

**RODAN FIELDS UNBLEMISH REGIMEN FOR ACNE, BLEMISHES AND BREAKOUTS-
sulfur, benzoyl peroxide, titanium dioxide, zinc oxide
Rodan & Fields, LLC.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Acne Treatment Sulfur Wash

30 mL / 1.0 Fl. Oz. U.S.

Drug Facts

Active Ingredient

Sulfure 3%

Purpose

Acne treatment

Uses

- the treatment of acne
- Helps keep skin clear of new acne blemishes, acne pimples, blackheads and whiteheads

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
- do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor

Do not use on

- broken skin
- large areas of the skin

When using this product

- apply only to areas with acne

Keep out of reach of children.

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

Directions

- 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

Inactive Ingredients

Water/Aqua/Eau, Sodium Laureth Sulfate, Propylene Glycol, Distearyl Phthalic Acid Amide, Lauryl Glucoside, Aloe Barbadensis Leaf Juice, Diisodecyl Adipate, Glycerin, Hydrogenated Polyisobutene, Polyacrylamide, Cetearyl Alcohol, Titanium Dioxide (CI 77891), Arnica Montana Flower Extract, Camellia Sinensis Leaf Extract, Cetyl Alcohol, Magnesium Aluminum Silicate, Cetareth-20, Laureth-7, PEG-100 Stearate, C13-14 Isoparaffin, Bisabolol, Glyceryl Stearate, Xanthan Gum, Fragrance/Parfum, Methylparaben, Glutaral, Chlorphenesin, Diazolidinyl Urea, Phenoxyethanol, Propylparaben, Citronellol, Geraniol, Limonene, Linalool, Violet 2 (CI 60725), Red 33 (CI 17200).

Questions

1-888-995-5656

Clarifying Toner

30 mL / 1.0 Fl. Oz. U.S.

Product Details

Directions

Apply evenly to entire face with a fresh gauze pad, avoiding the eye area. Do not rinse off. Allow to dry. Use once daily and increase to twice daily as tolerated.

Warnings

For external use only. Do not swallow. If product is swallowed, get medical help or contact a Poison Control Centre right away. Keep entirely clear of eye area. If product enters eye, rinse with water. If irritation or rash occur, discontinue use and consult your doctor. Keep out of reach of children. Use only as directed. It is recommended that prior to exposure to the sun, users cover areas where alpha-hydroxy acids (AHAs) have been applied with sunscreen. Contact of the product with the skin must be of limited frequency and duration.

Ingredients

Water/Aqua/Eau, Hamamelis Virginiana (Witch Hazel) Water, Ethoxydiglycol, Aloe Barbadensis Leaf Juice, Glycolic Acid, Polysorbate 20, Alcohol, Sodium Hydroxide, Panthenol, Camellia Sinensis Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sodium Hyaluronate, Leuconostoc/Radish Root Ferment Filtrate, Arginine, Niacinamide, Azelaic Acid, Menthyl Lactate, Atelocollagen, Zinc Phenosulfonate, Lecithin, PEG-12 Dimethicone, Benzophenone-9, Xanthan Gum, Sodium Chondroitin Sulfate, Fragrance/Parfum, Butylene Glycol, Propylene Glycol, Disodium EDTA, DMDM Hydantoin, Chlorphenesin, Phenoxyethanol, Citronellol, Geraniol, Limonene, Linalool, Blue 1 (CI 42090), Red 33 (CI 17200).

Dual Intensive Acne Treatment

2 x 4 mL / 0.13 Fl. Oz. U.S.

Drug Facts

Active Ingredient

Benzoyl Peroxide 2.5%

Purpose

Acne treatment

Uses

- for the treatment of acne
- helps keep skin clear of new acne blemishes, acne pimples, blackheads and whiteheads

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

Directions

- Clean the skin thoroughly before applying this product
- Dispense 1–2 pumps from each side. Blend product evenly
- Cover the entire affected area with a thin layer one to three times daily
- Do not rinse product off face
- 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
- Wash hands after application to help avoid staining fabrics

Inactive Ingredients

Water/Aqua/Eau, Ethoxydiglycol, Glycerin, Polyacrylamide, Allantoin, Niacinamide, Panthenol, Ceramide AP, Ceramide NP, Ceramide EOP, Punica Granatum Extract, Yucca Glauca Root Extract, Chamomilla Recutita (Matricaria) Flower Extract, Aloe Barbadosensis Leaf Juice, Biosaccharide Gum-1, Phytosphingosine, Cholesterol, Corn Starch Modified, C13-14 Isoparaffin, PEG-7 Glyceryl Cocoate, Disodium Oleamido MEA-Sulfosuccinate, Laureth-7, Sodium Lauroyl Lactylate, Sodium Sulfite, Xanthan Gum, Carbomer, Triethanolamine, Fragrance/Parfum, Disodium EDTA, BHT, Propylene

Glycol, Ethylhexylglycerin, Phenoxyethanol, Benzyl Alcohol, Citronellol, Geraniol, Limonene, Linalool.

