

Contaminants

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143. Very few studies, described below, have investigated the potential contaminants in Echinacea preparations, including heavy metals, moulds and mycotoxins.

144. From 1999-2004, 13,504 adults participated in National Health and Nutrition Examination Survey (NHANES) interviews, examinations and had their blood lead levels assessed (Buettner et al., 2009). The aim was to determine whether there was an association between self-reported herbal supplements use and blood lead levels. The focus was on herbal supplements reported to contain excess lead in previous studies or product testing available to the public, or that had been implicated in heavy metal poisoning. The study also considered prevalence of use of specific herbal supplements in study participants and Echinacea was one of the more commonly used herbs (4.3% of all participants reported the use of specific herbal supplement and 1.1% of the participants used Echinacea). The authors fitted a regression model for women of child-bearing age (16-45 years), which showed that those who used herbal supplements had adjusted blood lead levels 20% (95% CI 5%-34%, $p = 0.008$) higher than women who did not. However, when broken down by the specific herbal supplement, the difference was not significant for Echinacea supplements (8%, 95% CI -15% - 35%, $p = 0.55$).

145. Filipiak-Szok et al., (2015) measured the concentrations of heavy metals (Pb, Cd, As, Al, Ni, Ba, Sb) in raw plant material of selected medicinally used herbs and dietary supplements containing them, on the Polish market. The plant samples, purchased from STANLAB (Poland), were dried and ground prior to undergoing microwave digestion with ultrapure nitric acid (65%) for 30 minutes. Samples were analysed using an inductively coupled plasma mass spectrometer (ICP-MS) with quadrupole mass analyser. Three samples were used for each analysis. The authors compared the results against the limits set by WHO (0.3 mg/kg for cadmium, 10 mg/kg for lead and 5.0 mg/kg for arsenic) and by the EU Commission Regulation (EC) No. 1881/2006 (1.0 mg/kg for cadmium and 3.0 mg/kg for lead). The levels found in the dried Echinacea purpurea samples were considerably lower with 0.02 mg/kg cadmium, 0.6 mg/kg lead and 0.16 mg/kg arsenic.

146. Another study analysed popular food supplements, including seven Echinacea containing brands, for presence of heavy metals and microbial contamination (Raman et al., 2004). The supplements analysed were in the forms of tablets, capsules or soft gels. Tablets were powdered, whilst the soft gels and capsules digested individually. Concentrated nitric acid was added to the samples and they were digested using a hot plate 75°C for 16 hours. Analysis was conducted using an ICP-MS. The authors determined the daily dose of each heavy metal that would be ingested if the supplement was taken as recommended by the manufacturer. Depending on the Echinacea brand, the daily doses of heavy

metals would be: lead 0.034-2.901 µg/day, cadmium 0.004 – 0.967 µg/day, arsenic 0.027 – 0.908 µg/day, chromium 0.125-8.838 µg/day, thallium 0.002 – 0.383 µg/day. Mercury was not detected in the samples. The authors compared these values to tolerable intake levels at the time of publication and concluded that the supplements do not pose risk to consumers.

147. *Alternaria alternata*, *Aspergillus* spp., *Fusarium* spp., *Phoma* spp. and yeasts have been detected in Echinacea herbal supplements at 100-1,000 CFU/g with 71% of the Echinacea samples (n=7) harbouring fungi (Tournas, 2009). Twenty one samples were analysed as part of a study investigating the presence of moulds and their secondary metabolites in Echinacea dietary supplements available on the Polish market (Pilarska et al., 2022). It was found that 12 samples were contaminated with *Aspergillus* spp., whilst *Eurotium* and *Penicillium* spp. were detected in 8 of the samples. Mycotoxin contamination was found in 18 of the samples with zearalenone (18/21), deoxynivalenol (5/21) and T-2 (3/21) occurring at the highest frequencies.