

**CELLULAR DAY DEFENSE FIRING SPF 25- zinc oxide, oxybenzone, and octinoxate cream**  
**Aloette Cosmetics Inc.**

*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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**ALOETTE**  
**Cellular Day Defense**

**Drug Facts**

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**Active Ingredient**

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Octinoxate 7.5%	Sunscreen
Oxybenzone 3.0%	Sunscreen
Zinc Oxide 5.0%	Sunscreen

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**Uses**

Helps prevent sunburn. Higher SPF gives more sunburn protection.

**Warning**

For external use only.

**When using this product**

Keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor**

If rash or irritation develops and lasts.

**Keep out of reach of children:** if swallowed, get medical help or contact a poison control center right away.

**TO USE**

Apply evenly to dry skin, 30 minutes before sun exposure. Children under 6 months of age consult a doctor.

**INACTIVE INGREDIENTS**

ALOE BARBADENSIS LEAF EXTRACT, AQUA, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, CETYL ALCOHOL, ETHYLHEXYL PALMITATE, GLYCERIN, CETEARETH-20, BUTYROSPERMUM PARKII (SHEA BUTTER), MALTODEXTRIN, RICE CONCENTRATE, THEOBROMA CACAO (COCOA) SEED BUTTER, OLEA EUROPAEA (OLIVE) FRUIT OIL, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, PLANKTON EXTRACT, EPILOBIUM ANGUSTIFOLIUM FLOWER/LEAF/STEAM EXTRACT, MEL EXTRACT, VITIS VINIFERA (GRAPE) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, PUNICA GRANATUM EXTRACT, CITRUS GRANDIS (GRAPEFRUIT) PEEL OIL, TOCOPHERYL ACETATE, L-GLUTATHIONE, SODIUM CHLORIDE, XANTHAN GUM, GLYCERYL ISOSTEARATE, POLYHYDROXYSTEARIC ACID, PHENOXYETHANOL, CAPRYLYL GLYCOL, FRAGRANCE (PARFUM)

Dist. by Aloette Cosmetics Inc. Atlanta GA 30327

**PRINCIPAL DISPLAY PANEL - 50 g Jar Carton**

**ALOETTE**

**Cellular Day Defense**

Firming Complex with SPF 25

NET WT. 1.7 OZ/50 G

wgn9030d1



ALOETTE

**Cellular Day Defense**  
Firming Complex with SPF 25  
*Complexe Raffermissant avec SPF 25*

NET WT. 1.7 OZ/50 G



ALOETTE

**Drug Facts**

**Active Ingredient:**

Octinoxate 7.5% Sunscreen

Oxybenzone 3.0% Sunscreen

Zinc Oxide 5.0% Sunscreen

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**Drug Facts continued/Données pharmaceutiques continue**

**TO USE:** Apply evenly to dry skin, 30 minutes before sun exposure. Children under 6 months of age consult a doctor.

**MODE D'EMPLOI:** Appliquez uniformément sur la peau sèche 30 minutes avant l'exposition au soleil. Pour les enfants de moins de 6 mois, consultez un médecin.

**INACTIVE INGREDIENTS/INGRÉDIENT INACTIFS:** ALOE BARBADENSIS LEAF EXTRACT, AQUA, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, CETYL ALCOHOL, ETHYLHEXYL PALMITATE, GLYCERIN, CETEARETH-20, BUTYROSPERMIUM PARKII (SHEA BUTTER), MALTODEXTRIN, RICE CONCENTRATE, THEOBROMA CACAO (COCOA) SEED BUTTER, OLEA EUROPAEA (OLIVE) FRUIT OIL, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, PLANKTON EXTRACT, EPILOBIUM ANGUSTIFOLIUM FLOWER/LEAF/STEM EXTRACT, MEL EXTRACT, VITIS VINIFERA (GRAPE) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, PUNICA GRANATUM EXTRACT, CITRUS GRANDIS (GRAPEFRUIT) PEEL OIL, TOCOPHERYL ACETATE, L-GLUTATHIONE, SODIUM CHLORIDE, XANTHAN GUM, GLYCERYL ISOSTEARATE, POLYHYDROXYSTEARIC ACID, PHENOXYETHANOL, CAPRYLYL GLYCOL, FRAGRANCE (PARFUM)

Dist. by Aloette Cosmetics Inc. Atlanta GA 30327 1-800-ALOETTE www.aloette.com  
Made in Canada/Fabrique en Canada Imported by Aloette of Canada Mississauga, ON L4W 2Z2  
8046050



**ALOETTE**

**Les faits de drogue**

**Ingredient actif:**

Octinoxate 7.5% Écran solaire  
Oxybenzone 3.0% Écran solaire Zinc Oxide 5.0% Écran solaire

**Utilité:** Aide à prévenir les coups de soleil. Un FPS plus élevé donne une plus grande protection contre les coups de soleil.

**Avertissements:** Pour usage externe seulement.

**En utilisant ce produit:** Gardez hors des yeux. Rincez à l'eau pour le retirer.

**Cessez d'utiliser et consultez un médecin:** Si une éruption cutanée ou une irritation se développe et dure.

**Gardez hors de portée des enfants:** Si avélé, appelez immédiatement un médecin ou un centre antipoisson.

UPC# 847137000608

**CELLULAR DAY DEFENSE FIRING SPF 25**

zinc oxide, oxybenzone, and octinoxate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65447-050
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.0 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3.0 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
TRICAPRYLIN (UNII: 6P92858988)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65447-050-02	1 in 1 CARTON		
1	NDC:65447-050-01	50 g in 1 JAR		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/15/2011	

**Labeler** - Aloette Cosmetics Inc. (831761320)**Establishment**

Name	Address	ID/FEI	Business Operations
Du-Var Laboratory		246768782	MANUFACTURE(65447-050) , PACK(65447-050) , LABEL(65447-050)