# TIZO MINERAL SUN DEFENSE SPF 50- titanium dioxide, zinc oxide cream Fallien Cosmeceuticals 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.

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#### DRUG FACTS

#### **Active Ingredients:**

Titanium Dioxide 10%

Zinc Oxide 3%

#### Purpose

Sunscreen

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 aging caused by the sun.

#### Warnings:

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

When using this product, keep out of eyes. Rinse with water to remove.

**Keep out of the 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:

- After 40 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours
- Children under 6 months: Ask a doctor
- **Sun Protection Measures:** 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 SPF value of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10 am-2 pm
- Wear long-sleeved shirts, pants, hats, and sunglasses

## Inactive Ingredients:

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Ceteareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

#### **Other Information:**

- Protect this product from excessive heat and direct sun
- May stain some fabrics

# Principal Display Panel - 50 g Carton Label

**TiZO**<sup>®</sup>

#### MINERAL SUN DEFENSE

Tinted

SPF 50

#### DAILY MINERAL SUNSCREEN

Photoaging Defense

Titanium & Zinc Oxides

Antioxidants C & E

Broad Spectrum SPF 50

Water Resistant (40 Minutes)

Net Wt. 1.75 Oz./50 g



#### Directions:

Apply liberally 15 minutes before sun exposure. Reapply: • After 40 minutes of swimming or Reapply: - After 40 minutes of swimming or sweating - Immediately after towel drying - At least every 2 hours - Children under 6 months: Ask a doctor - **Sun Protection Measures:** 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 SPF value of IS or higher and other sun protection measures including: including:

including: • Limit time in the sun, especially from 10 am-2 pm • Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients: Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Ceteareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Clycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract. Mica. Microgradulline UM2, Octyddodecid Extract, Mica, Microcrystalline Wax, Octyldody Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

#### Other Information:

· Protect this product from excessive heat and direct sun · May stain some fabrics





RESERVATIVE FREE

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ANTIOXIDANTS C & E

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REEF FRIENDLY

ANIMAL TEST-FREE





## SUN DEFENSE Tinted



#### DAILY MINERAL SUNSCREEN

Photoaging Defense Titanium & Zinc Oxides Antioxidants C & E

Broad Spectrum SPF 50 Water Resistant (40 Minutes) Net Wt. 1.75 Oz./50 g

TiZO® Mineral Sun Defense is a gentle, tinted mineral sunscreen designed to help shield the skin every day from the damaging effects of the sun. Titanium and Zinc Oxides reflect away UVA and UVB rays, while Antioxidants help defend the skin against free radicals. Sheer satin finish is ideal for daily use.

• Titanium Dioxide/ Zinc Oxide blend

 Sheer tint, lightweight satin finish

· Gentle protection is ideal for daily use

FREE of chemical sunscreen filters, dyes, fragrances, oils and preservatives

Reef Friendly

Age Defying Fusion® When used regularly, TiZO Mineral Sun Defense helps to decrease the risk of skin cancer and early skin aging caused by the sun.

Fallien Cosmeceuticals Ltd. Eagleville, PA 19403 Made in USA

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**TIZO MINERAL SUN DEFENSE SPF 50** titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-128
Route of Administration	TOPICAL		

Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)       Titanium Dioxide 100 mg in 21mc Oxide - UNII:15FIX9V2JP)         Titanium Dioxide (UNII: SOI2LOH542) (Zinc Oxide - UNII:15FIX9V2JP)       Zinc Oxide 20mg in 21mc Oxide - UNII:15FIX9V2JP)         Inactive Ingredients       Ingredient Name Streng         BISMUTH OXYCHLORIDE (UNII: 42R7921587)       Streng         MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)       CAPRYLYL GLYCOL (UNII: 00YII-5380)       CAPRYLYL GLYCOL (UNII: 00YII-5380)         CAPRYLYL GLYCOL (UNII: 00YII-5380)       CAPRYLYL GLYCOL (UNII: 00YII-5380)       GLYCOL (UNII: 00YII-5380)         POLYOXYL 20 CETOSTEARYL ETHER (UNII: 8NL036F6MM)       CYCLOMETHICONE 5 (UNII: 8NL036F50M)       GLYCENNI (UNII: 92RU3N3Y1O)         EDETATE DISODIUM ANHYDROUS (UNII: 8NL036F6MM)       FERRIC OXIDE RED (UNII: 109F3675)       GLYCENNI (UNII: 809F3675)         FERRIC OXIDE RED (UNII: 109F3675)       SIGODODCANE (UNII: 100F3675)       GLYCENNI (UNII: 800F3675)         FERRIC OXIDE RED (UNII: 100F3675)       SIGODODCANE (UNII: 100F370)       GLYCENNI (UNII: 100F3703KY)       GLYCENNI (UNII: 100F3703KY)         SIGOPADACCARE (UNII: 100K3700K3K)       GLYCENNI (UNII: 100F3703KY)       GLYCENNI (UNII: 100F3108K)       GLYCENNI (	Active Ingredi	ent/Active Moiety		
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII: SOI2LOH54Z)     Zinc Oxide     30 mg in       Inactive Ingredients     Ingredient Name     Streng       BISMUTH OXYCHLORIDE (UNII: C942L2170)     CAPRYLYL GYCOL (UNII: 097805K99W)     CAPRYLYL GYCOL (UNII: 097805K99W)       CAPRYLYL GYCOL (UNII: 007195438U)     Optoxyl GYCOL (UNII: 007195438U)     Optoxyl GYCOL (UNII: 007195438U)       POLVOXYL 20 CETOSTEARYL ETHER (UNII: YRC5285WUY)     CYCLOMETHICONE 6 (UNII: XHK33010BA)     GYCOMETHICONE 6 (UNII: XHK33010BA)       CYCLOMETHICONE (UNII: SUN3510BA)     CYCLOMETHICONE (UNII: SUN3510BA)     GYCOMETHICONE 6 (UNII: SUN30566564BB)       GYCELIN (UNII: PDC6A3C00X)     GYCELIN (UNII: SUN35710)     GYCERIN (UNII: SUN35710)       ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3N8F25684B)     GYCERIN (UNII: SUN35710)       IGYCERIN (UNII: SUSSOURT)     FERRIC OXIDE (UNII: XM987537)     GYCERIN (UNII: SUSSOURT)       FERRIC OXIDE (UNII: KA98902MRT)     FERRIC OXIDE (UNII: MON575370)     GYCERIN (UNII: SUSSOURT)       ISODOBCANE (UNII: 82438021RT)     GYCERIN (UNII: SUSSOURT)     GYCERIN (UNII: SUSSOURT)       FERRIC OXIDE (UNII: XM0487537)     GYCERIN (UNII: SUSSOURT)     GYCERIN (UNII: SUSSOURT)       ISODOBCANE (UNII: 82438021R)     GYCERIN (UNII: X04597073877)     GYCERIN (UNII: SUSSOURT)       FERRIC OXIDE (UNII: SUSSOURT)     GYCERIN (UNII: SUSSOURT)     GYCERIN (UNII: SUSSOURT)     GYCERIN (UNII: SUSSOURT)       ISODOBCANE (UNII: SUSSOURT)     G		Ingredient Name	Basis of St	rength Strength
Inactive Ingredients         Ingredient Name         Streng           BISMUTH OXYCHLORIDE (UNII: 42R7921587)         MEDIUM-CHAIN TRICLYCERIDES (UNII: C9H2L21V7U)         CAPRYLYNOXAMIC ACID (UNII: 09YR05890W)         CAPRYLYNOXAMIC ACID (UNII: 09YR05890W)         CAPRYLYL GLYCOL (UNII: 00YIU5438U)         POLYOXYL 20 CETOSTEARVL ETHER (UNII: YRC3285WUY)         CYCLOMETHICONE 5 (UNII: 00YIU5438U)         CYCLOMETHICONE 5 (UNII: 01YII: 01YII: YRC3285WUY)         CYCLOMETHICONE 5 (UNII: 01YII: 01YII: YRC3285WUY)         CYCLOMETHICONE 5 (UNII: 01YII: 01YII: 01YII: 20X8725684B)         CYCLOMETHICONE 5 (UNII: 01YII:	Titanium Dioxide	(UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FI)	(9V2JP) Titanium Dioxid	de 100 mg in 1 g
