CONTROL DYNAMICS KIT JAFRA- control dynamics tester
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.

Control Dynamics Kit

Active Ingredients Purpose

Avobenzone 2.75% Sunscreen

Octisalate 5% Sunscreen

Octocrylene 7.5% Sunscreen

Oxybenzone 2% Sunscreen

Uses
· helps prevent sunburn
· If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

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

Stop use and ask a doctor if rash occurs

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.

Directions
· Apply liberally 15 minutes before sun exposure
· Reapply at least every 2 hours
· Use a water resistant sunscreen if swimming or sweating
· Children under 6 months: Ask a doctor

· Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including:
· limit time in the sun, especially from 10 a.m. - 2 p.m.
· wear long-sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

Water/Aqua, Aluminum Starch Octenlsuccinate, Sodium Polyacrylate, Hydrogenated Polydecene, Trideceth-6, Phenoxyethanol, Hexylene Glycol, Caprylyl Glycol, Potassium Sorbate, Saccharide Isomerate, Decamethylcyclopentasiloxane, Azadirachta Indica Extract, Tagetus Erecta (African Marigold) Extract, Ipomoea Digitata (Fingerleaf Morning Glory) Extract, Butylene Glycol, Panthenol, Chondrus Crispus (carageenan) Extract, Biosaccharide Gum-4, Lysine Thiazolidine Carboxylate, DMDM Hydantoin, Tocopheryl Acetate, Trisodium EDTA, Malic Acid, Hydrolyzed Prunus Amygdalus Dulcis (Sweet Almond) Protein, Butyl Avocadate, Fragrance/Parfum, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Polysorbate 20, Ethoxylated Castor Oil, Blue 1/CI42090, Yellow 5/CI 19140, Pentylene Glycol, Hydroxyphenyl Propamidobenzoic Acid,Zingiber Officinale (Ginger) Extract, Bisabolol.

MATTIFYING LOTION BROAD SPECTRUM SPF 15

Drug Facts

Active ingredients	Purpose
Avobenzone 2.75%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7.5%	Sunscreen
Oxybenzone 2%	Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

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

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. - 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses

Drug Facts (continued)

Inactive ingredients

Water/Aqua, Aluminum Starch Octenylsuccinate, Sodium Polyacrylate, Hydrogenated Polydecene, Trideceth-6, Phenoxyethanol, Hexylene Glycol, Caprylyl Glycol, Potassium Sorbate, Saccharide Isomerate, Decamethylcyclopentasiloxane, Azadirachta Indica Extract, Tagetus Erecta (African Marigold) Extract, Ipomoea Digitata (Fingerleaf Morning Glory) Extract, Butylene Glycol, Panthenol, Chondrus Crispus (Carrageenan) Extract, Biosaccharide Gum-4, Lysine Carboxymethyl Cysteinate, LysineThiazolidine Carboxylate, DMDM Hydantoin, Tocopheryl Acetate, Trisodium EDTA, Malic Acid, Hydrolyzed Prunus Amygdalus Dulcis (Sweet Almond) Protein, Butyl Avocadate, Fragrance/Parfum, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Polysorbate 20, Ethoxylated Castor Oil, Blue 1/CI 42090, Yellow 5/CI 19140,Pentylene Glycol, Hydroxyphenyl Propamidobenzoic Acid, Zingiber Officinale (Ginger) Extract, Bisabolol

Other information

- protect this product from excessive heat and direct sun

Tester - not for resale / Muestra solamente. No etiquetado para su venta individual.
Tester - nicht zum Wiederverkauf bestimmt / Tester - vietata la vendita

JAFRA

Founded by Jan and Frank Day
SINCE 1956

Made in Mexico for: JAFRA Cosmetics International, Inc.
Westlake Village, CA 91361
Distributed in EU: JAFRA Cosmetics D-80636 Munich
www.JAFRA.com

Hecho en México para:
Distribuidora Comercial JAFRA, S.A. de C.V.
Blvd. Adolfo López Mateos 515, Col. Tlacopac,
México, D. F., 01040. JAFRA es Marca Registrada

