

REBORNCCELL HAIR CLINIC - dimethicone shampoo
And Us Co., 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.

Drug Facts

dimethicone

water, menthol, etc.

skin protectant

keep out of reach of the children

apply proper amount to the hair and wash away

1. Do not use in the following cases(Eczema and scalp wounds)

2.Side Effects

1)Due to the use of this drug if rash, irritation, itching and symptoms of hypersensitivity occur discontinue use and consult your pharmacist or doctor

3.General Precautions

1)If in contact with the eyes, wash out thoroughly with water. If the symptoms are severe, seek medical advice immediately

2)This product is for external use only. Do not use for internal use

4.Storage and handling precautions

1)If possible, avoid direct sunlight and store in cool and area of low humidity

2)In order to maintain the quality of the product and avoid misuse

3)Avoid placing the product near fire and store out of reach of children

for external use only

FORMULA INGREDIENTS STATEMENT

PRODUCT NAME: REBORNCCELL HAIR CLINIC SHAMPOO

Material contained in 100grams

19-Aug-14

NO.	INGREDIENTS	w/w%	CAS.NO	FUNCTION	SOURCE
1	Water	45.3293	7732-18-5	SOLVENT	ICID
2	Sodium Laureth Sulfate	20.0000	1335-72-4	SURFACTANT	ICID
3	Cocamidopropyl Betaine	10.0000	61789-40-0	SURFACTANT	ICID
4	Aloe Barbadensis Leaf Water	10.0000	8001-97-6	FRAGRANCE INGREDIENT	ICID
5	Ammonium Lauryl Sulfate	5.0000	2235-54-3	SURFACTANT	ICID
6	Dimethicone	2.0000	9006-65-9	SKIN CONDITIONING AGENT	ICID
7	Cocamide DEA	2.0000	61791-31-9	SURFACTANT	ICID
8	Propylen Glycol	2.0000	57-55-6	SKIN CONDITIONING AGENT	ICID
9	Cetyl Alcohol	0.5000	36653-82-4	EMULSION STABILIZER	ICID
10	Camellia Sinensis Leaf Extract	0.5000	84650-60-2	SKIN CONDITIONING AGENT	ICID
11	Polyquaternium-10	0.3000	53568-66-4	ANTISTATIC Agent	ICID
12	Lavandula Angustifolia (Lavender) Oil	0.3000	8000-28-0	SKIN CONDITIONING AGENT	ICID
13	Menthol	0.3000	89-78-1	FLAVORING AGENT	ICID
14	Salicylic Acid	0.2500	69-72-7	SKIN CONDITIONING AGENT	ICID
15	Panthenol	0.2000	81-13-0	HAIR CONDITIONING AGENT	ICID
16	Mentha Piperita (Peppermint) Oil	0.2000	8006-90-4	SKIN CONDITIONING AGENT	ICID
17	Disodium EDTA	0.1000	139-33-3	CHELATING AGENT	ICID
18	Swertia Japonica Extract	0.1000	94167-11-0	SKIN CONDITIONING AGENT	ICID
19	Sodium Citrate	0.1000	68-04-2	BUFFERING AGENT	ICID
20	Panax Ginseng Root Extract	0.1000	90045-38-8	SKIN CONDITIONING AGENT	ICID
21	Artemisia Vulgaris Extract	0.1000	84775-45-1	SKIN CONDITIONING AGENT	ICID
22	Sophora Angustifolia Root Extract	0.1000	CTFA ID:9062	SKIN CONDITIONING AGENT	ICID
23	Curcuma Longa (Turmeric) Root Extract	0.1000	84775-52-0	FRAGRANCE INGREDIENT	ICID
24	Yeast Extract	0.1000	8013-01-02	SKIN CONDITIONING AGENT	ICID
25	Glycyrrhiza Glabra (Licorice) Root Extract	0.1000	84775-66-6	SKIN CONDITIONING AGENT	ICID
26	Paeonia Lactiflora Root Extract	0.1000	CTFA ID: 15845	SKIN CONDITIONING AGENT	ICID
27	Piroctone Olamine	0.0500	68890-66-4	COSMETIC BIOCID	ICID
28	Niacinamide	0.0500	98-92-0	SKIN CONDITIONING AGENT	ICID
29	Biotin	0.0100	58-85-5	SKIN CONDITIONING AGENT	ICID
30	Sodium Hyaluronate	0.0100	9067-32-7	SKIN CONDITIONING AGENT	ICID
31	Methylchloroisothiazolinone	0.0005625	26172-55-4	PRESERVATIVE	ICID
32	Methylisothiazolinone	0.0001875	2682-20-4	PRESERVATIVE	ICID
	Total	100.000			

COMMITMENT OF MANUFACTURER:

THE MANUFACTURER HEREBY WOULD LIKE TO BEAR FULL RESPONSIBILITY AND TO ASSURE THAT THE COMPOSITION DOES NOT CONSIST ANY SUBSTANCES WHICH IS PROHIBITED TO USE IN THE COSMETIC AND ALSO CONFIRM THAT THE PRODUCT WAS MANUFACTURED IN CONFORMITY WITH THE ABOVE MENTIONED.

SIGNED BY 
 ENBIOSCIENCE CO., LTD

REBORNCCELL HAIR CLINIC

dimethicone shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70353-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70353-0004-1	300 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/25/2015	

Labeler - And Us Co., Ltd (688461137)

Registrant - And Us Co., Ltd (688461137)

Establishment

Name	Address	ID/FEI	Business Operations
And Us Co., Ltd		688461137	manufacture(70353-0004)

Revised: 12/2015

And Us Co., Ltd