

AGE BRIGHT SPOT FADER- salicylic acid gel
Dermalogica, 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.

AGE Bright Spot Fader

Drug Facts

Active Ingredient

Salicylic Acid (2.0%)

Purpose

Acne treatment

Indications

For the treatment of acne

Warnings

For external use only

When using this product

- Skin irritation and dryness are 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 a Poison Control Center right away.

Directions

- Apply directly upon first sign of breakout. Reapply twice a day until spot fades.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Inactive Ingredients

Water/Aqua/Eau, Butylene Glycol, Hamamelis Virginiana (Witch Hazel) Water, Isopropyl Lauroyl Sarcosinate, Niacinamide, Propanediol, Polyacrylate Crosspolymer-6, Caprylyl Methicone, Glycereth-26, Saccharide Isomerate, Hexylresorcinol, Salvia Sclarea (Clary) Oil, Malic Acid, Aloe Barbadensis Extract, Salvia Sclarea (Clary) Extract, Lavandula Angustifolia (Lavender) Oil, Citrus Limon (Lemon) Peel Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Lavandula Hybrida Oil, Sclerotium Gum, Sodium Carrageenan, Thymol, Terpeneol, Pullulan, Lecithin, Glycerin, Dimethyl Isosorbide, PEG-12 Dimethicone/PPG-20 Crosspolymer, Xanthan Gum, Sodium Citrate, Ethylhexylglycerin, Tetrasodium Glutamate Diacetate, Silica, Tocopherol, Sea Salt, Potassium Sorbate, Sodium Benzoate, Sodium Hydroxide, Citric Acid, Benzoic Acid, Aminomethyl Propanol, Phenoxyethanol.

Questions or comments

Call toll free 1-800-831-5150 in the US.

PRINCIPAL DISPLAY PANEL - 15 mL Tube Carton

NEW

brightening
spot
treatment

Active Clearing

0.5 US FL OZ / 15 mL e

AGE bright spot fader

This two-in-one spot treatment reduces the appearance of active breakouts and post-breakout marks. Salicylic Acid works to clear breakouts, while Niacinamide and Hexylresorcinol work synergistically to improve uneven skin tone.

Ce traitement ciblé deux-en-un réduit l'apparence des éruptions actives et des marques post-acné. L'acide salicylique veille à éliminer rapidement les éruptions, tandis que la niacinamide et l'hexylrésorcine fonctionnent en synergie pour égaliser le teint.



dermalogica.info

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AGE bright spot fader

NEW NOUVEAU

Drug Facts (continued)

Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Lavandula Hybrida Oil, Sclerotium Gum, Sodium Carrageenan, Thymol, Terpineol, Pullulan, Lecithin, Glycerin, Dimethyl Isosorbide, PEG-12 Dimethicone/PPG-20 Crosspolymer, Xanthan Gum, Sodium Citrate, Ethylhexylglycerin, Tetrasodium Glutamate Diacetate, Silica, Tocopherol, Sea Salt, Potassium Sorbate, Sodium Benzoate, Sodium Hydroxide, Citric Acid, Benzoic Acid, Aminomethyl Propanol, Phenoxyethanol.

