Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	291481	Zea Relief Kunzea Balm

ARTG entry for	Medicine Listed
Sponsor	Australian Kunzea Pty Ltd
Postal Address	209/87 Griffith Street, Coolangatta, QLD, 4225 Australia
ARTG Start Date	13/07/2017
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Preparations that contain, as their therapeutically active ingredient, Kunzea ambigua in topical products only, are subject to the following conditions: (i) Must include the label warning (EXTERN) - For external use only; and (ii) Must include the label warning (CHILD) - Keep out of reach of children (or words to that effect).

Products

1 . Zea Relief Kunzea Balm

Product Type	Single Medicine Product	**Effective Date**	4/03/2021

Permitted Indications

Decrease/reduce/relieve skin dryness

Soothe skin

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Jar/Can	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Cream
Route of Administration	Topical

Visual Identification

Active Ingredients	
Evening Primrose Oil	**75 mg/g**
Kunzea ambigua herb Oil essential	**50 mg/g**
Rose Oil	**10 mg/g**

Other Ingredients (Excipients)
Grape seed oil
jojoba esters
Olive Oil
white beeswax

Public Summary