

SKINCOACH CLEAN- salicylic acid liquid
SKIN COACH SL.

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.

| Active ingredient | Purpose |
|----------------------------|-----------------|
| Salicylic Acid USP 2%----- | Acne medication |

Uses
Skin cleanser for the treatment of acne.

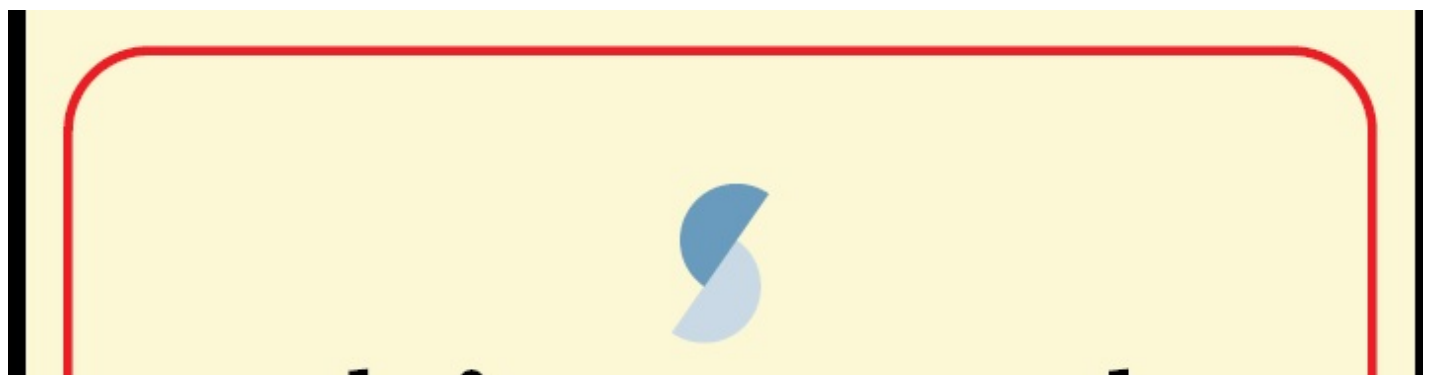
Warnings
For external use only
Keep away from eyes, lips, and mouth.
Using other topical medications, while using this product or immediately thereafter, may increase dryness or irritation. If this occurs discontinue use and see your doctor.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center.
Sunscreen use is recommended with any glycolic acid product and for an additional week thereafter because some individuals may be more sensitive to sunlight.

Directions
Wet affected area, apply, and rinse well. • Because excessive drying of the skin can occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a physician • If bothersome dryness occurs, reduce application to once a day or every other day.

Inactive ingredients
Camellia sinensis (Green Tea) Polyphenols, Cocamidopropyl Betaine, Disodium EDTA, Fragrance, Glycolic Acid, Linoleamidopropyl PG-Dimonium Chloride Phosphate, Polysorbate-20, Purified Water, Red #40 [CI-16035], Sodium C12-15 Pareth-15 Sulfonate, Sodium C14-16 Olefin Sulfonate, Triethanolamine, Yellow #5 [CI-19140], Zinc PCA.

Principal display panel



skincoach

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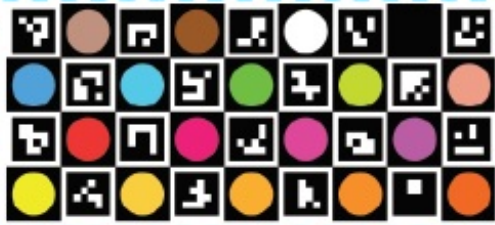
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Glycolic Acid 5% & Salicylic Acid USP, 2%
Acne Cleanser

Net wt 6.7 fl oz (200 ml)



Drug Facts

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Rev. 8/19 Made in USA NDC73047-004-01

SKINCOACH CLEAN

salicylic acid liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73047-004 |
| 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 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| POLY(DL-LACTIC-CO-GLYCOLIC ACID), (50:50; 46000 MW) (UNII: LQ35R50VR1) | |
| LINOLEAMIDOPROPYL PROPYLENE GLYCOL-DIMONIUM CHLORIDE PHOSPHATE (UNII: 5Q87K461JO) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| SODIUM C12-15 PARETH-15 SULFONATE (UNII: 353VA59XH8) | |
| SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| ZINC PIDOLATE (UNII: C32PQ86DH4) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:73047-004-01 | 200 mL in 1 TUBE; Type 0: Not a Combination Product | 08/07/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333D | 08/07/2019 | |

Labeler - SKIN COACH SL. (468534978)

Registrant - SKIN COACH SL. (468534978)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| Topiderm Inc. II | | 078841698 | manufacture(73047-004) |

Revised: 8/2019

SKIN COACHSL.