



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

OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

Chemical: Propazine
PC Code: 080808
DP Barcode: D345936

MEMORANDUM

DATE: June 16, 2008

SUBJECT: Transmittal of the Environmental Fate and Effects Division's (EFED) Response to Comments on Data Gaps Identified in the Registration Science Chapter for the Ecological Risk Assessment of Propazine New Use on Sorghum (DP 310326) dated November 2, 2006

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Attached please find the Environmental Fate and Effects Division's (EFED) response to comments submitted by Griffin LLC (the registrant of propazine use on sorghum) on the data gaps outlined in EFED's new use risk assessment dated November 3, 2006. In that assessment, EFED identified a number of data gaps and summarized the need for each study in the context of the risk conclusions in the assessment. The data gaps identified by EFED are summarized below.

Data Gaps

The environmental fate profile is sufficient to conduct a risk assessment and estimate potential exposures due to the use of propazine. In general, the environmental fate data provide the necessary information to estimate exposures. However, data on anaerobic aquatic metabolism



(OPPTS Guideline 835.4400) aerobic aquatic metabolism (OPPTS Guideline 835.4300) and terrestrial field dissipation (OPPTS Guideline 835.6100) will reduce uncertainty in the risk assessment. Several studies are missing in the ecotoxicity data set for propazine; especially chronic/reproduction testing in birds (OPPTS Guideline 850.2300) and acute toxicity studies in freshwater and marine estuarine fish (OPPTS Guideline 850.1075). Again, data from these studies will reduce uncertainty in the risk assessment.

Selected uncertainties and data gaps are summarized in the following tables.

Environmental Fate Data Requirements for Propazine		
Guideline #	Data Gap	Value of Additional Testing
162-3 835.4400	Anaerobic Aquatic Metabolism	Medium. Lack of data led to assumption of half life in aquatic exposure modeling. Submission of data can remove uncertainty in this assumption
162-4 835.4300	Aerobic Aquatic Metabolism	Medium. Lack of data led to assumption of half life in aquatic exposure modeling. Submission of data can remove uncertainty in this assumption
164-1 835.6100	Terrestrial Field Dissipation	Low. Data classified as supplemental. Additional data, or a new study, needed to confirm leaching potential of compound. Lack of storage stability data and fact that propazine was found in controls is problematic.

Ecological Toxicity Data Requirements for Propazine		
Guideline #	Data Gap	Value of Additional Testing
71-4 850.2300	Avian reproduction (bobwhite quail) (mallard duck)	High. No study is available. Other chemicals in this class indicate reproductive effects to birds. Sublethal effects in the acute avian studies coupled with similar effects observed in the mammalian reproduction study increase the uncertainty for effects observed in birds following chronic exposure.
72-1 850.1075	Freshwater fish acute LC ₅₀ (rainbow trout) (bluegill sunfish)	Medium. No valid studies available. Chronic toxicity NOAEC/LOAEC from fathead minnow study plus a comparison with chemicals from similar class indicate that LC ₅₀ is likely sufficiently high not to exceed acute LOC for endangered species.
72-2 850.1075	Freshwater invertebrate acute EC ₅₀ (daphnia)	Pending. A study has been reviewed but not finalized by the Agency (MRID 442873-05). The study is scientifically sound but does not fulfill guideline requirements because daphnids were not exposed up to 100 ppm ai. Consequently, the acute toxicity of propazine to freshwater invertebrates cannot be categorized. If it can be shown that the test was conducted up to the limit of solubility, the study could be upgraded to acceptable. However, for these requested uses, a comparison of the highest concentration tested in the daphnid study with the peak EEC for the proposed uses shows that there were no effects in daphnids at concentrations 61 times higher than the highest peak EEC.
72-3a	Estuarine/marine fish acute LC ₅₀ (sheepshead minnow)	Medium. No studies available. Chronic toxicity NOAEC/LOAEC from sheepshead minnow study plus a comparison with chemicals from similar class indicate that LC ₅₀ is likely sufficiently high not to exceed acute LOC for endangered species.

Ecological Toxicity Data Requirements for Propazine		
Guideline #	Data Gap	Value of Additional Testing
72-4a 850.1400	Freshwater fish early life stage (fathead minnow)	Low. The study was classified as supplemental because pH and hardness exceeded recommended levels, potentially affecting solubility.
72-4d 850.1350	Estuarine/marine invertebrate life cycle (mysid)	Low. The study was classified as supplemental due to deviations in study design.

EFED Response to Comments

EFED's summary of data gaps identified in the November 3, 2006 ecological risk assessment are based on the current data requirements for a pesticide registration at the time of the assessment. These data requirements are spelled out in detail under 40CFR, Part 158. The environmental fate data requirements are under Subpart N, section 158.1300 while the ecotoxicity data requirements are under Subpart G, sections 158.630 (non-target organisms) and 158.660 (non-target plants). The gaps identified above were developed from the current list of required studies which may be found in detail at the following website:

http://www.epa.gov/pesticides/regulating/data_requirements.htm#fate

A summary of the current requirement for each study listed in the Griffin letter as well as individual comment responses are presented below.

