

REBORNCCELL AQUA RICH- dimethicone cream
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, butylene glycol, etc.

skin protectant

keep out of reach of the children

apply proper amount to the skin

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 AQUA RICH CREAM

Material contained in 100grams

02-Jan-14

| NO. | INGREDIENTS | w/w% | CAS.NO | FUNCTION | SOURCE |
|-----|--|-----------|----------------|----------------------------|--------|
| 1 | Water | 70.4348 | 7732-18-5 | SOLVENT | ICID |
| 2 | Butylene Glycol | 5.0000 | 107-88-0 | SKIN CONDITIONING AGENT | ICID |
| 3 | Caprylic/Capric Triglyceride | 3.0000 | 65381-09-1 | SKIN CONDITIONING AGENT | ICID |
| 4 | Glycerin | 3.0000 | 56-81-5 | HUMECTANT | ICID |
| 5 | Glyceryl Stearate | 2.7500 | 123-94-4 | SURFACTANT | ICID |
| 6 | Cetyl Alcohol | 2.5000 | 36653-82-4 | EMULSION STABILIZER | ICID |
| 7 | Cetyl Ethylhexanoate | 2.0000 | 59130-69-7 | SKIN CONDITIONING AGENT | ICID |
| 8 | Cyclopentasiloxane | 2.0000 | 541-02-6 | SKIN CONDITIONING AGENT | ICID |
| 9 | Polysorbate 60 | 1.5000 | 9005-67-8 | SURFACTANT | ICID |
| 10 | Simmondsia Chinensis (Jojoba) Seed Oil | 1.0000 | 61789-91-1 | SKIN CONDITIONING AGENT | ICID |
| 11 | Natto Gum | 1.0000 | 9079-02-01 | VISCOSITY INCREASING AGENT | ICID |
| 12 | Sodium Hyaluronate | 1.0000 | 9067-32-7 | SKIN CONDITIONING AGENT | ICID |
| 13 | Sorbitan Stearate | 0.5000 | 1338-41-6 | SURFACTANT | ICID |
| 14 | Stearic Acid | 0.5000 | 57-11-4 | SURFACTANT | ICID |
| 15 | Carapa Guaianensis Seed Oil | 0.5000 | CTFA ID: 10101 | SKIN CONDITIONING AGENT | ICID |
| 16 | Centella Asiatica Extract | 0.5000 | 84696-21-9 | SKIN CONDITIONING AGENT | ICID |
| 17 | Glycyrrhiza Glabra (Licorice) Root Extract | 0.5000 | 84775-66-6 | SKIN CONDITIONING AGENT | ICID |
| 18 | Dimethicone | 0.4000 | 9006-65-9 | SKIN CONDITIONING AGENT | ICID |
| 19 | PEG-100 Stearate | 0.2500 | 9004-99-3 | SURFACTANT | ICID |
| 20 | Panthenol | 0.2000 | 16485-10-2 | HAIR CONDITIONING AGENT | ICID |
| 21 | Chlorphenesin | 0.2000 | 104-29-0 | COSMETIC BIOCID | ICID |
| 22 | Illicium Verum(Anise) Fruit Extract | 0.1000 | CTFA ID: 16112 | SKIN CONDITIONING AGENT | ICID |
| 23 | Citrus Paradisi(Grapefruit) Fruit Extract | 0.1000 | CTFA ID: 9756 | SKIN CONDITIONING AGENT | ICID |
| 24 | Nelumbium Speciosum Flower Extract | 0.1000 | CTFA ID: 8893 | SKIN CONDITIONING AGENT | ICID |
| 25 | Paeonia Suffruticosa Root Extract | 0.1000 | CTFA ID: 9852 | SKIN CONDITIONING AGENT | ICID |
| 26 | Scutellaria Baicalensis Root Extract | 0.1000 | 94279-99-9 | SKIN CONDITIONING AGENT | ICID |
| 27 | Tocopheryl Acetate | 0.1000 | 58-95-7 | SKIN CONDITIONING AGENT | ICID |
