

**TOTY SOLARIA MINERAL- titanium dioxide, zinc oxide cream**  
**Chipican LLC**

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**toty Solaria Mineral**

**Active Ingredients**

Titanium Dioxide 7.0%

Zinc Oxide 6.0%

**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 aging 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**

- Shake well before use
- 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 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. - 2 p.m.

Wear long-sleeved shirts, pants, hats, and sunglasses

- Children under 6 months of age: Ask a doctor

### **Other information**

- Do not expose the product to high temperatures
- Protect the product in this container from excessive heat and direct sun

### **Inactive Ingredients**

Water, Dimethicone, Isododecane, C12-15 Alkyl Benzoate, Hydrogenated Didecene, Butyloctyl Salicylate, Aluminum Hydroxide, Styrene/Acrylates Copolymer, Phenethyl Benzoate, PEG-9 Polydimethylsiloxyethyl Dimethicone, Nylon-12, Calaguala ( *Polypodium leucotomos*) Leaf Extract, Ferulic Acid, 3-O-Ethyl Ascorbic Acid, Tocopheryl Acetate, Tocopherol, Cutleaf Grouncherry (*Physalis angulata*) Extract, Green Tea ( *Camellia sinensis*) Extract, Plankton ( *Chlamydomonas reinhardtii*) Extract, Arginine, Melanin, Caprylyl Glycol, Isohexadecane, Disteardimonium Hectorite, Hydrogen Dimethicone, Phenylpropanol, Polyhydroxystearic Acid, Magnesium Sulfate, Dimethicone/PEG-10/15 Crosspolymer, Propanediol, Triethoxycaprylylsilane, Propylene Carbonate, Caprylic/Capric Triglyceride, Panthenyl Triacetate, Butylene Glycol, Propylene Glycol, Ethyl Linoleate, Oleyl Alcohol, Pentylene Glycol, Oxothiazolidine, Dipropylene Glycol, Sodium Citrate, Palmitoyl Hydroxypropyltrimonium Amylopectin/Glycerin Crosspolymer, 1,2-Hexanediol, Lecithin, Sodium Benzoate, Hydrogenated Lecithin, Phenoxyethanol, Ethylhexylglycerin, Iron Oxides (Ferric Oxide Red (CI 77491), Ferric Oxide Yellow (CI 77491), Ferrosoferric Oxide (CI 77499)).

### **Package Label.Principal Display Panel- Sample**

#### **NDC 82141-3161-2 (toty Solaria Mineral, Sample)**

toty.

SOLARIA

MINERAL

SPF 50+

ANTIOXIDANT

SUNSCREEN SERUM

SERUM ANTIOXIDANTE

PROTECTOR SOLAR

.....  
BROAD SPECTRUM SPF 50+

VERY WATER RESISTANT

(80 MINUTES)

AMPLIO ESPECTRO SPF 50+

MUY RESISTENTE AL AGUA

(80 MINUTOS)

0.17 oz/5g

Sunscreen is the best accessory.  
El protector solar es el mejor accesorio.

**toty.**

**SOLARIA  
MINERAL**

SPF 50+

**ANTIOXIDANT  
SUNSCREEN SERUM  
SERUM ANTIOXIDANTE  
PROTECTOR SOLAR**

BROAD SPECTRUM SPF 50+  
VERY WATER RESISTANT  
(80 MINUTES)

AMPLIO ESPECTRO SPF 50+  
MUY RESISTENTE AL AGUA  
(80 MINUTOS)

0.17 oz. / 5g

BATCH / LOT.: XXXX  
EXP / CAD.: XX/XXXX

**Drug Facts**

**Active ingredients Purpose**  
Titanium Dioxide, Zinc Oxide — sunscreen

**Uses**  
● Helps prevent sunburn  
● Used in conjunction 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.

**When using this product**  
● Keep out of eyes. Rinse with water to remove.  
● Stop use and ask a doctor if rash occurs.

**Directions**  
● Shake well before use.  
● Apply liberally 15 minutes before sun exposure.

**Precautions**  
● Wear 30 minutes of swimming or sweating.  
● Reapply after towel drying.

● Reapply every 2 hours.  
● 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 a.m. – 2 p.m.  
● Wear long-sleeved shirts, pants, hats, and sunglasses.

● Children under 6 months of age: Ask a doctor.

