURANTIFOLIA (LIME) PEEL EXTRACT • ACETYL GLUCOSAMINE • PVP/HEXADECENE COPOLYMER • TOURMALINE • YEAST POLYSACCHARIDES • CAPRYLYL GLYCOL • ROSA DAMASCENA (ROSE) FLOWER OIL • YEAST EXTRACT\FAEX\EXTRAIT DE LEVURE • ISOSTEARIC ACID • PROPYLENE GLYCOL DICAPRATE • HORDEUM VULGARE (BARLEY) EXTRACT\EXTRAIT D'ORGE • STEARIC ACID • TROMETHAMINE • ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLT AURATE COPOLYMER • GALACTOARABINAN • NYLON-12 • ZEOLITE • SYNTHETIC FLUORPHLOGOPITE • TOCOPHERYL LINOLEATE/OLEATE • SODIUM HYALURONATE • BORON NITRIDE • XANTHAN GUM • POLYSORBATE 80 • SILICA • ALUMINUM HYDROXIDE • ALCOHOL DENAT. • TIN OXIDE • DISODIUM EDTA • BHT • LINALOOL • GERANIOL • CITRONELLOL • LIMONENE • PHENOXYETHANOL • [+/- TITANIUM DIOXIDE (CI 77891) • IRON OXIDES (CI 77491) • IRON OXIDES (CI 77492) • IRON OXIDES (CI 77499) • MICA] <ILN45014>

Other information

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

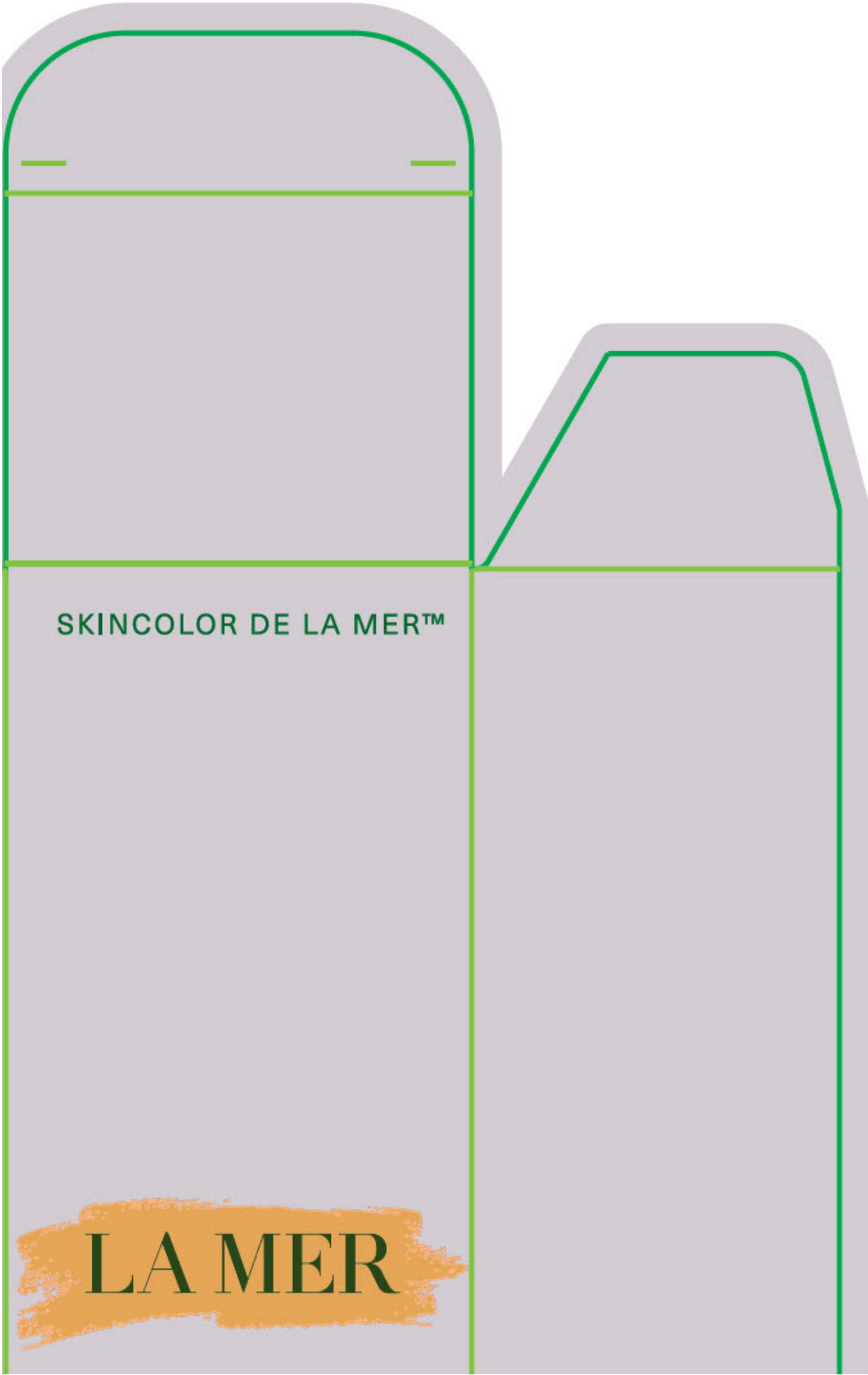
PRINCIPAL DISPLAY PANEL - 40 ml Tube Carton