Ingredient Name         Streng           BISMUTH OXYCHLORDE (UNII: 427792(587)	Zinc Oxide (UNII: S	OI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	30 mg in 1 g
BISMUTH OXYCHLORIDE (UNII: 4ZR792IS87) MEDIUM-CHAIN TRGLYCERIDES (UNII: C9H2L217/U) CAPRYLHYDROXAMIC ACID (UNII: 09H205K999W) CAPRYLH GLYCOL (UNII: 00H7950(599W) CYCLOMETHICONE 6 (UNII: 7HF2FCIOR) DIMETHICONE 6 (UNII: 7HF3PCIOR) DIMETHICONE 6 (UNII: 7HF3PCIOR) DIMETHICONE 6 (UNII: 7HF3PCIOR) DIMETHICONE (UNII: 8H2030F6MM) ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B) GLYCERIN (UNII: 9DC6A3C00X) FERRIC OXIDE RED (UNII: 1K09F36675) FERRIC OXIDE RED (UNII: 100P126) MELISSA OFERRIC OXIDE (UNII: 100P126) MELISSA OFERRIC OXIDE (UNII: 100P126) MELISSA OFERRIC OXIDE (UNII: 100P126) MICROCRYSTALLINE WAX (UNII: 87597(3KY) OCTYLDODECYL NEOPENTANOATE (UNII: 91830277) SODIUM CHLORIDE (UNII: 451/497(38X) TETRAHEXYLDECYL ASCORBATE (UNII: 9184307AZ) 				
BISMUTH OXYCHLORIDE (UNII: 4ZR792IS87) MEDIUM-CHAIN TRGLYCERIDES (UNII: C9H2L217/U) CAPRYLHYDROXAMIC ACID (UNII: 09H205K999W) CAPRYLH GLYCOL (UNII: 00H7950(599W) CYCLOMETHICONE 6 (UNII: 7HF2FCIOR) DIMETHICONE 6 (UNII: 7HF3PCIOR) DIMETHICONE 6 (UNII: 7HF3PCIOR) DIMETHICONE 6 (UNII: 7HF3PCIOR) DIMETHICONE (UNII: 8H2030F6MM) ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B) GLYCERIN (UNII: 9DC6A3C00X) FERRIC OXIDE RED (UNII: 1K09F36675) FERRIC OXIDE RED (UNII: 100P126) MELISSA OFERRIC OXIDE (UNII: 100P126) MELISSA OFERRIC OXIDE (UNII: 100P126) MELISSA OFERRIC OXIDE (UNII: 100P126) MICROCRYSTALLINE WAX (UNII: 87597(3KY) OCTYLDODECYL NEOPENTANOATE (UNII: 91830277) SODIUM CHLORIDE (UNII: 451/497(38X) TETRAHEXYLDECYL ASCORBATE (UNII: 9184307AZ) 	Inactive Ingre	dients		
TOCOPHEROL (UNII: R0Z B2556P8)       Image: Comparison of the		Ingredient Name		Strength
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) CAPRYLYL GLYCOL (UNII: 00YIU5438U) POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC5285WUY) CYCLOMETHICONE 5 (UNII: 0THT5PCIOR) DIMETHICONE 5 (UNII: 0THT5PCIOR) DIMETHICONE (UNII: 92RU3N3710) EDETATE DISODIUM ANHYDROUS (UNII: 8NL036F66MM) ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B) GLYCERIN (UNII: PDC6A3C00X) FERRIC OXIDE RED (UNII: 1K09F3675) FERRIC OXIDE RED (UNII: 1K09F3675) ISODDECANE (UNII: 8483802MRT) FERRIC OXIDE RED (UNII: 1K09F3675) ISODDECANE (UNII: 848802MRT) FERRIC OXIDE RED (UNII: 1K09F357) ISODDECANE (UNII: 848802MRT) FERRIC OXIDE RED (UNII: 1K09F370) ISODDECANE (UNII: 848802MRT) FERRIC OXIDE RED (UNII: 1K09F3703KY) OCTYLDODECVL NEOPENTANOATE (UNII: 87758883T) PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 97139057FO) SODIUM CHLORIDE (UNII: 451W4710EX) TETRAHEXYLDECYL ASCORBATE (UNII: 92R3607AZ) .ALPHATOCOPHEROL ACETATE (UNII: 92R3607AZ) .ALPHATOCOPHEROL ACETATE (UNII: 92R3607AZ) .ALPHATOCOPHEROL (UNII: 1LC331P08E) WATER (UNII: 05590F0KOOR) PACKagING # Item Code Package Description Marketing Start Marketing E 1 NDC:58892-128- 1 In 1 CARTON 50 g in 1 TUBE; Type 0: Not a Combination Product # Item Code Package Description 03/01/2023	<b>ВІЅМИТН ОХҮСН</b>	<b>ORIDE</b> (UNII: 4ZR792I587)		
