



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	354463	WELEDA RASH RELIEF CREAM
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Weleda Australia Pty Ltd	
<b>Postal Address</b>	Unit 16 / 2 Daydream Street, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	8/02/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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**

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Pack Size

Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Cream

**Route of Administration** Topical

**Visual Identification**

**Active Ingredients**

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

**Other Ingredients (Excipients)**

glycerol

self-emulsifying glyceryl monostearate

sodium alginate

yellow beeswax

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