SKINCOLOR DE LA MER™

LA MER

THE RADIANT SKINTINT
BROAD SPECTRUM SPF 30

1.4 fl. oz. liq. /40 ml e



SKINCOLOR DE LA MER™

LA MER

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BROAD SPECTRUM SPF 30

1.4 fl. oz. liq. /40 ml e

Drug Facts

Active Ingredients Purpose

Drug Facts (continued)

(EVERLASTING) EXTRACT •
CUCURBITACETIC ACID (CUCURBITACIN)

OCTINOXATE 7.5%
OCTISALATE 2.0%
TITANIUM DIOXIDE 5.3% } SUNSCREEN

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CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT • PEG-100 STEARATE • HYDROGENATED LECITHIN • CORALLINA OFFICINALIS EXTRACT • GELIDIUM CARTILAGINEUM EXTRACT • SACCHAROMYCES LYSATE EXTRACT • MENTHA VIRIDIS (SPEARMINT) • PELARGONIUM GRAVEOLENS (GERANIUM) FLOWER OIL • LAMINARIA SACCHARINA EXTRACT • CITRUS GRANDIS (GRAPEFRUIT) PEEL OIL • LAMINARIA DIGITATA EXTRACT • METHYLDIHYDROJASMONATE • SIGESBECKIA ORIENTALIS (ST. PAUL'S WORT) EXTRACT • ACETYL HEXAPEPTIDE-8 • SUCROSE • GLYCERIN • GLYCYRRHETINIC ACID • CAFFEINE • PROPYLENE GLYCOL DIETHYLHEXANOATE • LECITHIN • ISOHEXADECANE • POLYGLYCERYL-3 BEESWAX • WHEY PROTEIN\LACTIS PROTEIN\PROTEINE DU PETIT-LAIT • DIMETHOXYTOLYL PROPYLRESORCINOL • CITRUS AURANTIFOLIA (LIME) PEEL EXTRACT • ACETYL GLUCOSAMINE • PVP/HEXADECENE COPOLYMER • TOURMALINE • YEAST POLYSACCHARIDES • CAPRYLYL GLYCOL • ROSA DAMASCENA (ROSE) FLOWER OIL • YEAST EXTRACT\FAEX\EXTRAIT DE LEVURE • ISOSTEARIC ACID • PROPYLENE GLYCOL DICAPRATE • HORDEUM VULGARE (BARLEY) EXTRACT\EXTRAIT D'ORGE • STEARIC ACID • TROMETHAMINE • ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER • GALACTOARABINAN • NYLON-12 • ZEOLITE • SYNTHETIC FLUORPHLOGOPITE • TOCOPHERYL LINOLEATE/OLEATE • SODIUM HYALURONATE • BORON NITRIDE • XANTHAN GUM • POLYSORBATE 80 • SILICA • ALUMINUM HYDROXIDE • ALCOHOL DENAT. • TIN OXIDE • DISODIUM EDTA • BHT • LINALOOL • GERANIOL • CITRONELLOL • LIMONENE • PHENOXYETHANOL • [+/- TITANIUM DIOXIDE (CI 77891) • IRON OXIDES (CI 77491) • IRON OXIDES (CI 77492) • IRON OXIDES (CI 77499) • MICA] <LN45014>