Questions

1-888-995-5656

Oil Control Lotion Broad Spectrum SPF 20

12 mL / 0.41 Fl. Oz. U.S.

Drug Facts

Active Ingredients

Titanium Dioxide 0.7%

Purpose

Sunscreen

Zinc Oxide 4.75%

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on

damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if rash occurs

Keep out of reach of children.

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

Directions

- Apply a generous amount evenly over the entire face every morning
- Apply liberally 15 minutes before sun exposure
- Reapply every 2 hours
- Use a water-resistant sunscreen if swimming or sweating
- **Sun Protection Measures.**
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 spectrum SPF of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m.–2 p.m.
- wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: Ask a doctor

Other Information

- Protect this product from excessive heat and direct sun

Inactive Ingredients

Water/Aqua/Eau, Cyclopentasiloxane, Isododecane, Pentylene Glycol, Cetearyl Alcohol, Polysilicone-11, Butylene Glycol, PEG-10 Dimethicone, Dimethicone, Azelaic Acid, Tetrahexyldecyl Ascorbate, Tocopherol, Boerhavia Diffusa Root Extract, Atelocollagen, Nordihydroguaiaretic Acid, Oleanolic Acid, Lecithin, Tropolone, PEG-60 Almond Glycerides, Glycerin, Cholesterol, Squalane, Glyceryl Stearate, PEG-100 Stearate, Stearic Acid, Xanthan Gum, Polysorbate 60, Dimethiconol, Ceteth-10 Phosphate, Dicetyl Phosphate, Hexyl Laurate, Polyglyceryl-4 Isostearate, Sorbitan Isostearate, Alumina, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Carbomer, Sodium Metabisulfite, Sodium Chondroitin Sulfate, Citric Acid, Sodium Citrate, Disodium EDTA, Fragrance/Parfum, 1,2-Hexanediol, Caprylyl Glycol, Potassium Sorbate, Sodium Benzoate, Chlorphenesin, Methylisothiazolinone, Phenoxyethanol, Citronellol, Geraniol, Limonene, Linalool.

Questions

1-888-995-5656

Principal display Panel - Rodan Fields Unblemish Acne Treatment Sulfur Wash Label

RODAN + FIELDS®

UNBLEMISH

1 Acne Treatment

Sulfur Wash

RODAN+FIELDS®
UNBLEMISH

1

Acne Treatment
Sulfur Wash

PURPOSE: For the treatment of acne. Penetrates pores to control acne blemishes.

DIRECTIONS: Wet skin with lukewarm water. Using fingertips, gently and evenly massage a quarter-sized amount onto entire face for 30–60 seconds, avoiding contact with eyes. Rinse thoroughly; pat dry. Use once daily and increase to twice daily as tolerated.

ACTIVE INGREDIENT: Sulfur 3%

WARNINGS: For external use only. Using other topical acne medications at the same time or immediately following 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. Do not get into eyes. If excessive skin irritation develops or increases discontinue use and consult a doctor. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Manufactured for Rodan & Fields, LLC
San Francisco, CA 94105
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QUESTIONS OR COMMENTS 1-888-995-5656

125 mL/4.2 Fl.Oz.

Principal display Panel - Rodan Fields Unblemish Dual Intensive Acne Treatment Label

RODAN + FIELDS®
UNBLEMISH

3 Dual Intensive
Acne Treatment

3

Dual Intensive
Acne Treatment

RODAN+FIELDS
UNBLEMISH

Benzoyl Peroxide Lotion

ACTIVE INGREDIENT: Benzoyl Peroxide 5.0% -
Acne Treatment

USES: For the treatment and prevention of acne,
blemishes and breakouts.

