

June 24, 2004

William Claude White  
Manager, Product Safety  
Lyondell Chemical Company  
One Houston Center  
Suite 1600  
Houston, TX 77010

Dear Mr. White:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Allyl Alcohol posted on the ChemRTK HPV Challenge Program Web site on January 23, 2004. I commend Lyondell Chemical Company 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 Challenge Web site, 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 enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Lyondell Chemical Company advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov) and [chem.rtk@epa.gov](mailto:chem.rtk@epa.gov).

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages 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](mailto: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

Enclosure

cc: W. Penberthy  
M. E. Weber

## EPA Comments on Chemical RTK HPV Challenge Submission: Allyl Alcohol

### Summary of EPA Comments

The sponsor, Lyondell Chemical Company, submitted a test plan and robust summaries to EPA for allyl alcohol (CAS No. 107-18-6) dated December 16, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 23, 2004.

EPA has reviewed this submission and reached the following conclusions:

1. Physicochemical Properties. The data are adequate for the purposes of the HPV Challenge Program.
2. Environmental Fate. The data are adequate for the purposes of the HPV Challenge Program. However, the submitter needs to incorporate stability-in-water information in the robust summary.
3. Health Effects. The acute, repeated-dose, and genetic toxicity data are adequate for the purposes of the HPV Challenge Program. Reproductive toxicity data are expected to be adequate based on (1) reproduction data from a repeated-dose study and (2) anticipated data from ongoing repeated-dose studies and from a developmental or reproductive/developmental toxicity screening study. EPA agrees with the submitter that testing is needed for developmental toxicity. However, EPA recommends using the reproductive/developmental screening protocol OECD TG 421 rather than the developmental toxicity protocol OECD TG 414.
4. Ecological Effects. The acute toxicity data for fish are adequate for the purposes of the HPV Challenge Program. The toxicity data for invertebrates are inadequate, and testing is needed to satisfy this endpoint.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

### EPA Comments on the Allyl Alcohol Challenge Submission

#### Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data for all endpoints are adequate.

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

The data for all endpoints are adequate.

*Stability in Water*. EPA agrees with the submitter's statement that allyl alcohol is not susceptible to hydrolysis; however, the submitter needs to incorporate this information in the robust summary.

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

Submitted data for acute, repeated-dose, and genetic toxicity are adequate.

*Acute Toxicity*. The submitter needs to be aware that data submitted to EPA show that dermal administration of  $\leq 84$  mg/kg-day to rabbits resulted in convulsions (TSCATS 1992).

*Repeated-Dose Toxicity.* Although two of the three existing studies are limited (low airflow in the inhalation study, incomplete histopathologic evaluation in an oral study), the data are adequate on a weight-of-evidence basis. In addition, ongoing 13-week oral NTP studies in mice and rats will provide additional data.

*Genetic Toxicity.* Table 6 of the test plan incorrectly cites a gene mutation assay in various Salmonella strains as Lijinsky and Andrews (1987). The correct citation is Lijinsky and Andrews (1980).

*Reproductive Toxicity.* Data from the 15-week repeated-dose drinking water study, from the two ongoing 13-week NTP studies, and from the proposed developmental toxicity study or the EPA-recommended reproductive/developmental toxicity screening study (OECD TG 421; see below) will provide adequate data for this endpoint. The data from the repeated-dose study and data from the proposed screening study need to be presented in separate robust summaries.

*Developmental Toxicity.* The submitter plans to conduct a developmental toxicity study following OECD TG 414. EPA suggests that the submitter consider using OECD TG 421 (reproductive/developmental toxicity screen protocol) based on the HPV Challenge Program policy for all new developmental toxicity studies (FR notice 65 81686-81698, December 26, 2000 - <http://www.epa.gov/chemrtk/ts42213.pdf>). The submitter needs to specify species and route of exposure.

#### Ecological Effects (fish, invertebrates, and algae)

*Fish, Invertebrates, and Algae.* The submitted test data for fish are adequate, but those for invertebrates are inadequate because of study and reporting limitations. There are no data for algae. EPA agrees with the submitter's plan to conduct tests on invertebrates and algae, but emphasizes the use of mean measured concentrations.

### **Specific Comments on the Robust Summaries**

#### Health Effects

*Acute Toxicity.* Robust summaries for acute oral gavage studies in rats do not include information on body weight monitoring and the dose levels tested.

*Repeated-Dose Toxicity.* A robust summary for a 15-week oral toxicity study in rats does not include information on the full range of tissues examined.

*Genetic Toxicity.* A robust summary for a negative *in vivo* micronucleus test assay in rat bone marrow cells does not report the number of animals in the positive control group.

#### Ecological Effects

*Fish.* The robust summary does not provide the water temperature values for each test.

### **Followup Activity**

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.