# BIOELEMENTS SPOTLESS CLEANSER- salicylic acid gel 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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## **Spotless Cleanser**

Active Ingredient Purpose

Salicylic Acid 2% Acne treatment gel

- -For the treatment of acne
- -Dries up acne pimples
- -Helps prevent new acne pimples
- -Reduces the number of acne pimples
- -Penetrates pores to eliminate most acne blemishes
- -Helps prevent new acne blemishes, blackheads and whiteheads.

Keep out of reach of children.

if swallowed, get medical help or contact poison control center right away

-For external use only

When using this product: using other topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. If sensitive to the sun or when increased sun exposure is expected use a sunscreen when using this and other acne products.

- -Apply one pump to wet skin and massage over face avoiding eye area
- -Use morning and night
- -If dryness or peeling occurs, reduce usage to once a day

Inactive Ingredients: Water (Aqua, Eau), Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Sodium Lauryl Glucose Carboxylate, Glycerin, Lauryl Glucoside, Sodium Citrate, Ananas Sativus (Pineapple) Fruit Extract, Carica Papaya (Papaya) Fruit Extract, Panthenol, Allantoin, PEG-150 Distearate, Sodium Chloride

## Spotless Cleanser

This highly effective cleanser washes away excess oil, makeup and trouble-some bacteria that can clog pores. Plus, salicylic acid and exfoliating enzymes help keep skin smooth, clean and clear. Fragrance free.

FORMULA INTEGRITY

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



BIOELEMENTS® Box 13289, Chicago, IL 60613

Manufactured for Bioelements

Made in USA

bioelements.com

**Drug Facts** 

Active ingredient
Salicylic Acid 2% ......

Purpose . Acne treatment gel

Uses
For the treatment of acne • Dries up acne pimples • Helps
prevent new acne pimples • Reduces the number of acne
pimples • Penetrates pores to eliminate most acne
blemishes • Helps prevent new acne blemishes, blackheads
and whiteheads.

# Warnings For external use only

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#### Directions

Apply one pump to wet skin and massage over face avoiding eye area • Use morning and night • If dryness or peeling occurs, reduce usage to once a day

Mactive ingredients
Water (Aqua) (Eau), Ammonium Lauryl Sulfate,
Ammonium Laureth Sulfate, Cocamidopropyl Betain,
Glycerin, Polyacrylate-1 Crosspolymer, Ananas Sativa
(Pineapple) Extract, Carica Papaya (Papaya) Extract,
Allantoin, Ponthenol, Sodium Hydroxide, Chlorphenesin,
Methylisothiazolinone, Citric Acid

#AL002

Other: Questions? Call 1.800.433.6650 Monday - Friday 8:00AM - 5:00PM MST

BIOELEMENTS

ACNE CLEARING SYSTEM

PROFESSIONAL SKIN CARE

Spotless Cleanser®

Salicylic Acid Cleanser "Used by leading estheticians in professional facials"...

With daily use, Spotless Cleanser helps:

- ✓ Unclog pores
- ∠Clear skin
- ✓ Control excess oil
- ✓ Deep cleanse without stripping

#### **About Bioelements**

Chances are, if you have ever had a professional facial, you've experienced specialists have been using our highly individualized formulas to treat the individualized formulas to freat 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.

88 mL. / 3 Fl. Oz.

What it is: A highly effective cleanser formulated with salicylic acid and exfoliating enzymes to keep skin Fragrance free.

What it does: Washes away excess oil, makeup and troublesome skin and deep cleanses without

#### Who it's for: Acne Skin Types

Key Ingredients: Salicylic Acid (exfoliating and antiseptic); Panthenol (soothing, moisturizing); Allantoin (soothing); Pineapple, Papaya (exfoliating)

## Made in USA

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

Bioelements.com

ART: 120207

### Drug Facts

Active ingredient Salicylic Acid 2% ...... Purpose
... Acne treatment deanser

#### Uses

For the treatment of acne • Dries up acne pimples • Helps prevent new acne pimples • Reduces the number of acne pimples • Penetrates pores to eliminate most acne blemishes • Helps prevent new acne blemishes, blackheads and whiteheads.

