U. S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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MEMORANDUM

DATE: June 11, 2003

SUBJECT: Comments to 60-Day Response by Registrant to the EFED Reregistration Elegibility Decision Chapter of **Oxadiazon**

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The registrant of oxadiazon, Bayer Environmental Science, submitted a 60-Day Response to the Environmental Fate and Ecological Effects (EFED) Risk Assessment for the Reregistration Elegibility Decision of Oxadiazon. The registrant presented the following comments:

Comment: *The registrant's new name is Bayer Environmental Science.*
Response: All references to "Aventis" or "Aventis Environmental Science" will be changed to "Bayer" or "Bayer Environmental Science."

Comment: *The Tier II Aquatic Plant Testing (123-2) has been met by submission of MRID# 41610108 and 41610105.*
Response: EFED agrees, the requirement does not apply. The EFED Risk Assessment for the Reregistration Eligibility Decision of Oxadiazon will be revised accordingly.

Comment: *EFED required Acute and Chronic Sediment Toxicity Testing for oxadiazon (similar comments appear in the cover memo, and in Appendix G). The registrant believes that the requirement may not be applicable for this chemical.*
Response: Oxadiazon is a persistent, lipophilic compound that has a strong capacity to bind to particulate and organic carbon in the water column. This combination of chemical/physical attributes and the relatively

high toxicity profile to fish and invertebrates suggest concern for accumulation in the sediments. Since sediments can act as a repository for lipophilic compounds, there can be direct impact to aquatic organisms through respiration, ingestion, dermal contact, and/or indirect impact through alterations of the food chain. According to monitoring that has been conducted on aquatic ecosystems in suburban watersheds, one of the chemicals most frequently detected in water (low ppt) and sediment (low ppb) was oxadiazon (Armbrust *et. al.*, 2003). Both liquid and granular formulations labels of oxadiazon specify that the chemical's effectiveness is improved if it is wetted in after application. Furthermore, both labels recommend mowing the grass prior to application. Although the turf could present a barrier towards erosion, it also appears that oxadiazon can quickly runoff during the period after the application, but thereafter, the chemical could reach soil surfaces or be intercepted by the foliage. The exact mechanism of runoff for oxadiazon from a turf site to an adjacent body of water can show variation with time. While oxadiazon is expected to bind to soil particles, the turf scenarios offer vegetation interception. EFED believes that the sediment testing outlined in the RED is consistent with Division policy and is still a requirement.

Comment: *EFED required a phototoxicity study on fathead minnow because oxadiazon is a LDPH, which could be the cause of enhanced toxicity in the presence of solar radiation. The registrant objects to this requirement. Similar comments appear in the cover memo, and Chapter 3 of the document.*
Response: Enhanced toxicity of oxadiazon to aquatic organisms after light exposure is an uncertainty. The inhibition of protoporphyrinogen oxidase, the rapid accumulation of protoporphyrin IX with the resulting generation of singlet oxygen (free radicals)and eventual cell membrane destruction suggest that exposure to this compound may increase toxicity to aquatic organisms. This issue was evaluated by EFED's Aquatic Biology Tech Team (ABTT) with recommendations that phototoxicity studies be conducted on "herbicides with this mode of action to determine if animals exposed to LDPHs and intense light (similar to sunlight) show increased toxicity relative to controls exposed to LDPHs and low intensity light. The results of these studies will help to determine if animals that are exposed to sunlight in LDPH use areas are at higher risk than guideline toxicity studies suggest".

The ABTT has requested that a LDPH phototoxicity protocol be submitted for review by the registrants for evaluation by EFED prior to study initiation since fish and other aquatic organisms are expected to be exposed to LDPHs through run-off. Aquatic organisms inhabiting small, shallow water bodies, exposed to high levels of solar radiation would be expected to be at greatest risk for potential phototoxic effects. Therefore, the ABTT is requesting a small fish species be used in a phototoxicity assay to assess the potential of light enhanced LDPH toxicity.

The ABTT requests that the study adequately address the following issues and suggests the paper, "Photoenhanced Toxicity of a Carbamate Insecticide to Early Life Stage Anuran Amphibians",and other studies in the peer-reviewed scientific literature serve as sources of additional guidance:

Species
The fathead minnow may be an appropriate test species because of existing toxicity protocols which may be adapted for this study.

Exposure Duration
A subchronic exposure duration would be adequate for proof of principle. A single exposure may not allow adequate time for porphyrin accumulation, however, a life-cycle is not necessary to identify a phototoxic effect.

Dosing
A range finding study should be conducted under defined low light conditions to identify an LC50 value and lower dose levels expected to be similar to controls. Doses used in the phototoxicity study should not be expected to result in significant mortality in low light controls. Dissolved concentrations of the test chemical should be confirmed by an appropriate analytical method.

Endpoints
Behavioral observations should be made in addition to measurements of mortality, growth, weight, morphology, and appearance. Ideally, measurements of protoporphyrin and heme concentrations in the blood and protox activity in the liver of each test organisms should be made.

Light sources
Artificial light may be preferred to natural light that will vary in different regions and seasons as well as with weather. If artificial light is used, the light should resemble full, natural sunlight as closely as possible, particularly around 400 nm. The most important wavelength for porphyrin induced phototoxicity in ~400 nm. No matter what the light source, the duration and intensity of UV and visible light should be reported at all wavelengths (200-800 nm). At this point EFED does not have a specific recommendation for an artificial light source.

Dark, Light, and Positive Controls
As this study is intended to identify potential effects of light on LDPH toxicity, an appropriate study protocol should include a dark, or low light, control group. Another group not exposed to chemicals but exposed to full light should be included (a full light control). In addition to the dark and light controls, a positive control group using protoporphyrin IX may be useful.

