

MAX SHEER ALL DAY MOISTURE DEFENSE- sunscreen lotion spf 30 lotion
Peter Thomas Roth Labs LLC

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.

Peter Thomas Roth Max Sheer All Day Moisture Defense Lotion Sunscreen SPF 30

Drug Facts

Active Ingredients

Avobenzone 3%
Homosalate 10%
Octinoxate 7.5%
Octisalate 5%
Octocrylene 2%
Oxybenzone 6%

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

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

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if involved in swimming or intense physical activities where sweating will occur
- reapply at least every 2 hours
- **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 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

❑ Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Ascorbyl Palmitate, Bentonite, Butylene Glycol, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Carbomer, Ceramide 3, Cetyl Alcohol, Dimethicone, Ginkgo Biloba Leaf Extract, Glyceryl Stearate, Panthenol, PEG-100 Stearate, Phenoxyethanol, Phospholipids, Potassium Sorbate, Propylene Glycol, Retinyl Palmitate, Sodium Benzoate, Stearic Acid, Tetrasodium EDTA, Tocopheryl Acetate, Triethanolamine, Water/Aqua/Eau.

❑ Other Information

protect this product from excessive heat and direct sun

❑ Questions or comments?

Call toll free 1-800-PTR-SKIN (787-7546)

❑ PRINCIPAL DISPLAY PANEL

PRINTS SPOT GLOSS
TURN ON LAYER TO SEE

6 13/16

11 9/64

Drug Facts

Active Ingredients	Purpose
Avoberzone 3%	Sunscreen
Homosalate 1.0%	
Octinoxate 7.5%	
Octisalate 5%	
Oxybenzone 2%	
Oxybenzone 6%	

Uses

- help prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decrease 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

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if involved in swimming or intense physical activities
- where sweating will occur
- reapply at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increase your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 4 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Ascorbyl Palmitate, Bentonite, Butylene Glycol, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Carbomer, Ceramide 3, Cetyl Alcohol, Dimethicone, Ginkgo Biloba Leaf Extract, Glyceryl Stearate, Panthenol, PEG-100 Stearate, Phenoxyethanol, Phospholipids, Potassium Sorbate, Propylene Glycol, Retinyl Palmitate, Sodium Benzoate, Stearic Acid, Tetrasodium EDTA, Tocopheryl Acetate, Triethanolamine, Water/Aqua/Eau.

LOTION ÉCRAN SOLAIRE
Sans huile, anti-âge, SPF 30 à large spectre, hydratation intense à base de céramides, aloé et apaisant, vitamines A, C & E, provitamine B5. Pour tous types de peau.

Avvertimenti: Per uso esterno solamente. **Guardarlo in casa, lontano dai bambini.**

Mode d'emploi: Appliquer généreusement sur le visage et le cou 15 minutes avant l'exposition au soleil. Appliquer de nouveau au moins toutes les deux heures.

LOCIÓN PROTECTOR SOLAR
Sin aceite, anti-envejecimiento, FPS 30 de amplio espectro, hidratación duradera con ceramidas, aloe calmante, vitaminas A, C & E, provitamina B5. Para todo tipo de piel.

Advertencias: Solo para uso externo. **Manténgase fuera del alcance de los niños.**

Istruzioni: Applicare generosamente in la cara y cuello 15 minutos antes de la exposición al sol. Vuelva a aplicar cada dos horas.

PROTEZIONE SOLARE
Senza olio, anti-età, filtro solare SPF 30 ad ampio spettro, idratazione duravole grazie alle ceramidi, effetto calmante dell'aloe, vitamine A, C & E, provitamina B5. Per tutti i tipi di pelle.

Precauzioni: Solo per uso esterno. **Tenere fuori dalla portata dei bambini.**

Istruzioni: Applicare generosamente sul viso e sul collo 15 minuti prima di esporsi al sole. Ripetere l'applicazione almeno ogni due ore.

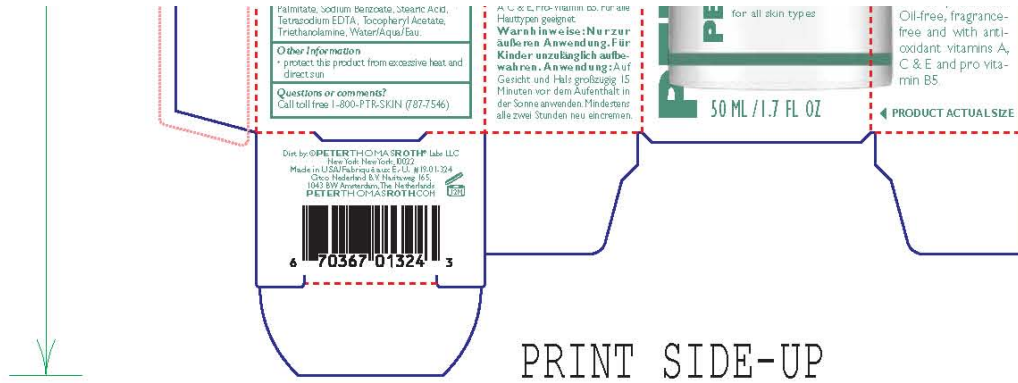
SONNENSCHUTZLOTION
Ölfrei, Anti-aging, Breitpektrum-LSPF 30, lang anhaltende Feuchtigkeit, beruhigend mit Ceramiden, beruhigend Aloe vera, Vitamin A, C & E, Provitamin B5.