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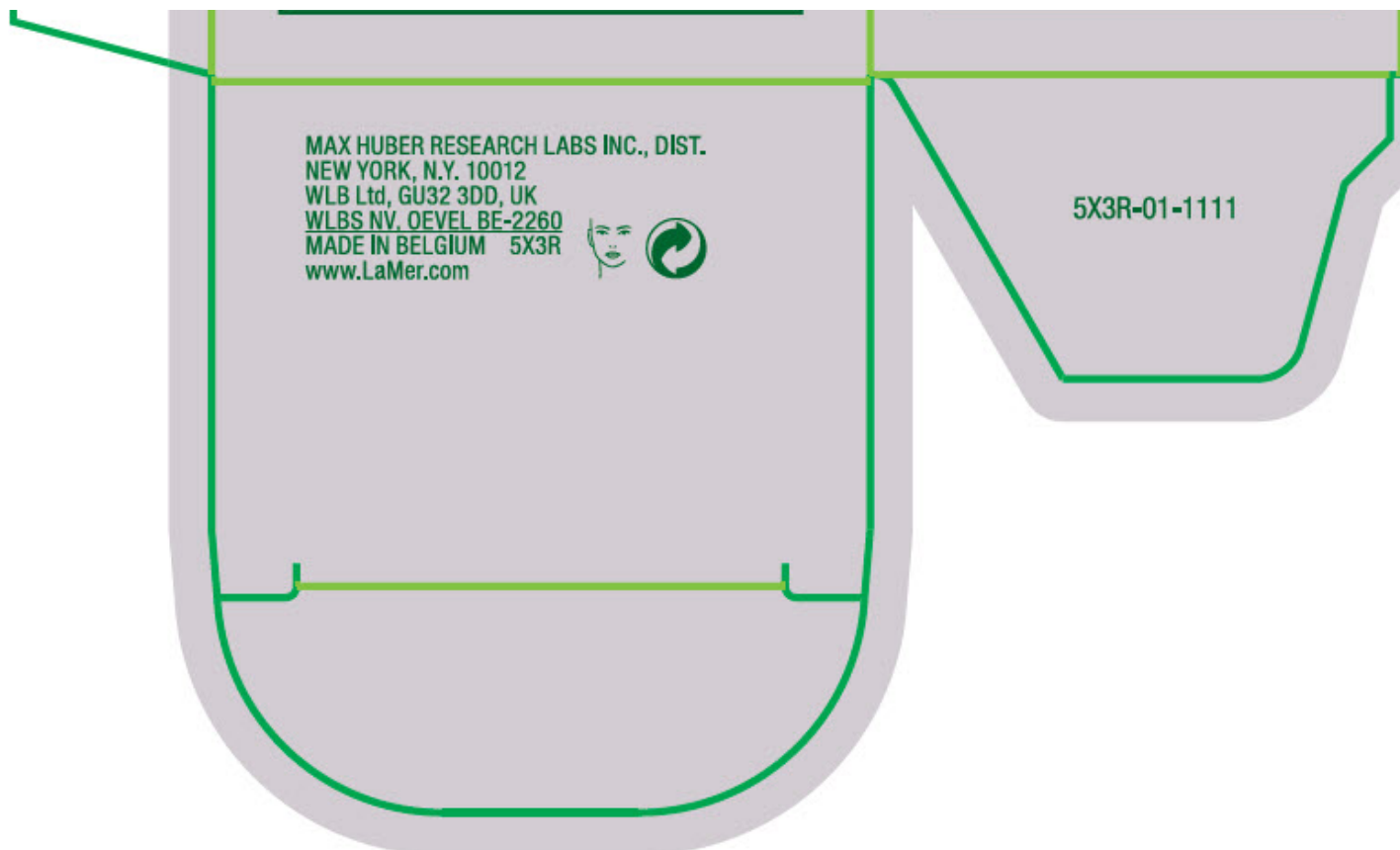
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LA MER THE RADIANT SKINTINT BROAD SPECTRUM SPF 30

