

THE ENRICHED EYE CREME BROAD SPECTRUM SPF15- zinc oxide emulsion
Rationale Group Pty Ltd

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.

The Enriched Eye Creme Broad Spectrum SPF15

Drug Facts

Active Ingredient

Zinc Oxide 12%

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

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 ageing. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m -2p.m.
 - Wear long sleeved shirts, pants, hats and sunglasses.
 - Children under 6 months of age: Ask a doctor.

Other Information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Aqua (Water), Dimethicone, Glycerin, Pentylene Glycol, PEG-10 Dimethicone, Tribehenin PEG-20 Esters, Ethylhexyl Methoxycrylene, Coco-Caprylate, Polyhydroxystearic Acid, Propanediol, Argania Spinosa Kernel Oil, Dimethicone Crosspolymer, Polyurethane-62, Tocopheryl Acetate, CI 77891 (Titanium Dioxide), Polyacrylamide, 1,2-Hexanediol, Silica, C13-14 Isoparaffin, Maltodextrin, Mica, Sodium Potassium Aluminum Silicate, Tocopherol, Butylene Glycol, Limonene, Tocotrienols, Laureth-7, Caprylhydroxamic Acid, Disodium EDTA, Hydrolyzed Keratin, Santalum Spicatum (Sandalwood) Seed Oil, Trideceth-10, Voandzeia Subterranea Seed Extract, Behenyl Alcohol, Bisabolol, Polyglyceryl-10 Pentastearate, Helianthus Annuus (Sunflower) Seed Oil, Citrus Aurantium Dulcis (Orange) Oil, Anigozanthos Flavids Flower Extract, Davidsonia Jerseyana Fruit Extract, Syzygium Luehmannii Fruit Extract, Tin Oxide, Citric Acid, Cetareth-25, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Grandis (Grapefruit) Peel Oil, Citrus Limon (Lemon) Peel Oil, Fructose, Litsea Cubeba Fruit Oil, Sodium Hydroxide, Urea, Citral, Citrus Aurantium Bergamia (Bergamot) Leaf Oil, Juniperus Mexicana Oil, Pelargonium Graveolens Oil, Citrus Aurantium Amara (Bitter Orange) Flower Oil, Eugenia Caryophyllus (Clove) Leaf Oil, Sodium Stearoyl Lactylate, CI 77491 (Iron Oxides), Ceramide NP, 7-Dehydrocholesterol, Cetyl Alcohol, Elaeis Guineensis (Palm) Oil, Melanin, Allantoin, Maltose, Sodium Chloride, Sodium Lactate, Sodium PCA, Trehalose, Magnesium Aspartate, Zinc Gluconate, Linalool, Behenic Acid, Ceramide AP, Cholesterol, Ceramide NG, Phytosphingosine, Ceramide NS, Sodium Hyaluronate, Glycine, Acetyl Tetrapeptide-22, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Serine, Glutamic Acid, Ceramide EOP, Ceramide EOS, Copper Gluconate, Glucose, Aspartic Acid, Leucine, Caprooyl Phytosphingosine, Caprooyl Sphingosine, Alanine, Lysine, Ethylhexylglycerin, Arginine, Tyrosine, Phenylalanine, Proline, Threonine, Valine, Isoleucine, Histidine.

Package Labeling:20ml

RATIONALE

Drug Facts (Continued)

● **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin ageing. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10 a.m.- 2p.m.
- Wear long sleeved shirts, pants, hats and sunglasses.
- Children under 6 months of age: Ask a doctor.

Other Information

● Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Aqua (Water), Dimethicone, Pentaerythritol Glycol, PEG-10 Dimethicone, Glycerin, Triphenyl PEG-20 Esters, Ethylhexyl Methoxycrylene, Coco-Caprylate, Butylene Glycol, CI 77891 (Titanium Dioxide), Polyhydroxysebacic Acid, Propanediol, Mica, Argania Spinosa Kernel Oil, Dimethicone Copolymer, Polyurethane-62, Tocopheryl Acetate, Niacinamide, Polyacrylamide, 1,24-Hexanediol, Silica, C13-14 Isoparaffin, Malloxdotin, Fraxinus Excelsior Bark Extract, Sodium Potassium Aluminum Silicate, Glycolic Acid, Laureth-7, Tocopherol.

