



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	354463	WELEDA RASH RELIEF CREAM
ARTG entry for	Medicine Listed	
Sponsor	Weleda Australia Pty Ltd	
Postal Address	Unit 16 / 2 Daydream Street, Warriewood, NSW, 2102 Australia	
ARTG Start Date	8/02/2021	
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.

Products

1 . WELEDA RASH RELIEF CREAM

Product Type	Single Medicine Product	Effective Date	18/02/2021
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Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve itchy/prickling skin associated with mild eczema/dermatitis
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis
- Traditionally used in Western herbal medicine to soothe skin
- Traditionally used in Western herbal medicine to decrease/reduce/relieve skin chafing
- Traditionally used in Western herbal medicine to soothes/relieves heat rash
- Traditionally used in Western herbal medicine to soothe/relieve skin inflammation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve skin irritation
- Traditionally used in Western herbal medicine to antipruritic/Relieves itchy skin
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of nappy rash
- Traditionally used in Western herbal medicine to decrease/reduce/relieve prickly heat skin rash
- Traditionally used in Western herbal medicine to decrease/reduce/relieve skin redness

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 Product presentation must only refer to mild eczema.

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
Tube	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Page 1 of 2

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Cream

Route of Administration Topical

Visual Identification

Active Ingredients

Aloe vera leaf inner juice Dry	1 mg/g
Equivalent: Aloe vera (Fresh)	200 mg/g
Arnica montana flower Extract liquid	51.5 mg/g
Equivalent: Arnica montana (Dry)	4.4 mg/g
Arnica montana flower Infusion	6.1 mg/g
Equivalent: Arnica montana (Dry)	300 microgram/g
Calendula officinalis flower Extract liquid	180.5 mg/g
Equivalent: Calendula officinalis (Dry)	15.3 mg/g
Calendula officinalis flower Infusion	121.8 mg/g
Equivalent: Calendula officinalis (Dry)	6.09 mg/g
Echinacea purpurea whole plant Tincture	35 mg/g
Equivalent: Echinacea purpurea (Fresh)	11.7 mg/g
Hamamelis Water	10 mg/g
Hypericum perforatum flower Extract liquid	50 mg/g
Equivalent: Hypericum perforatum (Fresh)	10 mg/g
Lavender Oil	4.8 mg/g
Matricaria chamomilla flower Extract liquid	103.2 mg/g
Equivalent: Matricaria chamomilla (Dry)	8.8 mg/g
Orange Oil	1.5 mg/g
Peru Balsam Oil	3 mg/g
Petitgrain Oil Paraguay	500 microgram/g
Rosemary Oil	1 mg/g
Rosmarinus officinalis leaf Extract liquid	103.2 mg/g
Equivalent: Rosmarinus officinalis (Dry)	8.8 mg/g
Sage Oil Spanish	500 microgram/g
Urtica urens herb Infusion	115.7 mg/g
Equivalent: Urtica urens (Dry)	5.785 mg/g
Ylang Ylang Oil	1.7 mg/g
zinc oxide	100 mg/g

Other Ingredients (Excipients)

glycerol

self-emulsifying glyceryl monostearate

sodium alginate

yellow beeswax

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