



Member Alert

Poisons Standard Scheduling of Herbs that contain Arbutin

What is the issue?

Some herbs naturally contain the herbal component, “arbutin”. Arbutin is a glycoside of “hydroquinone”. In other words, arbutin is hydroquinone molecule attached to a sugar molecule. Arbutin is a naturally occurring component of some herbs and foods.

Hydroquinone for therapeutic use in humans in oral medicines is included in Schedule 4 (Prescription Only Medicines) of the [Poisons Standard](#) (also known as the SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons). The Poisons Standard sets out levels of access to potentially harmful substances, which is then applied within State and Territory legislation as well as federal therapeutic goods legislation.

Because arbutin is a glycoside of hydroquinone, arbutin is included as a **cross-reference** to hydroquinone in the Appendices to the Poisons Standard. Some literature sources note that in the acidic gastrointestinal environment it is theoretical possibility that arbutin *might* hydrolyse into free hydroquinone.

Due to the cross-reference in the Appendices, this means that arbutin in preparations, including herbal preparations, for human oral therapeutic use is effectively included in Schedule 4 and is therefore not eligible for general sale and supply when in present in a medicine at a level above 10 parts per million (10 ppm). Preparations above 10ppm of arbutin by inclusion in Schedule 4 are considered high safety-risk substances and therefore only eligible to be sold in Australia if applied for as a Prescription-Only medicine.

How did this happen and why is it an issue now?

Records show that Hydroquinone was included in Schedule 4 as early as **1991**. Arbutin first appeared as a cross-reference to hydroquinone in the **August 2010** version of the Poisons Standard.

In **May 2018**, the TGA published a website update noting that in accordance with the Poisons Standard entry, herbs which contain arbutin as a herbal component in a concentration exceeding 10ppm will not be eligible to be included in listed complementary medicines in Australia (those medicines sold with an “AUST L” on the label).

If any herb contains **less than 10ppm** arbutin, it can still be included in complementary medicines. Therefore, you will continue to see some of the affected herbs still included in AUST L medicines.

Has the TGA done this to target herbal medicines?

No. This is an TGA administrative follow-through on some long-ago Scheduling decisions based on technical information about the chemical substance hydroquinone and related substances.

Why is there no transition period?

Although the Poisons Standard already restricts arbutin, the connection to herbs that are included listed complementary medicines on the Australian Register of Therapeutic Goods will be effective as of late June 2018 when the TGA publish the list of Permissible Ingredients. Industry request an 18-month transition for all changes, however because arbutin is already in the Poisons Standard and already not eligible for supply, the Complementary Medicines Branch of the TGA have provided that they do not have the legal powers to designate any transition period available for arbutin. That is, the TGA regulatory branch cannot override the requirements of the Poisons Standard.

Are arbutin-containing herbs unsafe?

While CMA has not yet conducted a full safety evaluation at this time, it seems to be improbable based on preliminary information available and feedback from our technical experts. However, Australian laws and processes must be complied with and unless and until de-Scheduling occurs, arbutin will remain restricted for medicinal purposes.

Which herbs are affected due to natural Arbutin content?

The herb most known to be affected is the Bearberry leaf (*Arctostaphylos uva ursi*). The British Pharmacopoeia requires that the dried leaf of Bearberry contains 7% (or 70,000ppm) of arbutin as the active therapeutic component. Herbal extracts of Bearberry leaf have even higher concentrations.

Due to the high level of arbutin in Bearberry, it will no longer be available in any AUST L medicines (including medicines labelled as Practitioner Only.)

Confirmed Affected	
<i>Arctostaphylos uva ursi</i> (leaf)	Bearberry (leaf)
Potentially Affected	
<i>Achillea millefolium</i>	Yarrow
<i>Chimaphila umbellata</i>	Umbellate Wintergreen, Pipsissewa, or Prince's Pine
<i>Kalmia latifolia</i>	Mountain laurel
<i>Ledum palustre</i>	Marsh Tea / Marsh Labrador Tea / Wild Rosemary
<i>Origanum majorana</i>	Marjoram
<i>Pyrus communis</i>	Pear
<i>Pyrus pyrifolia</i>	Asian Pear
<i>Rhododendron ferrugineum</i>	Alpine Rose
<i>Turnera diffusa</i>	Damiana
<i>Vaccinium vitis-idaea</i> (leaf)	Lingonberry (leaf)



How are raw materials (such as liquid herbal extracts) for extemporaneous compounding by Naturopaths, Herbalists, and other health practitioners affected?

The *Therapeutic Goods Regulations 1990* (Schedule 5) excludes medicines that are extemporaneously compounded by practitioners from the requirement to be included on the Australian Register of Therapeutic Goods and to be subject to GMP manufacturing requirements.

Because the final product is still considered a medicine for human therapeutic use, practitioner-compounded medicines are **not exempt from the restricted supply of arbutin-containing herbs**. Any medicine containing more than 10ppm arbutin is considered to be Schedule 4 Prescription Only.

What has been done so far?

Complementary Medicines Australia has sent a letter to the TGA requesting that the level of arbutin in permissible herbs within listed complementary medicines to be increased to a level of 25ppm. This is because there is no direct concern with arbutin, the concern is with free hydroquinone. According to the molecular weight of arbutin, 25ppm arbutin is the equivalent of 10ppm hydroquinone.

The TGA's ability to accept this request will depend on scheduling rules and we are waiting on a response.

What will be done to get these herbs back?

Complementary Medicines Australia will be coordinating an industry-wide application to the TGA's Advisory Committee on Medicines Scheduling to either **remove or down-schedule arbutin** from the Schedules, or to **exempt herbs that contain arbutin** from the Schedules.

How can you help?

Companies and practitioners who are not already members of Complementary Medicines Australia can support CMA efforts by becoming a member and receiving member benefits.

Individual practitioners only pay a flat, low annual fee. For more information, contact members@cmaustralia.org.au

Members who can provide technical assistance to CMA can contact technical@cmaustralia.org.au

Please be aware that the de-scheduling applications and TGA processes are involved and are very lengthy and protracted: in almost all cases the time period involved is extended (such as 1 to 2 years).

When the TGA receive the application to decrease the scheduling of arbutin, the TGA open Public Consultation on proposed amendments. At this time, CMA will let members know and ask them to write letters to the TGA Public Consultation in support of de-scheduling arbutin-containing herbs.

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