LOS ANGELES - ZURICH - MUNICH
MEXICO CITY - MILAN - MOSCOW

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OIL CONTROL GEL CLEANSER

OIL CONTROL PURIFYING TONER

JAFRA

CONTROL
DYNAMICS

TESTER

Contains: 4 Samples

1 OIL CONTROL GEL CLEANSER / 1 OIL CONTROL PURIFYING TONER
1 MATTIFYING LOTION BROAD SPECTRUM SPF 15 / 1 BALANCING NIGHT CREAM

CONT. NET. 55 ml ℮ 1.85 FL OZ (US)

BALANCING NIGHT CREAM

Jafra

Control Dynamics

Tester

Contains 4 samples

1 Oil Control Gel Cleanser/1 Oil Control Purifying Toner/1 Mattifying Lotion Broad Spectrum SPF 15/1 Balancing Night Cream

Cont. Net. 55 ml 1,85 Fl Oz (US)

CONTROL DYNAMICS KIT JAFRA

control dynamics tester kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68828-121

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-121-01	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	14 TUBE	100 mL
Part 2	7 TUBE	7.4 mL
Part 3	7 BOTTLE	7.4 mL
Part 4	7 TUBE	7.4 mL

Part 1 of 4

MATTIFYING BROAD SPECTRUM SPF 15 JAFRA

avbobenzone, octisalate, octovrylene, oxybenzone lotion

Product Information

Item Code (Source)	NDC:68828-122		
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.75 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PANTHENOL (UNII: WV9CM0O67Z)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
LYSINE THIAZOLIDINE CARBOXYLATE (UNII: WUG63M652E)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
MALIC ACID (UNII: 817L1N4CKP)	
TEA TREE OIL (UNII: VIF565UC2G)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDROXYPHENYL PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)	
GINGER (UNII: C5529G5JPQ)	
LEVOMENOL (UNII: 24WE03BX2T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-122-01	7.4 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/22/2013	

Part 2 of 4

OIL CONTROL CLEANSER JAFRA

face and neck (excluding shaving preparations)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**SODIUM LAURETH SULFATE** (UNII: BPV390UAP0)	
INGR	**COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX)	
INGR	**DISODIUM LAURETH SULFOSUCCINATE** (UNII: D6DH1DTN7E)	
INGR	**PEG-150 PENTAERYTHRITYL TETRASTEARATE** (UNII: 8L4OOQ76AM)	
INGR	**DECYL GLUCOSIDE** (UNII: Z17H97EA6Y)	
INGR	**PEG-7 GLYCERYL COCOATE** (UNII: VNX7251543)	
INGR	**CALENDULA OFFICINALIS FLOWER** (UNII: P0M7O4Y7YD)	
INGR	**BUTYLENE GLYCOL** (UNII: 3XUS85K0RA)	
INGR	**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)	
INGR	**DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4)	
INGR	**IODOPROPYNYL BUTYLCARBAMATE** (UNII: 603P14DHEB)	
INGR	**SALICYLIC ACID** (UNII: O414PZ4LPZ)	
INGR	**DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B)	
INGR	**ARGININE** (UNII: 94ZLA3W45F)	
INGR	**POLYSORBATE 20** (UNII: 7T1F30V5YH)	
INGR	**PANTHENOL** (UNII: WV9CM0O67Z)	
INGR	**ALLANTOIN** (UNII: 344S277G0Z)	
INGR	**SODIUM CHLORIDE** (UNII: 451W47IQ8X)	
INGR	**EDETATE SODIUM** (UNII: MP1J8420LU)	
INGR	**CARBOCYSTEINE LYSINE** (UNII: 1D1Y95PXXA)	
INGR	**LYSINE THIAZOLIDINE CARBOXYLATE** (UNII: WUG63M652E)	
INGR	**TEA TREE OIL** (UNII: VIF565UC2G)	
INGR	**POLYSORBATE 20** (UNII: 7T1F30V5YH)	
INGR	**D&C GREEN NO. 5** (UNII: 8J6RDU8L9X)	
INGR	**PENTYLENE GLYCOL** (UNII: 50C1307PZG)	
INGR	**HYDROXYPHENYL PROPAMIDOBENZOIC ACID** (UNII: 25KRT26H77)	
INGR	**FD&C YELLOW NO. 5** (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/22/2013	