**Other information**

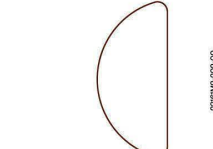
● Do not expose the product to high temperatures.  
● Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients**

Water, Dimethicone, Acrylate, C12-15 Alkyl Benzoate, Hydrogenated Dicaprylate/Dicaprylate, Aluminum Hydroxide, Diphenylsiloxane Condensate, Phenyl Trimethylammonium Chloride, Titanium Dioxide, Zinc Oxide, Carbocysteine, PEG-4 Polydimethylsilyl Dimethylsiloxane, Mica, Tri-Calcylate Phosphate, Inorganic Zinc Oxide, Ferulic Acid, 2-Ethylhexanoic Acid, Tocopheryl Acetate, Tocopherol Cellulose Succinate, Phytol, Isopropyl Alcohol, Citrus Aurantium Extract, Panthenol, Chamomilla recutitana (Matricaria) Extract, Arginine, Maltitol, Caprylyl Glycol, Tetrahydrofuran, Carbomer, Citrus Aurantium Extract, Hydroxyethyl Methacrylate, Phenoxyethanol, Polymethylsilyoxane, Magnesium Sulfate, Dimethicone/PEG-10/15 Copolymer, Propylparaben, Tetrahydrofuran, Propylene Carbonate, Caprylyl Glycol, Hydroxyethyl Methacrylate, Carbomer, Citrus Aurantium Extract, Panthenol, Ethylhexanoic Acid, Magnesium Sulfate, Propylene Glycol, Ethylhexanoic Acid, Methyl Methacrylate, Dimethylsiloxane, Dimethylsiloxane, Sodium Citrate, Polybutyl Methacrylate, Hydroxyethyl Methacrylate, Carbomer, Tetrahydrofuran, Sodium Benzoate, Hydroxyethyl Methacrylate, Phenoxyethanol, Ethylhexanoic Acid, Iron Oxides, Ferric Oxide, Red (CI 77491), Ferric Oxide Yellow (CI 77492), Ferric Oxide Blue (CI 77490).

**Questions or comments?**

Call Toll Free 1-800-455-7991 9 a.m. – 4 p.m. EST, Monday-Friday



**Shake well before use.  
Agitar bien antes de usar.**



DISTRIBUTED BY:  
DISTRIBUIDOR POR  
Chicago, I.L.O. 2011 Lake Park Dr.  
Wilmington, DE 19806  
USA

MADE IN SPAIN /  
FABRICADO EN ESPAÑA

Package Label.Principal Display Panel

**NDC 82141-3161-1 (toty Solaria Mineral)**

toty.

