

40 C.F.R. § 79.53

Tier 2.

- (a) *Generally.* Subject to the provisions of § 79.53(b) through (d), the combustion emissions of each fuel or fuel additive subject to testing under this subpart must be tested in accordance with each of the testing guidelines in §§ 79.60 through 79.68, except that fuels and additives in the methane and propane fuel families (pursuant to § 79.56(e)(1)(v) and (vi)) need not undergo the Salmonella mutagenicity assay in § 79.68). Similarly, subject to the provisions of § 79.53(b) through (d), the evaporative emissions of each designated evaporative fuel and each designated evaporative fuel additive subject to testing under this subpart must be tested according to each of the testing guidelines in §§ 79.60 through 79.67 (excluding § 79.68, *Salmonella typhimurium* Reverse Mutation Assay).
- (b) Manufacturer Determination. Manufacturers shall determine whether the information gathered pursuant to the literature search in § 79.52(d) contains the results of adequately performed and adequately documented previous testing which provides information reasonably comparable to that supplied by the health tests described in §§ 79.62 through 79.68 regarding the carcinogenicity, mutagenicity, neurotoxicity, teratogenicity, reproductive/fertility measures, and general toxicity effects of the emissions of the fuel or additive. When manufacturers make an affirmative determination, they need submit only the information gathered pursuant to § 79.52(d) for such tests. EPA maintains final authority in judging whether the information is an adequate substitution in lieu of conducting the associated tests. EPA's determination of the adequacy of existing information shall be guided by the considerations described in paragraph (d) of this section. If EPA finds that the manufacturer has relied upon inadequate test data, then the manufacturer will not be considered to be in compliance until the corresponding tests have been conducted and the results submitted to EPA.

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