POWDER- titanium dioxide powder
Oxygen Development LLC

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

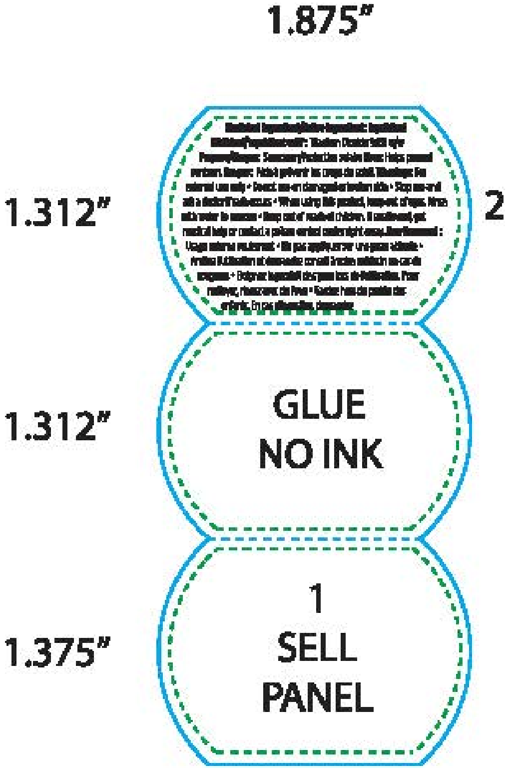
Mica, Caprylic/Capric Triglyceride, Boron Nitride, Bismuth Oxychloride, Zinc Stearate, Magnesium Silicate, Sodium Starch Octenylsuccinate, Mannitol, Sodium Gluconate, Citric Acid, Sodium Citrate, Waltheria Indica Leaf Extract, Dextrin, Ferulic Acid, Lactic Acid (L), Butyrospermum Parkii (Shea) Butter, Retinol, Ceramide AP, Silica, Tocopheryl Acetate, Aqua, Glucosamine HCI, 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).

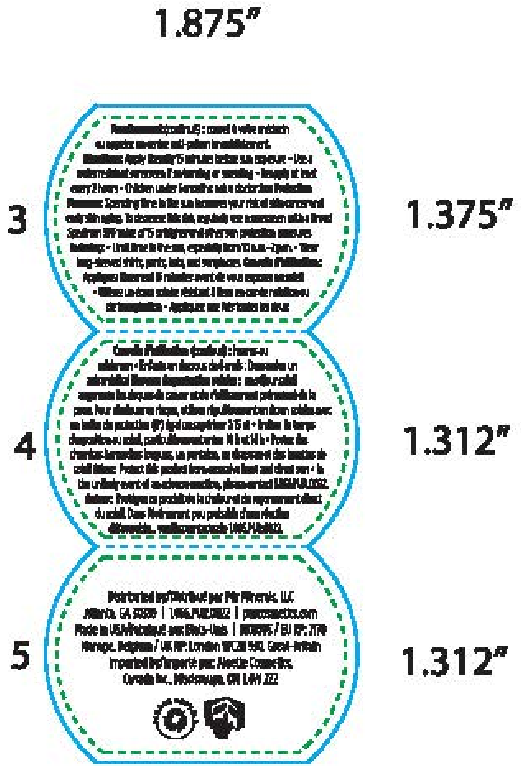
Package label - Principal display panel

STANDWILL PACKAGING, INC.

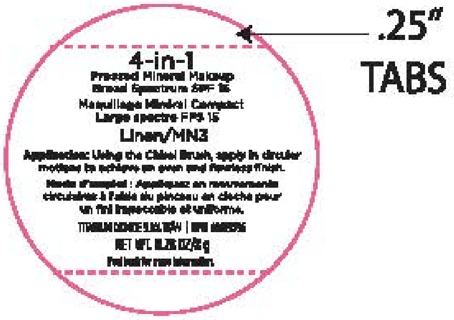
220 SHERWOOD AVENUE, FARMINGDALE NEW YORK 11735 • (631) 752-1236 FAX (631)752-3036 EMAIL PRINT @STANDWILL.COM

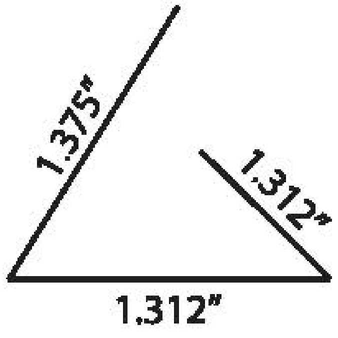
DATE: 4/15/11	SIZE: .75" DIA	ALLCRAFT#20248
PO# A8256	REV:	
ITEM DESCRIPTION:	APPROVAL DATE:	
ITEM NUMBER: 30277636	SIGNATURE:	





