

June 22, 1994

DRAFT

RECOMMENDED INHALATION TESTING

HAZARDOUS AIR POLLUTANTS TO BE CONSIDERED FOR TSCA SECTION 4 TEST
RULE PROCESS (1ST RULE)

Biphenyl

- Acute/Subchronic Systemic
- Acute/Subchronic Respiratory
- Acute/Subchronic Neurotoxicity
- 1 species Developmental Toxicity
- 2-Generation Reproductive Test

Carbonyl Sulfide

- Acute/Subchronic Systemic
- Acute/Subchronic Respiratory
- Acute/Subchronic Neurotoxicity
- 2 species Developmental Toxicity
- 2-Generation Reproductive Test
- Cancer test (2 species in both sexes)
- Ames, in vitro gene mutation mammalian test, bone marrow cytogenetics

Chlorine

- Acute Systemic (in both sexes)
- Acute Respiratory (in both sexes)

Chlorobenzene

- Acute/Subchronic Systemic
- Acute/Subchronic Respiratory
- Acute/Subchronic Neurotoxicity

Chloroprene

- Acute Systemic
- Acute Respiratory
- Acute/Subchronic Neurotoxicity
- 1 species Developmental Toxicity
- 2-Generation Reproductive Test

Cresols (mixture or isomers)

- Acute/Subchronic Systemic
- Acute/Subchronic Respiratory
- Acute Neurotoxicity

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Hydrochloric Acid

- Acute Respiratory

Hydrogen Fluoride

- Acute/Subchronic Systemic
- Acute/Subchronic Respiratory
- Acute/Subchronic Neurotoxicity
- 2 species Developmental Toxicity
- 2-Generation Reproductive Test

Maleic Anhydride

- Acute Systemic
- Acute Respiratory
- Acute/Subchronic Neurotoxicity
- 1 species Developmental Toxicity
- Cancer Test (2 species in both sexes)

Methyl Isobutyl Ketone

- Acute Systemic
- Acute Respiratory
- 2-Generation Reproductive Test

Methyl Methacrylate

- Acute Systemic
- Acute Respiratory
- Acute/Subchronic Neurotoxicity
- 2-Generation Reproductive Test

Naphthalene

- Acute Systemic
- Acute Respiratory
- Acute/Subchronic Neurotoxicity
- 2-Generation Reproductive Test

Phenol

- Acute Systemic
- Acute Respiratory

Phthalic Anhydride

- Acute/Subchronic Systemic
- Acute/Subchronic Respiratory
- Acute/Subchronic Neurotoxicity
- 2 species Developmental Toxicity
- 2-Generation Reproductive Test
- Cancer Test(2 species in both sexes)

TOXICITY TESTING OF HAZARDOUS AIR POLLUTANTS

On June 22, 1994, EPA held a briefing to provide industry with background information on the Hazardous Air Pollutant (HAP) Test Rule that will be proposed this Fall. EPA also distributed a list of the HAPs and the testing that will be proposed for each of the chemicals. Briefings have already been held with the environmental groups and other interested parties.

In order to make multi-chemical risk assessment/risk management decisions, the Office of Air Quality Planning and Standards has requested that 3 TSCA section 4 Test Rules be promulgated for HAPs that are missing inhalation data. The data generated by the test rules would provide EPA with a consistent/even data base and allow them to do residual risk analyses on mixtures. EPA's intent is that this test rule respond to the CAA concern for both cancer and non-cancer health effects and that a dose-response via the inhalation route be established.

EPA stated that if the database for a chemical was rich in oral data, they might agree that focused pharmacokinetic will provide enough data for route-to-route extrapolation. In that case, EPA would also require subchronic inhalation studies to evaluate entry portal sensitivity and damage. Only drinking water or feeding studies will be considered when oral data is evaluated.

EPA is seeking industry comment in several areas:

- There will be a problem testing low vapor pressure chemicals, EPA feels that conducting aerosol testing may mimic human exposure and is seeking comment.
- Even though EPA wants all testing by the inhalation route, it is seeking industry input on the most appropriate routes of exposure. EPA is also soliciting feedback on what testing will give the best information to make risk assessments.
- EPA realized that there may not be an adequate number of inhalation chambers available and is looking for ways to "piggy-back" tests.
- Test standards will be proposed with the test rule and EPA will be seeking comment on the appropriateness of the methods.
- EPA is trying to generate good histopathological data on the respiratory system.

The proposed rule will require all testing via the inhalation route. The rat will be the species of choice unless otherwise noted.

EPA expects the proposed test rule to be published in the early or late Fall of 1994.

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