

Technical Alert

Safety Evaluation - Fennel oil

Dear member,

This Alert is to advise that the TGA has completed a safety evaluation of fennel oil, an ingredient used in a number of listed medicines.

Fennel oil is currently available for use in listed medicines without restriction and is used as an active and/or excipient ingredient in various listed medicines. The TGA recently carried out a compliance review of a listed medicine containing fennel oil as an active ingredient intended for oral use in infants. During the review it was noted that several international regulatory agency reports state that fennel oil is contraindicated in children and adolescents under the age of 18.

Consequently, the TGA conducted a safety assessment of fennel oil for use in infant preparations.

The evaluation has found that fennel oil contains estragole (methyl chavicol) which is carcinogenic at higher doses and is of particular concern to infants, pregnant and breastfeeding individuals. The evaluation has recommended:

- Fennel oil, 'Fennel bitter seed dry', Fennel sweet seed dry' and *Foeniculum vulgare* should be restricted to adults and children over the age of 12 years, non-pregnant and non-breastfeeding individuals.
- Fennel oil should be included in Schedule 5 of the Poisons Standard (SUSMP)
- The maximum daily dose must provide no more than 150mg of fennel oil.

As a result of the evaluation, the TGA will be working with sponsors of products on the ARTG containing fennel oil as either an active or excipient ingredient to alert them to the risks associated with this ingredient. It is expected that sponsors will voluntarily remove these products from the ARTG, reformulate the product to remove ingredients that may pose a safety concern or amend the dosage instructions/indications accordingly.

In light of the safety evaluation outcomes, the TGA are preparing to vary the *Therapeutic Goods (Permissible Ingredients) Determination No.2 of 2016* to restrict the use of Fennel oil in listed medicines as detailed above. The TGA has submitted an application to amend the Poisons Standard to include a new Schedule 5 entry for Fennel oil with the same restrictions as Basil oil.

No reports regarding Fennel oil or *Foeniculum vulgare* were located in TGA's Database of Adverse Event Notifications.

If you have any concerns or would like to discuss this issue further, please contact the TGA Complementary and OTC Medicines Branch at complementary.medicines@tga.gov.au or alternatively please feel welcome to contact the CMA at Emma.Burchell@cmaustralia.org.au