
[General Chapter <2232> Elemental Contaminants in Dietary Supplements](#)

Type of Posting: General Announcement

Posting Date: 27–Apr–2012

The objective of this general chapter <2232> is to limit the amounts of elemental contaminants in finished dietary supplement dosage forms labeled as conforming to *USP* or *NF* standards. This general chapter is not intended to set limits for dietary ingredients. Limits for dietary ingredients are set in the corresponding individual monographs.

The focus of <2232> is on the four major elements of toxicological concern: arsenic, cadmium, lead, and mercury. The extent of testing can be determined using a risk-based approach considering the likelihood of contamination. Manufacturers should consider the presence of unexpected elemental contaminants to determine compliance. Permitted Daily Exposure (PDE) is derived from the Provisional Tolerable Weekly Intake (PTWI) that is recommended by the Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO) by subtracting the daily exposure ($\mu\text{g/day}$) to each elemental contaminant from air, food, and drinking water. Other regulations (i.e.: Proposition 65 in California) may require different limits; manufacturers are responsible for compliance with applicable local requirements differing from these PDE values.

The chapter has been peer-reviewed and approved for publication in PF 38(3) [May–June 2012].

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Should you have any questions, please contact Maria Monagas, Scientific Liaison, at 301-230-7422 or MJM@USP.org.