

DT COLLAGEN- octocrylene cream

DT Collagen, 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.

DT Collagen

Octocrylane 10%, Homosalate 10%, Octinoxate 7.5%, Octinoxate 5%, Avobenzone 3.5%

Sunscreen

Helps prevent sunburn

For external use only.

Do not use on damaged or borken skin.

When using this product: keep out of eyes, rinse eyes with water to remove, stop use and ask a doctor if rash occurs.

If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

Directions

Apply liberally 15 minutes before sun exposure.

Reapply: after 80 minutes of swimming or sweating, immediatly after towel drying, at least every 2 hours.

Children under 6 months ask a doctor.

Other information

Do not store in excessive heat or direct sunlight.

Aqua, vinyl dimethicone copolymer, shea butter, C13-14 isoparafin, caprylic/capric triglyceride, ceramide2, cetearyl alcohol, cetyl alcohol, cyclomethicone, dimethicone, di=panthenol, ethylhexyl palimitate, ethylhexylglycerin, glycerin, glyceryl stearate, hyaluronic acid, laureth-7, PEG-100, stearate, phenoxyethanol, polyacrylamide, polisorbate 20, propylene glycol, soluble collagen, tocopheryl acetate, triethanolamine





Dermatologist/Pharmacist Recommended

1.69 oz. / 50 mL



Dermatologist/Pharmacist Recommended

Drug Facts

Active Ingredients
Cinneryl alcohol 10%
Homosalate 10%
Octinoxate 7.5%
Octisalate 5%
Avobenzone 3.5%

Uses

• Helps prevent sunburn.

• Keep out of eyes.

• Discontinue use if irritation occurs.

• Stop use if redness or itching occurs.

• Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions: • Apply liberally 15 minutes before sun exposure. Reapply • after 80 minutes of swimming or sweating • immediately after towel drying, 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 the risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including • limit time in sun, especially between 10 a.m. and 4 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses • Use lip sunscreen • Use a shade umbrella.

Other Ingredients: Aqua (deionized water), Methyl dimethacrylate/methacrylates copolymer, butyrosaminum pectin (shea butter), C13-14 isoparaffin, caprylic/capric triglyceride, ceramide 2, cetyl alcohol, cyclomethicone, dimethicone, di-penthanol, ethylhexyl palmitate, ethylhexylglycolate, ethylhexyl glycolate, glyceryl stearate, hydroxyethyl acrylate, lauric acid, laureth-7, parifan (fragrance), PEG-100 stearate, polyacrylamide, polyacrylamide, polyacrylate-20, propylene glycol, soluble collagen, tocopheryl acetate (vitamin E), tetrahydrofuran.

Other Information: Do not store in excessive heat or direct sunlight.

Distributed by: DT Collagen AWT-AE186, Pasadena, TX 77504, DTcollagen.com, 877-392-4938

Dermatologist/Pharmacist Recommended



6.25"

DT COLLAGEN
octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70522-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE 100 (UNII: RO266O364U)	
PANTHENOL (UNII: WV9CM0O67Z)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
HYALURONIC ACID (UNII: S270N0TRQY)	
LAURETH-7 (UNII: Z95S6G8201)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
.ALPHA.-TOTORIENOL (UNII: B6LXL1832Y)	
TRIETHANOLAMINE OLEATE (UNII: DZ7P3IE35F)	
CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE (UNII: U73D397055)	
CERAMIDE 2 (UNII: C04977SRJ5)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
PROPYLENE GLYCOL 2-OLEATE (UNII: R3FST8K0ZL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70522-001-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2016	

Labeler - DT Collagen, Inc. (011478279)

Registrant - DT Collagen (011478279)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		080354456	manufacture(70522-001)

Revised: 12/2017

DT Collagen, Inc.