Part 3 of 4

OIL CONTROL PURIFYING TONER JAFRA

face and neck (excluding shaving preparations)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**POLYSORBATE 20** (UNII: 7T1F30V5YH)	
INGR	**SODIUM PYRROLIDONE CARBOXYLATE** (UNII: 469OTG57A2)	
INGR	**ARGININE** (UNII: 94ZLA3W45F)	
INGR	**SALICYLIC ACID** (UNII: O414PZ4LPZ)	
INGR	**CALENDULA OFFICINALIS FLOWER** (UNII: P0M7O4Y7YD)	
INGR	**BUTYLENE GLYCOL** (UNII: 3XUS85K0RA)	
INGR	**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)	
INGR	**DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4)	
INGR	**IODOPROPYNYL BUTYLCARBAMATE** (UNII: 603P14DHEB)	
INGR	**PANTHENOL** (UNII: WV9CM0O67Z)	
INGR	**ALLANTOIN** (UNII: 344S277G0Z)	
INGR	**PENTYLENE GLYCOL** (UNII: 50C1307PZG)	
INGR	**HYDROXYPHENYL PROPAMIDOBENZOIC ACID** (UNII: 25KRT26H77)	
INGR	**EDETATE TRISODIUM** (UNII: 420IP921MB)	
INGR	**CARBOCYSTEINE LYSINE** (UNII: 1D1Y95PXXA)	
INGR	**LYSINE THIAZOLIDINE CARBOXYLATE** (UNII: WUG63M652E)	
INGR	**MENTHOL** (UNII: L7T10EIP3A)	
INGR	**TEA TREE OIL** (UNII: VIF565UC2G)	
INGR	**DENATONIUM BENZOATE** (UNII: 4YK5Z54AT2)	
INGR	**D&C GREEN NO. 5** (UNII: 8J6RDU8L9X)	
INGR	**FD&C YELLOW NO. 5** (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/22/2013	

Part 4 of 4

BALANCING NIGHT CREAM JAFRA

face and neck (excluding shaving preparations)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**C12-15 ALKYL BENZOATE** (UNII: A9EJ3J61HQ)	
INGR	**PHYLLANTHUS EMBLICA FRUIT** (UNII: YLX4CW2576)	
INGR	**CENTELLA ASIATICA** (UNII: 7M867G6T1U)	
INGR	**BUTYLENE GLYCOL** (UNII: 3XUS85K0RA)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**SODIUM POLYACRYLATE (8000 MW)** (UNII: 285CYO341L)	
INGR	**XYLITOL** (UNII: VCQ006KQ1E)	
INGR	**XYLITAN** (UNII: 5KQL0CX6R6)	
INGR	**CYCLOMETHICONE 5** (UNII: 0THT5PCI0R)	
INGR	**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)	
INGR	**DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4)	
INGR	**IODOPROPYNYL BUTYLCARBAMATE** (UNII: 603P14DHEB)	
INGR	**BENZOPHENONE-9** (UNII: 7925W14T4L)	
INGR	**PANTHENOL** (UNII: WV9CM0O67Z)	
INGR	**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)	
INGR	**EDETATE TRISODIUM** (UNII: 420IP921MB)	
INGR	**MANGANESE CARBONATE** (UNII: 9ZV57512ZM)	
INGR	**HYDROXYPHENYL PROPAMIDOBENZOIC ACID** (UNII: 25KRT26H77)	
INGR	**GINGER** (UNII: C5529G5JPQ)	
INGR	**LEVOMENOL** (UNII: 24WE03BX2T)	
INGR	**FD&C BLUE NO. 1** (UNII: H3R47K3TBD)	
INGR	**D&C RED NO. 33** (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/22/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/22/2013	

Labeler - Jafra Cosmetics International Inc (041676479)

Registrant - Jafra Cosmetics International Inc (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-121, 68828-122)