SOLARIA

MINERAL

SPF 50+

ANTIOXIDANT

SUNSCREEN SERUM

SERUM ANTIOXIDANTE

PROTECTOR SOLAR

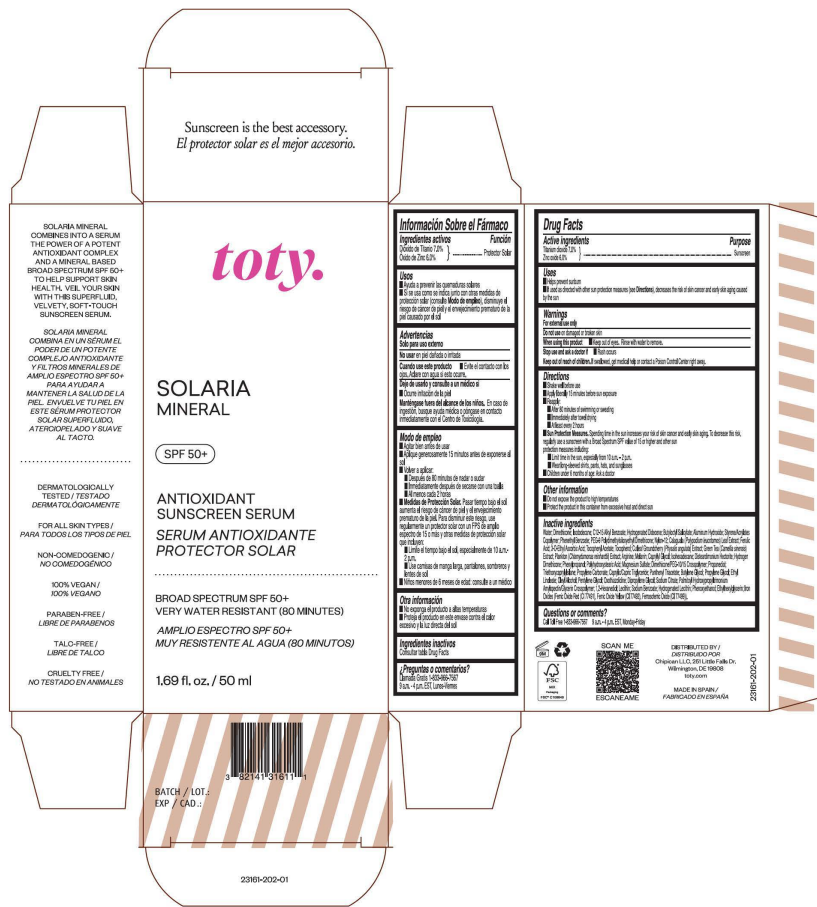
.....  
BROAD SPECTRUM SPF 50+

VERY WATER RESISTANT (80 MINUTES)

AMPLIO ESPECTRO SPF 50+

MUY RESISTENTE AL AGUA (80 MINUTOS)

1.69 fl. oz/50 mL



**Package Label. Princip[al Display Panel- Travel Size)  
NDC 82141-3161-3 (toty Solaria Mineral, Travel Size)**

toty.

SOLARIA

MINERAL

SPF 50+

ANTIOXIDANT

SUNSCREEN SERUM

SERUM ANTIOXIDANTE

PROTECTOR SOLAR

.....  
BROAD SPECTRUM SPF 50+

VERY WATER RESISTANT (80 MINUTES)

AMPLIO ESPECTRO SPF 50+  
 MUY RESISTENTE AL AGUA (80 MINUTOS)  
 1.0 fl. oz/30 mL



## TOTY SOLARIA MINERAL

titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82141-3161
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: TYP81E471F)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>POLYHYDROXYSTEARIC ACID STEARATE</b> (UNII: 8KQ7I65XZE)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>OXOTHIAZOLIDINE</b> (UNII: M6U1ZG59XD)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>3-PHENYL-1-PROPANOL</b> (UNII: U04IC2765C)	
<b>HYDROGENATED DIDECENE</b> (UNII: 048B98MT50)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>PHENETHYL BENZOATE</b> (UNII: 0C143929GK)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>PHYSALIS ANGULATA</b> (UNII: W4TKW9D5GG)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>PHLEBODIUM AUREUM LEAF</b> (UNII: BG58BW230G)	
<b>DIMETHICONE/PEG-10/15 CROSSPOLYMER</b> (UNII: 21AS8B1BSS)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>ETHYL LINOLEATE</b> (UNII: MJ2YTT4J8M)	
<b>OLEYL ALCOHOL</b> (UNII: 172F2WN8DV)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER</b> (UNII: V5RS026Q0H)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>ARGININE</b> (UNII: 94ZLA3W45F)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>FERULIC ACID</b> (UNII: AVM951ZWST)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>3-O-ETHYL ASCORBIC ACID</b> (UNII: 6MW60CB71P)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>MAGNESIUM SULFATE HEPTAHYDRATE</b> (UNII: SK47B8698T)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>ANHYDROUS TRISODIUM CITRATE</b> (UNII: RS7A450LGA)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	



**PANTHENOL TRIACETATE, (+)-** (UNII: 1206E8961B)

**CHLAMYDOMONAS REINHARDTII** (UNII: QS58JP94CS)

**MELANIN SYNTHETIC (TYROSINE, PEROXIDE)** (UNII: O0CV1RMR44)

**DIMETHICONE** (UNII: 92RU3N3Y1O)

**PALMITOYL HYDROXYPROPYLTRIMONIUM AMYLOPECTIN/GLYCERIN CROSSPOLYMER** (UNII: 7F9WLW26M2)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82141-3161-1	1 in 1 CARTON	06/01/2023	01/31/2024
1		50 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:82141-3161-2	1 in 1 CARTON	06/01/2023	
2		5 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:82141-3161-3	1 in 1 CARTON	01/08/2024	
3		30 g in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:82141-3161-4	1 in 1 CARTON	06/01/2023	
4		50 g in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/01/2023	

**Labeler** - Chipican LLC (118132015)

## Establishment

Name	Address	ID/FEI	Business Operations
Industrial Farmaceutica Cantabria SA		470471158	manufacture(82141-3161) , label(82141-3161) , pack(82141-3161)

Revised: 2/2024

Chipican LLC