

SEA BREEZE ACTIVES DEEP-CLEAN ASTRINGENT- salicylic acid liquid

Idelle Labs, Ltd

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.

Sea Breeze Actives Deep-Clean Astringent

Active ingredient

Salicylic acid 1%

Purpose

Acne medication

Uses

- for the treatment of acne
- clears blackheads

Warnings

For external use only.

When using this product

- and other topical acne medication at the same time or immediately following use of this product, dryness or irritation of the skin may be increased. If this occurs, only one medication should be used unless directed by a doctor.

Keep out of reach of children.

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

Flammable,

keep away from open fire or flame.

Directions

- clean skin thoroughly before applying medication.
- moisten a cotton ball and smooth the cotton ball over your face one to three times daily.

Inactive ingredients

Benzoic acid, camphor, clove (eugenia caryophyllus) oil, eucalyptus globulus oil, fragrance, glycerin, methyl propanediol, orange 4, PPG-12-buteth-16, SD alcohol 40-B, yellow 5, water.

Questions or comments?

1-800-487-7273 or visit us at www.seabreezeclean.com

PRINCIPAL DISPLAY PANEL

REFRESHING CLEAN

SEA
BREEZE[®]

Actives

With 2% Salicylic Acid
Acne Treatment

**DEEP-CLEAN
ASTRINGENT**

Oil control formula
that treats and
prevents breakouts

10 fl. oz. (295 ml)

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label

SEA BREEZE ACTIVES DEEP-CLEAN ASTRINGENT

salicylic acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41595-3022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CLOVE OIL (UNII: 578389D6D0)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)	
PPG-14 BUTYL ETHER (UNII: R199TJT95T)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41595-3022-1	295 mL in 1 BOTTLE		
2	NDC:41595-3022-2	474 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	02/01/2003	

Labeler - Idelle Labs, Ltd (128822926)

Registrant - Idelle Labs, Ltd (128822926)

Establishment

Name	Address	ID/FEI	Business Operations
Marianna Industries, Inc.		045570736	MANUFACTURE

Revised: 4/2011

Idelle Labs, Ltd