CLINICAL SKIN CARE

MAX SHEER ALL DAY MOISTURE DEFENSE[®] LOTION SUNSCREEN LOTION

LOTION ÉCRAN SOLAIRE
oil-free
anti-aging
broad spectrum
spf 30
lasting hydration
with ceramides
soothing aloe
vitamins A, C & E
pro-vitamin B5

An ultra light, anti-aging hydrator with moisturizers, ceramides, soothing aloe and broad spectrum SPF 30 protection.



Mechanical File		PETER THOMAS ROTH CLINICAL SKIN CARE		460 Park Ave.16		th fl., New York, NY 10022			
FILE SPECS		ARTWORK SPECS		APPROVALS					
FILE NAME: PTR USA 19-01-324_Crtn_130227	COLORS BREAKDOWN:	STOCK: Soft Touch	PD	TK	SG	KL	DS	RF	ART
PATH: Art/Art Dept/PTR/Packaging/2012/New Products/PTR USA 19-01-324 Max Sheer All Day Moisture Defense Lotion/ Carton/1st Submission	GREEN ART 100% PMS 625 C YELLOW SUN 100% PMS 109 C IMAGE CMYK process Die (do not print)	COMPONENT:	NAME						
DIELINE: X 1/2" W x X 1/2" H x X 1/2" D		COMMENTS TO PRINTER:		DATE					
DECO AREA:		PROOF REQUIRED FOR APPROVAL							
UPC #: 67036701324-3									
DATE: 08/27/12									
ART RELEASE DATE: 02/27/12									
DESIGNER: Andrea Zamloot									
CONTACT: Andrea Zamloot		EMAIL: azamloot@peterthomasroth.com	PHONE: 212.581.5800 ext 159						



Mechanical File		PETER THOMAS ROTH CLINICAL SKIN CARE		460 Park Ave. 16 th fl., New York, NY 10022						
FILE SPECS		ARTWORK SPECS		APPROVALS						
FILE NAME: PTR USA 19-03-324_WrpLbl_130401	COLORS BREAKDOWN: GREEN TEXT custom green YELLOW ART 100% PMS 109 C Die (do not print)	STOCK: WHITE Stock	NAME	PD	MKTG			PKG D	R&D	ART
PATH: Art/Art Dept/PTR/Packaging/2013/PTR USA 19-03-324 Max Sheer All Day Moisture Defense Lotion/Wrap Label/1st Submission		COMPONENT:		TK	SG	KL	SN	DS	RF	AZ
DELINE: 4.2" W x 1.5" H .125" Corner Radius		COMMENTS TO PRINTER: Proof requested for approval.								
DECO AREA:										
UPC #:										
DATE: 03/19/13										
ART RELEASE DATE: 04/01/13										
DESIGNER: Andrea Zamloot										
CONTACT: Andrea Zamloot	EMAIL: azamloot@peterthomasroth.com	PHONE: 973.567.3388	DATE							



Mechanical File		PETER THOMAS ROTH CLINICAL SKIN CARE		460 Park Ave. 16 th fl., New York, NY 10022										
FILE SPECS		ARTWORK SPECS			APPROVALS									
FILE NAME: PTR USA 19-04-324 WrpLbl_130422		COLORS BREAKDOWN:			STOCK: White BOPP		PD	MKTG			PKG D	R&D	ART	
PATH: Art/Art Dept/PTR/Packaging/2013/PTR USA19-04-324 Max Sheer All Day Moisture Defense Lotion SPF 30/Primary/Wrap Label/1st Submission		<div style="display: flex; flex-direction: column; gap: 5px;"> <div style="display: flex; align-items: center;"> GREEN TEXT 100% PMS 625 C</div> <div style="display: flex; align-items: center;"> YELLOW ART 100% PMS 109 C</div> <div style="display: flex; align-items: center;"> Die (do not print)</div> </div>			COMPONENT:		NAME	TK	SG	KL	SN	DS	RF	AZ
DIELINE: 5.0" W x 2.125" H		COMMENTS TO PRINTER:												
DECO AREA:					Unwind Position #4 Proof required for approval.		DATE							
UPC #:														
DATE: 04/12/13														
ART RELEASE DATE: 04/22/13														
DESIGNER: Andrea Zamloot														
CONTACT: Andrea Zamloot		EMAIL: azamloot@peterthomasroth.com			PHONE: 973.567.3388									

4.95 in.

