

**ENVIO 30 DAY DAILY ESSENTIALS TRIO- benzoyl peroxide and salicylic acid**  
**Smart Skin Health, LLC**

*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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**ENVIO 30 Day Daily Essentials Trio**

**B.P.O. Cleanser**

***Drug Facts***

**Active Ingredients**

Benzoyl Peroxide 5%

**Purpose**

Acne Treatment Gel

**Use**

for the management 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
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

**Do not use if you**

- have very sensitive skin
- are sensitive to benzoyl peroxide

**Stop use and ask a doctor**

- if irritation becomes severe

**Keep out of reach of children**

- If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions**

- *apply a small amount to dampened skin*
  - *cover the entire affected area with a thin layer and rinse thoroughly one to three times daily*
  - *because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor*
  - *if bothersome dryness or peeling occurs, reduce application to once a day or every other day*
  - *if going outside, apply sunscreen after using this product*
  - *if irritation or sensitivity develops, stop use of both products and ask a doctor.*
- Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.*

## **Inactive Ingredients**

Water, Sodium C14-16 Olefin Sulfonate, Glycerin, Acrylates Copolymer, Cocamidopropyl Betaine, Cetearyl Alcohol, Glycol Distearate, Cetyl Alcohol, Panthenol, Aloe Barbadensis Leaf Extract, Sodium Hyaluronate, Allantoin, Ethylhexylglycerin, Phenoxyethanol, Sodium Hydroxide

## **Other Information**

Protect this product from excessive heat and direct sun.

## **Questions or Comments**

Toll Free within USA 833-93-ENVIO

Dist. By: Smart Skin Health, LLC, Naples, FL 34108

## **S.A. Serum**

### ***Drug Facts***

## **Active Ingredients**

Salicylic Acid 2%

## **Purpose**

Acne Gel Treatment

## **Use**

for the management 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
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

#### Do not use if you

- have very sensitive skin
- are sensitive to Salicylic Acid

**Stop use and ask a doctor** if irritation becomes severe

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

#### Directions

- *apply evenly to affected area and allow to dry completely*
- *Can be used twice daily or as directed by a doctor*
- *because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor*
- *if bothersome dryness or peeling occurs, reduce application to once a day or every other day*
- *if irritation or sensitivity develops, stop use of both products and ask a doctor.*  
*Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.*

#### Inactive Ingredients

Water, Hydroxypropyl Starch Phosphate, Glycerin, Decyl Glucoside, Hamamelis Virginiana (Witch Hazel) Bark Extract, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-6 Caprylate/Caprates, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Allantoin, Panthenol, Xanthan Gum, Glyceryl Stearate, Glyceryl Stearate Citrate, Lavandula Hybrid (Lavender Grosso) Oil<sup>1</sup>, Salix Alba (Willow) Bark Extract, Camellia Sinensis (Green Tea) Leaf Extract<sup>1</sup>, Ethylhexylglycerin, Phenoxyethanol

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<sup>1</sup> Certified Organic Ingredients

## **Other Information**

Protect this product from excessive heat and direct sun.

## **Questions?**

Toll Free within USA 833-93-ENVIO

Dist. By: Smart Skin Health, LLC  
Naples, FL 34108

## **PRINCIPAL DISPLAY PANEL - Kit Carton**

envio



## **PRINCIPAL DISPLAY PANEL - 44 mL Tube Label**

envio™  
skin

B.P.O. 5% CLEANSER  
Benzoyl Peroxide Acne Treatment

1.5 fl. oz./44 mL

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Benzoyl Peroxide 5%.....	Acne Treatment Gel
<b>Use</b> for the management of acne	
<b>Warnings</b> For external use only.	
<b>When using this product</b> • 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 • avoid unnecessary sun exposure and use a sunscreen • avoid contact with the eyes, lips, and mouth • avoid contact with hair and dyed fabrics, which may be bleached by this product • skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.	
<b>Do not use if you</b> • have very sensitive skin • are sensitive to benzoyl peroxide	
<b>Stop use and ask a doctor</b> • if irritation becomes severe	
<b>Keep out of reach of children</b> • If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> • apply a small amount to dampened skin • cover the entire affected area with a thin layer and rinse thoroughly one to three times daily • because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • if bothersome dryness or peeling occurs, reduce application to once a day or every other day • if going outside, apply sunscreen after using this product • if irritation or sensitivity develops, stop use of both products and ask a doctor. Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.	
<b>Inactive Ingredients:</b> Water, Sodium C14-16 Olefin Sulfonate, Glycerin, Acrylates Copolymer, Cocamidopropyl Betaine, Cetearyl Alcohol, Glycol Distearate, Cetyl Alcohol, Panthenol, Aloe Barbadosis Leaf Extract, Sodium Hyaluronate, Allantoin, Ethylhexylglycerin, Phenoxyethanol, Sodium Hydroxide	
<b>Other Information:</b> Protect this product from excessive heat and direct sun.	
<b>Questions or Comments:</b> Toll Free within USA 833-93-ENVIO	

