

US EPA ARCHIVE DOCUMENT



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

JUN 4 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

BRIEFING MEMORANDUM

Subject: Registration of Dithiopyr (DIMENSION® Turf Herbicide (MON-15151), DIMENSION® Turf Herbicide (MON-15104), and MON-15100 Herbicide (a Manufacturing and Formulating Use Product)

FROM: Anne E. Lindsay, Director
Registration Division (H-7505C) *Anne E Lindsay*

TO: Douglas D. Campt, Director
Office of Pesticide Programs (H-7501C)

On January 15, 1989 Monsanto Company applied for registration of three herbicides that contained the new chemical, 3,5-pyridine-dicarbothioic acid, 2-(difluoromethyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-S,S-dimethyl ester (proposed common name "Dithiopyr"). The first application was for a product that contained 90% dithiopyr and was for manufacturing and formulating use. The other two applications were for end-use products that contained 12.9% dithiopyr (later, amended to claim 12.7% and 13.2% dithiopyr). These products were assigned the following EPA File Symbols:

- MON 15100 Herbicide524-UGN
- DIMENSION® Turf Herbicide (MON-15151)524-UGR
- DIMENSION® Turf Herbicide (MON-15104)524-UGU

The proposed use of the two end-use products is for the control of annual grasses and broadleaf weeds in established ornamental turf. These products are claimed to be effective when applied either preemergence or postemergence to certain annual grass weeds and certain broadleaf weeds. The proposed labeling bears the following claims:

"For Professional Turf Applicator Use Only". "This product can only be applied once per year at a maximum use rate of 2 quarts per acre (1/2 pound a.i. per acre). Do not make repeat or split applications of this product during a single growing season."

The end-use products have been field tested for two years under an EPA Experimental Use Permit (524-EUP-69).

Agency reviews of the product chemistry, environmental fate and ground water, toxicology and ecological effects have been completed. The available data support the conditional registration of dithiopyr for those use-patterns discussed above. Data gaps exist in all disciplines except for product chemistry (see discussion under Scientific Findings).

Tables A, B, and C (attached) list the data requirements, for the disciplines of toxicology, environmental fate, and ecological effects, for the proposed turf use, per 40 CFR Part 158. These tables also indicate whether or not the data requirements have been fulfilled. The following data requirements are currently not satisfied and are required as a condition of the registration; (164-1) terrestrial field dissipation, and (72-2) freshwater invertebrate acute toxicity. The specific deficiencies of these studies are discussed under Scientific Findings.

The following conditionally required data requirements are included as conditions of the registration; (85-2) dermal penetration (dermal absorption/adsorption), two worker exposure studies, (71-4) avian reproduction; (72-3) estuarine/marine, (72-2) aquatic invertebrate life-cycle and (122-1, 122-2) Tier II plant protection studies.

An anaerobic aquatic metabolism study is also required as a condition of the registration. This study is usually not required for terrestrial, nonfood uses. However EFGWB believes that useful information will be provided on the persistence, movement and fate of dithiopyr in the environment.

Scientific Findings

The Toxicology Branch has concluded that sufficient toxicology data are available to support the conditional registration of dithiopyr for use in the culture of ornamental turf. The technical product, MON 15100 Herbicide, used to manufacture the two end-use products is also supported for conditional registration. The toxicology data deficiency identified in the review process was dermal absorption/adsorption data.

The following acute studies required for the proposed products for use on ornamental turf were reviewed and determined to be acceptable: Acute oral toxicity (in rats and mice), acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation and dermal sensitization. The primary dermal irritation

study indicated that MON-15104 was slightly irritating. The primary dermal irritation study indicated that MON-15151 was severely irritating, but clearing occurred within 14 days. Based on these studies the appropriate signal word for these products is "WARNING", toxicity category II.

The following acute studies required for the proposed product for manufacturing and formulating use, MON 15100 Herbicide, were reviewed and determined to be acceptable: An acute oral toxicity (in rats and mice), acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation and dermal sensitization. This product had an inhalation LC₅₀ greater than 5.89 mg/L in both male and female rats in a study conducted by nose only exposure and was slightly irritating in a primary eye irritation study. Based on these studies the appropriate signal word for this product is "CAUTION", toxicity category IV.