Anaerobic Aquatic Metabolism (162-3) and Aerobic Aquatic Metabolism (162-4)

Both the anaerobic and aerobic aquatic metabolism studies are current required studies for registration of terrestrial uses. The registrant also appears to argue that these studies are not needed because propazine on sorghum will only be in arid locations and thus aquatic exposures are not expected. First, there is no geographic restriction of the registration to arid only areas and clearly sorghum is grown in areas where both flowing and standing water bodies reside. In fact, the registrants have acknowledged this fact by initiating a monitoring study for total triazines (including propazine) in the sorghum growing areas of Texas. While arid areas may receive less rainfall than wetter climates, there are numerous surface water bodies that run through arid regions and thus the need for these studies is clear. Based on these facts EFED believes these data still represent a data gap.

Terrestrial Field Dissipation (164-1)

The terrestrial field dissipation data gap was based on a review of the submitted studies that appears to have failed to take into account the agreement on protocol deviations that occurred during a meeting on May 14, 1996 between the registrant and EFED. The agreement is outlined in a memorandum of understanding (MOU) attached to the registrant's response to comments. In the

MOU it was agreed that the registrant would conduct two field dissipation studies along with a single lysimeter study. However, the field dissipation studies were modified to reduce the depth of sampling and that degradates would be tracked. Several of the deficiencies noted in the original data evaluation record (DER) for the field dissipation studies noted deficiencies which are adequately addressed in the current comments from the registrant. These include a rationale for the lack of time zero sampling (day one results were reported with little degradation relative to expected residues at time zero), the rate and pattern of degradate formation and decline is sufficiently described in the comments, and the occurrence of cross contamination in the deeper day one samples is acknowledged but does not influence the overall results of the study. Based on the results of the study and the comments it does appear that propazine is persistent and has some tendency to leach. Therefore, EFED believes the studies should remain supplemental but submission of additional field dissipation data is unnecessary.

Avian Reproduction (71-4)

As with the data gap for anaerobic and aerobic aquatic metabolism studies described above the registrant appears to rely on two arguments for not submitting this data. First, the registrant argues that previous documents from the early 1990's did not require these studies and second, they argue that the product will only be applied in arid regions where migratory birds are seldom present and agricultural practices in sorghum preclude exposures. As with the metabolism studies described above, the current Part 158 requirements are that the avian reproduction studies (850.2300) are required for all terrestrial uses, which would include the use of propazine on sorghum. Second, impounded waters are present in the area of sorghum cultivation in Texas, including the arid regions where the registrant is currently conducting a drinking water monitoring study. Also, there is sufficient evidence in the public literature of migratory bird pathways covering this portion of the country as seen in Figure 1. Based on these facts EFED believes these data still represent a data gap.

