

## **ACNE TONER BIOELEMENTS- salicylic acid cream**

**Bioelements, 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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### **Acne Toner**

Active ingredient	Purpose
Salicylic Acid 0.5%	Acne treatment

Uses

For the treatment of acne

Keep out of reach of children. If swallowed get medical help or contact Poison Control Center right away.

When using this product: Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

warnings

For external use only

Directions

Use after cleansing, day and night, avoiding eye area. Apply to cotton pad and gently wipe over skin. Do not rinse. If dryness or peeling occurs, reduce usage to once a day.

Inactive ingredients

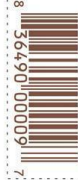
Water (Aqua, Eau), Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, SD Alcohol, Pentylene Glycol, Hexylene Glycol, PEG-40 Hydrogenated Castor Oil, Glycerin, Vitis Vinifera (Grape) Fruit Extract, Mel (Honey) Extract (Miel Extrait de miel), Sodium Hydroxide, Ananas Sativus (Pineapple) Fruit Extract, Citrus Medica Limonium (Lemon) Fruit Extract, Citrus Aurantifolia (Lime) Fruit Extract, Lavandula Angustifolia (Lavender) Extract, Citrus Grandis (Grapefruit) Fruit Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Actinidia Chinensis (Kiwi) Fruit Extract, Carica Papaya (Papaya) Fruit Extract, Citrus Grandis (Grapefruit) Peel Oil, Canarium Luzonicum Gum Nonvolatiles, Citrus Aurantium Dulcis (Orange) Oil, Caprylic/Capric Triglyceride, Lavandula Hybrid (Lavandin) Oil, Tetrahexyldecyl Ascorbate, Ethylhexylglycerin, Phenoxyethanol.

BIOELEMENTS®  
Made in USA

Manufactured for  
Bioelements  
3502 E. Boulder St.  
Colorado Springs, CO  
80909

Bioelements.com

SKU: AL103  
ART: 130213



### Drug Facts

Active ingredient	Purpose
Salicylic Acid 0.5%	Acne Treatment

**Use**  
For the treatment of acne.

**Warnings**  
**For external use only**  
**When using this product:** Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.  
**Keep out of reach of children.** If swallowed, get medical help or contact poison control center right away.

**Directions**  
Use after cleansing, day and night, avoiding eye area. Apply to cotton pad and gently wipe over skin. Do not rinse. If dryness or peeling occurs, reduce usage to once a day.

**Inactive ingredients**  
Water (Aqua, Eau), Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, SD Alcohol, Pentylene Glycol, Hexylene Glycol, PEG-40 Hydrogenated Castor Oil, Glycerin, Vitis Vinifera (Grape) Fruit Extract, Mel (Honey) Extract (Miel Extrait de miel), Sodium Hydroxide, Ananas Sativus (Pineapple) Fruit Extract, Citrus Medica Limonum (Lemon) Fruit Extract, Citrus Aurantifolia (Lime) Fruit Extract, Lavandula Angustifolia (Lavender) Extract, Citrus Grandis (Grapefruit) Fruit Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Actinidia Chinensis (Kiwi) Fruit Extract, Carica Papaya (Papaya) Fruit Extract, Citrus Grandis (Grapefruit) Peel Oil, Canarium Luzonicum Gum Nonvolatiles, Citrus Aurantium Dulcis (Orange) Oil, Caprylic/Capric Triglyceride, Lavandula Hybrid (Lavandin) Oil, Tetrahexyldecyl Ascorbate, Ethylhexylglycerin, Phenoxylethanol

**Questions?**  
Call 1.800.433.6650 Monday - Friday 7:30AM - 4:30PM MST

# BIOELEMENTS

PROFESSIONAL SKIN CARE

## Acne Toner

0.5% salicylic acid  
acne treatment

For skin that has Acne

236 mL / 8 Fl. Oz.

**Active ingredient:** Salicylic Acid 0.5%

**Warnings:** For external use only. When using this product skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

**Directions:** Use after cleansing, day and night, avoiding eye area. Apply to cotton pad and gently wipe over skin. Do not rinse. If dryness or peeling occurs, reduce usage to once a day.

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Colorado Springs, CO 80909  
Bioelements.com

SKU: AL003  
ART: 130604

BIOELEMENTS

Acne Clearing  
System

Acne  
Toner

0.5% salicylic acid  
acne treatment

88 mL / 3 Fl. Oz.

Saturate your skin with acne clearing salicylic acid and oil-absorbing botanicals. This fragrance-free formula is designed to restore the balance acneic skin needs, as it keeps skin clear of new acne pimples, blackheads and whiteheads.

