

**PURPLEU BAOBAB AND ROSE DEEP HYDRATION CREAM THERAPY-
dimethicone cream**

Purple U 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.

90069-201

Active Ingredients

Dimethicone 0.3%

Purpose

Skin Protectant

Uses

Helps protectant the skin from outside environment

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes

Rinse with water to remove

Warnings

Stop use and ask a doctor if rash occurs

Warnings

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Use at any desired time. Scoop the desired amount of the luxurious hydration cream with the spatula that is provided with the cream. Then apply in an upward and outward motion to the face and it also can be applied on the neck and body.

Inactive ingredients

Water, Adansonia Digitata Fruit Extract, Glycerin, Butylene Glycol, Octyldodecanol, Cyclopentasiloxane, Glyceryl Stearate, Pentylene Glycol, Phenyl Trimethicone, Cetearyl Alcohol, Cetyl Alcohol, Cyclohexasiloxane, 1,2-Hexanediol, Butyrospermum Parkii (Shea) Butter, Hydrogenated Vegetable Oil, Rosa Damascena Flower Water, Copernicia Cerifera (Carnauba) Wax, Eclipta Prostrata Extract, Melia Azadirachta Leaf Extract, Melia Azadirachta Flower Extract, Adansonia Digitata Seed Oil, Camellia Japonica Seed Oil, Camellia Oleifera Seed Oil, Helianthus Annuus

(Sunflower) Seed Oil, Curcuma Longa(Turmeric) Root Extract, Ocimum Sanctum Leaf Extract, Pelargonium Graveolens Flower Oil, Corallina Officinalis Extract, Moringa Oleifera Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Ficus Carica (Fig) Fruit Extract, Ginkgo Biloba Nut Extract, Morus Alba Fruit Extract, Punica Granatum Fruit Extract, Hamamelis Virginiana (Witch Hazel) Extract, Hyaluronic Acid, Hydrolyzed Hyaluronic Acid, Sodium Hyaluronate, Diisostearyl Malate, Dipentaerythryl Hexahydroxystearate/Hexastearate/ Hexarosinate, PEG-20 Methyl Glucose Sesquistearate, PEG/PPG-17/6 Copolymer, PEG-100 Stearate, Bis-Diglyceryl Polyacyladipate-2, Panthenol, Hydroxyacetophenone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tromethamine, Sodium Polyacrylate Starch, Dimethicone/ Vinyl Dimethicone Crosspolymer, Ethylhexylglycerin, Disodium EDTA, Phenoxyethanol, Fragrance(Parfum), Citronellol, Hexyl Cinnamal, Geraniol, Butylphenyl Methylpropional, Farnesol, Benzyl Benzoate, Amylcinnamyl Alcohol, Linalool

Package Label

Drug Facts	
Active Ingredients	Purpose
Dimethicone 0.3%.....	Skin Protectant
Uses ■ Helps protectant the skin from outside environment	
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Distributed by	PurpleU International, LLC 2822 South Redwood Road West Valley City, UT 84119 Questions or comments? Contact us at: (385) 259-0263 or cs@purpleu.com
	Made in Korea www.purpleu.com

PURPLEU BAOBAB AND ROSE DEEP HYDRATION CREAM THERAPY

dimethicone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90069-201
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.3 g in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength

CAMELLIA JAPONICA SEED OIL (UNII: U37N0S910T)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	
PEG-20 METHYL GLUCOSE SESQUISTEARATE (UNII: 0345752X7U)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
PANTHENOL (UNII: WV9CM0067Z)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
FARNESOL (UNII: EB41QIU6JL)	
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)	
ADANSONIA DIGITATA SEED OIL (UNII: 77MKL7AR5I)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
HOLY BASIL LEAF (UNII: SCJ765569P)	
GINKGO BILOBA SEED (UNII: 8CQ734K3W7)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
PEG/PPG-17/6 COPOLYMER (UNII: P5QZM4T259)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C00X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAMELLIA OIL (UNII: T1PE06G0VE)	
TURMERIC (UNII: 856YO1Z64F)	
ROSEMARY (UNII: IJ67X351P9)	
WHITE MULBERRY (UNII: MN25R0HH5A)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
HYALURONIC ACID (UNII: S270N0TRQY)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
DIPENTAERYTHRITYL HEXASTEARATE (UNII: WTF09990PK)	
ADANSONIA DIGITATA FRUIT (UNII: 51N9TR1W6P)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
OCTYLDODECANOL (UNII: 461N10614Y)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SHEA BUTTER (UNII: K49155WL9Y)	
ECLIPTA PROSTRATA LEAF (UNII: H86R96580E)	
.ALPHA.-AMYL CINNAMYL ALCOHOL (UNII: DKB52S61GU)	
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
MORINGA OLEIFERA SEED OIL (UNII: REM6A5QMC0)	
FIG (UNII: TGD87RII2U)	
POMEGRANATE (UNII: 56687D1Z4D)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

TROMETHAMINE (UNII: 023C2WHX2V)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
GERANIOL (UNII: L837108USY)	
BENZYL BENZOATE (UNII: N863NB338G)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90069-201-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/02/2020	

Labeler - Purple U Co., Ltd (694823532)

Registrant - RECIPE CO., LTD (631158768)

Establishment

Name	Address	ID/FEI	Business Operations
RECIPE CO., LTD		631158768	manufacture(90069-201)

Revised: 9/2020

Purple U Co., Ltd