

AMERICAN CREW- pyrithione zinc shampoo
Revlon Consumer Products Corp

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.

American Crew 2-In-1 Anti-Dandruff & Sebum Control Shampoo

Active Ingredients :

Active Ingredients
Pyrithione Zinc 1%

Purpose

Anti Dandruff

Uses:

Controls itching & flaking due to dandruff.

Warnings:

For external use only.

- 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.
- Consult a physician prior to use in children under 2 years of age.
- KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hair thoroughly.
- Massage a small amount of shampoo evenly into scalp and leave on for a few minutes.
- Rinse well.
- For best results use at least twice a week or as directed by a physician.

Inactive Ingredients

Aqua (Water) (Eau), Sodium Laureth Sulfate, Acrylates Copolymer, Cocamidopropyl Betaine, Glycerin, PEG-12 Dimethicone, Di-PPG-2 Myreth-10 Adipate, Triethanolamine, Hydroxyethylcellulose, Propylene Glycol, Sodium Chloride,

Polyquaternium-7, Melaleuca
 Alternifolia (Tea Tree) Leaf Oil,
 Mentha Piperita (Peppermint) Oil,
 Rosmarinus Officinalis (Rosemary)
 Leaf Extract, Salvia Officinalis
 (Sage) Leaf Extract, Sodium
 Acetate, Parfum (Fragrance),
 Limonene, Phenoxyethanol,
 Ethylparaben, Methylparaben

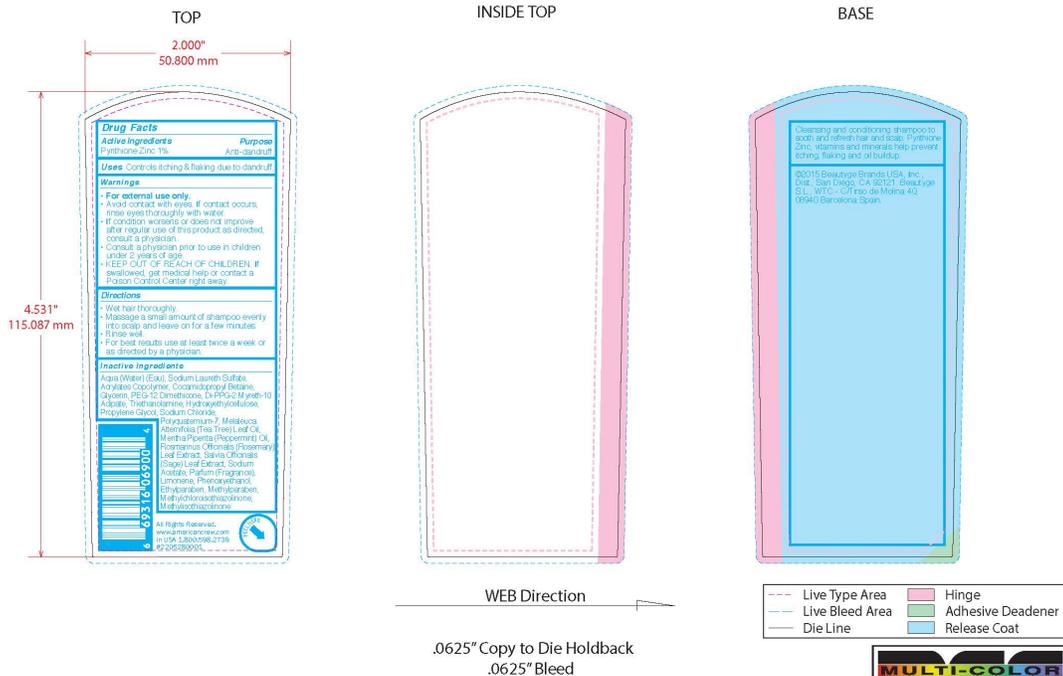
Keep out of Reach of Children

Label

American Crew 2-In-1 Anti-Dandruff & Sebum Control Shampoo

Job Name: American Crew Anti-dandruff + sebum control shampoo 250ml US-back peel off label
 Colomer Part Number: 2205280001
 Color: cyan prints white
 Packaging Material: label
 Reason for Submission: Updated Part Number to 2205280001 - Dist. Line Change - New Deline from Vendor
 Countries Product Sold: USA
 Components: bottle, cap, back overlabel
 Contact: Abi VerVallin
 Phone Number: 212.527.4598
 E-mail Address: Abi.VerVallin@Revlon.com
 Date of Submission: 03/4/15

Supplier: MULTI-COLOR Corporation
Application: Pressure Sensitive



Customer: REVLON	Date: 2/26/15
File: RDCT	Drawn by: MK

MULTI-COLOR
GLOBAL LABEL SOLUTIONS
 405 Willow Springs Lane
 York, PA 17408
 Phone: 717-266-9875
 1-888-800-YORK (9675)
 Customer Service Fax: 717-266-9835

AMERICAN CREW			
pyrithione zinc shampoo			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10967-650

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
DI-PPG-2 MYRETH-10 ADIPATE (UNII: 4IN301M0KJ)	
TROLAMINE (UNII: 9O3K93S3TK)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
TEA TREE OIL (UNII: VIF565UC2G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SAGE OIL (UNII: U27K0H1H2O)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL PARABEN (UNII: 14255EXE39)	
METHYL PARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-650-25	250 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/01/2013	

Labeler - Revlon Consumer Products Corp (788820165)

Establishment

Name	Address	ID/FEI	Business Operations
REVLON, INC.		809725570	manufacture(10967-650)

Revised: 11/2019

Revlon Consumer Products Corp