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skin

[envioskin.com](http://envioskin.com)

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Manufactured in the USA

Free of Fragrance, Parabens, Sulfates, Phthalates

Please Recycle ♻️

EN.0101

**B.P.O. 5% CLEANSER**

Benzoyl Peroxide Acne Treatment

1.5 fl.oz./44 mL

## PRINCIPAL DISPLAY PANEL - 14 g Tube Label

envio™  
skin

S.A. 2% GEL SERUM  
Salicylic Acid Acne Treatment

0.5 oz/14 g

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Salicylic Acid 2%.....	Acne Gel Treatment
<b>Use</b> for the management of acne	
<b>Warnings</b>	
<b>For external use only</b>	
<p><b>When using this product</b> • 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 • avoid unnecessary sun exposure and use a sunscreen • avoid contact with the eyes, lips, and mouth • avoid contact with hair and dyed fabrics, which may be bleached by this product • skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.</p>	
<p><b>Do not use if you</b> • have very sensitive skin • are sensitive to Salicylic Acid</p>	
<p><b>Stop use and ask a doctor</b> if irritation becomes severe</p>	
<p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	
<p><b>Directions:</b> • apply evenly to affected area and allow to dry completely • Can be used twice daily or as directed by a doctor • because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • if bothersome dryness or peeling occurs, reduce application to once a day or every other day • if irritation or sensitivity develops, stop use of both products and ask a doctor. <i>Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.</i></p>	
<p><b>Inactive Ingredients:</b> Water, Hydroxypropyl Starch Phosphate, Glycerin, Decyl Glucoside, Hamamelis Virginiana (Witch Hazel) Bark Extract, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-6 Caprylate/Caprate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Allantoin, Panthenol, Xanthan Gum, Glyceryl Stearate, Glyceryl Stearate Citrate, Lavandula Hybrid (Lavender Grosso) Oil*, Salix Alba (Willow) Bark Extract, Camellia Sinensis (Green Tea) Leaf Extract*, Ethylhexylglycerin, Phenoxyethanol *Certified Organic Ingredients</p>	
<p><b>Other Information:</b> Protect this product from excessive heat and direct sun.</p>	
<p><b>Questions?</b> Toll Free within USA 833-93-ENVIO</p>	

**Directions:**  
Apply evenly to affected area and allow to dry completely. Can be used twice daily or as directed by a physician.

**Active Ingredient:**  
2% Salicylic Acid

**Warnings:**  
**For external use only.** Avoid contact with the eyes, lips and mouth. Stop use and ask a doctor if irritation becomes severe.  
**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away. For full drug facts information, please refer to drug facts insert.

**Questions?**  
Toll Free within USA 833-93-ENVIO

**envioskin.com**  
Dist. By: Smart Skin Health, LLC  
Naples, FL 34108  
Manufactured in the USA  
Free of Fragrance, Parabens,  
Sulfates, Phthalates  
Please Recycle ♻️ EN.0201

**envio**<sup>™</sup>  
skin

**S.A. 2% GEL SERUM**  
Salicylic Acid Acne Treatment  
0.5 oz/14 g

## ENVIO 30 DAY DAILY ESSENTIALS TRIO

benzoyl peroxide and salicylic acid kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81252-1001
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81252-1001-1	1 in 1 CARTON	10/21/2021	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 TUBE	44 mL
<b>Part 2</b>	1 TUBE	14 g
<b>Part 3</b>	1 TUBE	30 g
<b>Part 4</b>	1 TUBE	21 mL

## Part 1 of 4

### B.P.O. CLEANSER

benzoyl peroxide gel

#### Product Information

**Item Code (Source)** NDC:81252-0101

**Route of Administration** TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Benzoyl Peroxide</b> (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	5 g in 100 mL

#### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium C14-16 Olefin Sulfonate</b> (UNII: O9W3D3YF5U)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Cocamidopropyl Betaine</b> (UNII: 5OCF3O11KX)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Glycol Distearate</b> (UNII: 13W7MDN21W)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>Panthenol</b> (UNII: WW9CM0O67Z)	
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)	
<b>Allantoin</b> (UNII: 344S277G0Z)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81252-0101-1	44 mL 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 final	part333D	10/21/2021	

## Part 2 of 4

### S.A. SERUM

salicylic acid gel

#### Product Information

Item Code (Source) NDC:81252-0201

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 g in 100 g

#### Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Decyl Glucoside (UNII: Z17H97EA6Y)	
Witch Hazel (UNII: 101I4J0U34)	
Tea Tree Oil (UNII: VIF565UC2G)	
Allantoin (UNII: 344S277G0Z)	
Panthenol (UNII: W9CM0O67Z)	
Xanthan Gum (UNII: TTV12P4NEE)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Glyceryl Stearate Citrate (UNII: WH8T92A065)	
Salix Alba Bark (UNII: 205MXS71H7)	
Green Tea Leaf (UNII: WZZU1RY8B0)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81252-0201-1	14 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 final	part333D	10/21/2021	



