



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	341817	Organic De-Stuff Rub
ARTG entry for	Medicine Listed	
Sponsor	Phytomed Australia Pty Ltd	
Postal Address	GPO Box 4467, SYDNEY, NSW, 2001 Australia	
ARTG Start Date	19/08/2020	
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 . Organic De-Stuff Rub

Product Type	Single Medicine Product	Effective Date	14/02/2024
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Permitted Indications

Traditionally used in Aromatherapy to decongestant/relieve nasal congestion

Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of common cold

Indication Requirements

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

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Ointment
Route of Administration	Topical

Visual Identification

Active Ingredients

Eucalyptus Oil	45.7 mg/g
Lavender Oil	110 microgram/g

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Peppermint Oil	63.28 mg/g
Pine Needle Oil Scotch	25.77 mg/g
Rosemary Oil	112.25 microgram/g
Thyme Oil	9.16 mg/g

Other Ingredients (Excipients)

Coconut Oil
Olive Oil
yellow beeswax

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