3 in.



Mechanical File		PETER THOMAS ROTH CLINICAL SKIN CARE		460 Park Ave. 16th fl., New York, NY 10022						
FILE SPECS		ARTWORK SPECS		APPROVALS						
FILE NAME: PTR USA 19-01-324_WrpLbI_130215	COLORS BREAKDOWN: GREEN TEXT custom green YELLOW ART 100% PMS 109 C Die (do not print)	STOCK: White BOPP Stock	NAME	PD	MKTG			PKG D	R&D	ART
PATH: Art/Art Dept/PTR/Packaging/2013/PTR USA 19-01-324 Max Sheer All Day Moisture Defense Lotion/Wrap Label/1st Submission		COMPONENT:		TK	SG	KL	SN	DS	RF	AZ
DIELINE: 4.95" W x 3.0" H 0.0625" Corner Radius		COMMENTS TO PRINTER: Proof requested for approval.		DATE						
DECO AREA:										
UPC #:										
DATE: 08/24/12										
ART RELEASE DATE: 02/15/13										
DESIGNER: Andrea Zamloot										
CONTACT: Andrea Zamloot	EMAIL: azamloot@peterthomasroth.com	PHONE: 973.567.3388								

MAX SHEER ALL DAY MOISTURE DEFENSE

sunscreens lotion spf 30 lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54031-324
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	.001 g in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	.0008 g in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	.0006 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	.0005 g in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	.0003 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	.0002 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	0.0048 g in 1 mL
Propylene Glycol (UNII: 6DC9Q167V3)	0.0004 g in 1 mL
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	0.0003 g in 1 mL
PEG-100 Stearate (UNII: YD01N1999R)	0.00025 g in 1 mL
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	0.0003 g in 1 mL
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	0.0002 g in 1 mL
Palmitic Acid (UNII: 2V16EO95H1)	0.0002 g in 1 mL
Phenoxyethanol (UNII: HIE492ZZ3T)	0.0001 g in 1 mL
Stearic Acid (UNII: 4ELV7Z65AP)	0.0001 g in 1 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.0001 g in 1 mL
Bentonite (UNII: A3N5ZCN45C)	0.000025 g in 1 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.000025 g in 1 mL
Dimethicone (UNII: 92RU3N3Y1O)	0.000025 g in 1 mL
Allantoin (UNII: 344S277G0Z)	0.00002 g in 1 mL
PEG-8 Dimethicone (UNII: GIA7T764OD)	0.000014 g in 1 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.00001 g in 1 mL
Cetyl Alcohol (UNII: 936JST6JCN)	0.00001 g in 1 mL
Panthenol (UNII: WV9CM0O67Z)	0.00001 g in 1 mL
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	0.0000087 g in 1 mL
EDETATE SODIUM (UNII: MP1J8420LU)	0.0000084 g in 1 mL
Myristic Acid (UNII: 0IBV7S25AW)	0.000006 g in 1 mL
Potassium Sorbate (UNII: 1VPU26JZZ4)	0.0000025 g in 1 mL
Sodium Benzoate (UNII: OJ245FE5EU)	0.0000025 g in 1 mL
Arachidic Acid (UNII: PQB8MJD4RB)	0.000002 g in 1 mL
Lauric Acid (UNII: 1160N9NU9U)	0.000002 g in 1 mL
Ascorbic Acid (UNII: PQ6CK8PD0R)	0.000001 g in 1 mL
Octyldodecanol (UNII: 461N1O614Y)	0.000001 g in 1 mL
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	0.000001 g in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.000001 g in 1 mL
Sodium Propoxyhydroxypropyl Thiosulfate Silica (UNII: 208G222332)	0.000001 g in 1 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.000001 g in 1 mL
Ceramide NP (UNII: 4370DF050B)	0.00000099 g in 1 mL
Butylene Glycol (UNII: 3XUS85K0RA)	0.000000395 g in 1 mL
GINKGO (UNII: 19FUJ2C58T)	0.0000002 g in 1 mL
Butyl Acetate (UNII: 464P5N1905)	0.00000001 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54031-324-01	1 in 1 CARTON	07/29/2013	
1	NDC:54031-324-00	1 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:54031-324-03	15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/29/2013	
3	NDC:54031-324-04	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/29/2013	
4	NDC:54031-324-06	1 in 1 CARTON	07/29/2013	

4	NDC:54031-324-05	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product
---	------------------	--

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/29/2013	

Labeler - Peter Thomas Roth Labs LLC (780458944)

Registrant - Peter Thomas Roth Labs LLC (780458944)

Establishment

Name	Address	ID/FEI	Business Operations
June Jacobs Labs LLC		082439410	manufacture(54031-324)

Revised: 6/2016

Peter Thomas Roth Labs LLC