

US EPA ARCHIVE DOCUMENT



ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

August 21, 1996

**MEMORANDUM**

**SUBJECT:** Division Director Concurrence for the Diflubenzuron RED (Case 0144)

**FROM:** Denise Keehner, Acting Director  
*Kathleen Keefe*  
Environmental Fate and Effects Division (7507C)

**TO:** Lois Rossi, Director  
Special Review & Reregistration Division (7508W)

I concur with conditions on the Diflubenzuron RED (Case 0144). SRRD has asked a number of questions and requested clarification on several issues. In addition to SRRD's questions, EFED has editorial changes that should be made. Our responses have been divided into two categories according to whether a change to the RED text is required.

**Text modification required.**

**1. Mammal data.**

Discussion: The EFED chapter has been amended to incorporate the updated mammal data. This new information does not change EFED's risk conclusions (EFED already had concluded minimal risk).

Action: Please see the attachment for the changes that must be made to EFED's chapter in order to incorporate the new data.

**2. Estuarine fish toxicity study (acute).**

Discussion: An estuarine fish toxicity study was required because diflubenzuron is used near estuarine and marine habitats. The study that was submitted was conducted on formulated product and not on active ingredient, as is required. While this study was found to be acceptable, meaning that it was determined to be scientifically sound, it does not provide the complete information that EFED needs or required in the DCI. Extrapolation from data based on a 25% formulation test material to the active ingredient would be difficult at best. In an effort to have consistent data and confirm



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our understanding of estuarine risk, EFED needs a study conducted on the technical grade active ingredient. EFED considers this study to be confirmatory, and requests that the data be submitted.

Action: To clarify the justification for calling in this study, please make the following changes to the RED:

- a. **Page 41, C.1. Ecological Toxicity Data.** Replace the last sentence in the section ("An acceptable study...") with "A study conducted on 25% formulation was submitted and found to be acceptable. However, data are still needed using the technical diflubenzuron."
- b. **Page 47, C.1.b.(3) Estuarine and Marine Animals.** Please modify the last two paragraphs (found after the Table) to read as follows:

"These results indicate that diflubenzuron is **very highly toxic** to marine/estuarine crustacea and **highly toxic** to marine/estuarine mollusks. The guideline requirements are fulfilled for an acute marine/estuarine mollusk study and for an acute marine/estuarine crustacea study. Testing of an estuarine crustacean species with the 25% formulation is waived. No further marine/estuarine mollusk or crustacea acute toxicity data are required at this time.

Results of the 96-hour acute toxicity study conducted using the 25% wettable powder formulation indicate that diflubenzuron is **practically non-toxic** to marine/estuarine fish. No further data are needed to support the 25% wettable powder formulation. However, a 96-hour acute toxicity study with an estuarine/marine fish is still outstanding for technical grade diflubenzuron. Therefore the estuarine/marine fish acute toxicity guideline requirement is not fulfilled. (MRIDs 00038611, 00038612, 00039088, 00056150, 00060377, 40098001, 41392001, and 43662001)"

3. **Significant digits in the RED.**

Discussion: SRRD suggested that significant digits should be standardized in EFED's chapter. Thanks for pointing this out.

Action: EFED favors using two decimal places if the value is < 1, and whole numbers for values > 1. Please make the necessary changes.

4. **Clarification of phrase.**

Discussion: Explanation of the sentence "Addenda to this study partially addressed concerns in the original review and analytical methodology, ..." in EFED's discussion of the forestry dissipation study (page 57, second paragraph, second sentence).

Action: Please modify this sentence to read "Addenda to this study partially addressed concerns in the original review of analytical methodology,...." This should clarify that EFED's original review was of the analytical methodology that was provided by the registrant.

5. **Spray drift studies.** EFED would like to clarify that the Drift Field Evaluation study is the only spray drift study that needs to be called in. EFED has an acceptable Droplet Size Spectrum (201-1), but still needs an acceptable Drift Field Evaluation (202-1). We apologize for any confusion.

Action: To clarify the spray drift data requirements, please modify the first paragraph of Page 57, (5) Spray Drift, as follows:

"Additional drift field evaluation data are required to fully characterize diflubenzuron drift. These requirements may be satisfied by the Spray Drift Task Force, on which the registrant participates. Data from the Spray Drift Task Force are currently under review and may ultimately affect the Agency's conclusions on diflubenzuron drift."

