

June 28,2002

Elmer Rauckman, Ph.D. DABT
Consulting Toxicologist for Ferro Corporation
1201 Anise Court
Freeburg, IL 62243

Dear Dr. Rauckman:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 1,2-dimethoxyethane, posted on the ChemRTK Web Site on January 29, 2002. I commend Ferro Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that Ferro Corporation advise the Agency, within 60 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: 1,2-dimethoxyethane

The Sponsor, Ferro Corporation, submitted a test plan and robust summaries to EPA on January 3, 2002, for 1,2-Dimethoxyethane (CAS No. 110-71-4). EPA posted the submission on the ChemRTK HPV Challenge Web site on January 29, 2002.

Summary of EPA Comments

EPA has reviewed the submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate Data. The data are adequate for the purposes of the HPV Challenge Program.
2. Health Endpoints. The data are adequate for the purposes of the HPV Challenge Program.
3. Ecotoxicity. The submitter needs to provide robust summaries for the SAR data for the fish and daphnia tests including the input values and enhance the robust summaries for the fish and daphnia studies.

EPA requests that the Submitter advise the Agency within 60 days of any modifications to this submission.

EPA Comments on the 1,2-dimethoxyethane Challenge Submission

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

The data are adequate for these endpoints for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

The data are adequate for these endpoints for the purposes of the HPV Challenge Program.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

The submitter has provided adequate data on 2,4-dimethoxyethane that address the endpoints for acute toxicity, genetic toxicity, and reproductive and developmental toxicity, and has provided repeated-dose toxicity studies on 2-methoxyethanol, a major metabolite of 2,4-dimethoxyethane. The test plan described in detail the metabolic pathway of 2,4-dimethoxyethane that adequately justifies the use of 2-methoxyethanol in these studies. EPA agrees that additional testing is not necessary to address the repeated-dose toxicity endpoint.

Ecotoxicity (fish, invertebrate and algal toxicity).

EPA considers the 24-hour daphnia test adequate because, although the test method is outdated, in this case no significant difference in toxicity between the measured and predicted values would be likely. The estimated LC₅₀ and EC₅₀ values using EPIWIN for fish, daphnia, and algae are in the same range as those for the measured values for 1,2-diethoxyethane, 1,2-methoxyethanol, or 1,2-dimethoxyethane, respectively. The submitter needs to enhance the robust summaries submitted for the fish and daphnia

studies and provide robust summaries for the fish and daphnia SAR data including the input values.

Specific Comments on the Robust Summaries

Health Effects.

The submitter needs to provide the percent purity of the test substance used in all toxicity testing.

Ecotoxicity.

Fish and Invertebrates. The submitter needs to provide the following missing critical data elements: pH, water hardness, temperature, number of replicates, DO, percent purity, nominal or measured concentrations, and type of water column assay system.

Follow-up Activity

EPA requests that the Submitter advise the Agency within 60 days of any modifications to this submission.