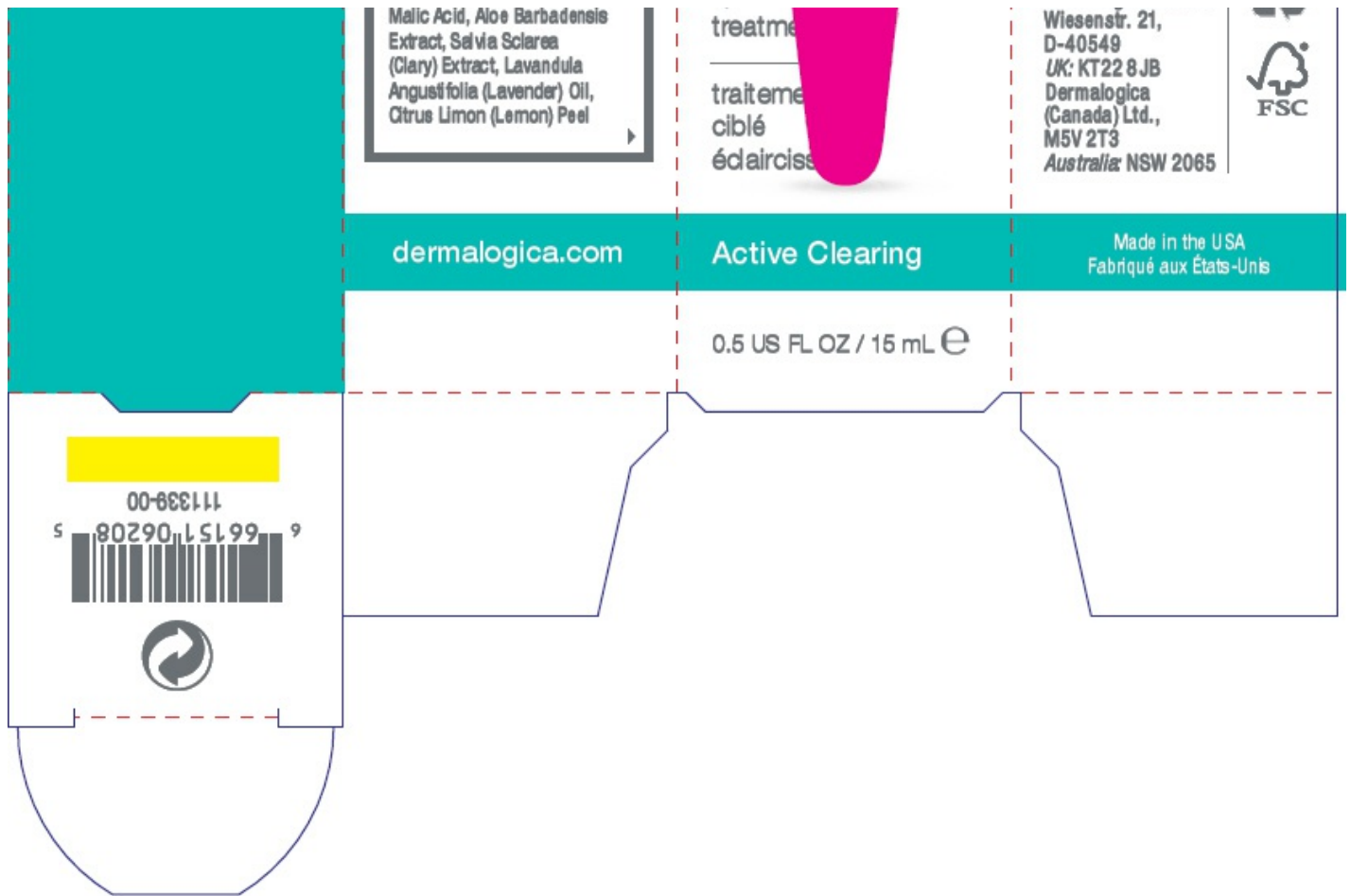
Questions or comments

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1-800-831-5150 in
the US.

bright spot

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Carson, CA 90746
1-800-831-5150
Dermalogica GmbH:





AGE BRIGHT SPOT FADER

salicylic acid gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68479-806 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ) | Salicylic Acid | 20 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Water (UNII: 059QF0KO0R) | |
| Butylene Glycol (UNII: 3XUS85K0RA) | |
| HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V) | |
| Isopropyl Lauroyl Sarcosinate (UNII: LYR06W430J) | |
| Niacinamide (UNII: 25X51I8RD4) | |
| Propanediol (UNII: 5965N8W85T) | |
| AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND | |

| |
|--|
| LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9) |
| CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL) |
| Glycereth-26 (UNII: NNE56F2N14) |
| Saccharide Isomerate (UNII: W8K377W98I) |
| Hexylresorcinol (UNII: R9QTB5E82N) |
| CLARY SAGE OIL (UNII: 87L0D4U3M0) |
| Malic Acid (UNII: 817L1N4CKP) |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |
| LAVENDER OIL (UNII: ZBP1YXW0H8) |
| LEMON OIL (UNII: I9GRO824LL) |
| ROSEMARY OIL (UNII: 8LGU7VM393) |
| LAVANDIN OIL (UNII: 9RES347CKG) |
| BETASIZOFIRAN (UNII: 2X51AD1X3T) |
| CARRAGEENAN SODIUM (UNII: 7CY8BVL34N) |
| Thymol (UNII: 3J50XA376E) |
| Terpineol (UNII: R53Q4ZWC99) |
| Pullulan (UNII: 8ZQ0AYU1TT) |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) |
| Glycerin (UNII: PDC6A3C0OX) |
| Dimethyl Isosorbide (UNII: SA6A6V432S) |
| PEG-12 Dimethicone/PPG-20 Crosspolymer (UNII: 965K72OQXO) |
| Xanthan Gum (UNII: TTV12P4NEE) |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) |
| Ethylhexylglycerin (UNII: 147D247K3P) |
| Tetrasodium Glutamate Diacetate (UNII: 5EHL50I4MY) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| Tocopherol (UNII: R0ZB2556P8) |
| Sea Salt (UNII: 87GE52P74G) |
| Potassium Sorbate (UNII: 1VPU26JZZ4) |
| Sodium Benzoate (UNII: OJ245FE5EU) |
| Sodium Hydroxide (UNII: 55X04QC32I) |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |
| Benzoic Acid (UNII: 8SKN0B0MIM) |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) |
| Phenoxyethanol (UNII: HIE492ZZ3T) |

| Packaging | | | | |
|------------------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:68479-806-02 | 1 in 1 CARTON | 06/06/2019 | |
| 1 | | 15 mL in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:68479-806-00 | 2 mL in 1 POUCH; Type 0: Not a Combination Product | 06/06/2019 | |
| 3 | NDC:68479-806-01 | 6 mL in 1 TUBE; Type 0: Not a Combination Product | 06/06/2019 | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL | part333D | 06/06/2019 | |

Labeler - Dermalogica, Inc (177698560)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|------------------------|
| McKenna Labs, Inc. | | 090631412 | MANUFACTURE(68479-806) |

Revised: 7/2019

Dermalogica, Inc