

BABY FACE AND BODY CREAMY - dimethicone lotion
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, glycerin, 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

MANUFACTURING CERTIFICATE

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FORMULA INGREDIENTS STATEMENT

Date: 11th. Nov. 2015.

BRAND NAME : Pororo

PRODUCT NAME : Baby Face and Body Creamy Lotion

Material contained in 100 grams

INGREDIENT NAME	%(w/w)	CAS No.	REFERENCE	FUNCTION
Water	65.500000%	7732-18-5	ICID	Solvent
Hydrogenated Polydecene	5.000000%	68037-01-4	ICID	Emollient
Butylene Glycol	4.000000%	107-88-0	ICID	Humectant
Glycerin	4.000000%	56-81-5	ICID	Humectant
Macadamia Ternifolia Seed Oil	3.000000%	128497-20-1	ICID	Emollient
Cetearyl Olivat	3.000000%	348616-34-2	ICID	Emulsifying Agent
Sorbitan Olivat	3.000000%	223706-40-9	ICID	Emulsifying Agent
Hydrogenated Polyisobutene	2.000000%	68937-10-0	ICID	Emollient
Butyrospermum Parkii (Shea) Butter	2.000000%	194043-92-0	ICID	Emollient
Helianthus Annuus (Sunflower) Seed Oil	1.500000%	8001-21-6	ICID	Emollient
Glyceryl Stearate	1.500000%	123-94-4	ICID	Emulsifying Agent
PEG-100 Stearate	1.500000%	9004-99-3	ICID	Emulsifying Agent
Cetyl Alcohol	1.200000%	36653-82-4	ICID	Emulsifying Agent
Portulaca Oleracea Extract	1.000000%	90083-07-1	ICID	Additive
Dimethicone	0.500000%	63148-62-9	ICID	Antifoaming Agent
Phenoxyethanol	0.400000%	122-99-6	ICID	Preservative
Chlorphenesin	0.250000%	104-29-0	ICID	Preservative
Carbomer	0.250000%	9003-01-4	ICID	Viscosity Increasing Agent
Donkey Milk	0.100000%	INCI Monograph ID: 18909	ICID	Additive
Potassium Hydroxide	0.100000%	1310-58-3	ICID	pH Adjuster
Perfume	0.100000%	-	Appendix	Fragrance
Disodium EDTA	0.050000%	139-33-3	ICID	Chelating Agent
Hydrogenated Lecithin	0.010000%	92128-87-5	ICID	Additive
Linoleic Acid	0.010000%	60-33-3	ICID	Additive
Ceramide 3	0.010000%	100403-19-8	ICID	Additive
Caprylic/Capric Triglyceride	0.010000%	68187-29-1	ICID	Additive
Camellia Japonica Seed Oil	0.010000%	INCI Monograph ID: 11695	ICID	Additive
	100.000000%			

APPROVED By Jong Wan, Choi
 Research Director

J. W. Choi

HANKOOK COSMETICS MANUFACTURING CO., LTD

BABY FACE AND BODY CREAMY

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70353-0008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70353-0008-1	350 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(70353-0008)