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. **Do not use if you** have very sensitive skin or are sensitive to benzoyl peroxide. **When using this product** 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 combination. **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: Clean the skin thoroughly before applying this product. Dispense 1-2 pumps from each side. Blend product and apply evenly over the entire face, avoiding the eye area. Allow to penetrate skin. Do not rinse off. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to twice daily as needed or as directed by a doctor. If bothersome dryness or peeling occur, reduce application to once 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.

Dist. Rodan & Fields, LLC
San Francisco, CA 94105
UNTT030 8500-07-0022 (6000-07-5052)
Please Recycle
visit rodanandfields.com

QUESTIONS 1-888-995-5656

2 x 22.5 mL / 0.76 Fl. Oz.

0A

RODAN + FIELDS®
UNBLEMISH

**4 Oil Control
Lotion**

**BROAD SPECTRUM SPF 20
SUNSCREEN**



Principal display Panel - Rodan Fields Unblemish Kit Label

RODAN + FIELDS®
UNBLEMISH™

Regiment for Acne, Blemishes and Breakouts

Based on Multi-Med® Therapy, UNBLEMISH is a complete skincare system that combines cosmetic and active OTC ingredients that penetrate pores where acne originates, and helps prevent breakouts before they are visible on the skin's surface.

This 4-product Regiment was developed by Stanford-trained

dermatologists Dr. Katie Rodan and Dr. Kathy Fields.

RODAN + FIELDS®

Acne Treatment Sulfur Wash

125 mL/

4.2 Fl.Oz. U.S.

Clarifying Toner

125 mL/

4.2 Fl.Oz. U.S.

Dual Intensive Acne Treatment

2 x 22.5 mL/

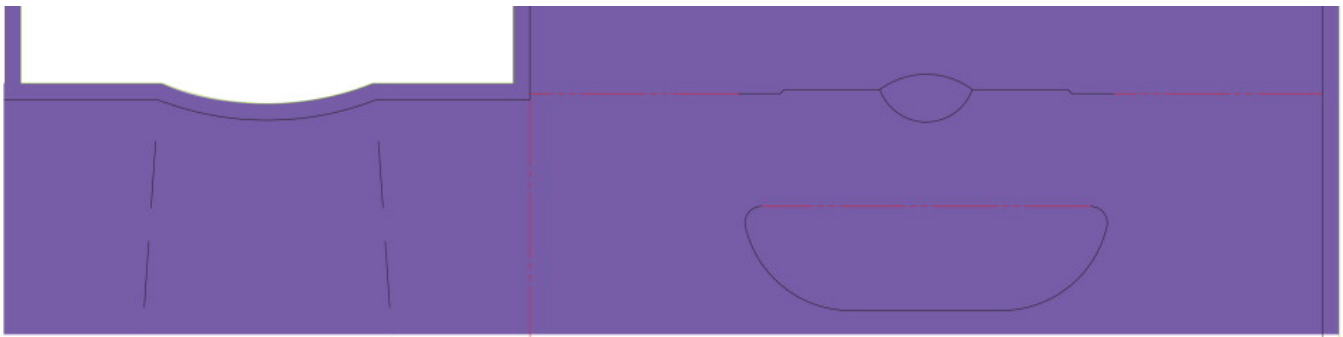
0.76 Fl.Oz. U.S.

Oil Control Lotion

Broad Spectrum SPF 20

30 mL/

1 Fl.Oz. U.S.



life-changing SKINCARE™

Acne Treatment Sulfur Wash
125 mL/4.2 Fl. Oz. U.S.

Drug Facts	Active Ingredients	Purpose
	Sulfur 3%	Acne treatment

Uses

- For the treatment of acne
- Helps keep skin clear of new acne blemishes, acne pimples, blackheads and whiteheads

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.
- Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor.

Do not use on

- Broken skin
- Large areas of the skin

When using this product

- Apply only to areas with acne

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

Directions

- 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

Inactive ingredients
Water/Aqua/Eau, Sodium Laureth Sulfate, Propylene Glycol, Disodium Phosphate Acid Anhydrous, Lauryl Glucoside, Aloe Barbadensis Leaf Juice, Disodium Adipate, Glycerin, Hydrogenated Polyisobutene, Polycarbamide, Cetylalcohol, Titanium Dioxide (CI 77891), Annona Montana Flower Extract, Camellia Sinensis Leaf Extract, Citri/Aldehyde, Magnesium Aluminum Silicate, C13-14 Isoparaffin, Disodium Stearoyl Sulfate, Xanthan Gum, Fragrance/Parfum, Methylparaben, Glycerol, Chlorphenesin, Disodium EDTA.

