

BREATHABLE TINT 1- titanium dioxide and zinc oxide cream
BREATHABLE TINT 2- titanium dioxide and zinc oxide cream
BREATHABLE TINT 3- titanium dioxide and zinc oxide cream
BREATHABLE TINT 4- titanium dioxide and zinc oxide cream
Quura Medical B.V

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.

Actives :

Inactives

Cyclopentasiloxane,Zinc Oxide,Dimethicone,Titanium Dioxide,Bismuth Oxychloride,Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone
Water (Aqua),Mica,Dimethicone/PEG-10/15 Crosspolymer,Hydroxypropylcocoate PEG-8 Dimethicone,Polyglyceryl-2 Diisostearate, Stearic Acid,Aluminum Hydroxide,Dimethicone/Vinyl Dimethicone Crosspolymer,Glycerin,Saccharomyces Lysate Extract,Cyclotetrasiloxane,Cyclohexasiloxane,Sodium Hyaluronate,Santalum Album (Sandalwood) Extract,Algae Extract,Centella Asiatica Extract,Artemisia Vulgaris Extract,Isohexadecane,Hydrated Silica,Malus Domestica Fruit Cell Culture,Hordeum Distichon (Barley) Extract,Lonicera Japonica (Honeysuckle) Flower Extract,PEG/PPG-18/18 Dimethicone,Xanthan Gum,Lecithin,Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone,Cyperus Rotundus Root Extract,Xanthium Sibiricum Fruit Extract,Phospholipids ,Olea Europaea (Olive) Leaf Extract,Mannitol,Sodium Benzoate,Ascorbyl Palmitate,Retinyl Palmitate,Squalane,Zinc PCA,Sodium Citrate,Acetyl Tetrapeptide-15,Tocopherol,Triethoxycaprylylsilane,Phellodendron Amurense Bark Extract,Beta-Carotene,Phenoxyethanol,Ethylhexylglycerin,Hexylene Glycol, Caprylyl Glycol,Iron Oxides (CI 77492),Iron Oxides (CI 77491),Iron Oxides (CI 77499),Titanium Dioxide (CI 77891)

Product label Almond shade



lycoco

BREATHABLE
TINT

SPF 30



lycogel®

Enjoy this luminous light coverage that gives your skin a healthy vibrant glow.

Apply a small amount of product to fingertips and spread evenly on skin. Reapply as needed.

