

**CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 CORAL CREAMY- octinoxate, zinc oxide stick
CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 FUCHSIA CREAMY- octinoxate, zinc oxide stick
CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 PINK CREAMY- octinoxate, zinc oxide stick
CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 NUDE CREAMY- octinoxate, zinc oxide stick
BEL STAR S A**

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.

**CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12**

Drug Facts

Active Ingredients

Octinoxate 2.50%

Zinc Oxide 3.92%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **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 and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- 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

Octyldodecanol, ricinus communis (castor) seed oil, butyrospermum parkii (shea) butter, helianthus annuus (sunflower) seed wax, polyethylene, copernicia cerifera (carnauba) wax, glycerin, vegetable oil, oryza sativa (rice) bran oil, olea europaea (olive) oil unsaponifiables, phytosteryl/behenyl/octyldodecyl lauroyl glutamate, oryza sativa (rice) bran wax, rhus succedanea fruit wax, dipentaerythrityl hexacaprylate/hexacaprate, fragrance, tridecyl trimellitate, disteardimonium hectorite, rhus verniciflua peel wax, shorea robusta resin, phenoxyethanol, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, tridecyl stearate, hexyl laurate, lauroyl lysine, punica granatum seed oil, prunus avium (sweet cherry) seed oil, pyrus malus (apple) seed oil, vaccinium macrocarpon (cranberry) seed oil, neopentyl glycol dicaprylate/dicaprate, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, water, lecithin, citrus paradisi (grapefruit) fruit extract, ascorbyl palmitate, tocopherol, citronellol.

May contain:

Mica, titanium dioxide, red 30 lake, red 7 lake, red 40 lake, synthetic fluorophlogopite, red 27 lake, hydrogenated polyisobutene, iron oxides, blue 1 lake, palmitic acid, talc.

Company Information

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

www.cyzone.com

Product Packaging - Fuchsia Creamy

Drug Facts		Warnings ■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ 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.
Active Ingredients		
Octinoxate 2.50%	Sunscreen	
Zinc Oxide 3.92%	Sunscreen	
Uses ■ Helps prevent sunburn.		
Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating. ■ 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: Octyldodecanol, ricinus communis (castor) seed oil, butyrospermum parkii (shea) butter, helianthus annuus (sunflower) seed wax, polyethylene, copernicia cerifera (carnauba) wax, glycerin, vegetable oil, oryza sativa (rice) bran oil, olea europaea (olive) oil unsaponifiables, phytosteryl/behenyl/octyldodecyl lauroyl glutamate, oryza sativa (rice) bran wax, rhus succedanea fruit wax, dipentaerythryl hexacaprylate/hexacaprate, fragrance, tridecyl trimellitate, disteardimonium hectorite, rhus verniciflua peel wax, shorea robusta resin, phenoxethanol, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, tridecyl stearate, hexyl laurate, lauroyl lysine, punica granatum seed oil, prunus avium (sweet cherry) seed oil, pyrus malus (apple) seed oil, vaccinium macrocarpon (cranberry) seed oil, neopentyl glycol dicaprylate/dicaprate, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, water, lecithin, citrus paradisi (grapefruit) fruit extract, ascorbyl palmitate, tocopherol, citronellol. **May contain:** Mica, titanium dioxide, red 30 lake, red 7 lake, red 40 lake, synthetic fluorophlogopite, red 27 lake, hydrogenated polyisobutene, iron oxides, blue 1 lake, palmitic acid, talc.

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

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TONE: FUCHSIA CREAMY

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CREAMY LIP BALM
Hidratante en barra para labios 24H FPS 12
3 g l Net Wt. 0.10 oz.

