

4 IN 1 PRESSED MINERAL SPF 15 DEEP - titanium dioxide powder
PUR MINERALS

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.

Active Ingredient : Titanium Dioxide 9 %

Purpose : Sunscreen

Discontinue use If rash or irritation develops and increases. If irritation persists, consult a health care practitioner or Contact a Poison Control Center right away.

Keep Out of Reach of Children .

Inactive Ingredients : Mica , Boron Nitride , Caprylic/Capric Triglyceride , Bismuth Oxychloride , Zinc Stearate , Magnesium Silicate , Magnesium Carbonate ,Sodium Starch Octenylsuccinate, Mannitol,

Sodium Gluconate , Citric Acid, Sodium Citrate , Walthena Indica Leaf Extract , Dextrin , Ferulic Acid, L-Lactic Acid, Butyrospermum Parkii (Shea Butter) , Silica, Thioctic Acid,Sodium Hyarluronate, Retinol,

L-Ascorbic Acid, Ceramide 6 II , Magnolia Officinalis Bark Extract, Vitis Vinifera (Grape) Seed Extract , Tocopherol , Lecithin , Maltodextrin , Vitis Vinifera (Grape) Fruit Skin, Glycerin, Palmitoyl Tripeptide-5,

L-Glucothione, Aloe Barbadosensis Leaf Extract, Hydrated Silica , Tocopheryl Acetate , Aqua, Glucosamine HCl, Pisum Sativum (Pea) Extract, Bambus Vulgaris Leaf/Stem Extract, Magnesium Carbonate ,

Iron oxide , May contain : Titanium Dioxide, Ultramarines.

For external use only. Please avoid contact inside eyes. Rinse with water to remove.

Drug Facts (continued)

Directions: Apply small amount evenly to dry skin prior to sun exposure. Children under 6 months of age consult a doctor.

Warnings: For external use only. Please avoid contact inside eyes. Rinse with water to remove. Discontinue use if skin irritation develops or increases. If irritation persists, consult a health care practitioner or contact a Poison Control Center right away. Keep out of reach of children.

Drug Facts/ Les Faits de drogue

Medicinal Ingredient/Active Ingredient: / Ingrédient Médicinal/Ingrédient actif :
 Titanium Dioxide 9.0% w/w

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

Other: / Autres: In the unlikely event of an adverse reaction, please contact 1.866.PUR.0022. / Dans l'événement peu probable d'une réaction défavorable... veuillez contactez le 1.866.PUR.0022.

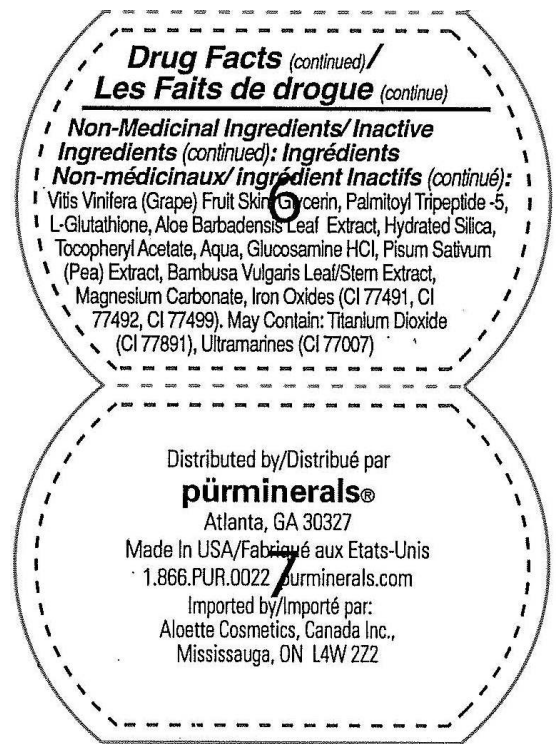
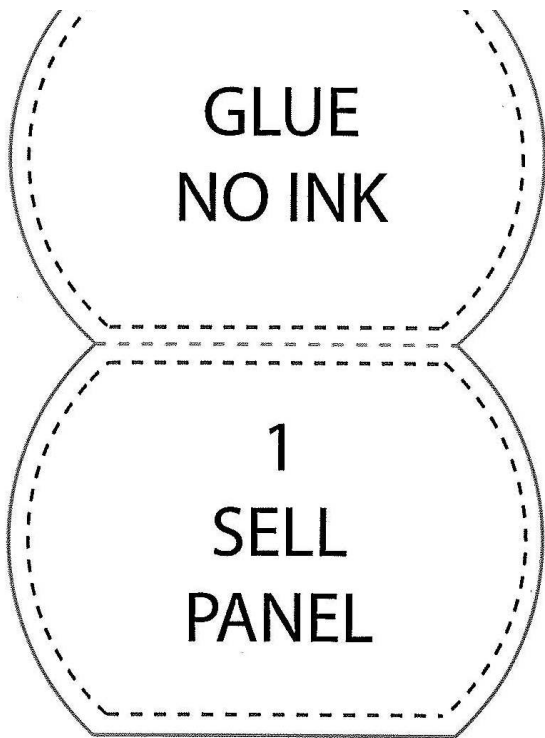
Les Faits de drogue (continue)

