

## **CLEAR PROOF ACNE SYSTEM- benzoyl peroxide and salicylic acid**

**Mary Kay 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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**Mary Kay**  
**Clear Proof Acne System**

### **Clarifying Cleansing Gel**

#### ***Drug Facts***

#### ***Active ingredient***

Salicylic Acid (2% W/W)

#### ***Purpose***

Acne Medication

#### ***Uses***

- for the management of acne
- reduces the number of blackheads and acne pimples
- helps prevent new acne pimples

#### ***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 contact with the eyes

#### **Stop use and ask a doctor if**

irritation or sensitivity develops or occurs

#### **Keep out of reach of children.**

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

#### ***Directions***

- cleanse skin thoroughly before applying medication
- cover the entire affected area with a thin layer then 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

#### ***Inactive ingredients***

arctium lappa root extract, butylene glycol, citric acid, cocamidopropyl betaine, cystoseira

amentacea/caespitosa branchycarpa extract, disodium EDTA, DMDM hydantoin, epilobium angustifolium flower/leaf/stem extract, ethylparaben, glycerin, methylparaben, phenoxyethanol, propylene glycol, propylparaben, sodium C14-16 olefin sulfonate, sodium chloride, triethanolamine, water

## **Blemish Control Toner**

### ***Drug Facts***

#### ***Active ingredient***

Salicylic Acid (2% W/W)

#### ***Purpose***

Acne Medication

#### ***Uses***

- for the management of acne
- reduces the number of blackheads and acne pimples
- helps prevent new acne pimples

#### ***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 contact with the eyes

##### **Stop use and ask a doctor if**

irritation or sensitivity develops or increases

##### **Keep out of reach of children.**

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

#### ***Directions***

- cleanse the skin thoroughly before applying this product
- cover the entire affected area with a thin layer 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

#### ***Inactive ingredients***

alcohol denat., citric acid, diethylhexyl sodium sulfosuccinate, eucalyptus globulus leaf oil, menthol, propylene glycol, simethicone, water

## **Acne Treatment Gel**

## **Drug Facts**

### ***Active ingredient***

Benzoyl Peroxide 5%

### ***Purpose***

Acne Medication

### ***Uses***

- for the management of acne
- dries up acne pimples
- helps prevent new acne pimples

### ***Warnings***

#### **For external use only**

#### **Do not use if you**

- have very sensitive skin
- are sensitive to benzoyl peroxide

#### **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.

#### **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.

- cleanse the skin thoroughly before applying this product
- cover the entire affected area with a thin layer 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.

#### ***Other information***

- store at 59° F to 86° F
- expiration date on tube crimp

## Inactive ingredients

aesculus hippocastanum (horse chestnut) seed extract, butylene glycol, carbomer, cucumis sativus (cucumber) fruit extract, diethylhexyl sodium sulfosuccinate, disodium EDTA, echinacea purpurea extract, glycerin, poloxamer 182, propylene glycol, silica, sodium hydroxide, water

## Oil-Free Moisturizer for Acne-Prone Skin

### INGREDIENTS:

Water/Eau, Glycerin, Cetearyl Ethylhexanoate, Butylene Glycol, Caprylic/Capric Triglyceride, Glyceryl Stearate, Dimethicone, Isostearyl Alcohol, Stearic Acid, Betaine, Niacinamide, PEG-100 Stearate, Cetyl Alcohol, Cucurbita Pepo (Pumpkin) Fruit Extract, Silybum Marianum Fruit Extract, Tocopheryl Acetate, Lactobacillus/Ganoderma Lucidum (Reishi) Extract/Lentinus Edodes (Truncated), PEG-4 Laurate, Triethanolamine, Xanthan Gum, Carbomer, Disodium EDTA, Iodopropynyl Butylcarbamate, Phenoxyethanol, Diazolidinyl Urea, Sodium Benzoate

