Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Product Type	Listed Medicine

ARTG Standard Conditions

The above Medicine Listed has been entered on the Register subject to the following conditions:

- Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.
- 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.

Product Specific Conditions

No specific conditions have been recorded against this entry.

Product Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support heart health

Product Indication Requirements

- Product presentation must not imply or refer to serious cardiovascular conditions.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

No specific indications have been recorded against this entry.

Warnings

- Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or

a major accident should not consume this product without medical advice (or words to that effect) [in 1.5 mm type]. (SHARK)

Dosage Form

- Powder

Route of Administration

- Sublingual

Visual Identification

Additional Product information