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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Reregistration Data Call In Requirements for Paraquat, Fluometuron, Trimethacarb, Lindane, Folpet DDVP and OBPA

FROM: Penelope Kerner-Crisp, Director
Health Effects Division (H7509C) 7/5/91

TO: Allan Abramson, Acting Director
Special Review and Registration Division (H7508W)

The following tables list changes which should be made to your June 5, 1991, draft of DCI's ("Status and Registrants Response") for the above-mentioned chemicals.

PARAQUAT, CASE NO 0262, CASWELL 634, SH 061601

The toxicology requirements are accurate on the draft. In response to your inquiry about the status of 82-4, 90 day Inhalation, a waiver of this study was granted on 4/23/90, HED #007876, and a copy of the review was previously forwarded to SRRD.

Numerous changes are needed in the CBII product and residue chemistry DCI requirements; new plant and animal metabolism studies will be required, residue analytical methods, storage stability, crop field trials and processing studies for various crops. Details will be given in a CBII update (currently in secondary review) to be sent to SRRD under separate cover. The update, and any footnotes to the tables, should be used to develop the revised DCI.

The following OREB requirements should be added to the DCI, because of current registered use patterns (foliage desiccant to aid potato harvesting) and due to the toxicity of this compound (Tox I-Dermal and Inhalation):

Reentry Protection

132-1B Soil Dissipation (potatoes)
133-3 Post-application Dermal Exposure (potatoes)
133-4 Post-application Inhalation Exposure (potatoes)

A complete exposure assessment was conducted in 1987 for the Registration Standard did not require mixer/loader applicator data for paraquat. OREB has determined that mixer/loader/applicator data are still not required at this time.

FLUOMETURON, CASE NO 0049, CASWELL 460A, SH 035503

The following tox requirements should be deleted from the DCI:

81-8 Acute Neuroxicity-Rat
82-5B 90 day Neurotox-Rat

These studies are not needed for this class of chemical; and, no evidence of neurotoxicity has been demonstrated for fluometuron.

The following CBII requirements should be deleted from the DCI:

171-4E Storage Stability

The need for this study will be determined later following review of requested plant and animal metabolism studies. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting the stability of these residues during storage will be required.

There are no Tox triggers for reentry or mixer, loader, or applicator studies, therefore no OREB data are needed in the DCI.

TRIMETHACARB, CASE NO 0112, CASWELL 893A, SH 102401

The following tox requirements should be added to the DCI:

81-8 Acute Neuroxicity-Rat (needed for carbamate chemicals)
82-5B 90 day Neurotox-Rat (needed for carbamate chemicals)

85-1 Metabolism

2

A metabolism study is needed because it was required since the 1985 standard, was reviewed in 1988, and was found to be not acceptable.

The following study was inadvertently excluded from the DCI and should be added to the CBII portion of the DCI:

63-11 Octanol Water Coefficient

There are no Tox triggers (trimethacarb is in acute dermal toxicity category III and acute inhalation toxicity category III) for reentry or mixer, loader, or applicator studies, therefore no OREB data are needed in the DCI.

LINDANE, CASE NO 0315, CASWELL 527, SH 009001

- The toxicology requirements on the draft DCI are accurate.

There are many changes needed in the product and residue chemistry portions of the DCI. Please refer the tables and footnotes in the January 31, 1991, CBII update (previously sent to SRRD under separate cover) for details.

In addition, because of the toxicity of this compound (Tox Category II-Inhalation), and the fact that lindane is a group C oncogen with a Q*, the following new requirements should also be included:

Reentry Protection

132-1A Foliar Dissipation
(grapes, turfgrass, greenhouse tomatoes)
133-3 Dermal Exposure
(apples, grapes, turfgrass, greenhouse tomatoes)
133-4 Inhalation Exposure
(apples, grapes, turfgrass, greenhouse tomatoes)

The Agency now requires that foliar dissipation studies be conducted concurrently with dermal exposure and inhalation exposure studies.

FOLPET, CASE NO 0630, CASWELL 464, SH 081601

The toxicology requirements on the draft DCI are accurate.

No changes are necessary to the CBRS portion of the DCI.

The following applicator exposure information should be included on the DCI because folpet is a B2 carcinogen and is in category 2 for inhalation toxicity.

Reentry Protection

133-3 Post-application Dermal Exposure
For plastics, this requirement may be waived if detailed descriptions for the use of treated products indicate that exposure is not of concern (see memorandum from Steven M. Knott to Venus Eagle dated May 22, 1991). OREB recommends that the registrant submit the protocol for this study prior to initiation of the study.

DDVP, CASE NO 0310, CASWELL 328, SH 084001

The following tox requirements should be added to the DCI:

81-8 Acute Neuroxicity-Rat
82-5B 90 day Neurotox-Rat (the determination of adverse effect on the eyes is strongly suggested)
85-7 Ocular Effects (6 month-dog; protocol for study must be submitted)

These studies are needed for the organophosphates.

To address the two Tox issues mentioned in the DCI, the cytogenetics test assaying for aberrations in spermatogonia and spermatocytes should be listed on the DCI as 84-4, other genotoxic effects (and not 84-2B, structural chromosomal aberrations). Note that the other mutagenicity requirements have been satisfied. Guideline 83-1A, chronic toxicity in the rat, should not be included on the DCI; based on cumulative information known about DDVP, there are no other toxicological endpoints of concern other than ChE inhibition. A NOEL for ChE inhibition has already been determined.

No changes are necessary to the CBRS portion of the DCI.

OREB agrees with the DCI, however notes that the following data have been identified to be required by the Agency as part of the Special Review DCI:

158.390 Reentry Protection

133-3 Dermal Exposure for:

indoor fogger use in commercial structures (dairy barns, milk rooms, mushroom houses, greenhouses, and tobacco warehouses) indoor coarse sprays applied in commercial structures

4

indoor sprinkling of floors in commercial structures (tobacco warehouses)

home gardens

mattresses

133-4 Inhalation Exposure for:

indoor fogger use in commercial structures (dairy barns, milk rooms, mushroom houses, greenhouses, and tobacco warehouses)

indoor coarse sprays applied in commercial structures

home gardens

mattresses

Mixer/Loader/Applicator Exposure Monitoring

231 Estimation of Dermal Exposure at Outdoor Sites:

dairy cattle applications

home garden applications

233 Estimation of Dermal Exposure at Indoor Sites:

indoor fogger use in commercial structures (dairy barns, milk rooms, mushroom houses, greenhouses, and tobacco warehouses)

indoor coarse sprays applied in commercial structures

mattresses

aerosols applied by homeowners

232 Estimation of Inhalation Exposure at Outdoor Sites

dairy cattle applications

home garden applications

234 Estimation of Inhalation Exposure at Indoor Sites

indoor fogger use in commercial structures (dairy barns, milk rooms, mushroom houses, greenhouses, and tobacco warehouses)

indoor coarse sprays applied in commercial structures

mattresses

aerosols applied by homeowners

OBPA, Oxybisphenoxarsine, CASE NO 0044, CASWELL 626B, SH 012601

The toxicology requirements on the draft DCI are accurate. No changes are necessary to the CBRS or OREB portions of the DCI.

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