

**POWDER- titanium dioxide powder**  
**Oxygen Development LLC**

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**PUR 4-in-1 Pressed Mineral Makeup - LINEN MN3**

**Active Ingredient**

Titanium Dioxide

**Purpose**

Sunscreen

**Uses**

Helps prevent sunburn.

**Warnings**

For external use only

**Do not use**

- Do not use on damaged or broken skin

**When using**

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

**Keep out of reach of children**

- 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 • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months: ask a doctor

**Other Information**

Protect this product from excessive heat and direct sun • In the unlikely event of an adverse reaction, please contact 1.866.PUR.0022.

**Inactive Ingredient**

Mica, Caprylic/Capric Triglyceride, Boron Nitride, Bismuth Oxychloride, Zinc Stearate, Magnesium Silicate, Sodium Starch Octenylsuccinate, Mannitol, Sodium Gluconate, Citric Acid, Sodium Citrate, Waltheria Indica Leaf Extract, Dextrin, Ferulic Acid, Lactic Acid (L), Butyrospermum Parkii (Shea) Butter, Retinol, Ceramide AP, Silica, Tocopheryl Acetate, Aqua, Glucosamine HCl, Pisum Sativum (Pea) Extract, Bambusa Vulgaris Leaf/Stem Extract, Magnesium Carbonate, Iron Oxides (CI 77491, CI 77492, CI 77499), May Contain: Titanium Dioxide (CI 77891), Ultramarines (CI 77007).

**Package label - Principal display panel**





## POWDER

titanium dioxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61354-189
<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	10 mg in 100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MAGNESIUM SILICATE</b> (UNII: 9B9691B2N9)	2 mg in 100 mg
<b>MANNITOL</b> (UNII: 3OWL53L36A)	1.67 mg in 100 mg
<b>BORON NITRIDE</b> (UNII: 2U4T60A6YD)	8 mg in 100 mg
<b>ZINC STEARATE</b> (UNII: H92E6QA4FV)	2.8 mg in 100 mg

<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	1.75 mg in 100 mg
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	0.5 mg in 100 mg
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	1.89 mg in 100 mg
<b>MICA</b> (UNII: V8A1AW0880)	51.05 mg in 100 mg
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)	10 mg in 100 mg
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	8 mg in 100 mg

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-189-01	1 in 1 CARTON	07/25/2025	
1		100 mg in 1 CUP; 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	07/25/2025	

**Labeler** - Oxygen Development LLC (137098492)

### Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-189)

### Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development DR Limited		815941560	pack(61354-189)

Revised: 3/2026

Oxygen Development LLC