Clarifying Toner
125 mL/4.2 Fl. Oz. U.S.

Product Details

Directions
Apply evenly to entire face with a fresh gauze pad, avoiding the eye area. Do not rinse off. Allow to dry. Use once daily and increase to twice daily as tolerated.

Warnings
For external use only.
For external use only. Do not swallow. If product is swallowed, get medical help or contact a Poison Control Center right away. Keep strictly clear of eye area. If product enters eye, rinse with water. If irritation or rash occur, discontinue use and consult your doctor.
Keep out of reach of children. Use only as directed. It is recommended that prior to exposure to the sun, users cover areas where alpha-hydroxy acids (AHAs) have been applied with sunscreen. Contact of the product with the skin must be of limited frequency and duration.

Ingredients
Water/Aqua/Eau, Hamamelis Virginiana (Witch Hazel) Water, Ethylhexylglycol, Aloe Barbadensis Leaf Juice, Glycolic Acid, Polysorbate 20, Alcohol, Sodium Hydroxide, Panthenol, Camellia Sinensis Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sodium Hyaluronate, Leucosutor/Radiol Root Ferment Filtrate, Arginine, Niacinamide, Azelaic Acid, Methylolactate, Alkylcetylglucoside, Zinc Phosphosulfate, Lecithin, PEG-12 Dimethicone, Benzophenone-3, Xanthan Gum, Sodium Chloride.

Benzoyl Peroxide Lotion
22.5 mL/0.76 Fl. Oz. U.S.

Drug Facts	Active Ingredients	Purpose
	Benzoyl Peroxide 5%	Acne treatment

Uses

- For the treatment of acne
- Helps keep skin clear of new acne blemishes, acne pimples, blackheads and whiteheads

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

Directions

- Clean the skin thoroughly before applying this product
- Dispense 1-2 pumps from each side, blend product evenly
- Cover the entire affected area with a thin layer one to three times daily
- Do not rinse product off face
- 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

Oil Control Lotion Broad Spectrum SPF 20
10 mL/1.8 Fl. Oz. U.S.

Drug Facts	Active Ingredients	Purpose
	Titanium Dioxide 0.7%, Zinc Oxide 4.75%	Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings
For external use only

When using this product
Keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if rash occurs

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

Directions

- Apply a generous amount evenly over the entire face every morning
- Apply liberally 15 minutes before sun exposure
- Reapply every 2 hours
- Use a water-resistant sunscreen if swimming or sweating

Sun Protection Measures.
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 spectrum SPF of 15 or higher and other sun protection measures including:
• Limit time in the sun, especially from 10 a.m. - 2 p.m.
• Wear long-sleeve shirts, pants, hats and sunglasses
• Children under 6 months: Ask a doctor

Other Information

Inactive Ingredients
Water/Aqua/Eau, Cyclopentasiloxane, Isododecane, Pentaerythritol, Cetylalcohol, Polyisobutene-1, Sulfinyl Glycol, PEG-10 Dimethicone, Dimethicone, Azelaic Acid, Tetrahydrodipropyl Acrylate, Tocopheryl Acetate, Biotin

Acne Treatment Sulfur Wash
125 mL/4.2 Fl. Oz. U.S.

Drug Facts (continued)
Phenoxyethanol, Propylparaben, Chlorhexol, Glycerol, Limonene, Lisinexil, Violet 2 (CI 60725), Red 33 (CI 17200).

Enhancement Gel
22.5 mL/0.76 Fl. Oz. U.S.

Product Details
Ingredients
Water/Aqua/Eau, Ethylhexylglycol, Cere Starch Modified, PEG-7 Glyceryl Cocoate, Phenoxyethanol, Carbomer, Triethanolamine, Fragrance/Parfum, BHT, Disodium EDTA, Ethylhexylglycol, Chlorhexol, Glycerol, Limonene, Lisinexil.

Benzoyl Peroxide Lotion
22.5 mL/0.76 Fl. Oz. U.S.

