

**REGENERATION WRINKLE CONTROL CREAM SPF 15- avobenzone, homosalate,  
octocrylene cream  
BeutiControl**

*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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<p>PRODUCT LINE: Regeneration          PRODUCT NAME: Smooth Wrinkle Control Day Creme SPF15          PRODUCT DESCRIPTION: Wrinkle Control Day Creme SPF15          COMPONENT: Tube          SIZE: Template          ILS LOG #: 14087</p>	<p>CONTAINER/PAPER COLOR: White pearl with Gold Flash          CAP COLOR: N/A          FILL COLOR: N/A          INK COLORS: 2 — PMS 267C, PMS 432C</p>	<p>PART #: P10861          PRODUCT/FINISHED GOOD #: 21233          FILENAME: RegSmooth_WrinkleControlDayCremeSPF15_Tube_P10861_21233_V2_e          VERSION: V2_e          UPDATED: 6/24/14-7/22/14-7/25/14-7/28/14-8/25/14-10/15/14-11/19/14          RELEASED TO VENDOR: 11/19/14</p>
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**Drug Facts**  
**Au sujet du médicament**

<b>Active/Medicinal Ingredients</b>	<b>Purpose</b>
<b>Avobenzone 3%, Homosalate 10%, Octocrylene 5%</b>	<b>Indication</b>
.....	<b>Sunscreen/Ecran solaire</b>

**Use/Utilité**  
 ■ Helps prevent sunburn/Aide à éviter les coups de soleil

**Warnings/Notes on usage**  
 ■ For external use only/Pour usage externe seulement

**Do not use/Ne pas utiliser**  
 ■ On damaged or broken skin/sur une peau irritée ou abîmée

**When using this product/Pendant l'utilisation de ce produit**  
 ■ Keep out of eyes. Rinse with water to remove. Éviter tout contact avec les yeux. Pour le retirer, rincer à l'eau.

**Stop use and ask a doctor if/Cesser d'utiliser et consulter un médecin en cas**  
 ■ Rash occurs/irritation.

**Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Conserver hors de la portée des enfants. En cas d'ingestion, contacter immédiatement un médecin ou le Centre antipoison.**

**Directions/Mode d'emploi:**  
 ■ Apply liberally and evenly 15 minutes before sun exposure/ Appliquer généreusement et uniformément sur la peau, 15 minutes avant l'exposition au soleil.  
 ■ Use a water resistant sunscreen if swimming or sweating/Pour la natation ou en cas de transpiration, utiliser un écran solaire résistant à l'eau.  
 ■ Children under 6 months of age: Ask a doctor/Enfants de moins de 6 mois : Demander conseil au médecin.  
 ■ Sun Protection Measures/Mesures de protection solaire : 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

**Drug Facts (continued) / Au sujet du médicament (suite)**

Spectrum SPF value of 15 or higher and other sun protection measures including: l'exposition au soleil augmente votre risque de vieillissement prématuré et de cancer de la peau. Pour diminuer ce risque, utiliser régulièrement un écran solaire à large spectre (FPS 15 ou plus) et d'autres mesures de protection solaire, notamment:

- Limit time in the sun, especially from 10 a.m. to 2 p.m./ Limiter l'exposition au soleil, particulièrement entre 10 h et 14 h.
- Wear long-sleeved shirts, pants, hats, and sunglasses. Porter une chemise à manches longues, un pantalon, un chapeau et des lunettes de soleil.

**Other Information/Autres informations**

■ Protect the product in this container from excessive heat and direct sun./ Garder le produit dans son emballage, à l'abri de la chaleur excessive et de la lumière directe du soleil.

**Inactive/Non-Medicinal Ingredients/ Excipients:** Water (Aqua), Propylmethyl Caprylate, Glycerin, PEG-40 Hydrogenated Castor Oil, Stearyl Alcohol, Polyglyceryl-10-Perisosteate, Saccharomyces/Xylitum/Black Tea Ferment, Behenyl Alcohol, Triisobutyl PVP, Xylitylglucoside, Hexapeptide-10, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Tetrahydroxyethyl Acrylate, Pentylene Triacetate, Tocopherol, Vitis Vinifera (Grape) Seed Extract, Anhydroxythol, Xylitol, Butylene Glycol, 1-Methylhydantoin-2-imide, Ethylhexyl Palmitate, Hydrogenated Lecithin, Sodium Stearoyl Lactylate, Xanthan Gum, Sodium PCA, Ethyl Linoleate, Citric Acid, Tixidulum Ethylenediamine Dioxichlorate, Hexylene Glycol, Oleyl Alcohol, Hydroxyethylcellulose, Carbomer, Sodium Citrate, Polysorbate 20, Sodium Hydroxide, Caprylyl Glycol, Phenoxyethanol, Potassium Sorbate, Fragrance (Parfum).

**Re-generation**  
SMOOTH / LISSE

wrinkle control day creme  
BROAD SPECTRUM SPF 15  
crème de jour anti-rides  
LARGE SPECTRE FPS 15  
DIN# 02430401

Dermatologist, sensitivity and allergy tested. Non-comedogenic. Eprouvé par des tests dermatologiques, de sensibilité et allergiques. Non comédogène.