octinoxate, octisalate, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65966-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	82.5 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	22 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	58.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LAURETH-4 (UNII: 6HQ855798J)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
NORI (UNII: 477TV3P5UX)	

SESAME OIL (UNII: QX10HYY4QV)	
ALFALFA SEED (UNII: 67PHZ58858)	
HELIANTHUS ANNUUS SEEDCAKE (UNII: 482WYF7XLC)	
EUCALYPTUS GUM (UNII: 72T9EZC2VX)	
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)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GAMO CHAETA PURPUREA FLOWER (UNII: KQV867ADR4)	
CUCUMBER (UNII: YY7C30VXJT)	
PEG-100 STEARATE (UNII: YD01N1999R)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
PLOCAMIMUM CARTILAGINEUM (UNII: 37LBZ0E1UE)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
SPEARMINT (UNII: J7I2T6IV1N)	
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
SACCHARINA LATISSIMA (UNII: 68CMP2MB55)	
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
METHYL DIHYDROJASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)	
SUCROSE (UNII: C151H8M554)	
GLYCERIN (UNII: PDC6A3C0OX)	
ENOXOLONE (UNII: P540XA09DR)	
CAFFEINE (UNII: 3G6A5W338E)	
PROPYLENE GLYCOL DIETHYLHEXANOATE (UNII: 8D8I9Z0F1Z)	
ISOHEXADECANE (UNII: 918X10UF1E)	
DIMETHOXYTOLYL PROPYLRESORCINOL (UNII: 4OD5GIH1UK)	
LIME PEEL (UNII: 544EQK5Q0W)	
N-ACETYLGLUCOSAMINE (UNII: V956696549)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ROSA X DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
PROPYLENE GLYCOL DICAPRATE (UNII: U783H9JHWY)	
BARLEY (UNII: 5PWM7YL17R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROMETHAMINE (UNII: 023C2WHX2V)	
GALACTOARABINAN (UNII: SL4SX1O487)	
NYLON-12 (UNII: 446U8J075B)	
ZEOLITE A (UNII: Y3NG9WF08W)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
XANTHAN GUM (UNII: TTV12P4NEE)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ALCOHOL (UNII: 3K9958V90M)
STANNIC OXIDE (UNII: KM7N50LOS6)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
GERANIOL (UNII: L837108USY)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65966-021-01	1 in 1 CARTON	02/26/2020	
1		40 mL in 1 TUBE; 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	02/26/2020	

Labeler - MAX HUBER RESEARCH LAB INC (926708694)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(65966-021) , REPACK(65966-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(65966-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(65966-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(65966-021)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(65966-021)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(65966-021) , REPACK(65966-021)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(65966-021) , REPACK(65966-021)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(65966-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(65966-021)

Revised: 2/2020

MAX HUBER RESEARCHLAB INC