Exposure Chambers and Light Filters
Light intensity should be measured inside test chambers if glass or any other material is placed between the light source and the test animals. Any filters should be cured under the study light for 72-hours prior to study initiation to ensure consistent transmittance.

References:

1 Matringe, M., J.-M. Camadro, P. Labbe, and R. Scalla. 1989. Protoporphyrinogen oxidase as a molecular target for diphenyl ether herbicides. Biochem. J. 260: 231-235.

2 Birchfield, N.B., and J.E. Casida. 1997. Protoporphyrinogen oxidase of mouse and maize: Target site selectivity and thiol effects on peroxidizing herbicide action. Pesticide Biochemistry and Physiology 57, 36-43.

3 Halling, B.P., D.A. Yuhas, V.F. Fingar, and J.W. Winkleman. 1994. "Protoporphyrinogen oxidase inhibitors for tumor therapy" in Porphyric Pesticides: Chemistry, Toxicology, and Pharmaceutical Applications, (S.O. Duke and C.A. Rebeiz, Eds.) pp. 280-290, American Chemical Society Symposium Series 559, Am. Chem. Soc., Washington, D.C., 1994.

4 Birchfield, N.B. Protoporphyrinogen Oxidase as a Herbicide Target: Characterization of the [3 H]Desmethylflumipropyn Binding Site. Dissertation. University of California, Berkeley. 1996.

5 American Society for Testing and Materials. 1994. Standard guide for conducting the frog embryo

teratogenesis assay-Xenopus. E 1439-91. In Annual Book of ASTM Standards, Vol 11.5, pp. 825-835. Philadelphia, PA.

Comment:
Environmental Risk Conclusions. d. Likelihood of Water Contamination: "The turf itself offers a vegetative interception layer (including thatch), that prevents rapid deposition of the oxadiazon on the surface of the soil."
Chapter 2: Introduction. b. Use Characterization: "Since efficacy (pre emergent control is based on oxadiazon reaching and remaining in the soil, product labels may specify to mow, if necessary, before application, and to irrigate, if rain is not expected shortly."
Chapter 4: Environmental Fate and Transport Assessment. Section: Fate and Transport Processes - Summary: "Thus, oxadiazon can be transported as sorbed species to erodible soil particles via surface runoff to nearby surface water bodies."
The registrant points out that "soil particles are not usually eroded from established turf and so this route of transport to surface water bodies is unlikely."
Response: Taken individually, each statement makes sense in context. However, EFED recognizes that all the sentences do not appear to be consistent, and will amend them in the EFED Chapter to clarify their meaning and context.

Comment: *The registrant indicates that the percentage of use of oxadiazon on golf courses is 77% instead of 65%. The former value agrees with the HED report.*
Response: EFED agrees and will make the necessary changes in the RED.

Comment: *Usage information was obtained from BEADS Qualitative Use Assessment, "Appendix K," which is not present in the document.*
Response: EFED submits that the correct identification of the appendix is Appendix H.

Comment: *RP-17623 and G 315 are product codes, and not trade names.*
Response: This will be corrected in the EFED document.

Comment: *The rat NOAEC is 200 ppm. It is stated in several places that it is 100 ppm (Table 2, Table C-5, Appendix F).*
Response: EFED will make this correction and the RQ's will be recalculated to reflect this change.

Comment: *The avian reproduction study using mallard resulted in a NOAEC>1000 ppm (highest dose tested). Since the study did not define a NOAEC, the study was classified as supplemental. The registrant requests reconsideration of the study classification.*
Response: EFED agrees (the highest terrestrial EEC is 960 ppm) and will make the appropriate changes in the RED.

Comment: *Individual growth data for the rainbow trout had not been provided by the registrant. These data were provided with this submission.*
Response: The data has been evaluated and the rainbow trout early life stage study (MRID41811601) has been upgraded to core.

Comment: *In Appendix C: Ecological Toxicity Data. Section: Aquatic Plants, a sentence reads: "Tier I of Tier II Aquatic Plant growth testing using the TEP is required for fungicides."*
Response: Inadvertently the word fungicides was used instead of herbicides. This will be corrected in the final report.

Comment: *In Appendix C. Table C.13, a study report was not referenced.*
Response: The cited study will be referenced: *Anabaena flos-aquae* study (MRID#'s 41610108 and 42659001).

Comment: *Chapter 5: Drinking Water Assessment: EFED used the tiered approach in estimating drinking water concentrations. The reported concentrations in the EFED report are the most conservative (Tier I). At a later time, HED requested additional refinements and EFED issued a revised drinking water memorandum. The revised Estimated Drinking Water Concentrations (EDWCs) using standard Percent of Crop Area (PCA) for golf courses produced the worst case drinking water exposure assessment for oxidiazon. The registrant sponsored and submitted a GIS study related to PCA calculation for golf courses conducted in Florida, where most of the oxadiazon is used.*

Response: Concurrently with the 60-Day Response, the registrant submitted the following document: Andrish, S.D., et.al. 2003. "Estimated Drinking Water Concentrations of Oxadiazon Residues in the Index Reservoir Associated with Use on Golf Course Turf," an unpublished report performed by Waterborne Environmental, Inc., Leesburg, VA, and sponsored by Bayer CropScience, Research Triangle Park, NC, Report No. WEI 746.29, B004306. (MRID# 45920102). EFED will not be able to complete the review of the submitted study within the 60-day response period. EFED intend to complete the review process in near future. In the meantime, EFED will continue to use EFED's guidance document in estimating drinking water concentrations for pesticides using recommended adjusting factors for the golf courses scenario.