Therapeutic Goods (Permissible Ingredients) Amendment Determination No. 2 of 2018

I, Dr Cheryl McRae, as delegate of the Minister for Health, make this Determination under section 26BC of the *Therapeutic Goods Act 1989*.

Dated 27 June 2018

(Signed by)

Dr Cheryl McRae
Delegate of the Minister for Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Permissible Ingredients) Amendment Determination No. 2 of 2018.*

2 Commencement

This Determination commences on the day after registration of the instrument on the Federal Register of Legislation.

3 Authority

This instrument is made under section 26BC of the *Therapeutic Goods Act 1989.*

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018

1 Table 1 in Part 2 of Schedule 1 (cell at table item 332, column 4, "Achillea millefolium")

Repeal the cell, substitute:

Arbutin is a mandatory component of Achillea millefolium.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

2 Table 1 in Part 2 of Schedule 1 (cell at table item 645, column 4, "Arctostaphylos uva-ursi")

Repeal the cell, substitute:

Arbutin is a mandatory component of Arctostaphylos uva-ursi.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

3 Table 1 in Part 2 of Schedule 1 (cell at table item 1308, column 4, "Chimaphila umbellata")

Repeal the cell, substitute:

Arbutin is a mandatory component of Chimaphila umbellata.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

4 Table 1 in Part 2 of Schedule 1 (cell at table item 2817, column 4, "Kalmia latifolia")

Repeal the cell, substitute:

Arbutin is a mandatory component of Kalmia latifolia.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

5 Table 1 in Part 2 of Schedule 1 (cell at table item 2936, column 4, "Ledum palustre")

Repeal the cell, substitute:

Arbutin is a mandatory component of Ledum palustre.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

When the route of administration is other than topical, the maximum recommended daily dose must not contain more than 0.001mg of the equivalent dry herbal material of Ledum palustre.

6 Table 1 in Part 2 of Schedule 1 (cell at table item 3564, column 4, "Origanum majorana")

Repeal the cell, substitute:

Arbutin is a mandatory component of Origanum majorana.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 50 millilitres.

When the concentration of Origanum majorana oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and following warning statement is required on the medicine label:
- (CHILD) 'Keep out of reach of children' (or words to that effect).

7 Table 1 in Part 2 of Schedule 1 (cell at table item 4192, column 4, "Pyrus communis")

Repeal the cell, substitute:

Arbutin is a mandatory component of Pyrus communis.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

8 Table 1 in Part 2 of Schedule 1 (cell at table item 4193, column 4, "Pyrus pyrifolia")

Repeal the cell, substitute:

Arbutin is a mandatory component of Pyrus pyrifolia.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

9 Table 1 in Part 2 of Schedule 1 (cell at table item 4272, column 4, "Rhododendron ferrugineum")

Repeal the cell, substitute:

Arbutin is a mandatory component of Rhododendron ferrugineum.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

10 Table 1 in Part 2 of Schedule 1 (cell at table item 5007, column 4, "Turnera diffusa")

Repeal the cell, substitute:

Arbutin is a mandatory component of Turnera diffusa.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

11 Table 1 in Part 2 of Schedule 1 (cell at table item 5055, column 4, "Vaccinium vitis-idaea")

Repeal the cell, substitute:

Arbutin is a mandatory component of Vaccinium vitis-idaea.

The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.

When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.