ACNEZZOL BASE- salicylic acid lotion
SOLUTION INTERNATIONAL 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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acnezzol™
base

Active ingredient:

Salicylic acid 1.0%

Uses:

For the treatment of acne.

Warnings:

For external use only. Avoid contact with eyes. If contact occurs, flush thoroughly with water. This product may cause irritation. If excess irritation occurs, discontinue use. Avoid unnecessary sun exposure and use sunscreen. Allow acnezzol™ base to dry, then follow the sunscreen directions. Do not use this product if you have sensitive skin or If you are sensitive to AH As.

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

Directions:

Apply a thin layer to affected area only, In the morning and evening. For best results, apply acnezzol™ activator after acnezzol™ base. Wash hands thoroughly after application.

Inactive Ingredients:

Water, Isopropyl alcohol, Propylene glycol, Hydroxyethylcellulose, Mandelic acid, Methyloxirane, Oxirane, Sodium benzoate, FD&C Blue #1.

Dist. by: SOLUTION INTERNATIONAL, INC.

Miami Beach, FL 33140 Made in USA ©2012

Principal Display Panel – Tube Label

Fast dual action
to clear skin

acnezzol™ base

Eliminates acne causing bacteria

Clinical results without a prescription

Gentle enough for everyday use

Dermatologist Recommended
FDA REGISTERED
MADE IN USA

NET WT. 1 OZ. (28 G)

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base

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★ ★ ★ ★ ★

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ACNEZZOL BASE

salicylic acid lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58268-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	1.0 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Isopropyl Alcohol (UNII: ND2M416302)	
Propylene Glycol (UNII: 6DC9Q167V3)	
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)	
Mandelic Acid (UNII: NH496X0UJX)	
Sodium Benzoate (UNII: OJ245FE5EU)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
Propylene Oxide (UNII: Y4Y7NYD4BK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58268-013-01	29.5735 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/10/2013	

Labeler - SOLUTION INTERNATIONAL INC (062639742)

Registrant - KANTIAN SKINCARE, LLC (078436984)

Establishment

Name	Address	ID/FEI	Business Operations
Kantian Skincare, LLC		078436984	LABEL(58268-013)

Establishment

Name	Address	ID/FEI	Business Operations
PhytogenX, Inc		010297942	MANUFACTURE(58268-013)