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

MAR 7 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Propazine (080808), Reregistration Case No. 0230.
Conversations with Registrant Representative.
No CBRS No., No DP Barcode No., No MRID No.

FROM: John Abbotts, Chemist
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TO: Chemistry Branch Files

On 2/27/96, representatives of CBTS/CBRS met with Dr. William Tweedy, consultant to Griffin Corporation, on a proposed use on sorghum. No registrant supported reregistration of propazine, and this proposal is being treated as a new use. CBTS has recently specified requirements for metabolism studies (Memo, 1/11/96, M.S. Metzger), and Dr. Tweedy desired further information on these requirements. During the 2/27 meeting, Dr. Tweedy made the comment that he would prefer not to discuss data on atrazine. This led the Chemistry Branch representatives present to believe that Griffin did not have access to toxicology data on hydroxyatrazine, which were relevant to the Metabolism Committee's recent decisions pertaining to atrazine. Consequently, discussion at the 2/27 meeting was rather general and we advised that we would have to give answers specific to propazine at a later date.

Subsequent to that meeting, Terri Stowe advised that Griffin had purchased access to the toxicology data on hydroxyatrazine from Ciba, and Mike Metzger advised that Metabolism Committee decisions should be considered public documents (personal communications). With this information, I contacted Dr. Tweedy by telephone on 3/6/96 to comment on the material he presented at the 2/27 meeting. The CBTS memo (1/11/96) was designed to set requirements for propazine consistent with Metabolism Committee decisions on atrazine. These decisions call for exposure

assessments based on three residue subsets: parent and chloro metabolites as the residues of concern for cancer, and analysis using RfD endpoints based on combined residues of free hydroxy metabolites, and also on TRR minus the combined free hydroxy residues.

With this background, I was able to comment on the proposals Dr. Tweedy had presented earlier for further work by Griffin:

1a. and 1b. Reanalyze samples from the sorghum metabolism study for chloro residues parent, G-3003, and G-28273; and for hydroxy residues GS-11526, GS-17794, and GS-17791 (see Figure 1 for structures). I advised that this proposal was consistent with the 1/11/96 memo, with the additional understanding that data on TRR would also be required. At the 2/27 meeting, Dr. Tweedy had also asked about residues to be analyzed during sorghum field trials, which are already in progress. I advised that data on parent and chloro metabolites would be required at a minimum. It may also prove to Griffin's advantage to measure residues of the free hydroxy metabolites, but if review of the metabolism study indicated these would be present at levels below the limit of detection of an analytical method for unlabeled residues, then we would waive the requirement for field trial data. He advised that the metabolism study had detected levels of GS-11526, but not the other free hydroxies.

2a. A goat metabolism study based on 0.25 ppm propazine in the feed. Dr. Tweedy indicated that this study was designed to substitute for a cold feeding study with parent only. I advised that since a metabolism study was already in progress at 10 ppm parent, such an additional study seemed of limited usefulness with regard to metabolism data. Moreover, if the proposed use proceeded to a point where granting tolerances for animal commodities might be considered, it seemed likely that the Agency would require a cattle feeding study with unlabeled residues. I advised that we would not require this additional goat metabolism study.

2b. A goat metabolism study at 0.25 ppm hydroxypropazine (GS-11526) in the feed. I noted that information in the PD1 for triazines (59 FR 60412, 11/23/94) indicated that transfer ratios, residues in tissues:residues in feed, were significantly higher for atrazine parent than for atrazine metabolites. With this information, a feeding study at low levels of hydroxypropazine might work to the petitioner's disadvantage if residues in tissues were below the limits of detection, thereby causing an artifically high transfer ratio that would be used in exposure assessment. I recommended feeding at least 10 ppm hydroxypropazine, and higher levels would be preferable if the goat could tolerate them. I advised that this requirement was also consistent with the CBTS memo of 1/11/96.