Product Packaging - Pink Creamy

Drug Facts		Warnings ■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ 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.
Active Ingredients		
Octinoxate 2.50%	Sunscreen	
Zinc Oxide 3.92%	Sunscreen	
Uses ■ Helps prevent sunburn.		
Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating. ■ 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: Octyldodecanol, ricinus communis (castor) seed oil, butyrospermum parkii (shea) butter, helianthus annuus (sunflower) seed wax, polyethylene, copernicia cerifera (carnauba) wax, glycerin, vegetable oil, oryza sativa (rice) bran oil, olea europaea (olive) oil unsaponifiables, phytosteryl/behenyl/octyldodecyl lauroyl glutamate, oryza sativa (rice) bran wax, rhus succedanea fruit wax, dipentaerythryl hexacaprylate/hexacaprate, fragrance, tridecyl trimellitate, disteardimonium hectorite, rhus verniciflua peel wax, shorea robusta resin, phenoxethanol, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, tridecyl stearate, hexyl laurate, lauroyl lysine, punica granatum seed oil, prunus avium (sweet cherry) seed oil, pyrus malus (apple) seed oil, vaccinium macrocarpon (cranberry) seed oil, neopentyl glycol dicaprylate/dicaprate, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, water, lecithin, citrus paradisi (grapefruit) fruit extract, ascorbyl palmitate, tocopherol, citronellol. **May contain:** Mica, titanium dioxide, red 30 lake, red 7 lake, red 40 lake, synthetic fluorophlogopite, red 27 lake, hydrogenated polyisobutene, iron oxides, blue 1 lake, palmitic acid, talc.

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

www.cyzone.com

TONE: PINK CREAMY

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CREAMY LIP BALM
Hidratante en barra para labios 24H FPS 12
3 g l Net Wt. 0.10 oz.

Product Packaging - Nude Creamy

Drug Facts		Warnings ■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ 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.
Active Ingredients		
Octinoxate 2.50%	Sunscreen	
Zinc Oxide 3.92%	Sunscreen	
Uses ■ Helps prevent sunburn.		
Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating. ■ 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: Octyldodecanol, ricinus communis (castor) seed oil, butyrospermum parkii (shea) butter, helianthus annuus (sunflower) seed wax, polyethylene, copernicia cerifera (carnauba) wax, glycerin, vegetable oil, oryza sativa (rice) bran oil, olea europaea (olive) oil unsaponifiables, phytosteryl/behenyl/octyldodecyl lauroyl glutamate, oryza sativa (rice) bran wax, rhus succedanea fruit wax, dipentaerythrityl hexacaprylate/hexacaprate, fragrance, tridecyl trimellitate, disteardimonium hectorite, rhus verniciflua peel wax, shorea robusta resin, phenoxethanol, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, tridecyl stearate, hexyl laurate, lauroyl lysine, punica granatum seed oil, prunus avium (sweet cherry) seed oil, pyrus malus (apple) seed oil, vaccinium macrocarpon (cranberry) seed oil, neopentyl glycol dicaprylate/dicaprate, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, water, lecithin, citrus paradisi (grapefruit) fruit extract, ascorbyl palmitate, tocopherol, citronellol. **May contain:** Mica, titanium dioxide, red 30 lake, red 7 lake, red 40 lake, synthetic fluorophlogopite, red 27 lake, hydrogenated polyisobutene, iron oxides, blue 1 lake, palmitic acid, talc.

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

www.cyzone.com

TONE: NUDE CREAMY

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CREAMY LIP BALM
Hidratante en barra para labios 24H FPS 12
3 g l Net Wt. 0.10 oz.

Product Packaging - Coral Creamy

Drug Facts	Purpose	Warnings ■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ 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.
Active Ingredients		
Octinoxate 2.50%.....	Sunscreen	
Zinc Oxide 3.92%.....	Sunscreen	
Uses ■ Helps prevent sunburn.		
Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating. ■ 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: Octyldodecanol, ricinus communis (castor) seed oil, butyrospermum parkii (shea) butter, helianthus annuus (sunflower) seed wax, polyethylene, copernicia cerifera (carnauba) wax, glycerin, vegetable oil, oryza sativa (rice) bran oil, olea europaea (olive) oil unsaponifiables, phytosteryl/behenyl/octyldodecyl lauroyl glutamate, oryza sativa (rice) bran wax, rhus succedanea fruit wax, dipentaerythryl hexacaprylate/hexacaprate, fragrance, tridecyl trimellitate, disteardimonium hectorite, rhus verniciflua peel wax, shorea robusta resin, phenoxethanol, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, tridecyl stearate, hexyl laurate, lauroyl lysine, punica granatum seed oil, prunus avium (sweet cherry) seed oil, pyrus malus (apple) seed oil, vaccinium macrocarpon (cranberry) seed oil, neopentyl glycol dicaprylate/dicaprate, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, water, lecithin, citrus paradisi (grapefruit) fruit extract, ascorbyl palmitate, tocopherol, citronellol. **May contain:** Mica, titanium dioxide, red 30 lake, red 7 lake, red 40 lake, synthetic fluorophlogopite, red 27 lake, hydrogenated polyisobutene, iron oxides, blue 1 lake, palmitic acid, talc.

