

# **ALUMIER MD SHEER HYDRATION TINTED MOISTURIZING SUNSCREEN- titanium dioxide, zinc oxide lotion**

**Alumier Labs**

*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.*

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## **Alumier MD Sheer Hydration Tinted Moisturizing Sunscreen**

### **Drug Facts**

#### **Active Ingredients**

Titanium Dioxide 7%

Zinc Oxide 6.28%

#### **Purpose**

Sunscreen

#### **Use**

- helps prevent sunburn

#### **Warnings**

- **For external use only.**

#### **When using this product**

- do not use on damaged or broken skin
- keep out of eyes. Rinse with water to remove.

#### **Stop use and ask a doctor**

if you develop severe irritation, burning or itching of the skin, hives, swelling of eyes and mouth, blistering or difficulty breathing.

#### **Keep out of reach of children.**

If swallowed, call a Poison Control Centre or get medical help right away.

#### **Directions**

- apply liberally/generously (and evenly) 15 minutes before sun exposure
- reapply at least every 2 hours
- for use on children less than 6 months of age, consult a health care practitioner
- **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

- use a water resistant sunscreen if swimming or sweating

### **Other Information**

- Do not use if security seal is broken or missing.
- You may report a serious adverse reaction event from using this product to: Alumier Labs Inc., 550 Cochituate Road, Suite 25, Framingham, MA 01701

### **Inactive Ingredients**

Water/Aqua/Eau, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Propanediol, Butyloctyl Salicylate, Glycerin, Cetearyl Alcohol, Aluminium Stearate, Glyceryl Stearate, PEG-100 Stearate, Synthetic Fluorphlogopite, Lecithin (Syn. Phosphatidylcholine), Vitis Vinifera Seed Extract, Resveratrol, Glutathione, Tocopheryl Acetate, Magnesium Ascorbyl Phosphate, Acacia Senegal Gum, Synthetic Wax, Polyhydroxystearic Acid, Ceteareth-20, Alumina, Microcrystalline Cellulose, Triethoxycaprylylsilane, Xanthan Gum, Cellulose Gum, C20-40 Pareth-10, Hydroxyethyl Behenamidopropyl Dimonium Chloride, Polyquaternium-67, Disodium EDTA, Ammonium Polyacrylate, Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499), Ethylhexylglycerin, Phenoxyethanol.

### **Company Information**

#### **Alumier MD**

#### **ALUMIER EUROPE LTD.**

5 ST. FREDERICK STREET  
VALLETTA VLT 1470, MALTA

#### **WWW.ALUMIERMD.COM**

EUROPE • UNITED STATES • CANADA  
UNITED KINGDOM

DISTRIBUTED IN CANADA BY

ALUMIER LABS INC.,

436 LIMESTONE CRESCENT

TORONTO, ON, M3J 2S4

DISTRIBUTED IN THE USA BY

ALUMIER LABS INC.,

550 COCHITUATE ROAD, SUITE 25

FRAMINGHAM, MA 01701

MANUFACTURED IN CANADA UNDER  
LICENSE FROM ALUMIER EUROPE LTD.