CAPRYLYL GLYCOL (UNII: 00YIIJ5438U)       Image: Constrary of the constraint of	MEDIUM-CHAIN TR	RIGLYCERIDES (UNII: C9H2L21V7U)		
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC5285WUY)          CYCLOMETHICONE 6 (UNII: 0THTSPCIOR)          DIMETHICONE (UNII: 92RU3N3Y1O)          EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)          ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)          GLYCERN (UNII: PDC6A3COOX)          FERRIC OXIDE RED (UNII: K09F36675)          FERRIC OXIDE RED (UNII: K38802MRT)          FERRIC OXIDE RED (UNII: K388020MRT)          FERRIC OXIDE RED (UNII: SA18802MRT)          FERRIC OXIDE RED (UNII: K388057)          ISODEZCANE (UNII: 3882896872)          ISOHEXADECANE (UNII: X06959703KY)          OCTYLDODECYL NEOPENTANOATE (UNII: X87258803T)          PGG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 97130057F0)          SODIUM CHLORIDE (UNII: 451W47I08X)          TETRAHEXYLDECYL ASCORBATE (UNII: 9E83802L0)          OCOPHEROL (UNII: 8028256F8)          TROLAMINE (UNII: 102331P08E)          WATER (UNII: 059676K00R)	CAPRYLHYDROXAN	MIC ACID (UNII: UPY805K99W)		
CYCLOMETHICONE 6 (UNII: XHK3U310BA)       Image: Cyclomethicone 5 (UNII: 0THTSpci0R)       Image: Cyclomethicone 5 (UNII: 0THTSpci0R)         DIMETHICONE (UNII: 92RU3N3Y10)       Image: Cyclomethicone 5 (UNII: 80R036F6MM)       Image: Cyclomethicone 5 (UNII: 80R036F6MM)         ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)       Image: Cyclomethicone 5 (UNII: 1K09F36675)       Image: Cyclomethicone 5 (UNII: 1K09F36675)         FERRIC OXIDE RED (UNII: 1K09F36675)       Image: Cyclomethicone 5 (UNII: 1K09F36675)       Image: Cyclomethicone 5 (UNII: 1K09F36675)         FERRIC OXIDE YELLOW (UNII: 1K08F36675)       Image: Cyclomethicone 5 (UNII: 1K09F36675)       Image: Cyclomethicone 5 (UNII: 1K08F36675)         FERRIC OXIDE RED (UNII: 1K08F36675)       Image: Cyclomethicone 5 (UNII: 1K08F36757)       Image: Cyclomethicone 5 (UNII: 1K08F36757)         ISODDECANE (UNII: 1K08F367675)       IsoDODECANE (UNII: 918X10UF1E)       Image: Cyclomethicone 5 (UNII: 918X10UF1E)         MICA (UNII: 918X10UF1E)       Image: Cyclomethicone 5 (UNII: 1K07F377)       Image: Cyclomethicone 5 (UNII: 1K07F377)         ISODDECANE (UNII: 1K08F37703KY)       Image: Cyclomethicone 5 (UNII: 1K07F37703KY)       Image: Cyclomethicone 5 (UNII: 1K07F37703KY)         OCTYLDODECYL NEOPENTANOATE (UNII: 1K07F37703KY)       Image: Cyclomethicone 5 (UNII: 1K07F37703KY)       Image: Cyclomethicone 5 (UNII: 1K07F37703KY)         OCTYLDODECYL NEOPENTANOATE (UNII: 918X106X)       Image: Cyclomethicone 5 (UNII: 1K07F37703KY)       Image: Cyclomethicone 5 (UNII: 1K07F	CAPRYLYL GLYCOI	L (UNII: 00YIU5438U)		
