

P.O.V. BABY MOISTURIZING FRAGRANCE FREE- dimethicone lotion**Apollo Health and Beauty Care 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.

Drug Facts**Active ingredient**

Dimethicone 1.2%

Purpose

Skin Protectant

Uses

temporarily protects and helps relieve chapped or cracked skin, and helps protect from the drying effects of wind and cold.

Warnings

For external use only.

When using this product

avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if

condition worsens, or if irritation or redness develops and lasts more than 7 days, or clears up and recurs within a few days.

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

apply as needed.

Other information

store at room temperature.

Inactive ingredients

Water (Aqua), Glycerin, Petrolatum, Isopropyl Palmitate, Distearyltrimonium Chloride, Cetyl Alcohol, Avena Sativa (Oat) Kernel Flour, Sodium Chloride, Sodium Hydroxide, Ethylhexylglycerin, Phenoxyethanol.

Questions or comments?

1-866-695-3030

Label Copy



BABY
MOISTURIZING
LOTION
FRAGRANCE FREE

- CONTAINS NATURAL COLLOIDAL OATMEAL
- DIMETHICONE SKIN PROTECTANT
- HYPOALLERGENIC

18 FL OZ
(532 mL)

06-22863



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MOISTURIZING
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FRAGRANCE FREE

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Questions or comments? 1-866-695-3030	

MADE IN CANADA

Distributed by:
Apollo Health & Beauty Care Inc.
1 Apollo Place, Toronto, ON M3J 0H2



0 67153 94908 2 06-22864

P.O.V. BABY MOISTURIZING FRAGRANCE FREE

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-319
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	12 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
PETROLATUM (UNII: 4T6H12BN9U)				
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)				
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
OATMEAL (UNII: 8PI54V663Y)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-319-18	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/24/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part347	11/24/2017	

Labeler - Apollo Health and Beauty Care Inc. (201901209)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-319)

Revised: 11/2017

Apollo Health and Beauty Care Inc.