

MAX MINERAL- titanium dioxide, zinc oxide cream
Peter Thomas Roth Labs, LLC

PTR Max Mineral Naked SPF 45

Titanium Dioxide 1.93%

Zinc Oxide 19.24%

Active Ingredients..... Purpose

Titanium Dioxide 1.93%..... Sunscreen

Zinc Oxide 19.24%..... 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

Directions

apply liberally 15 minutes before sun exposure

reapply at least every 2 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 of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. to 2 p.m.

wear long-sleeved shirts, pants, hats, and sunglasses

children under 6 months of age: ask a doctor

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.

Inactive Ingredients

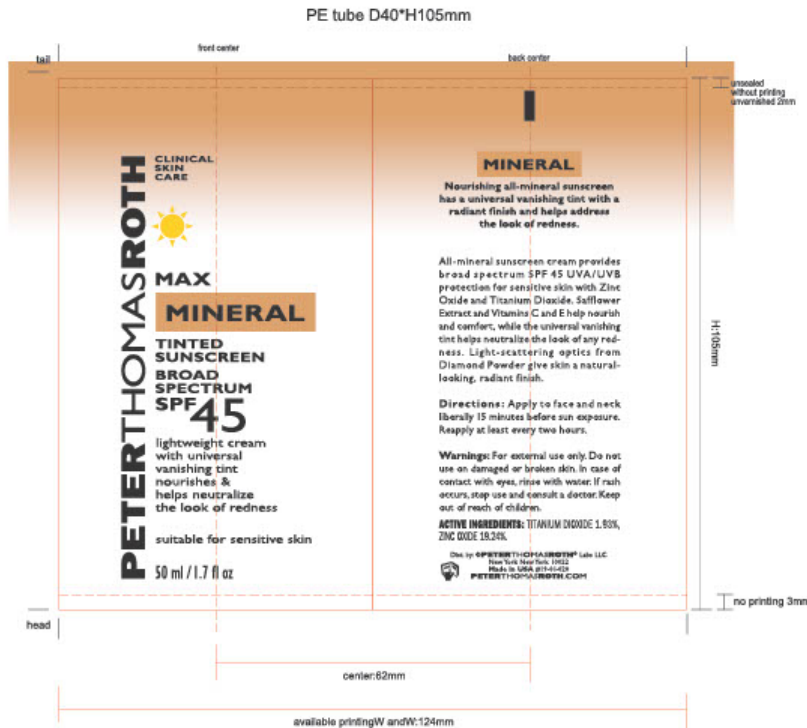
Water, Butyloctyl Salicylate, C9- 12 Alkane, Carthamus Tinctorius (Safflower) Oleosomes, Isodecyl Neopentanoate, Dicaprylyl Carbonate, Cetyl Alcohol, Coco-Caprylate/ Caprate, Propanediol, Ethylhexyl Oliviate, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Oliviate, Stearyl Phosphate, Triethoxycaprylylsilane, Phenoxyethanol, Oleth-3 Phosphate, Sorbitan Oliviate, HDI/Trimethylol Hexyllactone Crosspolymer, Alumina, Xanthan Gum, Polymethylsilsesquioxane, Polyhydroxystearic Acid, Squalane, Gluconolactone, Sodium

Phytate, Isopropyl Titanium Triisostearate, Sodium Benzoate, Hydrogen Dimethicone, Potassium Sorbate, Silica, Tocopheryl Acetate, Ascorbic Acid, Diamond Powder, Iron Oxides, Mica

Keep out of reach of children.

Question or comments?

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



Printing position tolerance:

Vertical: +/-1.0mm

Horizontal: +/-1.0mm

Suggest at least 1.5mm space to be kept for each silk screen color or multi-process printing.

