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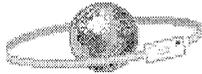


NCIC HPV
Sent by: Mary-Beth
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05/23/2003 09:53 AM

To: NCIC HPV, moran.matthew@epa.gov
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Subject: Environmental Defense comments on N-Methylphthalimide (CAS# 550-44-7)



Richard_Denison@environmentaldefense.org on 05/22/2003 10:32:52 AM

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Subject: Environmental Defense comments on N-Methylphthalimide (CAS# 550-44-7)

(Submitted via Internet 5/22/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Ronald.Joiner@GEP.GE.COM)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for N-Methylphthalimide (CAS# 550-44-7).

General Electric Company, in response to EPA's High Production Volume Challenge Program, has submitted a Robust Summary/Test Plan for N-methylphthalimide (PI). This Test Plan is somewhat cursory. It consists only of a Table of Contents for the Test Plan and Robust Summary, a single page describing the chemical structure, synonyms and use pattern of PI and a matrix of SIDS elements that have been addressed by available data or computer modeling. Thus, the Test Plan is not very useful other than to provide a checklist of studies done. Further, the use pattern does not provide assurance that the PI produced at the single plant indicated by the sponsor is used exclusively at that plant and is not transported in such a manner as to risk environmental and/or human exposure.

The matrix of studies done and proposed indicates most required SIDS elements have been addressed. The matrix also indicates the General Electric Company plans to conduct additional studies to provide data on repeat dose toxicity and developmental toxicity and teratogenicity. These proposed studies seem unnecessary, as our review of the Robust Summary indicates adequate studies that were conducted under GLP exist to address these SIDS elements. Results of these studies indicate PI has low to moderate toxicity in repeat dose studies. Further, it does not adversely effect development and is not a teratogen. Given these findings, and our interest in minimizing animal testing, we would not recommend that additional repeat dose or developmental toxicity/teratogenicity studies be conducted.

Reproductive toxicity studies are also proposed, but have not been conducted. We note that the reproductive organs were saved, but not examined, in the repeat dose studies. If those tissues are still available and a thorough histological examination indicates no adverse effects associated with PI administration, then we would recommend no additional testing for reproductive toxicity; otherwise, we concur with the proposal to conduct such testing.

And finally, although the acute toxicity studies described in the Robust Summary are not satisfactory to meet modern requirements, they should not be repeated, as the repeat dose studies adequately demonstrate the moderate

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to low toxicity of N-methylphthalimide.

Thank you for this opportunity to comment.

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