Manufactured for:
Quora Medical BV
1271 GK NL
Made in USA

LYCOGEL.COM



8 718226 880208

lycogel®

BREATHABLE
TINT
SPF 30

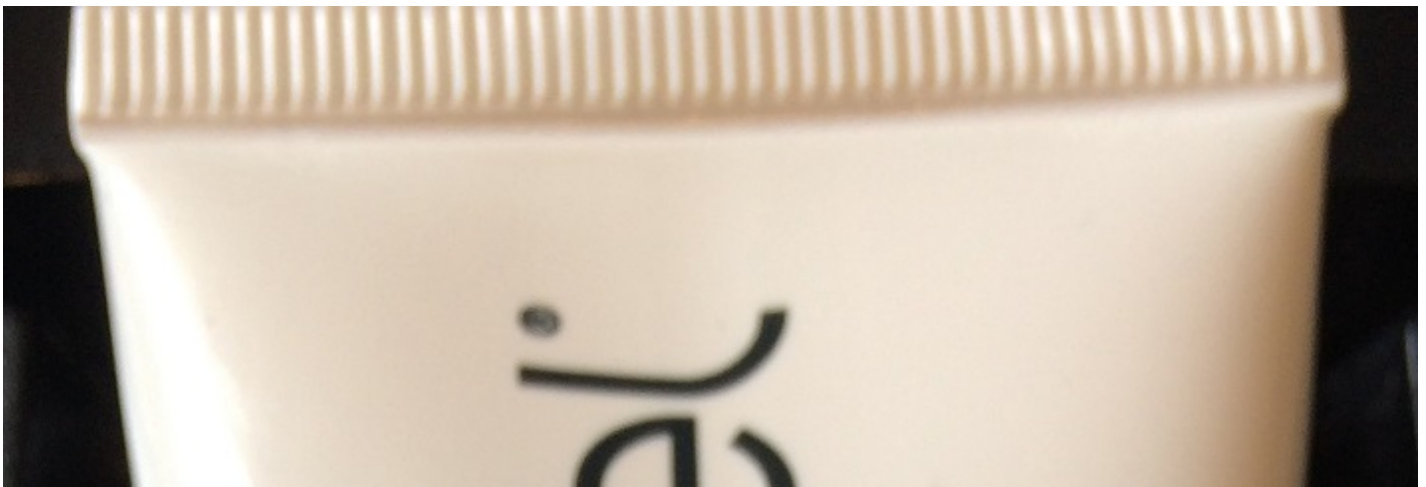
30ml e Nt Wt 1 fl oz

ACTIVE INGREDIENTS

6.4% Titanium Dioxide,
8.6% Zinc Oxide

INGREDIENTS

Cyclopentasiloxane, Water (Aqua), Dimethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Bismuth Oxichloride, Hydroxypropylcocoate PEG-8 Dimethicone, Polyglyceryl-2 Disostearate, Hydrated Silica, Stearic Acid, Aluminum Hydroxide, Mica, Dimethicone/Vinyl Dimethicone Crosspolymer, Glycerin, Saccharomyces Lysate Extract, Cyclotetrasiloxane, Cyclohexasiloxane, Sodium Hyaluronate, Santalum Album (Sandalwood) Extract, Algae Extract, Centella Asiatica Extract, Artemisia Vulgaris Extract, Isohexadecane, Malus Domestica Fruit Cell Culture, Hordeum Distichon (Barley) Extract, Lonicera Japonica (Honeysuckle) Flower Extract, PEG/PPG-18/18 Dimethicone, Xanthan Gum, Lecithin, Triethoxysilyethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Cyperus Rotundus Root Extract, Xanthium Sibiricum Fruit Extract, Phospholipids, Olea Europaea (Olive) Leaf Extract, Mannitol, Sodium Benzoate, Ascorbyl Palmitate, Retinyl Palmitate, Squalane, Zinc PCA, Sodium Citrate, Acetyl Tetrapeptide-15, Tocopherol, Triethoxycaprylylsilane, Phellodendron Amurense Bark Extract, Beta Carotene, Phenoxethanol, Ethylhexylglycerin, Hexylene Glycol, Caprylyl Glycol, May Contain: Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891)



lycogee

BREATHABLE
TINT

SPF 30



BREATHABLE TINT 1

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51790-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	86 mg in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
WATER (UNII: 059QF0KO0R)	
MICA (UNII: V8A1AW0880)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	

CYCLOMETHICONE 6 (UNII: XHK3U310BA)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SANDALWOOD (UNII: 3641YW25N2)
CHLORELLA VULGARIS (UNII: RYQ4R60M02)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)
ISOHEXADECANE (UNII: 918X1OUF1E)
Hydrated Silica (UNII: Y6O7T4G8P9)
APPLE (UNII: B423VGH5S9)
BARLEY (UNII: 5PWM7YLI7R)
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
XANTHAN GUM (UNII: TTV12P4NEE)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)
XANTHIUM SIBIRICUM WHOLE (UNII: H05ZV0N61A)
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)
MANNITOL (UNII: 3OWL53L36A)
SODIUM BENZOATE (UNII: OJ245FE5EU)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SQUALANE (UNII: GW89575KF9)
ZINC PIDOLATE (UNII: C32PQ86DH4)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
ACETYL TETRAPEPTIDE-15 (UNII: 6K389LE0MV)
TOCOPHEROL (UNII: R0ZB2556P8)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)
.BETA.-CAROTENE (UNII: 01YAE03M7J)
Phenoxyethanol (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Product Characteristics