Drug Facts (Continued)

Capryhydroxamic Acid, Disodium EDTA, Santalum Spicatum (Sandalwood) Seed Oil, Tin Oxide, Trideceth-10, Voandzeia Subterranea Seed Extract, Bisabolol, Tocotrienols, CI 77491 (Iron Oxides), Adansonia Digitala Pulp Extract, Angozanthos Flavivus Flower Extract, Davidsonia Jerseyana Fruit Extract, Syzygium Luehmanni Fruit Extract, Ceteareth-25, Helianthus Annuus (Sunflower) Seed Oil, Potassium Citrate, Silanetriol, 7-Dehydrocholesterol, Cetyl Alcohol, Melaleuca, Elaeis Guineensis (Palm) Oil, Magnesium Aspartate, Zinc Gluconate, Potassium Sorbate, Sodium Benzoate, Xanthan Gum, Behenic Acid, Ceramide NP, Cholesterol, Ceramide NS, Glycine, Phenoxylethanol, Sodium Hyaluronate, Acetyl Tetrapeptide-5, Serine, Glutamic Acid, Citric Acid, Ceramide AP, Ceramide EOP, Ceramide EOS, Copper Gluconate, Aspartic Acid, Leucine, Caprooyl Phytosphingosine, Caprooyl Sphingosine, Alanine, Lysine, Ethylhexylglycerin, Arginine, Tyrosine, Phenylalanine, Proline, Threonine, Valine, Isoleucine, Histidine.

RATIONALE 175-187 High St, Kyneton VIC Australia 3444
Distributed by: RATIONALE USA LLC 333 SE 2nd Ave, Suite 2000, Miami, FL 33131, USA

RATIONALE.com
Made in Australia

RATIONALE

The Enriched Eye Crème
Broad Spectrum SPF15



20mL / 0.7oz. e

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 12%	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 ageing 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply
- At least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.



Feet @ Base

Package Labeling:2ml

RATIONALE
175-187 High St, Kyneton
VIC Australia 3444

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RATIONALE.com
Made in Australia

RATIONALE

The Brilliance Collection



#3 The Enriched Eye Crème SPF15 Broad Spectrum

This sumptuous crème imbues the delicate eye zone with unparalleled illumination, hydration and nourishment. A fusion of Zinc and Iron Oxide technologies, botanical extracts and rejuvenating skin actives visibly brighten and refresh the orbital contours while providing superb solar and environmental protection for a pellucid finish.



2mL / 0.1oz e

Drug Facts	
Active Ingredient Zinc Oxide 12%	Purpose Sunscreen
Uses ● Helps prevent sunburn ● If used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin ageing 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 swallowed, get medical help or contact a Poison Control Center right away.	
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 ageing. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ● Limit time in the sun, especially from 10 a.m. - 2p.m. →	

Drug Facts (Continued)
● Wear long sleeved shirts, pants, hats and sunglasses. ● Children under 6 months of age: Ask a doctor.
Other Information ● Protect the product in this container from excessive heat and direct sun.
Inactive ingredients Aqua (Water), Dimethicone, Pentylene Glycol, PEG-10 Dimethicone, Glycerin, Tribehenin PEG-20 Esters, Ethylhexyl Methoxycrylene, Coco-Caprylate, Butylene Glycol, Ci 77891 (Titanium Dioxide), Polyhydroxystearic Acid, Propanediol, Mica, Argania Spinosa Kernel Oil, Dimethicone Crosspolymer, Polyurethane-62, Tocopheryl Acetate, Niacinamide, Polyacrylamide, 1,2-Hexanediol, Silica, C13-14 Isoparaffin, Maltodextrin, Fraxinus Excelsior Bark Extract, Sodium Potassium Aluminum Silicate, Glycolic Acid, Laureth-7, Tocopherol, Caprylhydroxamic Acid, Disodium EDTA, Santalum Spicatum (Sandalwood) Seed Oil, Tin Oxide, Trideceth-10, Voandzeia Subterranea Seed Extract, Bisabolol, Tocotrienols, Ci 77491 (Iron Oxides), Adansonia Digitata Pulp Extract, Anigozanthos Flavidus Flower Extract, Davidsonia Jerseyana Fruit Extract, Syzygium Luehmannii Fruit Extract, Ceteareth-25, Helianthus Annuus (Sunflower) Seed Oil, Potassium Citrate, Silanetriol, 7-Dehydrocholesterol, Cetyl Alcohol, Melanin, Elaeis Guineensis (Palm) Oil, Magnesium Aspartate, Zinc Gluconate, Potassium Sorbate, Sodium Benzoate, Xanthan Gum, Behenic Acid, Ceramide NP, Cholesterol, Ceramide NS, Glycine, Phenoxylethanol, Sodium Hyaluronate, Acetyl Tetrapeptide-5, Serine, Glutamic Acid, Citric Acid, Ceramide AP, Ceramide EOP, Ceramide EOS, Copper Gluconate, Aspartic Acid, Leucine, Caproyl Phytosphingosine, Caproyl Sphingosine, Alanine, Lysine, Ethylhexylglycerin, Arginine, Tyrosine, Phenylalanine, Proline, Threonine, Valine, Isoleucine, Histidine.

