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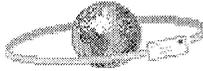
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To: NCIC HPV, moran.matthew@epa.gov

cc:

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Subject: Environmental Defense comments on Triclocarban (CAS# 101-20-2)



Richard_Denison@environmentaldefense.org on 05/20/2003 11:14:11 AM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, adecarvalho@sdaq.org

cc: luciery@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on Triclocarban (CAS# 101-20-2)

(Submitted via Internet 5/20/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, luciery@msn.com and adecarvalho@sdaq.org)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Triclocarban (CAS # 101-20-2).

The test plan and robust summaries for triclocarban (TCC) were prepared by the TCC Consortium of the Soap and Detergent Association. The sponsor has prepared a well-written and complete test plan and set of robust summaries. Information is included that goes beyond the required SIDS endpoints, including a 2-year cancer study and eye irritation and skin sensitivity data. These data are useful since TCC is used as an anti-microbial agent in a wide array of cleaning products such as soaps, detergents and cleansing lotions. The sponsor has included considerable information on environmental and human exposure and has used the exposure and hazard data to present a margin of exposure analysis for both ecological and human health effects. These risk assessments are not required by the HPV program, so we conducted only a cursory evaluation of the risk assessment methods and conclusions. The sponsor concludes that available data are sufficient to fulfill requirements of the HPV program and that no new studies are needed. We agree with this conclusion. Specific comments are as follows:

1. The mammalian toxicity data demonstrate that TCC has relatively low toxicity, is negative in genetic toxicity tests and is also negative for carcinogenesis in a 2-year bioassay in rats. Moreover, there are few or no apparent effects in well-conducted reproductive and developmental toxicity studies.
2. The repeat dose study in rats was conducted in 1960 and was not done according to GLP standards. This 30-day study produced an apparent NOAEL of 1000 mg/kg/day, which is in apparent conflict with data from interim sacrifices in a cancer study also cited by the sponsor, where a NOAEL of 25 mg/kg/day was reported. The year for this latter study was not reported in the robust summary, but we must assume that it was conducted much later than the 1960 study. We urge EPA and the sponsor to use data for the interim sacrifices of the carcinogenesis study as the basis for evaluating repeat dose effects.
3. Data presented for ecological effects indicate that aquatic invertebrates are the most sensitive endpoint, and the sponsor reports a NOEC of 1.46 ug/l. The predicted no effect concentration(PNEC) of 0.146 ug/l is derived using an uncertainty factor of 10. The sponsor states that

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modeled and field concentrations are below the PNEC. However, data presented in the test plan and robust summary report that one site along the Delaware River had surface water measurements of approximately 0.2 ug/l on two separate occasions. The test plan appropriately states that concentrations of TCC in wastewater are of potential concern because of its use as a detergent and soap, although approximately 80-90 percent is, according to the sponsor, removed by wastewater treatment. However, TCC is released to the environment after wastewater treatment and the concentrations found in some surface waters are close to levels toxic to aquatic invertebrates. Therefore, we urge that every effort be made to reduce the amounts of TCC that are entering the environment.

4. As stated above, the sponsor reports a NOEC of 1.46 ug/l for aquatic invertebrates. However, data reported on pages 24 and 25 of the robust summary seem to report that the NOEC is much lower in chronic toxicity studies on aquatic invertebrates. For example, a NOEC of 0.06 ug/l is reported for reproductive effects in *Mysidopsis bahia* and similar results are reported for other reproductive studies on aquatic invertebrates. If these data are correct, then current surface water concentrations of TCC are clearly too high and should be decreased.

Thank you for this opportunity to comment.

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