

**Comments on the Preliminary Materials for the
IRIS Toxicological Review of Ethyl *tert*-Butyl Ether
(ETBE) and *tert*-butyl alcohol (*tert*-butanol)**

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The American Petroleum Institute
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Comments on the Preliminary Materials for ETBE and TBA

General

- The scope of the assessments to be conducted, and the problem(s) to be addressed are not described in the materials released by EPA. Defining these elements are important prerequisites to gathering relevant data.
- Indication of critical studies, the rationale for selection, and data quality must be included in Evidence Tables in order to meet the Agency's stated goals for the enhanced IRIS process.
 - This information is needed to frame scientific issues, identify uncertainties and direct research.

Comments on the Preliminary Materials for ETBE and TBA

General

- Some aspects of the literature search strategy should be improved, notably:
 - review of ECHA's database of information submitted in support of REACH registration of these substances;
 - and consideration of excluded exposure studies and environmental fate studies in defining scope and problem formulation.
- Mode of Action (MOA) data should be considered in selecting pertinent data for Evidence Tables (e.g. male rat kidney effects).

Comments on the Preliminary Materials for ETBE and TBA

Specific

- Some aspects of the literature search strategy for these substances should be improved, notably:
 - inclusion of all studies conducted under the requirements of the Clean Air Act, Section 211(b);
 - consideration of the relationship of *tert*-Butanol data to evaluation of ETBE systemic toxicity;
- Tumor promotion data for ETBE should be removed from the Evidence Tables and Exposure Response-Arrays, since well conducted chronic rodent bioassays have been reported for this substance.

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Specific

- EPA should consider the current status of these substances as fuel additives in defining the scope and formulating problems to be addressed
- The Maltoni et al., 1999 study of (ETBE) should be evaluated in light of the National Toxicology Program's (NTP) subsequent review, and any assessment of data from this study should reflect the findings of NTP's review.



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Thank You for Your Attention

Any Questions?