GL3EES1A



THE ENRICHED EYE CREME BROAD SPECTRUM SPF15

zinc oxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83108-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
TRIBEHENIN PEG-20 ESTERS (UNII: 84K9EH29Y9)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
PROPANEDIOL (UNII: 5965N8W85T)	
ARGAN OIL (UNII: 4V59G5UW9X)	
POLYURETHANE-62 (UNII: TBK645J3J8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICA (UNII: V8A1AW0880)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
TOCOTRIENOLS (UNII: KP2MW85SSQ)	
LAURETH-7 (UNII: Z95S6G8201)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SANDALWOOD (UNII: 3641YW25N2)	
TRIDECETH-10 (UNII: G624N6MSBA)	
BAMBARA GROUNDNUT (UNII: 4T235SD5XE)	
DOCOSANOL (UNII: 9G1OE216XY)	
LEVOMENOL (UNII: 24WE03BX2T)	
POLYGLYCERYL-10 PENTASTEARATE (UNII: PMX5872701)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
ANIGOZANTHOS FLAVIDUS FLOWERING TOP (UNII: RP2O43NDZC)	
SYZYGIUM LUEHMANNII FRUIT (UNII: 47QSB3L4KG)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

CETEARETH-25 (UNII: 8FA93U5T67)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
LEMON OIL, COLD PRESSED (UNII: I9GRO824LL)	
FRUCTOSE (UNII: 6YSS42VSEV)	
LITSEA OIL (UNII: 2XIW34BN6O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
UREA (UNII: 8W8T17847W)	
CITRAL (UNII: T7EU009VPP)	
CITRUS BERGAMIA LEAF OIL (UNII: ZVY874111V)	
JUNIPERUS DEPPEANA WOOD OIL (UNII: 4739QA5686)	
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE91OXH)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CERAMIDE NP (UNII: 4370DF050B)	
7-DEHYDROCHOLESTEROL (UNII: BK1IU07GKF)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PALM OIL (UNII: 5QUO05548Z)	
ALLANTOIN (UNII: 344S277G0Z)	
MALTOSE (UNII: XJ6S9RV06F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
TREHALOSE (UNII: B8WCK70T7I)	
MAGNESIUM ASPARTATE (UNII: R17X820ROL)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BEHENIC ACID (UNII: H390488X0A)	
CERAMIDE AP (UNII: F1X8L2B00J)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CERAMIDE NG (UNII: C04977SRJ5)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GLYCINE (UNII: TE7660XO1C)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SERINE (UNII: 452VLY9402)	
GLUTAMIC ACID (UNII: 3KX376GY7L)	
3-DEHYDROXY CERAMIDE 1 (UNII: CROJ8RN66K)	
COPPER GLUCONATE (UNII: RV823G6G67)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
ASPARTIC ACID (UNII: 30KYC7MIAI)	
LEUCINE (UNII: GMW67QNF9C)	
CAPROOYL PHYTOSPHINGOSINE (UNII: 2FD4Y5XL2L)	
N-HEXANOYLSPHINGOSINE (UNII: 038753E78J)	
ALANINE (UNII: OF5P57N2ZX)	
LYSINE (UNII: K3Z 4F929H6)	

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ARGININE (UNII: 94ZLA3W45F)	
TYROSINE (UNII: 42HK56048U)	
PHENYLALANINE (UNII: 47E5O17Y3R)	
PROLINE (UNII: 9DLQ4CIU6V)	
THREONINE (UNII: 2ZD004190S)	
VALINE (UNII: HG18B9YRS7)	
ISOLEUCINE (UNII: 04Y7590D77)	
HISTIDINE (UNII: 4QD397987E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83108-002-00	1 in 1 BOX	12/08/2022	
1		20 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:83108-002-02	2 mL in 1 JAR; Type 0: Not a Combination Product	12/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/08/2022	

Labeler - Rationale Group Pty Ltd (756927393)

Revised: 12/2022

Rationale Group Pty Ltd