

BABY CREAMY SUN PROTECTOR 100 - 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, 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 Creamy Sun Protector 100

Material contained in 100 grams

INGREDIENT NAME	%(w/w)	CAS No.	REFERENCE	FUNCTION
Cyclopentasiloxane	25.000000%	541-02-6	ICID	Emollient
Water	24.050000%	7732-18-5	ICID	Solvent
Zinc Oxide	16.500000%	1314-13-2	ICID	Sunscreen Agent
Titanium Dioxide	6.450000%	13463-67-7	ICID	Sunscreen Agent
PEG-10 Dimethicone	5.000000%	68937-54-2	ICID	Emollient
Dipropylene Glycol	4.000000%	110-98-5	ICID	Emollient
Glycerin	3.500000%	56-81-5	ICID	Humectant
Butyloctyl Salicylate	3.000000%	190085-41-7	ICID	Emollient
Dimethicone	3.000000%	63148-62-9	ICID	Emollient
Stearic acid	1.500000%	57-11-4	ICID	Emulsifying Agent
Alumina	1.500000%	21645-51-2	ICID	Bulking Agent
Cetyl PEG/PPG-10/1 Dimethicone	1.000000%	144243-53-8	ICID	Emulsifying Agent
Sodium Chloride	1.000000%	7647-14-5	ICID	Viscosity Increasing Agent
Dimethicone/Vinyl Dimethicone Crosspolymer	1.000000%	243137-53-3	ICID	Viscosity Increasing Agent
Hydrogen Dimethicone	1.000000%	68037-59-2	ICID	Emollient
Polymethyl Methacrylate	0.500000%	9011-14-7	0	Film Former
Chlorphenesin	0.250000%	104-29-0	ICID	Preservative
Caprylyl Glycol	0.250000%	1117-86-8	ICID	Preservative
Perfume	0.200000%	1900-01-00	Appendix	Fragrance
Disteardimonium Hectorite	0.100000%	94891-31-3	ICID	Viscosity Increasing Agent
Butylene glycol	0.100000%	107-88-0	ICID	Humectant
Amica Montana Flower Extract	0.100000%	68990-11-4	ICID	Additive
Gentiana Lutea Root Extract	0.100000%	84775-45-1	ICID	Additive
Achillea Millefolium Extract	0.100000%	84082-83-7	ICID	Additive
Artemisia Vulgaris Extract	0.100000%	72968-42-4	ICID	Additive
Centella Asiatica Leaf Extract	0.100000%	84696-21-9	ICID	Additive
Lavandula Angustifolia (Lavender) Extract	0.100000%	90063-37-9	ICID	Additive
Monarda Didyma Leaf Extract	0.100000%	INCI Monograph ID: 7899	ICID	Additive
Mentha Piperita (Peppermint) Leaf Extract	0.100000%	84082-70-2	ICID	Additive
Freesia Refracta Extract	0.100000%	INCI Monograph ID: 10225	ICID	Additive
Chamomilla Recutita (Matricaria) Flower Extract	0.100000%	84082-60-0	ICID	Additive
Rosmarinus Officinalis (Rosemary) Leaf Extract	0.100000%	84604-14-8	ICID	Additive

100.000000%

APPROVED By Jong Wan, Choi
 Research Director

J. W. Choi

HANKOOK COSMETICS MANUFACTURING CO., LTD

BABY CREAMY SUN PROTECTOR 100

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70353-0007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	3 g in 100 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70353-0007-1	50 g in 1 TUBE; 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(70353-0007)

Revised: 12/2015

And Us Co., Ltd