SELL
PANEL

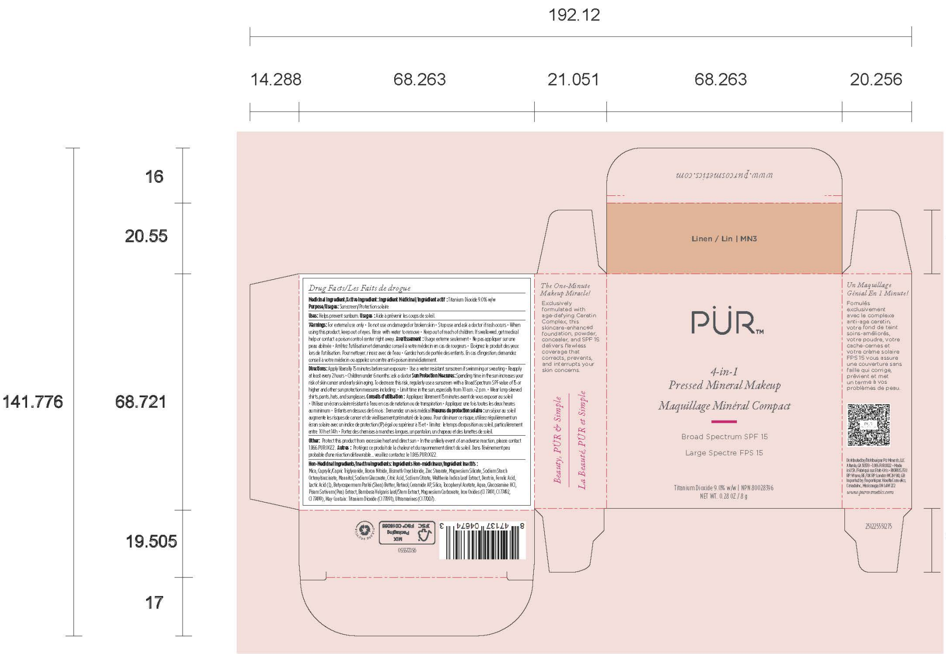




White Lable
Clear Backing

■ 100% Black

US BL # 251225552240
Item # 951225550
UPC # 847137048938



www.purcosmetics.com

Linen / Lin | MN3

PÜR™

4-in-1
Pressed Mineral Makeup
Maquillage Minéral Compact

Broad Spectrum SPF 15

Large Spectre FPS 15

Titanium Dioxide 9.0% w/w | NPN 80028396
NET WT. 0.28 OZ / 8 g

The One-Minute Makeup Miracle!

Exclusively formulated with age-defying Ceretin Complex, this skincare-enhanced foundation, powder, concealer, and SPF 15 delivers flawless coverage that corrects, prevents, and interrupts your skin concerns.

Beauty, PÜR & Simple

La Beauté, PÜR et Simple

Un Maquillage Génial En 1 Minute!

Fomulés exclusivement avec le complexe anti-age ceretin, votre fond de teint soins-améliorés, votre poudre, votre cache-cernes et votre crème solaire FPS 15 vous assure une couverture sans faille qui corrige, prévient et met un terme à vos problèmes de peau.

Distributed by/Distribué par PÜR Minerals, LLC Atlanta, GA 30339 • 1.866.PUR.0022 • Made in USA / Fabriqué aux États-Unis • BIORIUS/EU RP: Wavre, BE / UK RP: London WC2H 9JQ, GB Imported by / Importé par: Aloette Cosmetics Canada Inc., Mississauga ON L4W 2Z2
www.purcosmetics.com

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Drug Facts/Les Faits de drogue

Medicinal Ingredient/Active Ingredient : Ingrédient Médicinal/Ingrédient actif : Titanium Dioxide 9.0% w/w
Purpose/Usages: Sunscreen/ Protection solaire

Uses: Helps prevent sunburn. **Usages :** Aide à prévenir les coups de soleil.

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 reach of children. If swallowed, get medical help or contact a poison control center right away. **Avertissement :** Usage externe seulement • Ne pas appliquer sur une peau abîmée • Arrêtez l'utilisation et demandez conseil à votre médecin en cas de rougeurs • Éloignez le produit des yeux lors de l'utilisation. Pour nettoyer, rincez avec de l'eau • Gardez hors de portée des enfants. En cas d'ingestion, demandez conseil à votre médecin ou appelez un centre anti-poison immédiatement.

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 **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. **Conseils d'utilisation :** Appliquez librement 15 minutes avant de vous exposer au soleil • Utilisez un écran solaire résistant à l'eau en cas de natation ou de transpiration • Appliquez une fois toutes les deux heures au minimum • Enfants en dessous de 6 mois : Demandez un avis médical **Mesures de protection solaire :** un séjour au soleil augmente les risques de cancer et de vieillissement prématuré de la peau. Pour diminuer ce risque, utilisez régulièrement un écran solaire avec un indice de protection (IP) égal ou supérieur à 15 et • limitez le temps d'exposition au soleil, particulièrement entre 10 h et 14 h • Portez des chemises à manches longues, un pantalon, un chapeau et des lunettes de soleil.

Other: Protect this product from excessive heat and direct sun • In the unlikely event of an adverse reaction, please contact 1.866.PUR.0022. **Autres :** Protégez ce produit de la chaleur et du rayonnement direct du soleil. Dans l'événement peu probable d'une réaction défavorable... veuillez contactez le 1.866.PUR.0022.

Non-Medicinal Ingredients/Inactive Ingredients: Ingrédients Non-médicinaux/Ingrédient Inactifs :
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).

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FSC
MIX
Packaging
FSC® C016055

PLEASE RECYCLE

951225550

■ 100% Black

■ PMS
COOL GREY 11 C

■ Deboss Color for representation
ONLY DO NOT PRINT

■ PMS 9242U - 60%

■ PMS 9183U

FSC PAPER

Component # 251225551275

■
Shade Color
Color Match to corresponding
4 in 1 Product

POWDER

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-117
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)	51.05 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:61354-117-02	1 in 1 CARTON	10/27/2023	
1	NDC:61354-117-01	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(61354-117)