

JAFRA FRUTERIA COCO FRESCO LIP BALM- dimethicone gel
Jafra Cosmetics International, 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.

Active Ingredient

Dimethicone 1%

Purpose

Skin protectant

Uses

- Helps prevent and temporarily protects and helps relieve chapped or cracked lips
- Helps prevent and protect from the drying effects of wind and cold weather

Warnings

For external use only

When using this product ● do not get into eyes

Stop use and ask a doctor if ● condition worsens ● symptoms last more than 7 days or clear up and occur again in a few days

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

Directions

- apply as needed

Inactive Ingredients

Polybutene, Bis-Diglyceryl Polyacyladipate-2, Sesamum Indicum (Sesame) Seed Oil, Butyrospermum Parkii (Shea) Butter, Prunus Armeniaca (Apricot) Kernel Oil, Ozokerite, Garcinia Indica Seed Butter, Persea Gratissima (Avocado) Oil, Flavor/Aroma, Silica Dimethyl Silylate, Oleic / Linoleic / Linolenic Polyglycerides, Dimethicone, Pouteria Sapota Seed Oil, Tocopheryl Acetate, Benzyl Alcohol, Limonene.

Product label

Drug Facts

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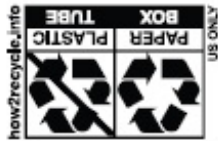
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Made in Mexico for JAFRA Cosmetics International, Inc.
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 JAFRA es Marca Registrada
 LOS ANGELES - ZURICH - MUNICH
 MEXICO CITY - JAKARTA

COCO FRESCO
 lip balm
 bálsamo para labios
 15 ml e 0.5 FL OZ (US)



Made with love & superfoods
 Hecho con amor y superfoods

JAFRA FRUTERIA COCO FRESCO LIP BALM

dimethicone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
SESAME OIL (UNII: QX10HYY4QV)	
SHEA BUTTER (UNII: K49155WL9Y)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
CERESIN (UNII: Q1LS2UJO3A)	
GARCINIA INDICA SEED BUTTER (UNII: US2H3D7800)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-010-01	1 in 1 CARTON	06/01/2023	
1		15 mL 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	06/01/2023	

Labeler - Jafra Cosmetics International, Inc. (041676479)**Establishment**

Name	Address	ID/FEI	Business Operations
Distribuidora Comercial Jafra, S.A. de C.V.		951612777	manufacture(68828-010)

Revised: 4/2023

Jafra Cosmetics International, Inc.