CYCLOMETHICONE 5 (UNII: 0THTSPCIOR)     Image: Cyclomethicone (Unii: 92RU3N3Y10)       DIMETHICONE (UNII: 92RU3N3Y10)     Image: Cyclomethicone (Unii: 92RU3N3Y10)       EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)     Image: Cyclomethicone (Unii: 800F36675)       ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W6F25684B)     Image: Cyclomethicone (UNII: 800F36675)       FERRIC OXIDE YELLOW (UNII: EX438022MRT)     Image: Cyclomethicone (UNII: 800F3767)       FSOODGECANE (UNII: 81800000000000000000000000000000000000	POLYOXYL 20 CET	OSTEARYL ETHER (UNII: YRC528SWUY)		
DIMETHICONE (UNII: 92RU3N3Y10)       Image: Content of the second s	CYCLOMETHICON	E 6 (UNII: XHK3U310BA)		
DIMETHICONE (UNII: 92RU3N3Y10) =	CYCLOMETHICON	E 5 (UNII: 0THT5PCIOR)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)       Image: State Sta				
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B) 9 GLYCERIN (UNII: PDC6A3C00X) 9 FERRIC OXIDE RED (UMI: 1K09F3G675) 9 FERRIC OXIDE YELLOW (UNII: EX43802MRT) 9 FERRIC OXIDE YELLOW (UNII: XM087F357) 9 ISODDECANE (UNII: A8289F68Y2) 9 ISOHEXADECANE (UNII: 38249F68Y2) 9 ISOHEXADECANE (UNII: 918X10UF1E) 9 MELISSA OFFICINALIS WHOLE (UNII: YF70189L0N) 9 MICR (UNII: V8A14W0880) 9 MICR (UNII: V8A14W0880) 9 OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T) 9 PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q057F0) 9 SODUM CHLORIDE (UNII: 451W47IQ8X) 9 TETRAHEXYLDECYL ASCORATE (UNII: 9E8X80D2L0) 9 OCTYLDODECYL NEOPENTANOATE (UNII: 9E8X80D2L0) 9 TCOCOPHEROL (UNII: R0Z B2556P8) 1 TROLAMINE (UNII: 0538933TK) 9 TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) 9 WATER (UNII: 0598F0KOR) 9 <b>P</b> <b>T</b> MCC528892-128- 1 in 1 CARTON 03/01/2023 9 1 NDC:58892-128- 1 in 1 CARTON 03/01/2023 9 1 NDC:58892-1 in 1 INE I				
GLYCERIN (UNII: PDC6A3C00X)       Image: Stress of Stre			IB)	
FERRIC OXIDE RED (UNII: 1K09F3G675)       Image: Second S				
FERRIC OXIDE YELLOW (UNII: EX43802/MRT)         Image: Strate				
FERROSOFERRIC OXIDE (UNII: XM0M87F357)         Image: State Stat				
ISODODECANE (UNII: A8289P68Y2)       Image: State				
ISOHEXADECANE (UNII: 918X10UF1E)		· · · · ·		
MELISSA OFFICINALIS WHOLE (UNII: YF70189L0N)       Image: Comparison of the system of t				
MICA (UNII: V8A1AW0880)				
MICROCRYSTALLINE WAX (UNII: X0F597Q3KY)       Image: Content of the system				
OCTYLDODECYL NEOPENTANOATE (UNII: x8725R883T)       Image: colspan="2">Image: colspan="2">Image: colspan="2">Image: colspan="2">Image: colspan="2">Image: colspan="2">Image: colspan="2" Colspan="	•	•		
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)         Image: Solum Chloride (UNII: 451W47IQ8X)         Image: Solum Chloride (UNII: 928C0010)         Image: Solum Chloride (UNII: 928C0010)         Image: Solum Chloride (UNII: 80Z82556P8)         Image: Solum Chloride (UNII: 80Z82556P8)         Image: Solum Chloride (UNII: 903K9353TK)         Image: Solum Chloride (UNII: 903K9353T				
SOlUM CHLORIDE (UNII: 451W47IQ8X)       Solum CHLORIDE (UNII: 451W47IQ8X)         TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)         ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)         TOCOPHEROL (UNII: R0ZB2556P8)         TOCOPHEROL (UNII: R0ZB2556P8)         TROLAMINE (UNII: 903K93S3TK)         TROXCAPRYLYISILANE (UNII: 1DC331P08E)         WATER (UNII: 0590F0K00R)         Marketing Start Date         Date         1         NDC:58892-128-         1         S0 g in 1 TUBE; Type 0: Not a Combination         Product			750)	
