

KOALA KUBS DIAPER RASH CREAM- diaper rash cream cream
Melaleuca, 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.

Koala Kubs Diaper Rash Cream

Active Ingredients

Active Ingredients

Zinc Oxide USP 15%

Purpose

Purpose

Skin Protectant

Uses

Uses

- Helps treat and prevent diaper rash
- Protects chaffed skin due to diaper rash and helps seal out wetness

When using this product

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- do not get into eyes

Stop use and ask doctor if

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- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

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- Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry
- Apply cream liberally and as often as necessary with each diaper change and

especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other Information

Other Information

- to open, twist off cap and remove quality seal
- do not use if quality seal is broken
- store at room temperature

Inactive Ingredients

Inactive Ingredients: water, decyl oleate, oleyl erucate, dicaprylyl ether, polyglyceryl-2 dipolyhydroxystearate, glycerin, polyglyceryl-3 diisostearate, magnesium stearate, sodium chloride, zinc stearate, benzyl alcohol, glycine soja (soybean) oil, sodium benzoate, ethylhexylglycerin, potassium sorbate, calendula officinalis (marigold) flower extract, tocopherol

Warnings

For external use only

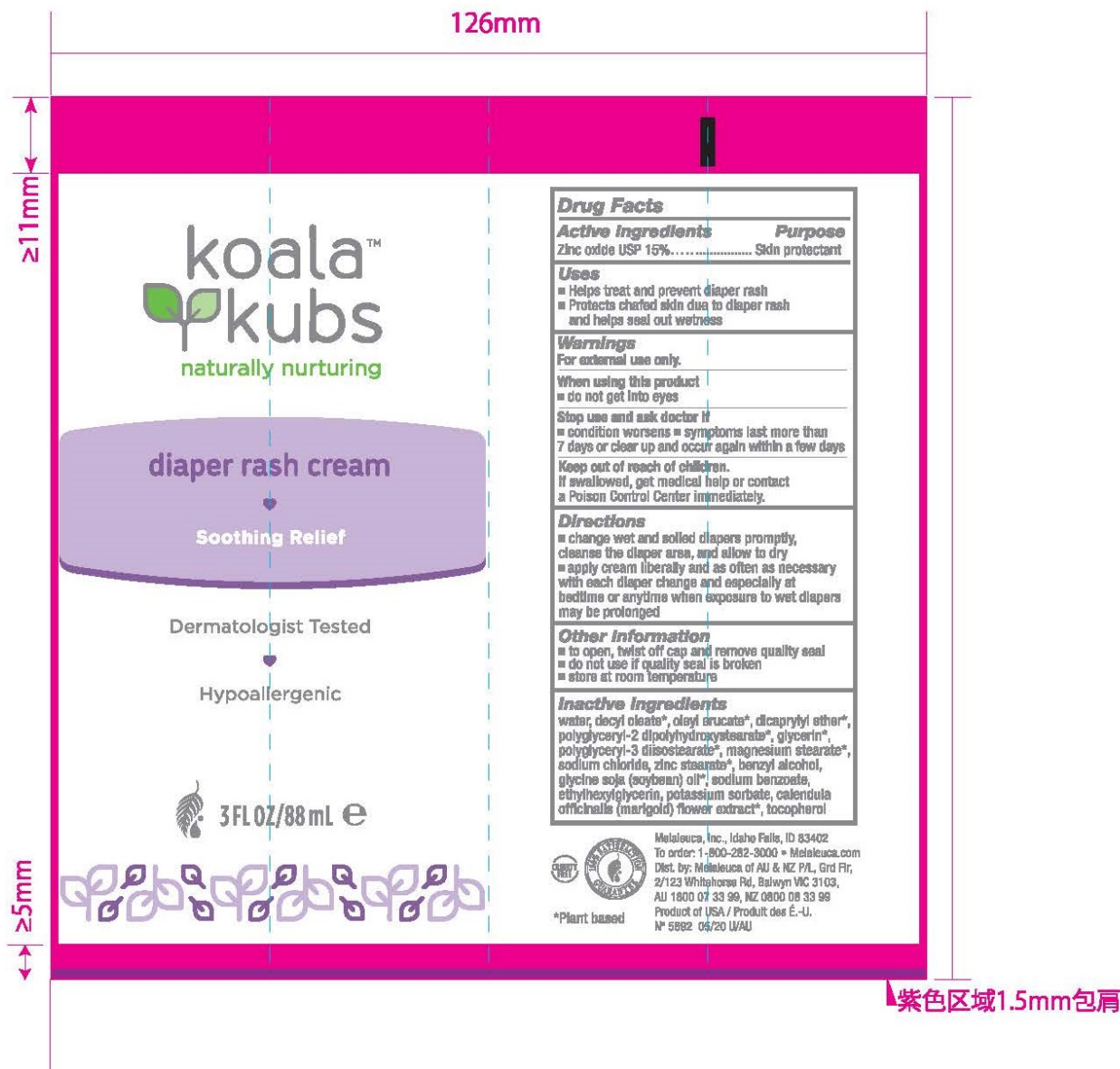
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Skin Protectant

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Label



KOALA KUBS DIAPER RASH CREAM

diaper rash cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-333
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	150 mg in 88 mL

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.154 mL in 88 mL

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1408 mL in 88 mL
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	0.011 mL in 88 mL
WATER (UNII: 059QF0KO0R)	44.4576 mL in 88 mL
DECYL OLEATE (UNII: ZGR06DO97T)	8.8 mL in 88 mL
TOCOPHEROL (UNII: R0ZB2556P8)	0.00132 mL in 88 mL
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	2.64 mL in 88 mL
SOYBEAN OIL (UNII: 241ATL177A)	0.42856 mL in 88 mL
ZINC STEARATE (UNII: H92E6QA4FV)	0.88 mL in 88 mL
OLEYL ERUCATE (UNII: 753W099NQ6)	4.4 mL in 88 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.2816 mL in 88 mL
GLYCERIN (UNII: PDC6A3C0OX)	2.64 mL in 88 mL
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	4.4 mL in 88 mL
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	1.76 mL in 88 mL
MAGNESIUM STEARATE (UNII: 70097M6I30)	1.76 mL in 88 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1.32 mL in 88 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.72512 mL in 88 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-333-03	88 mL in 1 TUBE; Type 0: Not a Combination Product	07/09/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/09/2021	

Labeler - Melaleuca, Inc. (139760102)

Registrant - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		079711683	manufacture(54473-333)

Revised: 1/2023

Melaleuca, Inc.