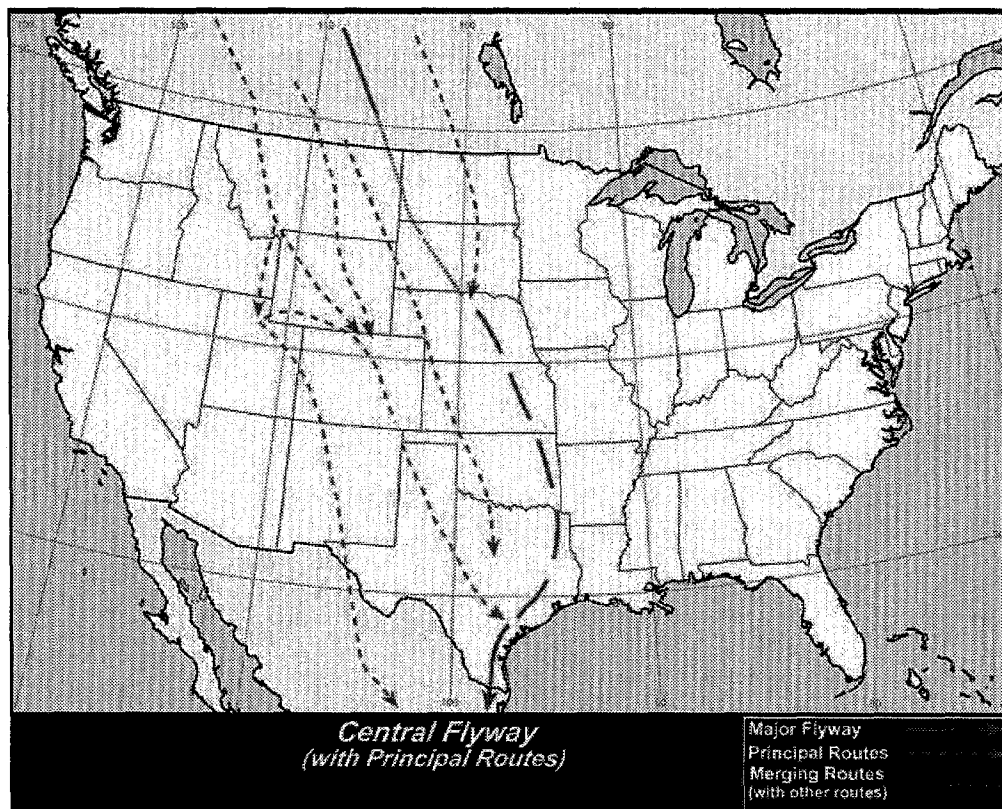


Figure 1. Migratory bird pathways over the central United States including the sorghum growing region of the Great Plains (source: <http://www.birdnature.com/flyways.html>)

Freshwater Fish Acute (72-1)

As noted in the original DER for the bluegill sunfish study (MRID 44287304) a number of issues were reported which resulted in classification of the study as invalid. Principal among these was that due to the limited solubility of propazine, the reported LC₅₀ and NOAEC value (> 4.5 mg ai/L) may underestimate the toxicity of propazine to bluegill sunfish (i.e., the reported LC₅₀ and NOAEC values may be higher than those from a study where the protocol takes solubility into account).

The DER states that precipitate was observed at both of the higher concentrations tested in the study (2.7 and 4.5 mg a.i. /L). The DER also states that the solubility limit for propazine is 3 mg/L.

There is no indication in the study that an attempt was made to either filter or centrifuge the water samples prior to analytical analysis. Therefore, the occurrence of precipitate at higher treatment levels raises a question of actual exposure and bioavailability. As indicated in the rejection rate analysis (EPA, 1994), failure to filter and/or centrifuge water samples prior to analytical analysis is sufficient to classify the study as invalid since the study failed to establish actual exposure concentrations. Erratic swimming behavior in fish treated with 1.0 and 1.8 mg/L of propazine may

represent a compound-related affect in treatments where propazine was freely soluble. In addition to the question on solubility, the review noted that the pH and hardness of the study water were outside the recommended range for conducting this study. Although the current harmonized guidelines with OECD state that hardness can range from 40 – 180 mg/L as CaCO₃, the reported higher range in this study (130 – 160 mg/L), coupled with a slightly higher pH (8.2 – 8.5 (guidelines recommend pH range of 6.0 – 8.0)) may further affect the solubility of propazine in this case. As a note, the review also stated that the temperature in the test system dropped to 19° C (the guidelines recommend a temperature of 22°C for warm water fish), although this was not a listed reason for invalidation of the study.

In the registrant's response, they acknowledge that data do not exist to clarify the solubility issue. In addition, the registrant provides no data to indicate that higher hardness and pH values do not affect propazine solubility in aquatic systems but only restate that they believe this does not influence the study results. Finally, the registrant indicates the reported 19°C temperature was in error and that the actual temperature was maintained within the desired range.

Based on the above summary the registrant appears to have submitted no new data or analysis (other than clarification of the temperature of the test system) to refute the reasons for invalidation of this study. Therefore, the study should remain classified as invalid.

Estuarine Fish Acute (72-3a)

The registrant's argument for this study classification appears to be focused on the fact that the study is not required. However, according to the current 40 CFR Part 158 this is a required study for terrestrial uses (850.1025, 850.1035, 850.1045, 850.1055, & 850.1075). In addition, the study did not determine a definitive LC₅₀ value. Therefore, EFED believes this study is required.

Freshwater Fish Early Life Stage (72-4a)

The original comment from EFED on the study (MRID 44287307) focused on limitations with dilution water. Specifically, both pH and hardness exceeded recommended levels potentially affecting solubility. As with the acute toxicity study with bluegill sunfish, propazine was tested beyond the limit of solubility (highest concentration tested was 4.64 mg a.i. /L). Although the NOAEC and LOAEC were below the solubility limit of 3 mg/L, due to the higher pH and hardness values, it is not known how these parameters affected the solubility of propazine. Again, as with the acute toxicity study with bluegill sunfish, there was no indication that an attempt was made to either filter or centrifuge the water samples prior to analytical analysis. Therefore, it is not possible to adequately characterize the exposure conditions in this study and the study should be reclassified as invalid.

Estuarine/Marine Invertebrate Life Cycle (72-4d)

The registrant notes that no DER was ever sent to registrant. In the new use risk assessment it was noted that the study (MRID 44184803) was classified as supplemental. This classification is based on a draft DER that notes that the study is scientifically sound; however, since second-generation mysids were not maintained for at least 4 days and observed for survival, development and behavior, the study does not fulfill guideline requirements. The draft DER is currently under secondary review and will be forwarded to the registrant upon completion.

References:

EPA. 1994. Pesticide Reregistration Rejection Rate Analysis. Ecological Effects. United States Environmental Protection Agency. Office of Prevention, Pesticides and Toxic Substances. Publication number EPA 738-R-94-035. December, 1994.