

COCOA BUTTER - petrolatum lotion
GREENBRIER INTERNATIONAL

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 |
|-------------------|-----------------|
| Petrolatum 5% | Skin Protectant |

Skin Protectant

Keep out of reach of children

Use daily, do not use around eye area

For external use only, Do not use around the eye area. Stop use and ask a doctor if redness or irritation develop and persist for more than 7 days

apply as needed

water, mineral oil, cetyl alcohol, glyceryl stearate, glycerin, dimethicone, propylene glycol, methylparaben, propylparaben, DMDM hydantoin, ammonium polyacrylate, steareth-30, tocopheryl acetate, cocoa butter, shea butter extract, fragrance, blue 1, red 33, yellow 5, yellow 6



COCOA BUTTER

petrolatum lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:33992-1108 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| petrolatum (UNII: 4T6H12BN9U) (petrolatum - UNII:4T6H12BN9U) | petrolatum | 5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| water (UNII: 059QF0KO0R) | |
| mineral oil (UNII: T5L8T28FGP) | |
| cetyl alcohol (UNII: 936JST6JCN) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| glycerin (UNII: PDC6A3C0OX) | |
| dimethicone (UNII: 92RU3N3Y1O) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| methylparaben (UNII: A28C7H9T) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| steareth-30 (UNII: 5776GCL1DG) | |
| cocoa butter (UNII: 512OYT1CRR) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:33992-1108-1 | 396.9 g in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 08/02/2011 | |

Labeler - GREENBRIER INTERNATIONAL (610322518)

Registrant - NINGBO PULISI DAILY CHEMICAL PRODUCTS CO., LTD. (529047265)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|---------------------|
| NINGBO PULISI DAILY CHEMICAL PRODUCTS CO., LTD. | | 529047265 | manufacture |

Revised: 8/2011

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