

Environmental Defense Comments on Methyl N-Amyl Ketone

(Submitted via Internet 3/29/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Methyl N-Amyl Ketone.

The test plan and robust summary submitted by Eastman Kodak conclude that existing data are adequate to fulfill the requirements of the HPV program. We agree with this conclusion with one exception as noted below. We also have a concern about occupational exposures to this chemical.

The repeat dose inhalation and oral studies were conducted at unknown times according to the test plan, no raw data were available for review, and the studies were conducted pre-GLP. The studies were published in 1972, 1979 and 1981. The adequacy of the repeat dose studies must be questioned because the publications were not geared to fulfill the HPV requirements as raw data were not available to the sponsor and the completeness of the study including the range of histological analyses cannot be judged. Without additional information, it does not appear that the repeat dose study meets the HPV criteria for inclusion.

The combined reproductive/developmental study does fulfill the requirements of the HPV program and it was used to establish a maternal NOEL of 80 ppm. We were disturbed to read that the OSHA PEL for methyl N-amyl ketone is 100 ppm and the TLV-TWA is 50 ppm. The overlap with the NOEL raises concern that workers may be exposed to potentially harmful levels of methyl N-amyl ketone. Is information available on the actual exposures encountered by workers under different exposure circumstances? Although this information is not mandated by the HPV program, it certainly should be addressed as an occupational health issue by the sponsor and OSHA.

Thank you for this opportunity to comment.

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