Australian Government

Department of Health

Therapeutic Goods Administration

Record Summary 301489 98 Alive Respiratory Health

Sponsor	98 Alive Pty Ltd
Therapeutic Type	Medicine
Product Category	Listed
ARTG Start date	2/04/2018 11:00:00 PM
Postal Address	[redacted]
Billing Address	

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 he records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other han those accepted in relation to the inclusion of the medicine in he Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 mon hs from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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.

Manufacturers

Name	Address	Manufacturing steps
[redacted]		

Products

1.98 Alive Respiratory Health

Product Type	Single Medicine Product	**Status**	Current
		Effective date	3/04/2018

Permitted Indications

Record Summary

Decrease/reduce/relieve symptoms of common colds and flu in adults

Maintain/support lung health during the day in adults only

Indication Requirements

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

Warnings

GEN2 If symptoms persist, seek the advice of a healthcare professional.

No Warnings included on Record

Specific Conditions

Components

1.

Dosage form Solution

Route of Administration Inhalation

Formulations

Active Ingredients	Category	Quantity	Units
Melaleuca alternifolia	**AHN**	**10**	**mg/mL**
Plant details (origin)	**Part**	**Preparation**	
	leaf	Oil essential	
Equivalent			
cineole		240	microgram/mL

Excipient Ingredients	Category	Quantity	Units
purified water	**AAN**		

Record Summary