

ANTI DANDRUFF- salicylic acid rinse
The Hain Celestial Group, 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.

For external use only. Avoid contact with eyes. Rinse eyes thoroughly with water in case contact occurs. Discontinue to use and contact your physician if irritation develops.

Drug Facts

Salicylic Acid 2.0%

Controls symptoms of dandruff, seboric dermatitis and psoriasis

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

For relief of flaking, scaling and itching associated with dandruff. Helps prevent Seborrheic Dermatitis

For the best results use at least three times each week. Apply to clean, wet hair. Rinse thoroughly.

Aloe Barbadensis Leaf Juice (1), Aqua (Water), Glyceryl Stearate SE, Caprylic/Capric Triglyceride, Stearic Acid, Cetyl Alcohol, Capryloyl Glycerin/Sebacic Acid Copolymer, Helianthus Annuus (Sunflower Seed Oil) (1), Diheptyl Succinate, Stearyl Alcohol, Olea Europaea (Olive) Fruit Oil (1), Simmondsia Chinensis (Jojoba) Seed Oil (1), Butyrospermum Parkii (Shea) Butter (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Eucalyptus Globulus Leaf Extract (1), Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract (1), Rosmarinus Officinalis (Rosemary) Leaf Extract (1), Styrax Benzoin Resin Extract, Malaleuca Alternifolia (Tea Tree) Leaf Oil (1), Rosmarinus Officinalis (Rosemary) Leaf Oil, Cedrus Atlantica Bark Oil, Citrus Aurantium Dulcis (Orange Peel Oil), Citrus Limon (Lemon) Peel Oil, Copaifera Officinalis (Balsam Copaiba) Resin, Coriandrum Sativum (Coriander) Fruit Oil, Geranium Maculatum Oil, Lavandula Angustifolia (Lavender) Oil, Mentha Piperita (Peppermint) Oil, Pogostemon Cablin Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Hydrolyzed Wheat Protein, Menthol, Tocopheryl Acetate, Xanthan Gum, Alcohol, Benzyl Alcohol, Sodium Benzoate, Potassium Sorbate

(1) Certified Organic Ingredients



3.8570

ANTI DANDRUFF

salicylic acid rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-1107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2.0 g in 397 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER (UNII: K49155WL9Y)	
CHAMOMILE (UNII: FGL3685T2X)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
ROSMARINUS OFFICINALIS FLOWER (UNII: NR1A27F29O)	
STYRAX BENZOIN RESIN (UNII: FE663Z8IRO)	
CEDRUS ATLANTICA BARK OIL (UNII: ZX5QRE4U60)	
ORANGE OIL (UNII: AKN3KSD11B)	
LEMON OIL (UNII: I9GRO824LL)	
COPAIFERA OFFICINALIS RESIN (UNII: 1VH544O5AT)	
CORIANDER OIL (UNII: 7626GC95E5)	
GERANIUM MACULATUM WHOLE (UNII: LFG25P7V8M)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
POGOSTEMON CABLIN WHOLE (UNII: H6UKY25H2P)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
DISODIUM COCOYL GLUTAMATE (UNII: MBK0CP8F5A)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
MENTHOL (UNII: L7T10EIP3A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-1107-9	397 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/17/2014	

Labeler - The Hain Celestial Group, Inc. (858894996)

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		858894996	manufacture(61995-1107)

Revised: 2/2014

The Hain Celestial Group, Inc.