## Part 3 of 4

### CLARIFYING CLAY MASK

paste masks (mud packs) paste

#### Product Information

Route of Administration TOPICAL

#### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>Water</b> (UNII: 059QF0KO0R)	
INGR	<b>Glycerin</b> (UNII: PDC6A3C0OX)	
INGR	<b>Bentonite</b> (UNII: A3N5ZCN45C)	
INGR	<b>Kaolin</b> (UNII: 24H4NWX5CO)	
INGR	<b>Glyceryl Ricinoleate</b> (UNII: ZUE0CEL42O)	
INGR	<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)	
INGR	<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
INGR	<b>Alcohol</b> (UNII: 3K9958V90M)	
INGR	<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
INGR	<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
INGR	<b>Cranberry</b> (UNII: 0MVO31Q3QS)	
INGR	<b>Salix Alba Bark</b> (UNII: 205MXS71H7)	
INGR	<b>Passiflora Incarnata Flower</b> (UNII: K8F3G29S6Z)	
INGR	<b>Chamomile</b> (UNII: FGL3685T2X)	
INGR	<b>Calendula Officinalis Flower</b> (UNII: P0M7O4Y7YD)	
INGR	<b>Rosemary Oil</b> (UNII: 8LGU7VM393)	
INGR	<b>Lonicera Japonica Flower</b> (UNII: 4465L2WS4Y)	
INGR	<b>Lonicera Caprifolium Flower</b> (UNII: 5N1WD9784U)	
INGR	<b>.Alpha.-Tocopherol Acetate, D-</b> (UNII: A7E6112E4N)	
INGR	<b>Allantoin</b> (UNII: 344S277G0Z)	
INGR	<b>Glycol Distearate</b> (UNII: 13W7MDN21W)	
INGR	<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
INGR	<b>Cocamidopropyl Hydroxysultaine</b> (UNII: 62V75NI93W)	
INGR	<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
INGR	<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
INGR	<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
INGR	<b>Fytic Acid</b> (UNII: 7IGF0S7R8I)	
INGR	<b>Maltodextrin</b> (UNII: 7CVR7L4A2D)	
INGR	<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
INGR	<b>Trisodium Ethylenediamine Disuccinate</b> (UNII: YA22H34H9Q)	
INGR	<b>Carbomer Homopolymer, Unspecified Type</b> (UNII: 0A5MM307FC)	
INGR	<b>Phenylethyl Alcohol</b> (UNII: ML9LGA7468)	
INGR	<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
INGR	<b>Potassium Sorbate</b> (UNII: 1VPU26JZZ4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 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
Cosmetic		10/21/2021	

## Part 4 of 4

### HYDRATOR

moisturizing gel

## Product Information

Route of Administration TOPICAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>Water</b> (UNII: 059QF0KO0R)	
INGR	<b>Glycerin</b> (UNII: PDC6A3C00X)	
INGR	<b>Totarol</b> (UNII: 67NH2854WM)	
INGR	<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
INGR	<b>Sandalwood</b> (UNII: 3641YW25N2)	
INGR	<b>Lavender Oil</b> (UNII: ZBP1YXW0H8)	
INGR	<b>Camphor Oil</b> (UNII: 75IZZ8Y727)	
INGR	<b>Orange Oil, Cold Pressed</b> (UNII: AKN3KSD11B)	
INGR	<b>Rosa X Damascena Flower Oil</b> (UNII: 18920M3T13)	
INGR	<b>Lonicera Japonica Flower</b> (UNII: 4465L2WS4Y)	
INGR	<b>Lonicera Caprifolium Flower</b> (UNII: 5N1WD9784U)	
INGR	<b>Chlorophyll</b> (UNII: 00WNZ48OR9)	
INGR	<b>Hamamelis Virginiana Top Water</b> (UNII: NT00Y05A2V)	
INGR	<b>Alcohol</b> (UNII: 3K9958V90M)	
INGR	<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
INGR	<b>Maltodextrin</b> (UNII: 7CVR7L4A2D)	
INGR	<b>Trisodium Ethylenediamine Disuccinate</b> (UNII: YA22H34H9Q)	
INGR	<b>Carbomer Homopolymer, Unspecified Type</b> (UNII: 0A5MM307FC)	
INGR	<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
INGR	<b>Sodium Metabisulfite</b> (UNII: 4VON5FNS3C)	
INGR	<b>Acetyltributyl Citrate</b> (UNII: 0ZBX0N59RZ)	
INGR	<b>Phenylethyl Alcohol</b> (UNII: ML9LGA7468)	

INGR	<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
INGR	<b>Potassium Sorbate</b> (UNII: 1VPU26JZZ4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		10/21/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/21/2021	

**Labeler** - Smart Skin Health, LLC (117039871)

Revised: 1/2023

Smart Skin Health, LLC