**Product Packaging - 60 mL**

**Alumier MD**

**Sheer Hydration**

Broad Spectrum SPF 40




TINTED MOISTURIZING

SUNSCREEN LOTION

VERSATILE TINT

NPN 80065824

**60 mL/2 fl oz**

<p><b>Alumier</b><sup>®</sup> ALUMIER EUROPE LTD. 5 ST. FREDERICK STREET VALLETTA VLT 1470, MALTA</p> <p><b>WWW.ALUMIERMD.COM</b></p> <p>EUROPE • UNITED STATES • CANADA UNITED KINGDOM</p> <p>DISTRIBUTED IN CANADA BY: ALUMIER AU CANADA PAR : ALUMIER LABS INC., 436 LIMESTONE CRESCENT TORONTO, ON M3J 2S4</p> <p>DISTRIBUTED IN THE USA BY: DISTRIBUÉ AUX ÉTATS-UNIS PAR : ALUMIER LABS INC., 550 COCHITUATE ROAD, SUITE 25 FRAMINGHAM, MA 01701</p> <p>MANUFACTURED IN CANADA UNDER LICENSE FROM ALUMIER EUROPE LTD. FABRIQUÉ AU CANADA SOUS LICENCE OCTROYÉE PAR ALUMIER EUROPE LTD.</p>  	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Titanium Dioxide 7%</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide 6.28%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p><b>Use</b> ■ helps prevent sunburn</p> <p><b>Warnings</b> ■ For external use only.</p> <p><b>When using this product</b> ■ do not use on damaged or broken skin ■ keep out of eyes. Rinse with water to remove.</p> <p><b>Stop use and ask a doctor if you develop severe irritation, burning or itching of the skin, hives, swelling of eyes and mouth, blistering or difficulty breathing</b></p> <p><b>Keep out of reach of children.</b> If swallowed, call a Poison Control Centre or get medical help right away</p> <p><b>Directions</b> ■ apply liberally/generously (and evenly) 15 minutes before sun exposure ■ reapply at least every 2 hours ■ for use on children less than 6 months of age, consult a health care practitioner ■ <b>Sun Protection Measures:</b> 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. ■ use a water resistant sunscreen if swimming or sweating</p> <p><b>Other Information</b> ■ Do not use if security seal on box is broken or missing. ■ You may report a serious adverse reaction event from using this product to: Alumier Labs Inc., 550 Cochituate Road, Suite 25, Framingham, MA 01701</p> <p><b>Inactive Ingredients/Ingrédients inactifs</b> 1911027 - Water/Aqua/Eau, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Propanediol, Butyloctyl Salicylate, Glycerin, Cetearyl Alcohol, Aluminium Stearate, Glycerol Stearate, PEG-100 Stearate, Synthetic Fluorophlogopite, Lecithin (Syn. Phosphatidylcholine), Vitis Vinifera Seed Extract, Resveratrol, Glutathione, Tocopheryl Acetate, Magnesium Ascorbyl Phosphate, Acacia Senegal Gum, Synthetic Wax, Polyhydroxystearic Acid, Ceteareth-20, Alumina, Microcrystalline Cellulose, Triethoxycaprylylsilane, Xanthan Gum, Cellulose Gum, C20-40 Pareth-10, Hydroxyethyl Behenamidopropyl Dimonium Chloride, Polyquaternium-67, Disodium EDTA, Ammonium Polysacrylate, Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499), Ethylhexylglycerin, Phenoxethanol.</p> <p>NON IRRITATING</p>	Active Ingredients	Purpose	Titanium Dioxide 7%	Sunscreen	Zinc Oxide 6.28%	Sunscreen	 <p><b>Sheer Hydration</b> Broad Spectrum SPF 40 Hydratante transparente FPS 40 à large spectre</p> <p>TINTED MOISTURIZING SUNSCREEN LOTION LOTION SOLAIRE TEINTÉE HYDRATANTE</p> <p><b>VERSATILE TINT</b> <b>TEINTÉ POLYVALENT</b></p> <p>NPN 80065824</p> <p><b>60 mL / 2 fl oz</b> e</p>	<p><b>Notice</b></p> <table border="1"> <thead> <tr> <th>Ingrédients actifs</th> <th>Utilisation</th> </tr> </thead> <tbody> <tr> <td>Dioxyde de titane 7 %</td> <td>Crème solaire</td> </tr> <tr> <td>Oxyde de zinc 6,28 %</td> <td>Crème solaire</td> </tr> </tbody> </table> <p><b>Usage</b> ■ protége contre les coups de soleil</p> <p><b>Avertissements</b> ■ Usage externe uniquement.</p> <p><b>Quand on utilise ce produit</b> ■ ne pas utiliser sur les peaux endommagées ou irritées ■ éviter le contact avec les yeux ; en cas de contact, rincer abondamment à l'eau</p> <p><b>Arrêtez l'utilisation et demandez à un docteur</b> si vous développez de l'urticaire, un gonflement des yeux ou de la bouche, des cloques ou si vous avez des difficultés à respirer</p> <p><b>Garder hors de portée des enfants.</b> En cas d'ingestion, contacter un centre antipoison ou appeler un médecin immédiatement.</p> <p><b>Conseils d'utilisation</b> ■ appliquer abondamment (et régulièrement) 15 minutes avant l'exposition au soleil ■ appliquer de nouveau au moins toutes les 2 heures ■ pour une utilisation sur des enfants de moins de 6 mois, consulter un professionnel de la santé ■ <b>Mesures de protection solaire :</b> L'exposition au soleil augmente le risque de cancer et de vieillissement précoce de la peau. Pour diminuer ce risque, utiliser régulièrement une crème solaire large spectre d'une valeur FPS de 15 ou plus, et d'autres mesures de protection solaire, telles que: - limiter la durée d'exposition au soleil, en particulier entre 10 h et 14 h - porter des hauts à manches longues, des pantalons, des chapeaux et des lunettes de soleil. ■ utiliser une crème solaire résistante à l'eau en cas de baignade ou de transpiration</p> <p><b>Autres Information</b> ■ Ne pas utiliser si le sceau de sécurité sur la boîte est endommagé ou manquant. ■ Vous pouvez signaler toute réaction indésirable liée à l'utilisation de ce produit à : Alumier Labs Inc., 550 Cochituate Road, Suite 25, Framingham, MA 01701</p> <p>NON IRRITANT</p>	Ingrédients actifs	Utilisation	Dioxyde de titane 7 %	Crème solaire	Oxyde de zinc 6,28 %	Crème solaire
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**ALUMIER MD SHEER HYDRATION TINTED MOISTURIZING  
SUNSCREEN**

titanium dioxide, zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69473-010
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	62.8 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	70 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>ALUMINUM MONOSTEARATE</b> (UNII: P9BC99461E)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>HYDROXYETHYL BEHENAMIDOPROPYL DIMONIUM CHLORIDE</b> (UNII: 9CO8OUL4TH)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>GLUTATHIONE</b> (UNII: GAN16C9B8O)	
<b>MAGNESIUM ASCORBYL PHOSPHATE</b> (UNII: 0R822556M5)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>C20-40 PARETH-10</b> (UNII: TE3MZI4V3F)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>VITIS VINIFERA SEED</b> (UNII: C34U15ICXA)	
<b>RESVERATROL</b> (UNII: Q369O8926L)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69473-010-01	1 in 1 CARTON	06/30/2020	
1		60 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69473-010-02	8 mL in 1 TUBE; Type 0: Not a Combination Product	06/30/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/30/2020	

**Labeler** - Alumier Labs (079603173)

Revised: 3/2022

Alumier Labs