## Principal Display Panel - Kit Carton

clear proof acne system

clarifying cleansing gel *salicylic acid acne medication* 4.5 OZ. NET WT. / 127 g

blemish control toner *salicylic acid acne medication liquid* 5 FL. OZ. / 147 ml

acne treatment gel *benzoyl peroxide acne medication* 1 OZ. NET WT. / 28 g

oil-free moisturizer for acne-prone skin 3 FL. OZ. / 88 ml



**MARY KAY**

**clear proof® acne system**

**this set contains:**

- clarifying cleansing gel 4.5 OZ. NET WT. / 127 g
- blemish control toner 5 FL. OZ. / 147 ml
- acne treatment gel 1 OZ. NET WT. / 28 g
- oil-free moisturizer for acne-prone skin 3 FL. OZ. / 88 ml

**Clarifying Cleansing Gel**  
A clear cleanser that deep-cleanses skin to remove dirt, excess oil and impurities. This salicylic acid formula helps reduce shine and unclog pores to help you achieve clearer skin.

**Blemish Control Toner**  
A salicylic acid liquid formula helps remove dead skin cells to help keep pores from clogging and prevent new pimples from forming. This toner cleanses skin completely to help tighten pores and appear less noticeable to give you healthy, clearer skin.

**Acne Treatment Gel**  
A lightweight benzoyl peroxide product that penetrates and clears pores to target bacteria and visibly reduce a pimple's redness. This night intensive cream absorbs quickly to help reduce the number of acne pimples and prevent new breakouts while allowing the skin to heal.

**Oil-Free Moisturizer for Acne-Prone Skin**  
A fast-absorbing, lightweight, non-comedogenic formula that helps provide the balanced hydration your skin needs. This formula helps control shine and excess oil to leave your skin feeling hydrated and healthier.

**Before**

**After**

Acne can happen when pores become blocked by dead skin cells, trapping oil and bacteria inside. As the skin continues to produce oil, blocked pores provide the perfect environment for the bacteria to flourish, increasing the chances for acne. Blemishes and skin redness. The Mary Kay Clear Proof Acne System was developed to target some of the contributing factors: clogged pores and bacteria. This unique system, composed of products including effective levels of salicylic acid and benzoyl peroxide, provides a serious solution to clear up acne. Salicylic acid exfoliates dead skin cells while benzoyl peroxide reduces bacteria. Together these ingredients help visibly reduce the number of acne blemishes, reduce their severity and prevent new pimples from forming. The Mary Kay Clear Proof Acne System will help you take control of your acne so you can feel more confident in your healthy, clearer skin.

Drug Facts	Purpose	Drug Facts (continued)
<b>Active Ingredient</b> Benzoyl Peroxide 2% w/w	Acne Treatment	<b>Use with this product</b> Do not use with other topical acne medications. Do not use with other topical acne medications that contain salicylic acid.
<b>Other Ingredients</b> Water, Glycerin, Cetearyl Ethylhexanoate, Butylene Glycol, Caprylic/Capric Triglyceride, Glyceryl Stearate, Dimethicone, Isostearyl Alcohol, Stearic Acid, Betaine, Niacinamide, PEG-100 Stearate, Cetyl Alcohol, Cucurbita Pepo (Pumpkin) Fruit Extract, Silybum Marianum Fruit Extract, Tocopheryl Acetate, Lactobacillus/Ganoderma Lucidum (Reishi) Extract/Lentinus Edodes (Truncated), PEG-4 Laurate, Triethanolamine, Xanthan Gum, Carbomer, Disodium EDTA, Iodopropynyl Butylcarbamate, Phenoxyethanol, Diazolidinyl Urea, Sodium Benzoate		<b>Do not use with a tanning bed or tanning lamp.</b> Do not use with a tanning bed or tanning lamp while using this product.
<b>Warnings</b> For external use only.		<b>Do not use with a tanning bed or tanning lamp.</b> Do not use with a tanning bed or tanning lamp while using this product.

