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Subject Environmental Defense comments on p-Toluenesulfonyl Isocyanate (CAS# 4083-64-1)

(Submitted via Internet 11/18/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and m.barmasse@snpe.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **p-Toluenesulfonyl Isocyanate (CAS# 4083-64-1)**.

The test plan and robust summaries for p-toluenesulfonyl isocyanate (PTSI) were submitted by Isochem Inc. PTSI is a highly reactive isocyanate that, and according to the test plan, appears to have a broad array of uses, including water scavenging for sealants, adhesives and coatings such as polyurethanes. It is also used in the synthesis of commercially important pharmaceuticals, agricultural chemicals and polymer products. PTSI reacts rapidly with water to form p-toluenesulfonamide (PTS), and the test plan states that this conversion is very fast and complete. However, the test plan does not provide any information on any residues of PTS in the various commercial products that involve PTSI. Moreover, the identities of the pesticides and pharmaceuticals formed from reaction with PTSI are not provided, so it is difficult to assess the potential for human exposure to either PTS or PTSI. Since PTSI is a reactive and dangerous substance, we recommend that the sponsor describe the measures used for worker protection. We also recommend that the sponsor provide any available information on environmental releases and environmental monitoring for PTS.

The sponsor uses data from both PTSI and PTS to conclude that existing data are adequate to meet criteria for all SIDS endpoints. While we agree that mammalian toxicity endpoints appear to be met, we disagree that no new tests are needed for physicochemical, environmental fate and ecotoxicity endpoints. We also have several questions concerning inconsistencies and lack of details in the test plan and robust summaries.

Specific comments are as follows:

1. The sponsor provides full physicochemical data descriptions for PTSI, but no such data are provided for PTS. Physicochemical data on PTS are required, as the rapid and complete conversion of PTSI to PTS under environmental conditions is the justification for using PTS data to address SIDS endpoints for mammalian toxicity.

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2. The test plan and robust summaries on the environmental fate endpoints are confusing. While it is stated that photodegradation data are for PTS, not PTSI, Table 1 indicates data for PTSI only. Table 1 also states that the hydrolysis, biodegradation and environmental transport data are for PTSI, although the 9-day biodegradation data must be for PTS. The robust summaries do not contain adequate detail to clarify these issues. In any event, we recommend that PTS data for all environmental fate endpoints be provided in a revised submission because PTS is the substance expected to be released into the environment when PTSI is used.
3. The sponsor reports a 60-day "EC" of 9 mg/L in fish based on experimental data. The robust summaries do not describe the EC endpoint other than to say it reflects changes in organ function; it is unclear, for example, even whether the value is an EC50 value. An ECOSAR estimate of the LC50 is 1300 mg/L for PTS. These data raise several additional concerns, including the possibility that fish are much more sensitive to chronic PTS exposures than acute exposures and that the ECOSAR estimates are flawed. Therefore, we recommend that the sponsor clarify the biological significance of the EC data and that experimental data should be obtained for acute fish exposures. If the ECOSAR fish estimates do turn out to be wrong, then we also recommend that experimental data be obtained for the other two ecotoxicity endpoints.
4. The robust summaries do not list the species used to obtain the oral LD 50 value.
5. The test plan indicates a NOEL of 120 mg/kg/day in the repeat dose study. However, the robust summaries indicate that increases in white blood cells were detected at this dose. Therefore a NOEL was not achieved in this study.
6. There is a consistent lack of details in the robust summaries that make it difficult to evaluate this submission. For example, the list of tissues examined by histological methods is not provided for the repeat dose study. These deficiencies need to be remedied so that the robust summaries comport with program requirements.

Thank you for this opportunity to comment.

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