Drug Facts (continued)
Directions
• If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor
• Wash hands after application to help avoid staining fabrics

Inactive ingredients
Water/Aqua/Eau, Glycerin, Polysorbate, Benzyl Alcohol, C13-14 Isoparaffin, Alantoin, Niacinamide, Panthenol, Ceramide AP, Ceramide NP, Ceramide EOP, Aloe Barbadensis Leaf Juice, Chamomilla Recutita (Matricaria) Flower Extract, Punica Granatum Extract, Yucca Glauca Root Extract, Biosaccharide Gum-1, Phylloblyssenoside, Cholesterol, Xanthan Gum, Carbomer, Disodium Oleoyl Sulfosuccinate, Laureth-7, Sodium Lauryl Sulfate, Sodium Salicylate, Disodium EDTA, Propylene Glycol, Phenoxyethanol.

When both lotions and gel are combined, Benzoyl Peroxide is 2.5% per pump

Clarifying Toner
125 mL/4.2 Fl. Oz. U.S.

Drug Facts (continued)
Sulfate, Fragrance/Parfum, Butylene Glycol, Propylene Glycol, Disodium EDTA, (DMG) Hyaluronic, Chlorphenesin, Phenoxyethanol, Citronellol, Geranyl, Limonene, Lisinexil, Blue 1 (CI 42090), Red 33 (CI 17200).

RODAN FIELDS UNBLEMISH REGIMEN FOR ACNE, BLEMISHES AND BREAKOUTS

sulfur, benzoyl peroxide, titanium dioxide, zinc oxide kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:14222-2020

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-2020-1	1 in 1 CARTON; Type 0: Not a Combination Product	06/01/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	125 mL
Part 2	2 BOTTLE, PUMP	45 mL
Part 3	1 TUBE	30 mL

Part 1 of 3

UNBLEMISH ACNE TREATMENT SULFUR WASH

sulfur cream

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sulfur (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70)	Sulfur	3.0 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Distearyl Phthalamic Acid (UNII: 5552GSZ9LI)	
Lauryl Glucoside (UNII: 76LN7P7UCU)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Diisodecyl Adipate (UNII: 3V0Q382O0P)	
Glycerin (UNII: PDC6A3C0OX)	
Hydrogenated Polybutene (1300 MW) (UNII: 7D1YQ9Y5EZ)	
Polyacrylamide (1500 MW) (UNII: 5D6TC4BRWV)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Arnica Montana Flower (UNII: OZ0E5Y15PZ)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
Laureth-7 (UNII: Z95S6G8201)	
PEG-100 Stearate (UNII: YD01N1999R)	
C13-14 Isoparaffin (UNII: E4F12ROE70)	
Levomenol (UNII: 24WE03BX2T)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	

Xanthan Gum (UNII: TTV12P4NEE)
Methylparaben (UNII: A2I8C7HI9T)
Glutaral (UNII: T3C89M417N)
Chlorphenesin (UNII: I670DAL4SZ)
Diazolidinyl Urea (UNII: H5RIZ3MPW4)
Phenoxyethanol (UNII: HIE492ZZ3T)
Propylparaben (UNII: Z8IX2SC1OH)
.Beta.-Citronellol, (R)- (UNII: P01OUT964K)
Geraniol (UNII: L837108USY)
Limonene, (+)- (UNII: GFD7C86Q1W)
Linalool, (+/-)- (UNII: D81QY6I88E)
D&C Violet No. 2 (UNII: 350KA7O6HK)
D&C Red No. 33 (UNII: 9DBA0SBB0L)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		125 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	06/01/2017	

Part 2 of 3

UNBLEMISH BENZOYL PEROXIDE

benzoyl peroxide lotion

Product Information

Route of Administration	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	5.0 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Diethylene Glycol Monoethyl Ether (UNII: A1A1I8X02B)	
Glycerin (UNII: PDC6A3C0OX)	
Polyacrylamide (1500 MW) (UNII: 5D6TC4BRWV)	
Allantoin (UNII: 344S277G0Z)	

