Conclusions - Raspberry leaf tea

In this guide

56. Overall, the COT concluded that the risk associated with raspberry leaf use during pregnancy was low but with high uncertainty. This was based on the results of two Australian human safety studies, comprising a retrospective cohort study and a double-blind, placebo-controlled, randomised trial. Neither reported adverse effects in mother or child following raspberry leaf consumption during pregnancy at doses of 1-8 cups of tea/tablets per day or a single dose of tincture, or 2.4 g extract daily, respectively. However, Members noted that the estimated combined consumption of raspberry leaf from tea (up to 10 g/person/day) or from tea, tinctures and capsules combined (up to 12.4 g/person/day), based on data collected from online sources by the FSA's exposure assessment team, was up to four or more times higher than the raspberry leaf dose tested in the randomised controlled trial.

57. The COT's conclusion was also based on the fact that there had been very few reports of adverse effects in pregnant women taking raspberry leaf or

their children received by the UKTIS since its inception in 1983 to the present date, despite the reported high prevalence of use of raspberry leaf. Members considered that the apparent poor oral bioavailability of the toxic constituents of raspberry leaf (based on indirect information) might also be why it appeared to be of low concern to human health. However, it was recognised that micronised or other modified raspberry leaf products might exhibit increased bioavailability and may require a separate safety evaluation.

58. Members identified a number of significant uncertainties in the risk assessment of raspberry leaf. These underpinned the high level of uncertainty in their conclusion on its safety for use during pregnancy and prevented the Committee from establishing a health-based guidance value for raspberry leaf. The main sources of uncertainty identified included: the lack of data available on the active components of raspberry leaf; the potential for the method of sampling and preparation to affect the activity of the supplement; the large variation in the literature as to raspberry leaf's critical effects (smooth muscle relaxation vs. contraction), which appeared to depend on numerous factors, such as the species, preparation and whether extracts were tested *in vitro* or *in vivo*; and the lack of clarity in the literature as to the most appropriate choice of animal model for studying raspberry leaf's effects in humans. Other sources of uncertainty included the lack of any specific information on pharmacokinetics of the key constituents, limitations on the amount of data available on the toxicity (including reproductive toxicity) of raspberry leaf, and on levels of contaminants and residues present.

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