Public Summary

Summary for ARTG Entry:	367197 Micro Clear
ARTG entry for	Medicine Listed
Sponsor	RN Labs Pty Ltd
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia
ARTG Start Date	26/05/2021
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

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.

Products

1 . Micro Clear

Product Type Single Medicine Product **Effective Date** 26/05/2021

Permitted Indications

Maintain/support intestinal health

Maintain/support intestinal good/beneficial/friendly flora

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Arctostaphylos uva-ursi leaf Extract dry concentrate	**200 mg**
Equivalent: Arctostaphylos uva-ursi (Dry)	4.5 g
Berberis vulgaris stem bark Extract dry concentrate	**100 mg**

Equivalent: Berberis vulgaris (Dry)	1 g
Lythrum salicaria herb Extract dry concentrate	**200 mg**
Equivalent: Lythrum salicaria (Dry)	2 g
Olea europaea leaf Extract dry concentrate	**100 mg**
Equivalent: Olea europaea (Dry)	1 g
Punica granatum fruit peel Extract dry concentrate	**100 mg**
Equivalent: Punica granatum (Dry)	5 g

Other Ingredients (Excipients)

ascorbyl palmitate
colloidal anhydrous silica
hypromellose
leucine
maltodextrin
silicified microcrystalline cellulose

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