**For skin that has acne**

**Dermatologist and clinically tested to be non-irritating.**

**So effective, it's used in acne facials by skin care professionals.**

BIOELEMENTS®  
Made in USA  
Manufactured for Bioelements  
3502 E. Boulder St.  
Colorado Springs, CO 80909  
Bioelements.com

SKU: AL003  
ART: 130405

**Drug Facts**

**Active ingredient Purpose**  
Salicylic Acid 0.5% Acne treatment

**Uses**  
For the treatment of acne

**Warnings**  
For external use only  
When using this product: Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.  
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

**Directions**  
Use after cleansing, day and night, avoiding eye area. Apply to cotton pad and gently wipe over skin. Do not rinse. If dryness or peeling occurs, reduce usage to once a day.

**Inactive ingredients**  
Water (Aqua, Eau), Hamamelis Virginiana (Witch Hazel) Bark/Leaf/ Twig Extract, SD Alcohol, Pentylene Glycol, Hexylene Glycol, PEG-40 Hydrogenated Castor Oil, Glycerin, Vitis Vinifera (Grape) Fruit Extract, Mel (Honey) Extract (Miel Extract de miel), Sodium Hydroxide, Annona Sativus (Pineapple) Fruit Extract, Citrus Medica Limonum (Lemon) Fruit Extract, Citrus Aurantifolia (Lime) Fruit Extract, Lavandula Angustifolia (Lavender) Extract, Citrus Grandis (Grapefruit) Fruit Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Actinidia Chinensis (Kiwi) Fruit Extract, Carica Papaya (Papaya) Fruit Extract, Citrus Grandis (Grapefruit) Peel Oil, Canarium Luzonicum Gum Nonvolatiles, Citrus Aurantium Dulcis (Orange) Oil, Caprylic/Capric Triglyceride, Lavandula Hybrid (Lavandin) Oil, Tetrahexyldecyl Ascorbate, Ethylhexylglycerin, Phenoxyethanol

**Other:**  
Questions, call 1.800.433.6650  
Monday - Friday 7:30am - 4:30pm MST

**BIOELEMENTS**

Acne Clearing System

Acne Toner

0.5% salicylic acid acne treatment

Hydrates, clears and eliminates excess oil

88 mL / 3 Fl. Oz.

**Bioelements – Used in Professional Facials**

Chances are, if you have ever had a professional facial, you've experienced Bioelements. Since 1991, skin care specialists have been using our highly individualized formulas to treat the skin, target complexion concerns and discourage skin-aging. And, unlike ordinary skin care, each Bioelements product is a professionally created treatment designed to make a major difference in the appearance of your skin.

**Bioelements Professional Formula Integrity**

- ✓ No artificial colorants
- ✓ No synthetic fragrance
- ✓ Not tested on animals
- ✓ Contains natural botanicals

Bioelements  
Acne Clearing System  
Acne Toner  
0.5% salicylic acid acne treatment  
Hydrates, clears and eliminates excess oil  
88 mL / 3 Fl Oz

**ACNE TONER BIOELEMENTS**

salicylic acid cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49825-130
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
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<b>WATER</b> (UNII: 059QF0KO0R)
<b>HAMAMELIS VIRGINIANA LEAF</b> (UNII: T07U1161SV)
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>WINE GRAPE</b> (UNII: 3GOV20705G)
<b>HONEY</b> (UNII: Y9H1V576FH)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>PINEAPPLE</b> (UNII: 2A88ZO081O)
<b>LEMON</b> (UNII: 24RS0A988O)
<b>LIME (CITRUS)</b> (UNII: 8CZS546954)
<b>LAVANDULA ANGUSTIFOLIA FLOWER</b> (UNII: 19AH1RAF4M)
<b>GRAPEFRUIT</b> (UNII: O82C39RR8C)
<b>ORANGE</b> (UNII: 5EVU04N5QU)
<b>KIWI FRUIT</b> (UNII: 71ES77LGJC)
<b>PAPAYA</b> (UNII: KU94FIY6JB)
<b>GRAPEFRUIT OIL</b> (UNII: YR377U58W9)
<b>ELEMI</b> (UNII: C13XI009KO)
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>LAVANDIN OIL</b> (UNII: 9RES347CKG)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-130-02	1 in 1 CARTON		
1	NDC:49825-130-01	88 mL in 1 BOTTLE		
2	NDC:49825-130-04	1 in 1 CARTON		
2	NDC:49825-130-03	236 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/17/2013	

**Labeler** - Bioelements, Inc. (174813923)

**Registrant** - Bioelements, Inc. (174813923)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises Ltd		017701475	manufacture(49825-130)