Color	white (Titanium Dioxide) , red (Iron Oxides)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51790-300-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/23/2017	

BREATHABLE TINT 2

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51790-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	86 mg in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MP.A.S) (UNII: RLA2U05Z4Q)	
WATER (UNII: 059QF0KO0R)	
MICA (UNII: V8A1AW0880)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SANDALWOOD (UNII: 3641YW25N2)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)	
ISOHEXADECANE (UNII: 918X10UF1E)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
APPLE (UNII: B423VGH5S9)	
BARLEY (UNII: 5PWM7YLI7R)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)
XANTHIUM SIBIRICUM WHOLE (UNII: H05ZV0N61A)
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)
MANNITOL (UNII: 3OWL53L36A)
SODIUM BENZOATE (UNII: OJ245FE5EU)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SQUALANE (UNII: GW89575KF9)
ZINC PIDOLATE (UNII: C32PQ86DH4)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
ACETYL TETRAPEPTIDE-15 (UNII: 6K389LE0MV)
TOCOPHEROL (UNII: R0ZB2556P8)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)
.BETA.-CAROTENE (UNII: 01YAE03M7J)
Phenoxyethanol (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Product Characteristics			
Color	white (Titanium Dioxide) , red (Iron Oxides)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51790-301-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/09/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/23/2017	

BREATHABLE TINT 3

titanium dioxide and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51790-302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	86 mg in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
WATER (UNII: 059QF0KO0R)	
MICA (UNII: V8A1AW0880)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SANDALWOOD (UNII: 3641YW25N2)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)	
ISOHEXADECANE (UNII: 918X10UF1E)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
APPLE (UNII: B423VGH5S9)	
BARLEY (UNII: 5PWM7YL17R)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)	
XANTHIUM SIBIRICUM WHOLE (UNII: H05ZV0N61A)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SQUALANE (UNII: GW89575KF9)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ACETYL TETRAPEPTIDE-15 (UNII: 6K389LE0MV)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	

.BETA.-CAROTENE (UNII: 01YAE03M7J)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Product Characteristics

Color	white (Titanium Dioxide) , red (IronOxides)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51790-302-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/23/2017	

BREATHABLE TINT 4

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51790-303
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	86 mg in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
WATER (UNII: 059QF0KO0R)	
MICA (UNII: V8A1AW0880)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	

HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)
STEARIC ACID (UNII: 4ELV7Z65AP)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
GLYCERIN (UNII: PDC6A3C0OX)
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SANDALWOOD (UNII: 3641YW25N2)
CHLORELLA VULGARIS (UNII: RYQ4R60M02)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)
ISOHEXADECANE (UNII: 918X1OUF1E)
Hydrated Silica (UNII: Y6O7T4G8P9)
APPLE (UNII: B423VGH5S9)
BARLEY (UNII: 5PWM7YLI7R)
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
XANTHAN GUM (UNII: TTV12P4NEE)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)
XANTHIUM SIBIRICUM WHOLE (UNII: H05ZV0N61A)
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)
MANNITOL (UNII: 3OWL53L36A)
SODIUM BENZOATE (UNII: OJ245FE5EU)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SQUALANE (UNII: GW89575KF9)
ZINC PIDOLATE (UNII: C32PQ86DH4)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
ACETYL TETRAPEPTIDE-15 (UNII: 6K389LE0MV)
TOCOPHEROL (UNII: R0ZB2556P8)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)
.BETA.-CAROTENE (UNII: 01YAE03M7J)
Phenoxyethanol (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Product Characteristics

Color	white (Titanium Dioxide) , red (Iron Oxides)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51790-303-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/23/2017	

Labeler - Quura Medical B.V (489419151)

Registrant - Quura Medical B.V (489419151)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Cosmetic Inc		926831603	manufacture(51790-300, 51790-301, 51790-302, 51790-302, 51790-303)

Revised: 1/2018

Quura Medical B.V