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TONE: CORAL CREAMY



CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 CORAL CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-309
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

GRAPEFRUIT (UNII: O82C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SWEET CHERRY SEED OIL (UNII: 9X3RP3R3FH)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SUNFLOWER (UNII: 834K0W0S5G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GLYCERIN (UNII: PDC6A3C0OX)	
RICE BRAN OIL (UNII: LZ06K1506A)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
RICE BRAN (UNII: R60QEP13IC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
APPLE SEED OIL (UNII: 9ACA4K9013)	
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CASTOR OIL (UNII: D5340Y2I9G)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-309-01	1 in 1 CARTON	10/07/2022	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/07/2022	

CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 FUCHSIA CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
GRAPEFRUIT (UNII: 082C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
WATER (UNII: 059QF0KO0R)
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
GLYCERIN (UNII: PDC6A3C0OX)
RICE BRAN OIL (UNII: LZ06K1506A)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
PALMITIC ACID (UNII: 2V16EO95H1)
TALC (UNII: 7SEV7J4R1U)
FD&C RED NO. 40 (UNII: WZB9127XOA)
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
RICE BRAN (UNII: R60QEP13IC)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
APPLE SEED OIL (UNII: 9ACA4K9013)
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
OCTYLDODECANOL (UNII: 461N1O614Y)
CASTOR OIL (UNII: D5340Y2I9G)
SHEA BUTTER (UNII: K49155WL9Y)
HEXYL LAURATE (UNII: 4CG9F9W01Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-306-01	1 in 1 CARTON	10/07/2022	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/07/2022	

CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 PINK CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-307
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
GRAPEFRUIT (UNII: O82C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GLYCERIN (UNII: PDC6A3C0OX)	
RICE BRAN OIL (UNII: LZ06K1506A)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TALC (UNII: 7SEV7J4R1U)	

HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)
FD&C RED NO. 40 (UNII: WZB9127XOA)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
RICE BRAN (UNII: R60QEP13IC)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
APPLE SEED OIL (UNII: 9ACA4K9013)
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
OCTYLDODECANOL (UNII: 461N1O614Y)
CASTOR OIL (UNII: D5340Y2I9G)
SHEA BUTTER (UNII: K49155WL9Y)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
HEXYL LAURATE (UNII: 4CG9F9W01Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-307-01	1 in 1 CARTON	10/07/2022	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/07/2022	

CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 NUDE CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-308
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g
Inactive Ingredients		
Ingredient Name	Strength	
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)		
LAUROYL LYSINE (UNII: 113171Q70B)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
D&C RED NO. 30 (UNII: 2S42T2808B)		
GRAPEFRUIT (UNII: O82C39RR8C)		
ASCORBYL PALMITATE (UNII: QN83US2B0N)		
TOCOPHEROL (UNII: R0ZB2556P8)		
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)		
MICA (UNII: V8A1AW0880)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CORN OIL (UNII: 8470G57WFM)		
D&C RED NO. 7 (UNII: ECW0LZ41X8)		
FERROSFERRIC OXIDE (UNII: XM0M87F357)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)		
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)		
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
CHLORPHENESIN (UNII: I670DAL4SZ)		
WATER (UNII: 059QF0KO0R)		
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
GLYCERIN (UNII: PDC6A3C0OX)		
RICE BRAN OIL (UNII: LZ06K1506A)		
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
PALMITIC ACID (UNII: 2V16EO95H1)		
TALC (UNII: 7SEV7J4R1U)		
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)		
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)		
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)		
RICE BRAN (UNII: R60QEP13IC)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
APPLE SEED OIL (UNII: 9ACA4K9013)		
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)		
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)		
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Labeler - BEL STAR S A (880160197)

Revised: 10/2022

BEL STAR S A