Mechanical File	PETERTHOMASROTH CLINICAL SKIN CARE		460 Park Ave.16th fl., New York, NY 10022						
FILE SPECS	ARTWORK SPECS		APPROVALS						
FILE NAME: PTR USA 19-01-020-301_Tb_210902	COLORS BREAKDOWN: BLACK TEXT 100% K YELLOW ART 100% PMS 109C PMS 721C (Custom Beige) Die (do not print)	STOCK: COMPONENT: Gloss Tube, 721C Gradient, White Gloss Cap with 2mm Gloss 109C Yellow Band, All deco Screen Prints NOTES TO PRINTER: Pre-Press Proof required for APPROVAL	NAME	OPR	MKTG	PROD DEV	PKG DEV	REG/ R&D	CREATIVE
PATH: Art Dept/PTR/Packaging/PTR USA 19-01-020 Max Mineral SPF 45/ PRIMARY/Tube Deco/4th Submission Revision DIELINE: DECO AREA: 126mm W x 89mm H UPC #: DATE: 07/27/20 ART RELEASE DATE: 09/24/20 DESIGNER: PRE-PRODUCTION DESIGNER: David Held				PTR	JB/CM/EH	SL	ME/RJ	BG	DH
CONTACT: David Held	EMAIL: dheld@peterthomasroth.com		DATE						
			PHONE: 212.581.5800 ext. 5808						



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216.297
[8.518]
SPOT GLOSS
TURN ON LAYER TO SEE

Mechanical File	PETER THOMAS ROTH CLINICAL SKIN CARE		480 Park Ave. 16th fl., New York, NY 10022					
FILE SPECS	ARTWORK SPECS		APPROVALS					
FILE NAME: PTR USA 19-01-020-922_Ctrn_210917	COLORS BREAKDOWN: ■ BLACK TEXT 100% K ■ YELLOW ART PMS 109C ■ PMS 721C ■ IMAGES CMYK process ■ (Do not print) ■ SPOT GLOSS 100% Magenta ■ 2 LEVEL EMBOSSED	STOCK: .018 SBS Soft Touch	OPR	MKTG	PROD DEV	PKG DEV	REG/ R&D	CREATIVE
PAT# Art Dept/PTR/Package/PTR USA 19-01-020 Max Mineral SPF 45/ CARTON/2nd Submission		COMPONENT:	NOTES TO PRINTER: Pre-Press Proof required for APPROVAL	PTR	JB/CMEH	SL	ME/RJ	BG
DIELINE: 2 1/8" W x 5 1/8" H x 1 1/4" D Pickup 31-01-009				NAME				
DECO AREA:			DATE					
UPC #: 6-70367-01593-3								
DATE: 10/07/20								
ART RELEASE DATE: 09/17/21								
DESIGNER:								
PRE-PRODUCTION DESIGNER: Susan Cheng								
CONTACT: David Held	EMAIL: dheld@peterthomasroth.com							PHONE: 212.581.5800 ext. 5808

MAX MINERAL

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54031-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9.271756 g in 48.19 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.9276575 g in 48.19 g

Inactive Ingredients

Ingredient Name	Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MICA (UNII: V8A1AW0880)	
C9-12 ALKANE (UNII: 7J5R5W72QM)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
STEARYL PHOSPHATE (UNII: F3C8G3904Y)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIAMOND (UNII: 6GRV67N0U2)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ETHYLHEXYL OLIVATE (UNII: HTC7G3S2PV)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	

PEG-100 STEARATE (UNII: YD01N1999R)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KOOR)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
SQUALANE (UNII: GW89575KF9)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

Product Characteristics

Color	brown (TINTED TAN)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54031-020-01	48.19 g in 1 TUBE; Type 0: Not a Combination Product	02/15/2021	
2	NDC:54031-020-02	48.19 g in 1 CARTON; Type 0: Not a Combination Product	02/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/15/2021	

Labeler - Peter Thomas Roth Labs, LLC (780458944)

Registrant - June Jacobs Labs, LLC (122610681)

Establishment

Name	Address	ID/FEI	Business Operations
JUNE JACOBS LABS, LLC		122610681	manufacture(54031-020)