March 19, 2002

Walter L. Jones
Pine Chemicals Association, Inc.
1117 Perimeter Center West
Suite 500E
Atlanta, Georgia 30338

Dear Mr. Jones:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Rosin Adducts and Adducts Salts, posted on the ChemRTK Web Site on, October 12, 2001. I commend the Pine Chemicals Association, Inc. 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 also must bring to your attention the fact that the acute toxicity test which you have proposed is specifically not recommended for use in the HPV Challenge Program (65 FR 81695) where the recommended guideline is OECD TG 425 (the "Up and Down Method"). In addition, the Organization for Economic Cooperation and Development (OECD) has made the decision to phase out OECD TG 401 and test data using the guideline generated after December 20, 2002 need not be accepted by other OECD countries under Mutual Acceptance of Data.

Note, also, that EPA encourages Challenge sponsors that have proposed acute toxicity testing to use an in vitro dose range-finding protocol to set the starting dose for the Up and Down test. Information on this protocol is available at http:/www.epa.gov/chemrtk/toxprtcl.htm.

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 the Pine Chemicals Association, Inc. advise the Agency, within 90 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:
Rosin Adducts and Adduct Salts

SUMMARY OF EPA COMMENTS

The sponsor, Pine Chemicals Association, Inc., submitted a test plan and robust summary to EPA for the Rosin Adducts and Adduct Salts category dated September 18, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on October 12, 2001. The six category members are identified below under Category Definition.

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

1. Category Justification. The grouping of the category members is generally well supported in the test plan. However, the submission provides insufficient discussion of the differences or similarities of maleated rosin adduct to other category members. Further, the submitter needs to describe the ratio of adduct to rosin in the product that will be tested and the range of ratios that are typically present in commercial products.

2. Physicochemical and Environmental Fate Data. The submitter's approach for these endpoints is generally acceptable for the purposes of the HPV Challenge Program. However, the submitter needs to provide hydrolysis data for the maleated rosin adduct. Hydrolysis rate data on the maleate adduct will help to determine the appropriate test substance for health effects and ecotoxicity testing.

3. Health Endpoints. EPA agrees with the submitter's test plan that health effects testing is necessary on a representative substance for all endpoints. EPA believes that maleated rosin may be a more appropriate representative substance for health effects testing than fumarated rosin because it may be more biologically active.

4. Ecotoxicity. (a) EPA believes that the submitter's claim that the fumarated and maleated rosins are similar is not well supported. Therefore, the submitter needs to explain why no other category members need to be tested. (b) The submitter needs to consider conducting a daphnid chronic study in addition to the proposed acute tests to determine the acute and chronic toxicity cutoff limits.

EPA requests that the Submitter advise the Agency within 90 days of any modifications to its submission.

EPA COMMENTS ON ROSIN ADDUCTS AND ADDUCT SALTS CATEGORY CHALLENGE SUBMISSION

Category Definition

The rosin adducts and adduct salts category contains fumarated rosin (65997-04-8), maleated rosin (8050-28-0), maleated/fumarated rosin (68554-16-5), fumarated rosin sodium salt (68201-59-2), fumarated rosin potassium salt (68649-83-2), and maleated rosin potassium salt (85409-27-4). The fumarate and maleate adducts of rosin are formed in a Diels-Alder reaction where the double bond of fumaric acid or maleic anhydride reacts with a resin acid containing a conjugated double bond (e.g., levopimaric, abietic, palustric, and communic acids). Because fumaric acid or maleic anhydride is added to an excess of rosin, the rosin is not fully converted to the adducted form. The ratio of rosin adducts to rosin depends upon the expected use of the product.

Category Justification

The submitter bases the category on the chemical similarities of the fumarated and maleated rosins. The justification of the category based on structural similarities is adequate; however, the submitter needs to describe

the range of adduct to rosin ratios for commercially available products and for the substance to be tested. Variations in the ratios of rosin adducts to rosin in the product will likely have an effect on the physicochemical properties (e.g., water solubility and partition coefficient) and environmental fate (e.g., biodegradation) as well as ecotoxicity and health effects. Therefore, the adducts:rosin ratio of the substance to be tested must be typical of commercially marketed product and the submitter needs to describe it in the test plan. In addition, in the post-testing final category analysis, the submitter needs to compare the results of the tests planned for the adducts with the parent rosin and provide insight into how different ratios of adducts to rosin might behave.

Test Plan

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

The submitter's approach for these endpoints is acceptable for the purposes of the HPV Challenge Program.

Environmental Fate (Photodegradation, Stability in Water, Biodegradation, Fugacity).

The submitter's approach for these endpoints is generally acceptable for the purposes of the HPV Challenge Program. On page 13 of the Test Plan, the submitter indicates that "Maleated rosin adduct will hydrolyze by addition into the acid form." Since hydrolysis is expected, the submitter needs to provide test data for this endpoint. Hydrolysis rate data on the maleate adduct will help determine the appropriate test substance for health and ecotoxicity testing.

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

Test Substance. The submitter proposes to conduct tests only on fumarated rosin as a representative of the category because of its relatively greater stability. EPA believes the submitter's rationale for selecting fumarated rosin as the representative material is not fully supported. The maleated rosin, according to the submitter, is the less chemically stable of the two adducts (presumably meaning that it undergoes hydrolysis to the corresponding diacid). Because its acylating ability allows it to react with proteins and other biomolecules, this material could be more biologically active than the fumarated rosin. This may be the case particularly at portals of entry, although a more distant target could also be affected depending on the hydrolysis rate. Thus, EPA believes that it may be more appropriate to use the maleated rosin as the representative test substance for health effects. Hydrolysis rate data on the maleate adduct should improve the basis for test substance selection.

Acute Toxicity. Note that the OECD guideline proposed for the acute toxicity test (OECD TG 401) is being phased out by the OECD; the HPV Challenge Program specifies OECD TG 425.

Ecotoxicity

The submitter proposes to conduct acute fish, algal, and invertebrate toxicity testing on fumarated rosin under conditions that will maximize solubility and reduce exposure to insoluble fractions. No information, however, was provided that explained how these conditions will be achieved. Normally these include neutralization to pH 7, or use of the sodium salt. Furthermore, insufficient information was provided to explain why the testing of fumarated rosin will adequately describe the aquatic toxicity of the maleated rosin adduct given the latter's ability to hydrolyze to the corresponding diacid. Additionally, aquatic toxicity studies of chemicals having low water solubility require testing at or below the water solubility limit and may be difficult to test. Guidance for testing chemicals of this type is provided in the Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (OECD, June 2000 available at http://www.oecd.org/ehs/test/monos.htm).

The submitter needs to consider daphnid chronic reproductive toxicity testing. EPA has indicated (65 FR 81695) (http://www.epa.gov/EPA-TOX/2000/December/Day-26/t32498.htm) that such testing may be needed when the log Kow equals or exceeds 4.2. The results of proposed testing for water solubility and partition coefficient will determine the need for the test.

Followup Activity

EPA requests that the Submitter advise the Agency within 90 days of any modifications to its submission.