

POWDER- titanium dioxide powder
Oxygen Development LLC

PUR 4-in-1 Pressed Mineral Makeup - PORCELAIN

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

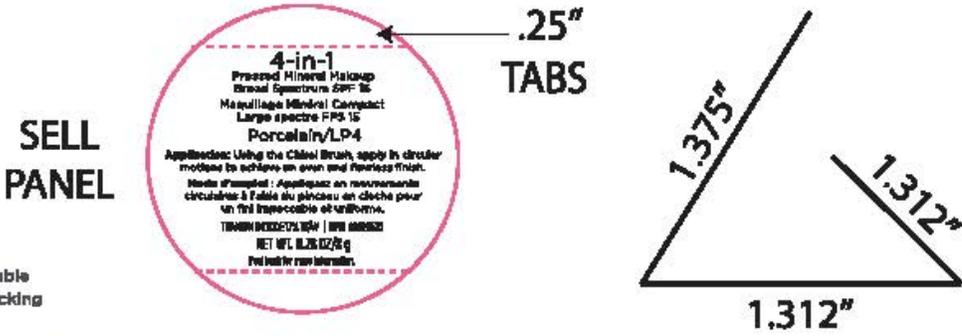
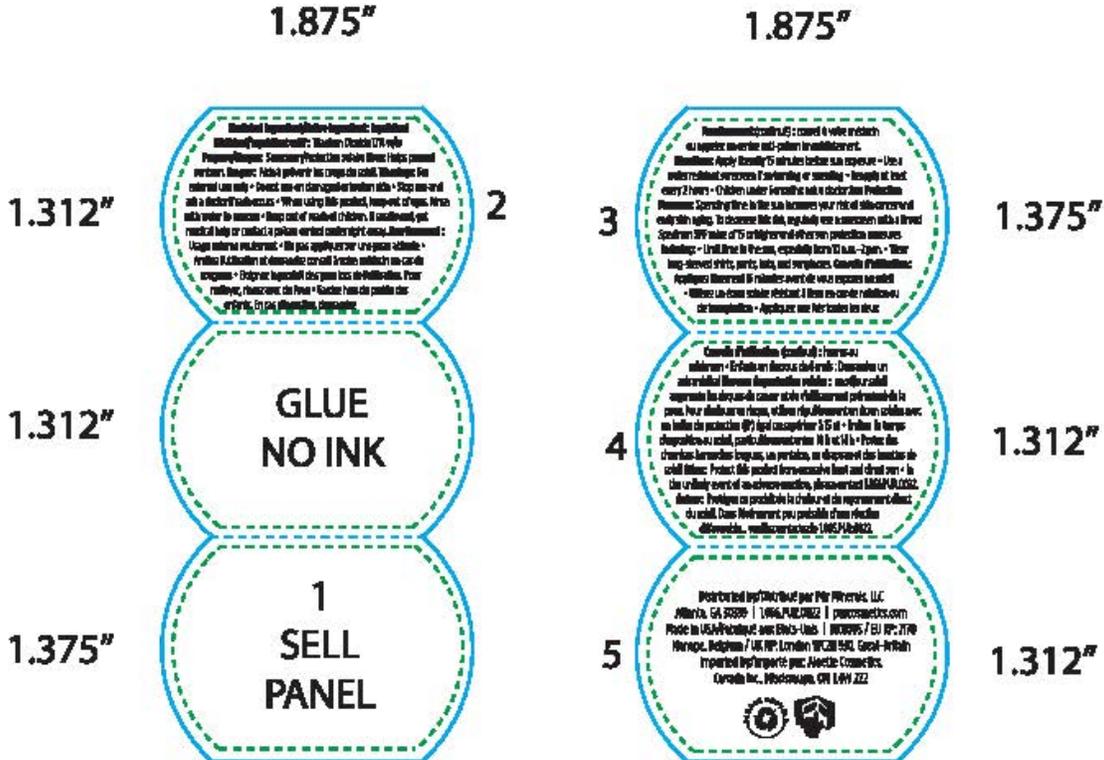




STANDWILL PACKAGING, INC.

220 SHERWOOD AVENUE, FARMINGDALE NEW YORK 11735 • (631) 752-1236 FAX (631)752-9036 EMAIL PRINT@STANDWILL.COM

DATE: 4/15/11	SIZE: .75" DIA	ALLCRAFT#20248
PO# AB258	REV:	
ITEM DESCRIPTION:	APPROVAL DATE:	
ITEM NUMBER: 30277836	SIGNATURE:	



White Label
Clear Backing
 100% Black

US BL # 25122501240
Item # 951225010
UPC # 847137048027

POWDER
titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-118
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	1.75 mg in 100 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	8 mg in 100 mg
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	2 mg in 100 mg
MANNITOL (UNII: 3OWL53L36A)	1.67 mg in 100 mg
BORON NITRIDE (UNII: 2U4T60A6YD)	8 mg in 100 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.5 mg in 100 mg
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	1.89 mg in 100 mg
MICA (UNII: V8A1AW0880)	53.09 mg in 100 mg
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	10 mg in 100 mg
ZINC STEARATE (UNII: H92E6QA4FV)	2.8 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-118-02	1 in 1 CARTON	10/27/2023	
1	NDC:61354-118-01	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	10/27/2023	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-118)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development DR Limited		815941560	pack(61354-118)

Revised: 5/2025

Oxygen Development LLC