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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Human Health Assessment of Propazine, PC Code 080808,
D22149, D224185

FROM: Kathryn Boyle, Chemist *Kathryn Boyle 8/7/96*
Risk Characterization and Analysis Branch
Health Effects Division

THROUGH: Michael Metzger, Chief *Michael Metzger*
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TO: Robert Taylor, PM Team 25
Fungicide-Herbicide Branch
Registration Division
and
Joseph Bailey
Special Review Branch
Special Review and Reregistration Branch

In response to the Agency's letter (Grassley-Allen notification) of August 18, 1995, notifying Griffin Corporation that the Agency was considering including propazine in the ongoing triazines special review, Griffin Corporation submitted on September 27, 1995, a Propazine Health Hazard Assessment. As a chemical, propazine is unusual in that it is going through the registration process as a new chemical and is also being considered for inclusion in the triazines special review. Thus, Health Effects Division (HED) was tasked by both Registration Division and Special Review and Reregistration Division to review the human health portions of the Griffin Assessment.

The registration for propazine was previously held by Ciba-Geigy Corporation. Thus, Ciba has ownership of the propazine database. However, the registration was voluntarily cancelled in 1990. Presently, the only uses of propazine are under the Section 18 emergency exemption. In reviewing a Section 18, the Agency can use all available data to make the best possible decision. However, for a new chemical registration, Griffin must either perform or purchase all studies used by the Agency to make the registration decision. HED has attempted to



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obtain information on exactly which of the Ciba studies were purchased by Griffin. However, the information provided has been conflicting, such as study titles being cited in one list, but the MRID number of the cited study is not in another list. HED requests that Registration Division obtain a listing of the studies purchased by Griffin with complete titles, MRID numbers and a statement specifying which guideline number each study is expected to fulfill. Please note that HED has attempted, as best possible, considering the conflicting information, to ascertain the data gaps that could exist in the Griffin propazine database. (Farwell memo July 2, 1996)

Without a complete toxicology database, HED was unable to have propazine reviewed by the RfD Committee and the Toxicology Endpoint Selection Committee (TESC). Therefore, HED cannot comment on the endpoints selected by Griffin in its assessment. Since it is not possible to complete the Hazard Identification /Dose Response Assessment portion of the review, this review can only be considered to partially fulfill HED's original tasking from RD and SRRD.

HED's Chemistry Branch Reregistration Support (CBRS) reviewed the dietary exposure section of the Assessment. Propazine is used on sorghum, which is used as livestock feed. Overall, Griffin's approach was similar to the approach that would be used by HED. The major comments from CBRS's review are that (1) it is not possible for HED to comment on the residue values in the Assessment since the metabolism studies on sorghum, lactating goats, and laying hens used in the assessment have not been submitted to or reviewed by HED, (2) data from the April 1994 version of Table II was used instead of the more recent Table II (September 95), and (3) a value of 7 percent crop treated (CT) was used. (Abbotts memo May 14, 1996)

HED's Occupational and Residential Exposure Branch (OREB) reviewed the worker exposure section of the Assessment. The RfD is not the traditionally selected endpoint for estimating occupational exposures. TESC would select appropriate endpoints for the short-term, intermediate-term and chronic scenarios. Also, in the absence of a TESC determination, 100% dermal absorption is assumed. OREB noted problems/deficiencies in the methodology used to derive unit exposure values from PHED, and used to extrapolate estimated doses from unit exposures. The exposures were recalculated. (Carleton memo May 20, 1996)

There are differences in the assumptions used in the drinking water assessment. HED uses the following equation:

$$\text{Exposure (mg/kg/day)} = (\text{ppb in the water consumed})(10^{-6})(22.6)$$

The 22.6 mg/kg-body wt/day used in this calculation was derived using water consumption values and self-reported body weights obtained from USDA's 1977-1978 Nationwide Food Consumption Survey. The other assumption used is assuming that water from the same source containing the same contaminant level is consumed throughout a 70 year lifetime. Most of the US population moves at some time during their life and does not live in the same area, drinking from the same water source for a 70 year lifetime. It could be considered as either an over-estimation or an under-estimation of risk depending on the contaminant levels in the other sources of drinking water.

The following must occur before HED can properly complete it's review of the human health portion of the Griffin Assessment:

- 1) HED must be given a complete listing of studies purchased by Griffin from Ciba, with subsequent HED/TOX rereview of the studies using the current guidelines (See Farwell memo),
- 2) Submission by Griffin of the sorghum, goat, and hen metabolism studies with subsequent HED/CBRS review of the studies,
- 3) Confirmation by BEAD (Biological and Economic Analysis Division) of the 7% CT,
- 4) Submission of the Griffin-performed toxicological studies with subsequent HED/TOX review of the studies,
- 5) Review of propazine by RfD Committee,
- 6) Review of propazine by TESC,
- 7) Review of propazine by CPRC (Cancer Peer Review Committee),
- 8) Possible review of propazine by HED Metabolism Committee,
- 9) Performance of DRES (Dietary Risk Evaluation System),
- 10) Calculation of occupational MOEs for short-term, intermediate-term and chronic scenarios,
- 11) Consultation with EFED (Environmental Fate and Effects Division) on the available data on propazine in groundwater and surface water.

HED would be willing to meet or to hold a conference call with Griffin to discuss these issues.

cc: Kit Farwell
Jim Carleton
John Abbotts
Bill Hazel
Debbie McCall
Mike Metzger
Terri Stowe (RD)
Andrea Medici (OGC - 2333)
RCAB files



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