TINTED MOISTURIZER SPF 46 UNIVERSAL TINT- zinc oxide, octinoxate cream
Neutraderm, 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.

Tinted Moisturizer SPF 46 Universal Tint

Drug Facts

Active ingredient

Zinc Oxide 12%

Octinoxate 7.5%

Purpose

Sunscreen

Use Helps prevent sunburn • If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings For external use only.

When using this product • keep out of eyes. Rinse with water to remove. Stop use and ask physician if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Apply to face and neck, avoiding the eye area. Wait at least 30 minutes before sun exposure, or as directed by a physician. Reapply after 80 minutes of swimming or sweating. Reapply immediately after towel drying at least every 2 hours.

Precautions • 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 value of SPF 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 physician.

Inactive Ingredients Water/Aqua/Eau, Cyclopentasiloxane, Niacinamide, Oleth-3 Phosphate, Octyldodecyl Neopentanoate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Glycerin, Polygonum Aviculare Extract, Sodium Hyaluronate, Tocopheryl Acetate, Ethylhexylglycerin, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, PEG-7 Trimethylolpropane Coconut Ether, Polyisobutene, Triethoxycaprylylsilane, Disodium EDTA, Iron Oxides, Phenoxyethanol

DRMTLGY®

MEDICAL GRADE SKIN CARE

Anti-Aging

Oil Free

Broad Spetrum Protection

Contains Anti-aging Ingredients

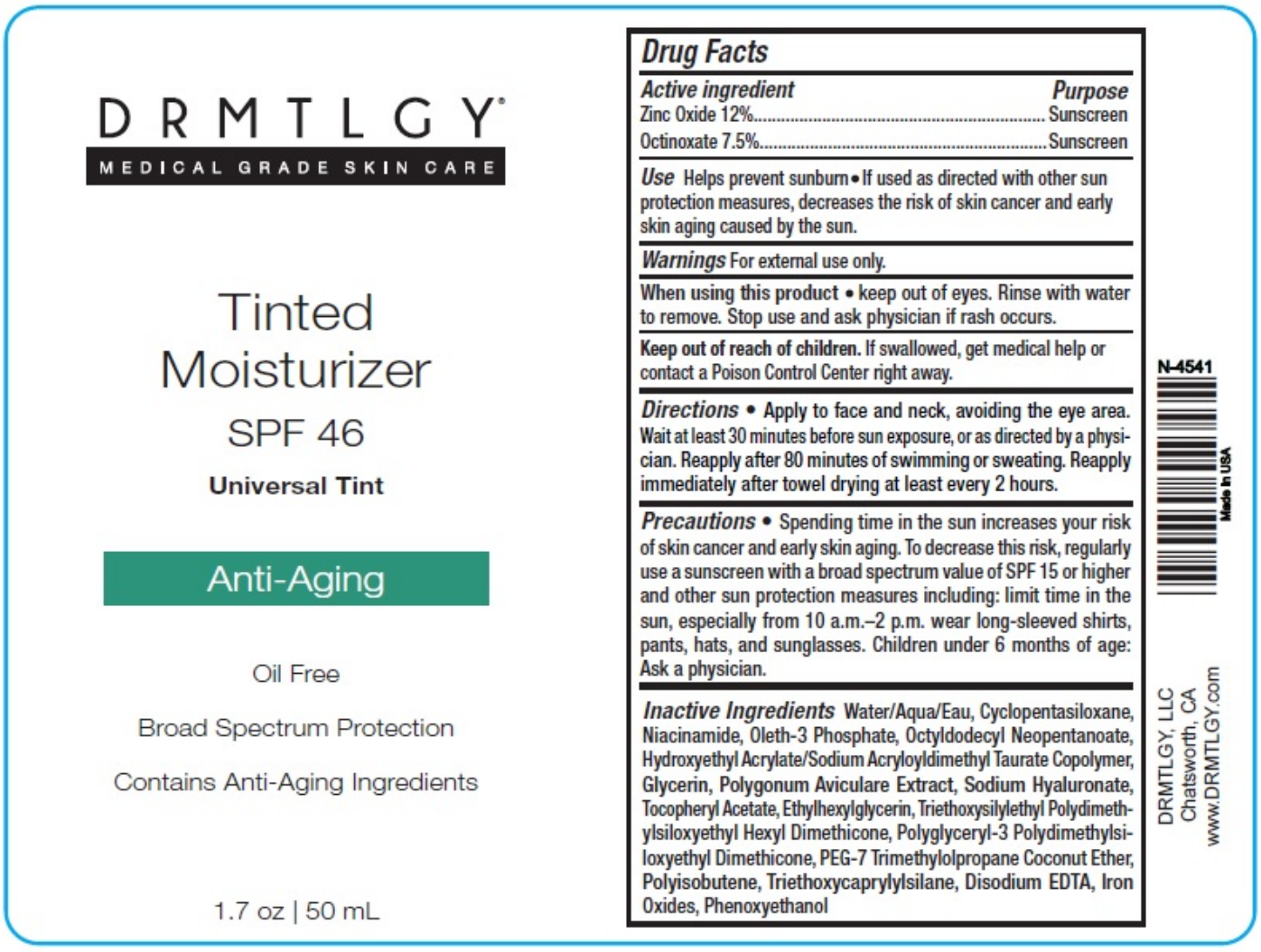
DRMTLGY, LLC

Chatsworth, CA

www.DRMTLGY.com

Made in USA

Packaging



TINTED MOISTURIZER SPF 46 UNIVERSAL TINT

zinc oxide, octinoxate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:39765-036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	12 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:39765-036-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/06/2020	

Labeler - Neutraderm, Inc. (146224444)

Establishment

Name	Address	ID/FEI	Business Operations
Neutraderm, Inc.		146224444	manufacture(39765-036)

Revised: 6/2020 Neutraderm, Inc.