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Apply one pump to wet skin and massage over face avoiding eye area, rinse off • Use morning and night • If dryness or peeling occurs, reduce usage to once a day

Inactive ingredients
Water (Aqup, Eau), Sodium (14-16 Olefin Sulfonate,
Cocamidopropyl Betaine, Sodium (114-16 Olefin Sulfonate,
Glycerin, Lauryl Glucoside, Sodium (11rate, Ananas Sañvas
(Pineapple) Truit Extract, Carica Papaya (Papaya) Fruit
Extract, Panthenol, Allantoin, PtG-150 Dislearate, Sodium
Choloride

Other: Questions, call 1.800.433.6650 Monday - Friday 7:30AM - 4:30PM MST

# OELEMENTS

PROFESSIONAL SKIN CARE

ACNE CLEARING

SYSTEM

Spotless Cleanser®

Salicylic Acid Cleanser

- ✓ Unclogs pores
- ✓ Clears skin
- ✓ Controls excess oil
- ✓ Deep cleanses without stripping

#### About Bioelements

Chances are, if you have ever had a professional facial, you've experienced Bioelements. Since 1991, skin care specialists have been using our highly 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.

PROFESSIONAL FORMULA INTEGRITY

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

Active ingredient: Salicylic Acid 2%

Warnings: For external use only. When using this product: Using other topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. If sensitive to the sun or when increased sun exposure is expected use a sunscreen when using this and other acne products. Keep out of reach of children. If swallowed, get medical help or contact poison control center right away.

**Directions:** Apply one pump to wet skin and massage over face avoiding eye area, rinse off. Use morning and night. If dryness or peeling occurs, reduce to once a day.

BIOELEMENTS®

Made in USA

Manufactured for Bioelements

3502 E Boulder St. Colorado Springs, CO 80909 SKU AL002

Bioelements.com

ART: 120223

Bioelements

Acne Clearing System

Spotless Cleanser

88 mL / 3 Fl. Oz.

Directions Apply one pump to wet skin and massage ACNE over face avoiding eye area. Use morning and night. CLEARING If dryness or peeling occurs, reduce to once a day. SYSTEM Active ingredient Salicylic Acid 2% Warnings For external use only. When using this product: Using other topical acne medication at the Spotless same time or immediately following the use of this product may increase dryness or irritation of the skin. If Cleanser® this occurs, only one medication should be used unless directed by a doctor. If sensitive to the sun or when increased sun exposure is expected use a sunscreen when using this and other acne products. Keep out of reach of children. If swallowed, get medical help or contact poison control center right away. Salicylic Acid Cleanser BIOELEMENTS® Box 13289 Chicago, IL 60613 Manufactured for Bioelements SKU: ALOO2 Made in USA Bioelements.c 88 mL / 3 Fl. Oz.\_\_\_

ART: 100421

Active ingredient: Salicylic Acid 2% ACNE I O E L E M E N T Warnings: For external use only. When using this CLEARING product: Using other topical acne medication at the SYSTEM same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. If sensitive to the sun or when **Spotless** increased sun exposure is expected use a sunscreen when using this and other acne products. Keep out of Cleanser® reach of children. If swallowed, get medical help or contact poison control center right away. Directions: Apply one pump to wet skin and massage over face avoiding eye area, rinse off. Use morning and night. If dryness or peeling occurs, reduce to once Salicylic Acid a day. Cleanser BIOELEMENTS® Made in USA Manufactured for Bioelements 3502 E. Boulder St. Colorado Springs, CO 80909 SKU: AL002 88 mL / 3 Fl. Oz..\_ Bioelements.com ART: 120207

### BIOELEMENTS SPOTLESS CLEANSER

salicylic acid gel

**Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:49825-113 **Route of Administration** TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 mL in 100 mL

