VITALE SENSITIVE SCALP 12 IN 1 INSTANT RELIEF ANTI DANDRUFF SPRAY - salicylic acid spray

JF Labs, 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.

Drug Facts

Active Ingredient	Purpose
1.8% Salicylic Acid	Anti-dandruff, anti seborrheic dermatitis, anti-psoriasis

USE

Controls the symptoms of dandruff, seborrheic dermatitis and psoriasis.

WARNINGS SECTION

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

Flammable. Keep away from heat and open flame.

For external use only

Ask a physician before use it you have a condition that covers a large area of your body.

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

If condition worsens or does not improve, after regular use of this product as directed, consult a physician.

DOSAGE AND ADMINISTRATION SECTION

Directions: Hold bottle 6 inches away from hair and spray evenly. Massage into hair and scalp and style. For curly hair and braids, use daily. On relaxed hair use before drying.

Other Information: Store away from direct sunlight.

INACTIVE INGREDIENT SECTION

Inactive ingedients: Water(Aqua), SD Alcohol 40B, Propylene Glycol, Cyclo-pentasiloxane, Isopropyl Palmitate, Phenyl Trimethicone, Sodium Citrate, Sodium Hydroxide, PPG-5 Ceteth-20, Olea Europaea (Olive) Oil, Aloe Barbadensis Leaf Juice, Mentha Piperita (Peppermint) Oil, Camphor, Menthol, Cetrimonium Chloride, Sulfur, Polysorbate-20, Methylparaben, Propylparaben, Tocopherol Acetate (Vitamin E), Retinyl Palmitate (Vitmin A), Rosmarinus Officinalis (Rosemary) Leaf Extract, Equisetum Arvense Extract, Pinus Sylvestris Leaf Extract, Humulus Lupulus (Hops) Extract, Citrus Limonum (Lemon) Peel Extract, Fragrance (Parfum)

HEALTHY SCALP, HEALTHY HAIR™



HEALTHY SCALP, HEALTHY HAIR™



- · On the Spot Relief
- · Helps Stop Itching, Flaking, Irritation & Dandruff
- Relieves Tension & Tightness Due to Braids & Weaves

8 Fl. Oz. @ 237 mL

HEALTHY SCALP, HEALTHY HAR**

What is Sensitive Scalp? Sensitive Scalp is a scalp that has frequent itchiness, dryness, tightness and easily irritated. Many factors can cause Sensitive Scalp.....

- · Improper Use of **Chemical Treatments** · Tension and Tightness Due to Braids and Weaves
- · Overuse of Heating Styling Tools (Blow Dryers and Curling Irons) Inferior Hair Products

Why Should I use Vitale Sensitive Scalp Products?

Vitale Sensitive Scalp Products are designed to relieve scalp problems that go beyond the fight against dandruff. It soothes, balance and controls underlying scalp conditions including tightness, itching, tenderness, tension and irritation. Formulated with a special blend of antioxidants, vitamins, essential oils and active ingredients, it restores the scalp back to normal

HEALTHY SCALP, HEALTHY HAIR™ FLAMMABLE Keep away from heat and open

idities. Sensitive Scalp Instant Rellef is an amazing versatile product that provides on the spot rellef to the scalp. It relleves dry litchy, irritated scalp associated with dandruff,

Drug Facts Anti-dandruff, anti seborrheio dermatile, anti-peoriasis Use: Controls the symptoms of dandruff, seborrheic dermatilis and psoriasis.

Warnings Flammable. Keep away from heat and open flame

Ask a physician before use if you have a condition that covers a large area of your body: Avoid contact with eyes. If contact occurs, rinse eyes thoroughly

If condition worsens or does not improve, after regular use of this product as directed, consult a physician. Keep out of reach of children. If swellowed, get medical help or contact a Poison Control Center immediately.

Directions: Hold bottle 6 inches away from hair and spray

eventy. Massage into heir and scalp and style. For curly hair and braids, use daily.

On relaxed hair use before drying.

Other information: Store away from direct sunlight. nactive ingredients: Water (Aqua), SD Alcohol 40B, Propylene Glycol, Cyclo-pentasiloxane, Isopropyl Palmitate, Phenyl Trimethicone, Sodium Clirate, Sodium Hydroxide, PPG-5 Cetelh-20, Glas Europeas (Olive) Oll Edinat, Alos Barbadensi Leef Jusos Mentha Piperla (Peppermirt) Ol, Cemphor, Menthol Cetimonium Chloride, Sulfur, Polysorbate-20, Methylpansben, Propylpansben, Tocopherol Acetale (Vitamin E), Retinyl Palmitato (Vitamin A), Posmarinus Officinalis (Rosemary) Leel Extract, Equisetum Arvense Extract, Pinus Sylvestris Leef Extract, Humulus Lupulus (Hops) Extract, Citrus Limonum (Lemon) Peel Extract , Fragrance (Parlum)

AFAM CONCEPT, INC. Chicago, IL 60629 773-838-1336 (800) 262-2326 MADE IN USA

40

HEALTHY SCALP, HEALTHY HAR!**

Why is a healthy scalp so

important? A healthy scalp

is vital for the growth of strong healthy hair. If the

scalp is tight and dry it

makes it difficult for hair to

delaying hair growth.

Tightness and dryness

can also lead to itching,

scratching and flaking.

Soothe, Balance & Control

The ANSWER to Dry,

Itchy Flaky and Easily

Registered # 1,387,930 Item #VS10

Problems.....

Irritated Scalp.

743690072055

LONDON NW 10 6JH, UK

www.vitaleproducts.com (773)838-1336, (800) 262-2326

Registered # 1,387,930

VITALE SENSITIVE SCALP 12 IN 1 INSTANT RELIEF ANTI DANDRUFF SPRAY

salicylic acid spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49681-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	15 mg in 1 mL	

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Alcohol (UNII: 3K9958V90M)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Olive Oil (UNII: 6UYK2W1W1E)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Peppermint Oil (UNII: AV092KU4JH)	
Camphor (UNII: 5TJD82A1ET)	
Menthol (UNII: L7T10EIP3A)	
Cetrimonium Chloride (UNII: UC9 PE9 5 IBP)	
Sulfur (UNII: 70 FD1KFU70)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Alpha-tocopherol Acetate (UNII: 9E8X80D2L0)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Equisetum Arvense Extract (UNII: 1L0 VKZ185E)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49681-002-05	237 mL in 1 BOTTLE, SPRAY		
Markating Info	vmatian		
Marketing Info	rillation		
Marketing Category	Application Number or Monograp	h Citation Marketing Start	Date Marketing End Date
OTC monograph final	part358	11/0 1/20 0 9	

Labeler - JF Labs, Inc. (047821728)

Registrant - JF Labs, Inc. (047821728)

Establishment			
Name	Address	ID/FEI	Business Operations
Afam Concept, Inc.		103330098	MANUFACTURE

Revised: 9/2009 JF Labs, Inc.