6. **Page 77, (5) Aquatic Invertebrates.** Please delete the third bullet, which reads "a restriction on the aquatic uses....". This statement implies incorrectly that EFED places restrictions on swimming.
7. **Page 77, (6) Estuarine and Marine Fish.** Please modify the last sentence of this section to read as follows: "However, this use.....believes that no additional risk mitigation is necessary."
8. **Page 78, (10) Surface Water.** EFED has concluded that there is a risk to aquatic organisms through surface water runoff that contains diflubenzuron. The RED text in this section concludes the opposite. This section must be replaced with the following:

"The Agency has determined that substantial amounts of diflubenzuron could be available for runoff to surface waters for several days to weeks post-application. This runoff will often be primarily via adsorption to eroding soil. In cases where the runoff volume is much greater than the sediment yield, dissolution in runoff water could contribute significantly to the total pesticide runoff. Contributions of diflubenzuron resulting from runoff that are adsorbed to suspended and bottom sediment, and concentrations in the water column pose significant exposure potential for aquatic organisms."

9. **Low use rate for citrus.**

**Discussion:** SRRD asked EFED to incorporate into the division's chapter the low use rate for citrus.

**Action:** Please see the attachment for the changes that must be made to EFED's chapter in order to incorporate the new data.

**No change necessary.**

1. **Buffer zone.**

The "buffer zone" (actually a "filter strip") of 25 feet is EFED's scientifically based recommendation for diflubenzuron. Evidently, the same-sized filter strip was also recommended for permethrin. It is our understanding that, as a result of negotiations, the risk managers changed the permethrin filter strip to 10 feet. EFED stands by its scientifically based recommendation of 25 feet for diflubenzuron.

2. **Exposure potential for honey bee larvae.**

SRRD asked if honey bee larvae could be exposed to diflubenzuron from adult honey bees who have returned to the hive from foraging in diflubenzuron-treated areas. It is not anticipated that there will be significant direct contact with, or feeding of larvae by the adult foraging worker honey bees. Honey bee larvae are isolated in combs and only come into direct contact with the nurse bees who feed them. The honey that is fed to the larvae is processed nectar generated by the adult bees. It is anticipated that the production of the honey in the bodies of the bees will probably metabolize diflubenzuron, resulting in minimal to no exposure of concern.

EFED is aware of research that was conducted about 20 years ago where effects were observed when dimilin was fed to bees (adults and larvae) at very high rates. The researchers concluded with the admonition that field exposure was the key for whether effects were likely. EFED is not aware of any field incidents of honey bee larvae poisonings by diflubenzuron. We would expect that bee keepers would have reported such incidents.

3. **Estuarine fish life-cycle study (chronic).**

EFED is not requesting another estuarine fish life-cycle study. This study was not one of the original data requirements. It was submitted voluntarily. EFED evaluated it and found it to be deficient. The freshwater fish life cycle study is adequate for EFED's risk assessment purposes. Therefore, EFED does not need any more fish life-cycle data.

4. **MRID numbers.** SRRD requested confirmation of certain MRID numbers. SRRD has resolved the problem.

5. **Mesocosm study.**

EFED is not aware of a mesocosm study. We do have a copy of a littoral enclosure study conducted in a natural pond under ambient environmental conditions. This study has not been submitted to EFED for review, but was conducted in Minnesota by EPA-Duluth. The littoral enclosure study is not a mesocosm study, and the results cannot be readily applied to other parts of the country. EFED has not reviewed this study and believes it to be of little value to the RED.

6. **Application of citrus use restrictions.**

SRRD asked whether the restrictions on citrus in Florida should apply to all other areas. The label restrictions for citrus apply only to Florida. EFED considered the probable success of applying these restrictions in other places if there are similar invertebrates of concern (like the shrimp in Florida). Upon analysis of the situation, EFED decided not to request an expansion of the restrictions.

In addition to the above changes to the RED text, EFED has other editorial suggestions on the draft RED document. These comments are noted on the attached pages.

If you have any questions, please call Mary Powell at 305-7384.

cc:	Dan Reider	Hank Jacoby	Doug Urban
	Kathy Monk	Sherry Sterling	Susan Jennings
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