



SASSI Comments – USP-NF and FCC monographs Duplication

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The [Synthetic Amorphous Silica and Silicate Industry Association](#) (SASSI), would like to share its comments and concerns on duplication of FCC and USP-NF monographs, specifically concerning silicon dioxide.

About SASSI

The Synthetic Amorphous Silica and Silicate Industry Association (SASSI) is a trade association that addresses industry-wide issues related to regulatory matters concerning the manufacture and use of synthetic amorphous silica and silicates. SASSI is a non-profit entity (IRS 501(c)(6) corporation) representing seven of major synthetic amorphous silica and silicate producers in the US.

SASSI came together as an association of manufacturers in 1993, commensurate with the 1992 formation of the Association of Synthetic Amorphous Silica Producers (ASASP), a Sector Group within [Cefic](#) one of the leading European trade associations with offices in Brussels.

Comments

SASSI thanks the USP staff for this opportunity to comment on the USP-NF and FCC monographs, specifically the FCC monograph for silicon dioxide and the USP General Chapter <232> Elemental Impurities concerning the testing for lead.

Silicon dioxide is used in for a number of food applications including its use as an anti-caking agent/free-flowing agent. The current FCC monograph for silicon dioxide includes a well-established test for lead using a hydrochloric acid-based leaching method. This method is aligned with the Environmental Protection Agency’s Method 3050B (Acid Digestion of Sediments, Sludges, and Soils)¹. It is also referenced in 21 C.F.R. § 73.575(b) for confirming that the lead content in titanium dioxide intended for use as a color additive in foods meets specification.

This hydrochloric acid-based leach method provides a more scientifically sound assessment of trace elements exposure taking into account bioavailability. USP <232> is a total digestion method with hydrofluoric acid. Hydrofluoric acid is not found in the human digestive track, and it is very toxic to mammalian life. Even minor dermal exposure can be fatal to humans. The hydrochloric acid-based leach method, though not a total digestion method, is representative of the human digestive tract and thus more relevant to the safety assessment of lead. There is no benefit to public health in using data from a total digestion versus acid leach, particularly when considering the extreme increase in safety risks to the analyst using hydrofluoric acid.

Sincerely,

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¹ <https://www.epa.gov/esam/epa-method-3050b-acid-digestion-sediments-sludges-and-soils>.