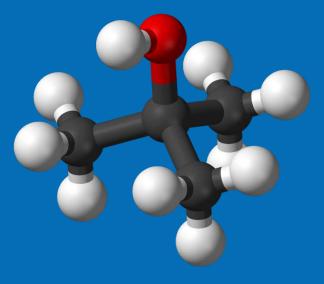


Preliminary Materials for the IRIS Assessment of *tert*-Butyl Alcohol (*tert*-Butanol)

Janice S. Lee, Assessment Manager



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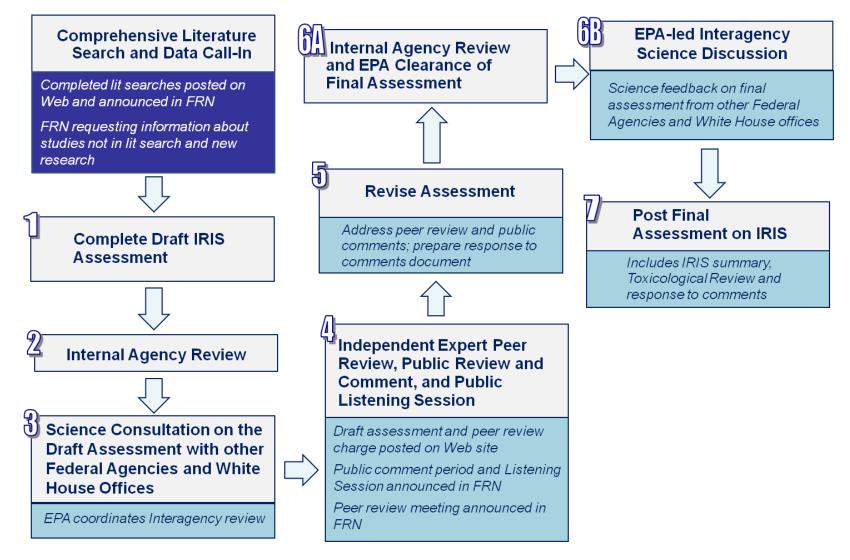
General Information

- *tert*-Butanol is a white crystalline solid or colorless liquid (above 77°C).
- *tert*-Butanol is used as a solvent, denaturant for alcohols, dehydrating agent, and in the manufacture of methyl methacrylate, flotation agents, fruit essences, perfumes, and proposed as an octane booster in gasoline
- tert-Butanol is subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) (Toxics Release Inventory (TRI) Chemical)

Exposure

- Individuals working at facilities where *tert*-butanol is produced or used may be exposed.
- General population exposures may occur through the ingestion of drinking water and foods and inhalation of air containing *tert* butanol.







Preliminary Materials for the IRIS Assessment of <u>tert-Butanol</u>:

- Draft literature search strategy
- Draft literature search results
- Preliminary evidence tables
- Preliminary exposure-response arrays

*These materials are available online at: <u>http://www.epa.gov/iris/publicmeeting/iris_bimonthly-dec2013/mtg_docs.htm</u>

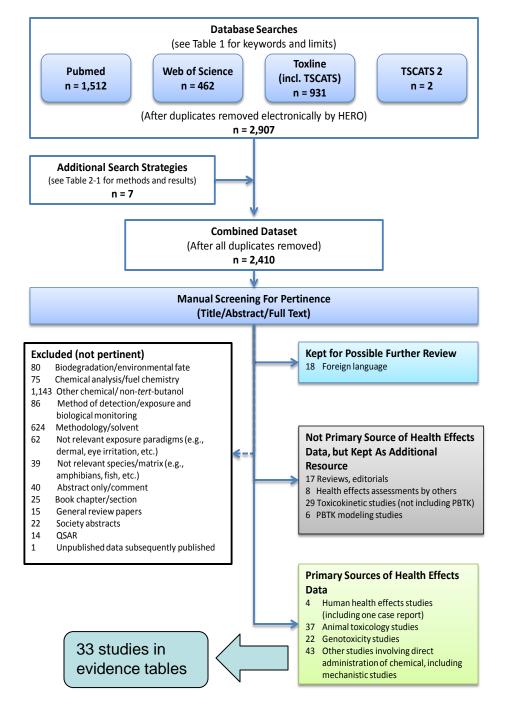


Literature Search Strategy

- The literature search identified more than 2,400 studies for *tert*-butanol.
- 184 references are being considered for the assessment after an initial screen for relevance.

Data Extraction to Evidence Tables

• 33 references directly informing hazard identification are described in evidence tables.





Features of the tert-Butanol Database

	Chronic	Subchronic	Two-Gen Repro/Dev	MOA Information	PBPK
Oral	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
Inhalation		\checkmark	\checkmark	✓	✓

• Human data on exposures to *tert*-butanol consist of a case report, an occupational study with co-exposures to other solvents, and studies assessing acute effects.



Endpoints with Data for Evaluating Hazard

- Kidney Effects
- Thyroid Effects
- Reproductive, Developmental, and Neurodevelopmental Effects
- Central Nervous System (CNS) Effects
- Other Systemic Effects (Body Weight, Liver, and Urinary Bladder)
- Genotoxic Effects

Scientific Considerations

- PBPK models
 - Metabolite in MTBE and ETBE models
- Kidney mode of action
 - Alpha2u-globulin-associatednephropathy
 - Chronic progressive nephropathy (CPN)
- Thyroid follicular cell tumors



EPA welcomes all comments, such as:

- Clarity and transparency of materials
- Additional approach for identifying studies
- Selection of studies for data extraction
- Study quality considerations
- Additional studies that may inform the assessment