- Best for skin types experiencing the visible signs of aging: wrinkles, pigmentation and stress.
- Rapidly reduces appearance of wrinkle depth
- Reduces appearance of skin dehydration
- Improves appearance of skin smoothness
- Improves evenness of skin tone
- Parfait pour tous types de peau présentant des marques de vieillissement : rides, pigmentation et stress
- Réduit rapidement la profondeur des rides
- Réduit l'aspect de déshydratation de la peau
- Rend la peau visiblement plus lisse
- Unifie le teint

**To use:** Apply in the morning after cleansing and toning. Massage gently into skin until completely absorbed.

**Mode d'emploi :** Appliquer le matin sur une peau nettoyée et tonifiée. Masser délicatement jusqu'à absorption complète.

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Dallas, TX 75381  
BeautiControl Canada  
Toronto, ON M1V 5M5 P10863

beauticontrol  
NET WT./POIDS NET  
2 OZ./60 g

<p><b>PRODUCT LINE:</b> Regeneration  <b>PRODUCT NAME:</b> Smooth Wrinkle Control Day Creme SPF15  <b>PRODUCT DESCRIPTION:</b> Wrinkle Control Day Creme SPF15  <b>COMPONENT:</b> Carton  <b>SIZE:</b> Template  <b>ILS LOG #:</b> 14087</p>	<p><b>CONTAINER/PAPER COLOR:</b> White pearl with Gold Flash  <b>CAP COLOR:</b> N/A  <b>FILL COLOR:</b> N/A  <b>INK COLORS:</b> 2 - PMS 267C, PMS 432C  <b>Blind embossed top panel: "be" logo does not print</b></p>	<p><b>PART #:</b> P10863  <b>PRODUCT/FINISHED GOOD #:</b> 21233  <b>FILE NAME:</b> Regeneration_WrinkleControlDayCremeSPF15_Carton_P10863_21233_V2_e  <b>VERSION:</b> V2_e  <b>UPDATED:</b> 8/24/14 - 7/25/14 - 7/28/14 - 8/25/14 - 10/15/14 - 11/19/14  <b>RELEASED TO VENDOR:</b> 11/19/14</p>
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**REGENERATION WRINKLE CONTROL CREAM SPF 15**  
avobenzone, homosalate, octocrylene cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57975-161
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0K00R)	55.84 g in 100 g
<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)	0.097 g in 100 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	3.09 g in 100 g
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	0.4 g in 100 g
<b>XYLITYLGLUCOSIDE</b> (UNII: O0IEZ166FB)	1.01 g in 100 g
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	0.81 g in 100 g
<b>CREATININE</b> (UNII: AYI8EX34EU)	0.5 g in 100 g
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	0.25 g in 100 g
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	2.4 g in 100 g
<b>TRIACONTANYL PVP (WP-660)</b> (UNII: N0SS3Q238D)	1.2 g in 100 g
<b>POLYGLYCERYL-10 STEARATE</b> (UNII: 90TF85HH91)	2.12 g in 100 g
<b>Docosanol</b> (UNII: 9G1OE216XY)	1.48 g in 100 g
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	0.4 g in 100 g
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	0.5 g in 100 g
<b>PROPYLHEPTYL CAPRYLATE</b> (UNII: 991Z19V2OD)	3.5 g in 100 g
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	3 g in 100 g
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	0.127 g in 100 g
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	0.58 g in 100 g
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	0.4825 g in 100 g
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	0.084 g in 100 g
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	0.5 g in 100 g
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	0.25 g in 100 g
<b>ETHYL LINOLEATE</b> (UNII: MJ2YTT4J8M)	0.17 g in 100 g
<b>OLEYL ALCOHOL</b> (UNII: 172F2WN8DV)	0.07 g in 100 g
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	0.005 g in 100 g
<b>SACCHAROMYCES LYSATE</b> (UNII: R85W246Z1C)	0.59 g in 100 g
<b>TEA LEAF</b> (UNII: GH42T47V24)	1.18 g in 100 g
<b>HYDROXYETHYL CELLULOSE (100 MPAS AT 2%)</b> (UNII: R33S7TK2EP)	0.03 g in 100 g
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	0.14 g in 100 g
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	0.018 g in 100 g
<b>BIOTIN</b> (UNII: 6SO6U10H04)	0.00004 g in 100 g
<b>HEXAPEPTIDE-10</b> (UNII: W9RS1K7T9I)	0.00025 g in 100 g
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	0.5 g in 100 g
<b>CARBOMER 934</b> (UNII: Z135WT9208)	0.025 g in 100 g

<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	0.0125 g in 100 g
<b>PALMITOYL TRIPEPTIDE-1</b> (UNII: RV743D216M)	0.00025 g in 100 g
<b>PALMITOYL TETRAPEPTIDE-7</b> (UNII: Q41S464P1R)	0.00013 g in 100 g
<b>VITIS VINIFERA SEED</b> (UNII: C34U15ICXA)	0.01 g in 100 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57975-161-02	1 in 1 CARTON		
1	NDC:57975-161-01	63 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/15/2014	

**Labeler** - BeautiControl (609044693)

### Establishment

Name	Address	ID/FEI	Business Operations
BeautiControl		609044693	manufacture(57975-161)

Revised: 2/2016

BeautiControl