Image: State stat			5/FO)	
ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)       Image: Comparison of the comp				
TOCOPHEROL (UNII: R0ZB2556P8)   TROLAMINE (UNII: 903K93S3TK)   TROLAMINE (UNII: 10C331P08E)   WATER (UNII: 059QF0K00R)   Package Description   Marketing Start Marketing E   1 NDC:58892-128-   1 in 1 CARTON   03/01/2023 50 g in 1 TUBE; Type 0: Not a Combination   Product Sol g in 1 TUBE; Type 0: Not a Combination				
Item Code       Package Description       Marketing Start Date       Marketing E Date         1       NDC:58892-128- 50       1 in 1 CARTON       03/01/2023       03/01/2023       I       I       I       I       S0 g in 1 TUBE; Type 0: Not a Combination Product       I       I       I       I       I       S0 g in 1 TUBE; Type 0: Not a Combination Product       I		· · ·		
Image: State	TOCOPHEROL (UNII: R0ZB2556P8)			
WATER (UNII: 059QF0K00R)         Marketing Start         #       Item Code       Package Description       Marketing Start       Marketing E         1       NDC:58892-128- 50 g in 1 TUBE; Type 0: Not a Combination Product       03/01/2023       Image: Colspan="3">Colspan="3">Colspan="3">Colspan="3">Colspan="3">Colspan="3">Colspan="3">Colspan="3">Colspan="3">Colspan="3"         1       NDC:58892-128- 50 g in 1 TUBE; Type 0: Not a Combination Product       03/01/2023       Image: Colspan="3">Colspan="3">Colspan="3"	TROLAMINE (UNII: 903K93S3TK)			
Item Code       Package Description       Marketing Start Date       Marketing E Date         1       NDC:58892-128- 50       1 in 1 CARTON       03/01/2023       03/01/2023         1       S0 g in 1 TUBE; Type 0: Not a Combination Product       Image: Complex of the second seco	TRIETHOXYCAPRY	LYLSILANE (UNII: LDC331P08E)		
#Item CodePackage DescriptionMarketing Start DateMarketing E Date1NDC:58892-128- 501 in 1 CARTON03/01/202303/01/2023150 g in 1 TUBE; Type 0: Not a Combination Product50 g in 1 TUBE; Type 0: Not a Combination1	WATER (UNII: 059Q	F0KO0R)		
#Item CodePackage DescriptionMarketing Start DateMarketing E Date1NDC:58892-128- 501 in 1 CARTON03/01/202303/01/2023150 g in 1 TUBE; Type 0: Not a Combination Product111				
#Item CodePackage DescriptionDateDate1NDC:58892-128- 501 in 1 CARTON03/01/2023150 g in 1 TUBE; Type 0: Not a Combination Product50 g in 1 TUBE; Type 0: Not a Combination	Packaging			
NDC:58892-128- 50         1 in 1 CARTON         03/01/2023           I         50 g in 1 TUBE; Type 0: Not a Combination Product         50 g in 1 TUBE; Type 0: Not a Combination	# Item Code	Package Description		Marketing End Date
50 g in 1 TUBE; Type 0: Not a Combination       Product		1 in 1 CARTON		
Marketing Information				
Marketing Information				
	marketing	Information		

Application Number or Monograph Marketing Start Marketing End

Marketing

Category	Citation	Date	Date
OTC monograph not final	part352	03/01/2023	
Indi			

# Labeler - Fallien Cosmeceuticals Ltd. (958388357)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Custom Analytics LLC		144949372	ANALYSIS(58892-128)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-128), PACK(58892-128)

Revised: 8/2023

Fallien Cosmeceuticals Ltd.