

Technical Alert

TGA Testing of Herbal Medicines that may contain Arbutin exceeding 25ppm

As part of their testing program the TGA laboratories are intending to test medicines likely to contain the component arbutin.

Currently the content limit applied for oral herbal preparations is 25ppm of arbutin. If any batch of medicine (finished product) contains *less than* 25ppm of arbutin, the batch of medicine remains eligible for sale and supply.

To avoid regulatory compliance actions, members should ensure they are not supplying any finished product that contains arbutin at a concentration **above 25ppm**.

Herbs that contain naturally occurring levels arbutin are listed below. Those that are understood to be of higher risk of exceeding the limit are in bold.

Achillea millefolium

Arctostaphylos uva-ursi (bearberry or uva ursi)

Chimaphila umbellata

Kalmia latifolia

Ledum palustre

Origanum majorana

Pyrus communis

Pyrus pyrifolia

Rhododendron ferrugineum

Turnera diffusa (damiana)

Vaccinium vitis-idaea.

There is currently an application to down-schedule arbutin in oral herbal preparations, which was recently considered by the Advisory Committee on Medicines Scheduling in late June. However, a recommendation from the application will not be made until February 2020. If there were to be a decision to down-schedule arbutin in oral herbal preparations, this would not occur until later in 2020 or 2021.

For a finished product to remain suitable for sale and supply, it must comply with the below:

- When for internal use, the concentration of arbutin in the medicine must not be more than 25 mg/Kg or 25 mg/L or 0.0025%.
- When for topical use, the concentration of arbutin in the medicine must not be more than 25 mg/Kg or 25 mg/L or 0.0025% unless used on the hair.
- When for use on hair, the concentration of arbutin in the medicine must not be more than 0.74%.

Resources

Member Alert: [Poisons Standard Scheduling of Herbs that contain Arbutin – Explainer](#) (15-06-18)

Member Alert: [Update to 25ppm](#) (21-06-2018).

ENDS