UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Methoxychlor Registration Standard Cover Memo

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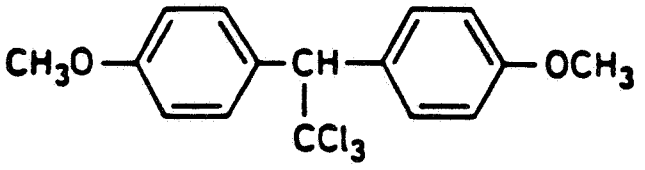
Introduction

Methoxychlor is an insecticide/acaricide registered for use on a wide variety of sites. Currently, of less than a total of a million pounds, about half is used for agriculture (food crops livestock alfalfa and farm premises), 15% for industrial/commercial (including grain storage), and the remainder on home and garden (especially orchards, ornamentals and flea/tick control). Methoxychlor is an organochlorine analogue of DDT with the follow structure:



Toxicology

The toxicological data base for methoxychlor is virtually devoid of acceptable studies due to multiple deficiencies. This includes two oncogenicity studies (rat and mouse) that were

negative for oncogenic effects. Methoxychlor is considered to have estrogenic activity. This observation is supported by the reproduction studies that indicate a possible reproductive effect with no fertilization occurring in one study. This is further corroborated by the teratology studies that showed a high incidence of fetal resorptions. Data from special reproduction studies conducted at the EPA laboratory (RTP) also support these findings. We cannot reliably conclude any special hazard concerns with the existing data base since data requirements are extensive.

Residue Chemistry

The nature of the residues of methoxychlor in plant and animals is not adequately understood and metabolism studies are required. The DDE analogue may be present in technical methoxychlor as a contaminant, but limited evidence does not clearly indicate that this is a metabolite in plants and mammals.

Of the many published tolerances (40 CFR 180.120), none are supported by adequate data and the new requirements for continued registration are extensive.

Tolerance Reassessment

The current RFD (PADI) recommended by HED is 0.005 mg/kg/day based on tentative results from a teratogenicity study. This is an order of magnitude lower than that established by a 1951 FDA chronic rat study. Since neither the toxicological data nor the residue data base are suitable, any comparison of the TMRC with the ADI is not appropriate at this time.

FDA surveillance data indicate that methoxychlor residues are rarely detected and dietary exposure to the general population is quite low. There is an apparent pattern of small grain/animal feed contamination, occasionally at rather high levels (260 ppm); however, corresponding residues do not appear to be common in poultry, eggs, or milk. There would appear to be no basis for concern over dietary residues at this time.

Ecological Effects

Acceptable data indicate that methoxychlor is practically nontoxic to birds on an acute basis; however, data are needed on potential reproductive effects. Technical methoxychlor is very highly toxic to warm and cold water fish, fresh water invertebrates, and marine species. Precautionary statements are required on labels. Note that the label for forestry use should

be revised. A risk assessment for aquatic organisms cannot be completed until additional toxicity and environmental fate studies are available.

Environmental Fate

None of the environmental fate studies submitted to the Agency satisfy requirements for registration and the data requirements are extensive.

Ground Water

Available data suggest that methoxychlor is unlikely to contaminate ground water because of its low solubility and adsorption to particulates. Methoxychlor residues have not been reported for nearly 1300 wells sampled in ten states. Other pesticide monitoring systems (Storet) indicate that methoxychlor has been reported from 205 of 10859 samples from widespread localities; however, the validity of these reports has not been determined Validation procedures are being developed by the monitoring program.

Worker Exposure

The available toxicity data and poisoning incidence information do not indicate a need for a reentry statement. When a more complete data base becomes available, the need for a reentry interval will be revisited.