Utilisation : Appliquer une petite quantité uniformément sur la peau sèche avant l'exposition au soleil. Les enfants de moins de 6 mois doivent consulter un médecin avant l'utilisation.

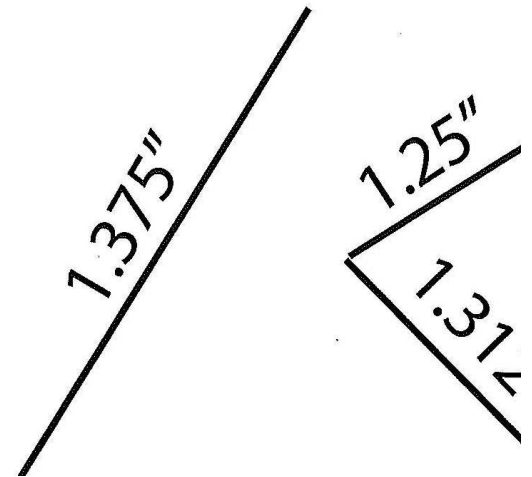
Avertissement : Pour usage externe seulement. Rincer avec de l'eau pour enlever. Éviter le contact avec les yeux. Cesser l'utilisation en cas d'irritation de la peau. Si l'irritation persiste, consulter un spécialiste de la santé ou contacter un centre anti-poison sur le champs. Garder hors de la portée des enfants.

Drug Facts (continued)/ Les Faits de drogue (continue)

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, Walthera Indica Leaf Extract, Dextrin, Ferulic Acid, L-Lactic Acid, Butyrospermum Parkii (Shea Butter), Silica, Thioctic Acid, Sodium Hyaluronate, Retinol, L-Ascorbic Acid , Ceramide 6 II, Magnolia Officinalis Bark Extract, Vitis Vinifera / Vitis Vinifera (Grape) Seed Extract, Tocopherol, Lecithin, Maltodextrin,



.25"
TABS



4 IN 1 PRESSED MINERAL SPF 15 DEEP
titanium dioxide powder

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67345-0788 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP) | Titanium Dioxide | 0.72 g in 8 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Mica (UNII: V8A1AW0880) | |
| Boron Nitride (UNII: 2U4T60A6YD) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| Bismuth Oxychloride (UNII: 4ZR792I587) | |
| Zinc Stearate (UNII: H92E6QA4FV) | |
| Magnesium Silicate (UNII: 9B9691B2N9) | |
| MAGNESIUM CARBONATE (UNII: 0E53J927NA) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| Shea Butter (UNII: K49155WL9Y) | |
| Acetate Ion (UNII: 569DQM74SC) | |
| Iron (UNII: E1UOL152H7) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:67345-0788-0 | 8 g in 1 CASE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 09/15/2011 | |

Labeler - PUR MINERALS (780516402)

Revised: 9/2011

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