WATER (UNII: 059QF0KO0R)  SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)  COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)  GLYCERIN (UNII: PDC6A3C0OX)  LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)  SODIUM CITRATE (UNII: 1Q73Q2JULR)  PINEAPPLE (UNII: 2A88ZO081O)  PAPAYA (UNII: KU94FIY6JB)  PANTHENOL (UNII: WV9CM0O67Z)	Inactive Ingredients			
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)  CO CAMIDO PRO PYL BETAINE (UNII: 50CF3O11KX)  GLYCERIN (UNII: PDC6A3C0OX)  LAURYL GLUCO SIDE (UNII: 76LN7P7UCU)  SODIUM CITRATE (UNII: 1Q73Q2JULR)  PINEAPPLE (UNII: 2A88ZO081O)  PAPAYA (UNII: KU94FIY6JB)  PANTHENOL (UNII: WV9CM0O67Z)	Ingredient Name	Strength		
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)  GLYCERIN (UNII: PDC6 A3 C0 O X)  LAURYL GLUCO SIDE (UNII: 76 LN7P7 UCU)  SO DIUM CITRATE (UNII: 1Q73 Q2 JULR)  PINEAPPLE (UNII: 2A8 8 Z0 0 8 1 O)  PAPAYA (UNII: KU94FIY6 JB)  PANTHENOL (UNII: WV9 CM0 O 67 Z)	WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)  LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)  SODIUM CITRATE (UNII: 1Q73Q2JULR)  PINEAPPLE (UNII: 2A88ZO081O)  PAPAYA (UNII: KU94FIY6JB)  PANTHENOL (UNII: WV9CM0O67Z)	SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)			
LAURYL GLUCO SIDE (UNII: 76 LN7P7UCU)  SO DIUM CITRATE (UNII: 1Q73Q2JULR)  PINEAPPLE (UNII: 2A88 ZO08 1O)  PAPAYA (UNII: KU94FIY6JB)  PANTHENOL (UNII: WV9CM0O67Z)	COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)  PINEAPPLE (UNII: 2A88ZO081O)  PAPAYA (UNII: KU94FIY6JB)  PANTHENOL (UNII: WV9CM0O67Z)	GLYCERIN (UNII: PDC6 A3C0 OX)			
PINEAPPLE (UNII: 2A88ZO081O) PAPAYA (UNII: KU94FIY6JB) PANTHENOL (UNII: WV9CM0O67Z)	LAURYL GLUCO SIDE (UNII: 76 LN7P7UCU)			
PAPAYA (UNII: KU94FIY6JB) PANTHENOL (UNII: WV9CM0O67Z)	SODIUM CITRATE (UNII: 1Q73Q2JULR)			
PANTHENOL (UNII: WV9CM0O67Z)	PINEAPPLE (UNII: 2A88ZO081O)			
	PAPAYA (UNII: KU94FIY6JB)			
ALL ANTEON (UNIII, 244C)77CO7	PANTHENOL (UNII: WV9CM0O67Z)			
ALLAN I O IN (UNII: 34452//G0Z)	ALLANTO IN (UNII: 344S277G0Z)			
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)			
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)	SO DIUM CHLO RIDE (UNII: 451W47IQ8X)			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:49825-113-02	1 in 1 BOX			
1	NDC:49825-113-01	88 mL in 1 BOTTLE			
2	NDC:49825-113-04	1 in 1 BOX			
2	NDC:49825-113-03	236 mL in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	05/05/2010		

# Labeler - Bioelements Inc. (174813923)

# Registrant - Bioelements Inc. (174813923)

Establishment					
Name	Address	ID/FEI	Business Operations		
United 1International		807878116	manufacture		

Establishment				
Name	Address	ID/FEI	Business Operations	
Bell International Laboratories		967781555	manufacture	

Revised: 4/2012 Bioelements Inc.