Niacinamide (UNII: 25X51I8RD4)
Panthenol (UNII: WV9CM0O67Z)
Ceramide AP (UNII: F1X8L2B00J)
Ceramide NP (UNII: 4370DF050B)
Ceramide 1 (UNII: 5THT33P7X7)
Punica Granatum Root Bark (UNII: CLV24I3T1D)
Yucca Glauca Root (UNII: 1A15YBH7N1)
Chamomile (UNII: FGL3685T2X)
Aloe Vera Leaf (UNII: ZY81Z83H0X)
Biosaccharide Gum-1 (UNII: BB4PU4V09H)
Phytosphingosine (UNII: GIN46U9Q2Q)
Cholesterol (UNII: 97C5T2UQ7J)
Modified Corn Starch (1-Octenyl Succinic Anhydride) (UNII: 461P5CJN6T)
C13-14 Isoparaffin (UNII: E4F12ROE70)
PEG-7 Glyceryl Cocoate (UNII: VNX7251543)
Disodium Oleamido MEA-Sulfosuccinate (UNII: 5M1101WGSY)
Laureth-7 (UNII: Z95S6G8201)
Sodium Lauroyl Lactylate (UNII: 7243K85WFO)
Sodium Sulfite (UNII: VTK01UQK3G)
Xanthan Gum (UNII: TTV12P4NEE)
Carboxypolymethylene (UNII: 0A5MM307FC)
Trolamine (UNII: 9O3K93S3TK)
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)
Propylene Glycol (UNII: 6DC9Q167V3)
Ethylhexylglycerin (UNII: 147D247K3P)
Phenoxyethanol (UNII: HIE492ZZ3T)
Benzyl Alcohol (UNII: LKG8494WBH)
.Beta.-Citronellol, (R)- (UNII: P01OUT964K)
Geraniol (UNII: L837108USY)
Limonene, (+)- (UNII: GFD7C86Q1W)
Linalool, (+/-)- (UNII: D81QY6I88E)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		22.5 mL in 1 BOTTLE, PUMP; 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	06/01/2017	

Part 3 of 3

UNBLEMISH OIL CONTROL BROAD SPECTRUM SPF 20
titanium dioxide, zinc oxide lotion

Product Information

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.7 g in 100 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	4.75 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Isododecane (UNII: A8289P68Y2)	
Pentylene Glycol (UNII: 50C1307PZG)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)	
Butylene Glycol (UNII: 3XUS85K0RA)	
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
Dimethicone (UNII: 92RU3N3Y1O)	
Azelaic Acid (UNII: F2VW3D43YT)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
Tocopherol (UNII: R0ZB2556P8)	
Boerhavia Diffusa Root (UNII: KR0SR09KYL)	
Marine Collagen, Soluble (UNII: 8JC99XGU4W)	
Nordihydroguaiaretic Acid, (+/-)- (UNII: 7PZ73W4ZNR)	
Oleanolic Acid (UNII: 6SMK8R7TGJ)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Tropolone (UNII: 7L6DL16P1T)	
PEG-60 Almond Glycerides (UNII: 4Y0E651N0F)	
Glycerin (UNII: PDC6A3C0OX)	
Cholesterol (UNII: 97C5T2UQ7J)	
Squalane (UNII: GW89575KF9)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
PEG-100 Stearate (UNII: YD01N1999R)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Xanthan Gum (UNII: TTV12P4NEE)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Dimethiconol (70 CST) (UNII: MOT8IL21AR)	
Ceteth-10 Phosphate (UNII: 4E05O5N49G)	
Dihexadecyl Phosphate (UNII: 2V6E5WN99N)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Sorbitan Isostearate (UNII: 01S2G2C1E4)	
Aluminum Oxide (UNII: LMI26O6933)	
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 MPA.S At 1.5%) (UNII: 86FQE96TZ4)	

Carboxypolymethylene (UNII: 0A5MM307FC)
Sodium Metabisulfite (UNII: 4VON5FNS3C)
Chondroitin Sulfate Sodium (Bovine) (UNII: 8QTV3DTT8W)
Citric Acid Monohydrate (UNII: 2968PHW8QP)
Sodium Citrate (UNII: 1Q73Q2JULR)
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)
1,2-Hexanediol (UNII: TR046Y3K1G)
Caprylyl Glycol (UNII: 00YIU5438U)
Potassium Sorbate (UNII: 1VPU26JZZ4)
Sodium Benzoate (UNII: OJ245FE5EU)
Chlorphenesin (UNII: I670DAL4SZ)
Methylisothiazolinone (UNII: 229D0E1QFA)
Phenoxyethanol (UNII: HIE492ZZ3T)
.Beta.-Citronellol, (R)- (UNII: P01OUT964K)
Geraniol (UNII: L837108USY)
Limonene, (+)- (UNII: GFD7C86Q1W)
Linalool, (+/-)- (UNII: D81QY6I88E)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		

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OTC monograph not final	part352	06/01/2017	

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unapproved drug other		06/01/2017	

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