| 28 | Carbomer | 0.1000 | 9003-01-4 | VISCOSITY INCREASING AGENT | ICID |
| 29 | Triethanolamine | 0.1000 | 102-71-6 | pH ADJUSTER | ICID |
| 30 | Citric Acid | 0.1000 | 77-92-9 | CHELATING AGENT | ICID |
| 31 | Althaea Rosea Flower Extract | 0.0500 | CTFA ID: 11299 | SKIN CONDITIONING AGENT | ICID |
| 32 | Aloe Barbadensis Leaf Extract | 0.0500 | 85507-69-3 | SKIN CONDITIONING AGENT | ICID |
| 33 | Allantoin | 0.0500 | 97-59-6 | SKIN CONDITIONING AGENT | ICID |
| 34 | Fragrance | 0.0400 | - | FRAGRANCE INGREDIENT | - |
| 35 | Ceramide 3 | 0.0250125 | 100403-19-8 | SKIN CONDITIONING AGENT | ICID |
| 36 | Bees wax | 0.0200 | 8012-89-3 | SKIN CONDITIONING AGENT | ICID |
| 37 | Disodium EDTA | 0.0200 | 139-33-3 | CHELATING AGENT | ICID |
| 38 | Portulaca Oleracea Extract | 0.0200 | 90083-07-1 | SKIN CONDITIONING AGENT | ICID |
| 39 | Lysine HCL | 0.0100 | 657-27-2 | SKIN CONDITIONING AGENT | ICID |
| 40 | Proline | 0.0100 | 147-85-3 | SKIN CONDITIONING AGENT | ICID |
| 41 | Sodium Ascorbyl Phosphate | 0.0100 | 66170-10-3 | ANTIOXIDANT | ICID |
| 42 | Acetyl Methionine | 0.0100 | 65-82-7 | SKIN CONDITIONING AGENT | ICID |
| 43 | Theanine | 0.0100 | 3081-61-6 | SKIN CONDITIONING AGENT | ICID |
| 44 | Vitis Vinifera(Grape) Callus Culture Extract | 0.0100 | CTFA ID:24315 | SKIN CONDITIONING AGENT | ICID |
| 45 | Nelumbo Nucifera Callus Culture Extract | 0.0100 | CTFA ID:24925 | SKIN CONDITIONING AGENT | ICID |
| 46 | Panax Ginseng Callus Culture Extract | 0.0100 | CTFA ID:9284 | SKIN CONDITIONING AGENT | ICID |
| 47 | Camellia Sinensis Callus Culture Extract | 0.0100 | CTFA ID:23950 | SKIN CONDITIONING AGENT | ICID |
| 48 | RH-Oligopeptide-1 | 0.0001 | 62253-63-8 | SKIN CONDITIONING AGENT | ICID |
| 49 | Hydrolyzed Pea Protein | 0.0000125 | 73049-73-7 | SKIN CONDITIONING AGENT | ICID |
| 50 | Lecithin | 0.0000125 | 8002-43-5 | SKIN CONDITIONING AGENT | ICID |
| 51 | Olea Europaea (Olive) Fruit Oil | 0.0000125 | 8001-25-0 | SKIN CONDITIONING AGENT | ICID |
| 52 | Phytosterols | 0.0000125 | CTFA ID: 15350 | SKIN CONDITIONING AGENT | ICID |
| 53 | Squalane | 0.0000125 | 111-01-3 | SKIN CONDITIONING AGENT | ICID |
| 54 | Butyrospermum Parkii (Shea Butter) | 0.0000125 | 68920-03-6 | SKIN CONDITIONING AGENT | ICID |
| 55 | Propanediol | 0.0000125 | 504-63-2 | SOLVENT | 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 AQUA RICH

dimethicone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70353-0001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 0.4 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|----------|
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70353-0001-1 | 50 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(70353-0001) |

Revised: 12/2015

And Us Co., Ltd