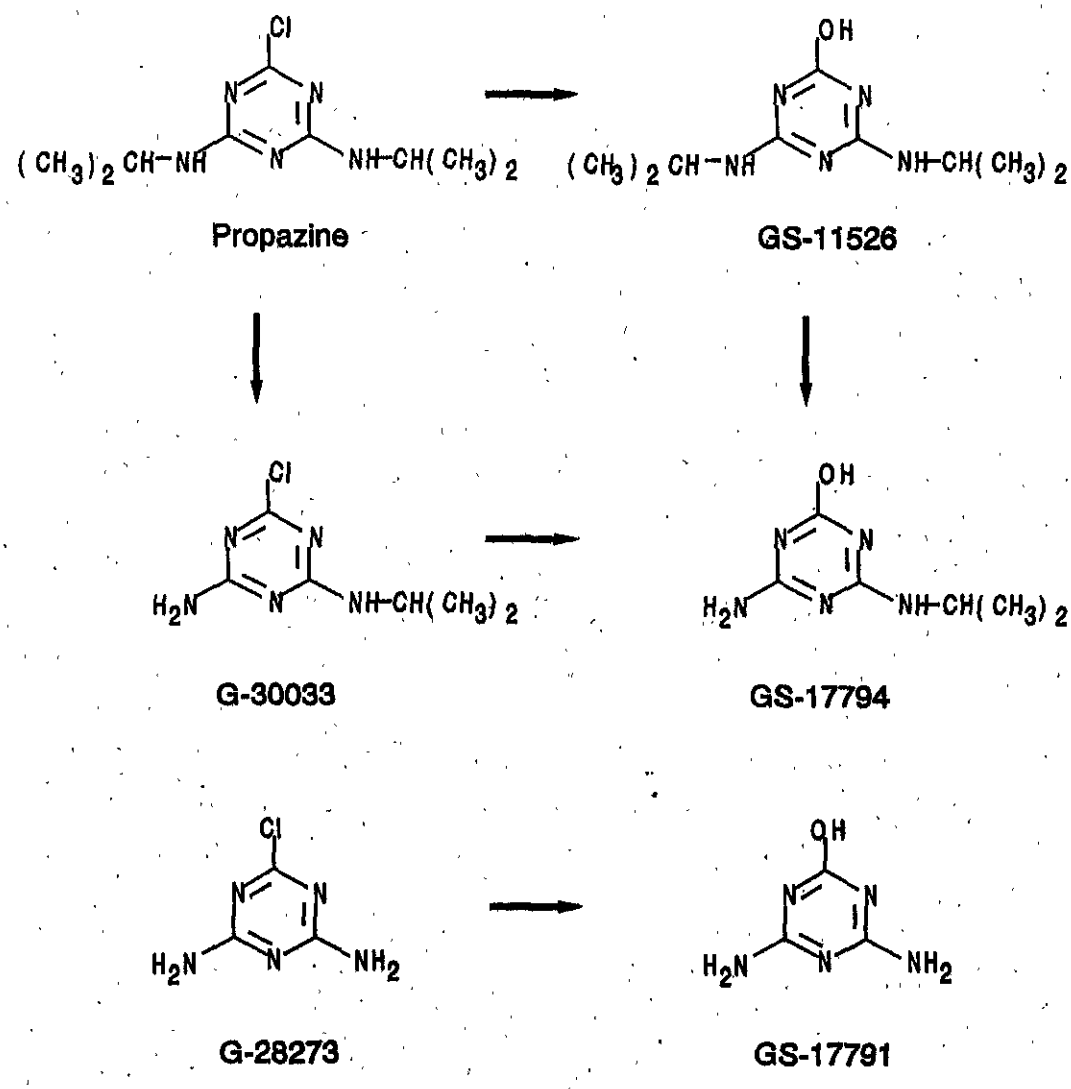

Figure 1. Propazine and potential metabolites.

3. A poultry metabolism study based on 0.25 ppm hydroxypropazine in the feed. We advised at the meeting that this did not seem to be required by the 1/11 memo, and would confer with Mike Metzger on this point. During the telephone conversation, I advised that in fact this study had not been required, and assuming that TRR in poultry tissues from the metabolism study with parent were 0.006 ppm or less, the usefulness of such a study seemed limited. We will not require this study.

Dr. Tweedy had additional questions on rotational crops, which he had not mentioned at the meeting on 2/27. He said that he had informed Mike Metzger that Griffin had limited data from confined studies, because of poor growth of the rotational crops, and Mike had advised that the company should proceed to limited field trials. Dr. Tweedy reported that limited field trials were also in progress, and asked what residues should be measured. I advised that similar considerations as with sorghum metabolism/field trials should be in effect: The confined studies should provide, to the best of the registrant's ability, data on parent and chloro metabolites, on free hydroxy metabolites, and on TRR. The field trials should include residue data on parent, chloros, and if feasible, on free hydroxies. As with the sorghum studies, however, if the confined studies indicated that residues of individual hydroxies would be below the limits of detection for the cold analytical method, the requirements for field trial data would be waived. (Mike Metzger, personal communication, has advised that he does not recall making recommendations to Griffin on rotational crop studies. However, if the limited rotational trials are underway, he concludes that the recommendations here are reasonable.)

I passed on a request from Terri Stowe for Dr. Tweedy to submit a memorandum of understanding based on our conversation. I advised that I would prepare a memorandum for the files with a copy to Ms. Stowe.

The conversation ended at this point.

cc:Abbotts, RF, Propazine List A File, SF, Terri Stowe (RD), Debra Edwards (HED,IO), Kathryn Boyle (RCAB).
RDI:ARRathman:3/7/96:RBPerfetti:3/7/96:EZager:3/7/96
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