**oil-free moisturizer for acne-prone skin 3 FL. OZ. / 88 ml**

**DRUG FACTS**

Drug Facts	Purpose	Drug Facts (continued)
<b>Active Ingredient</b> Benzoyl Peroxide 2% w/w	Acne Treatment	<b>Use with this product</b> Do not use with other topical acne medications. Do not use with other topical acne medications that contain salicylic acid.
<b>Other Ingredients</b> Water, Glycerin, Cetearyl Ethylhexanoate, Butylene Glycol, Caprylic/Capric Triglyceride, Glyceryl Stearate, Dimethicone, Isostearyl Alcohol, Stearic Acid, Betaine, Niacinamide, PEG-100 Stearate, Cetyl Alcohol, Cucurbita Pepo (Pumpkin) Fruit Extract, Silybum Marianum Fruit Extract, Tocopheryl Acetate, Lactobacillus/Ganoderma Lucidum (Reishi) Extract/Lentinus Edodes (Truncated), PEG-4 Laurate, Triethanolamine, Xanthan Gum, Carbomer, Disodium EDTA, Iodopropynyl Butylcarbamate, Phenoxyethanol, Diazolidinyl Urea, Sodium Benzoate		<b>Do not use with a tanning bed or tanning lamp.</b> Do not use with a tanning bed or tanning lamp while using this product.
<b>Warnings</b> For external use only.		<b>Do not use with a tanning bed or tanning lamp.</b> Do not use with a tanning bed or tanning lamp while using this product.

**MARY KAY**

clear proof® acne system

clarifying cleansing gel salicylic acid acne medication 4.5 OZ. NET WT. / 127 g

blemish control toner salicylic acid acne medication liquid 5 FL. OZ. / 147 ml

acne treatment gel benzoyl peroxide acne medication 1 OZ. NET WT. / 28 g

oil-free moisturizer for acne-prone skin 3 FL. OZ. / 88 ml

# CLEAR PROOF ACNE SYSTEM

benzoyl peroxide and salicylic acid kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51531-8977
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51531-8977-0	1 in 1 CARTON	08/15/2013	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	28 g
Part 2	1 BOTTLE	147 mL
Part 3	1 TUBE	127 g
Part 4	1 TUBE	88 mL

## Part 1 of 4

### CLEAR PROOF ACNE TREATMENT ACNE MEDICATION

benzoyl peroxide gel

## Product Information

<b>Route of Administration</b>	TOPICAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
CUCUMBER (UNII: YY7C30 VXJT)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		28 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	08/15/2013	

### Part 2 of 4

## CLEAR PROOF BLEMISH CONTROL TONER ACNE MEDICATION

salicylic acid liquid

### Product Information

Route of Administration	TOPICAL
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### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MENTHOL (UNII: L7T10EIP3A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		147 mL in 1 BOTTLE; 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	08/15/2013	

## Part 3 of 4

### CLEAR PROOF CLARIFYING CLEANSING GEL ACNE MEDICATION

salicylic acid gel

## Product Information

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)	
SODIUM C14 OLEFIN SULFONATE (UNII: N816E2SOKI)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ARCTIUM LAPPA ROOT (UNII: 597E9BIB33)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		127 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	08/15/2013	

## Part 4 of 4

### CLEAR PROOF OIL-FREE MOISTURIZER FOR ACNE-PRONE SKIN

other skin care preparations

## Product Information

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	BETAINE (UNII: 3SCV180C9W)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	NIACINAMIDE (UNII: 25X5118RD4)	
INGR	DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	PUMPKIN (UNII: SYW0QUB89Y)	
INGR	MILK THISTLE (UNII: U946SH95EE)	
INGR	IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	



**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		88 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		08/15/2013	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	08/15/2013	

**Labeler** - Mary Kay Inc. (103978839)**Establishment**

Name	Address	ID/FEI	Business Operations
Mary Kay Inc.		103978839	manufacture(51531-8977)

Revised: 6/2017

Mary Kay Inc.