According to the current Part 158 regulations, chronic feeding and oncogenicity studies are listed as conditionally required for terrestrial, nonfood uses. The critical factors which determine whether these studies are required include; (1) if the chemical is structurally related to a known carcinogen, (2) if the chemical causes mutagenic effects, (3) if the proposed use requires a tolerance or an exemption from the requirement of a tolerance and (4) if use of the pesticide results in human exposure over a portion of the human lifespan (significant in terms of the time of exposure or duration of exposure). Monsanto submitted a 90-day rat feeding study, a 21-day rat dermal study and 2 monkey pharmacokinetic studies along with 2 worker exposure studies to support their waiver request concerning the chronic feeding and oncogenicity data requirements. A dislodgeable residue study was also submitted, although this study was not an exposure data requirement for the proposed turf use. HED concluded after reviewing these studies that chronic feeding and oncogenicity studies were not required to support the proposed turf use of dithiopyr.

The following subchronic, teratogenic and mutagenic studies were reviewed and determined to be acceptable:

1. Subchronic dermal (21-day) toxicity study in rats. In this study the no observed effect level (NOEL) was 500 mg/kg/day and the lowest effect level (LEL) was 1,000 mg/kg/day based on increased liver weight in both male and females.
2. A 90-day subchronic study in rats. In this study the NOEL was 0.662 mg/kg/day and the LEL was 6.62 mg/kg/day. The effects seen were increased organ weights and diffused hepatocellular swelling.

3. Developmental toxicity studies in rabbits and rats. In both studies the NOEL was \geq 1,000 mg/kg/day, the highest dose tested.
4. Mutagenicity studies (Ames assay, CHO/HGPRT Mutation Assay, structural chromosome aberrations and an unscheduled DNA synthesis in primary rat hepatocyte culture). All studies indicated that dithiopyr was not a mutagenic agent under the test conditions.

The Occupational and Residential Exposure Branch has concluded that adequate data are available from the biological monitoring portion of an applicator exposure study to permit a calculation of internal dosage and risk to applicators. The margin of exposure (MOE) was estimated to be greater than 100 for applicators. Two worker exposure studies, a passive dosimetry study and a biological monitoring study were reviewed. They were both classified as "supplementary" (deficiencies must be addressed).

The worker exposure studies lacked an adequate field quality assurance program. In order to assess the seriousness of this deficiency, the following information is required: (1) the nature of urine collection and storage containers must be specified, (2) the nature of the degradation of dithiopyr under test and storage conditions must be demonstrated, and (3) an account must be provided of the fact that none of the worker samples contained DCTA (dicarbothioic acid, a metabolite of dithiopyr) within the concentration range used in the method validation.

HED indicated that based on the available information from these studies and the proposed use pattern, workers are not expected to be exposed at a significant level.

Environmental fate and ground water data have been reviewed and the following conclusions were made in that review:

Dithiopyr degrades slowly in water as indicated by an extrapolated half-life of 1053 days in water at pH 9. Hydrolysis is not a significant route of degradation. Photodegradation in soils appears to be insignificant (based on a supplementary study). Dithiopyr is biodegraded by ester hydrolysis to a diacid and two monacids. There were less than 6% of each of the degradates present after one year of incubation.

An aerobic metabolism study demonstrated that dithiopyr's dissipation rate was slow and that volatilization generally contributed more to dissipation than degradation.

Dithiopyr was determined to be slightly mobile to relatively immobile in soil. Dithiopyr has a half-life of between 17 and 61 days when applied to turf grasses. The three primary degradates dissipate within 1 year.

Leaching of dithiopyr and its primary degradates (the normal acid, reverse acid, and diacid degradates) under soil conditions highly favorable for leaching did not exceed 24 inches, and was usually not beyond 9-12 inches.

When used at the labeled rate of a single 1/2 lb a.i./A application, dithiopyr would not be expected to persist beyond the growing season and will not likely leach more than 24 inches into soil. Its low solubility in water and high tendency to bind to soil accounts for its resistance to leaching vertically into soils. Lateral movement when eroded with soil particles may present a source of surface water contamination.

There was a large difference between the half-life calculated from the aerobic metabolism study and the field dissipation study (1.63-6.3 years and 17-61 days, respectively). The reason(s) for these differences is not apparent and will be sought through the following required studies:

1. Anaerobic aquatic metabolism study (162-3).
2. Bare ground field dissipation study (164-1).

The field dissipation study, submitted in the original data package, was conducted on sites containing vegetation. A bare ground dissipation study is required for the proposed turf use. The Environmental Fate guidelines are vague concerning the requirement of bare ground field dissipation studies. However, an SOP on field dissipation studies has been available to applicants for several years. This SOP does clearly indicate when bare ground dissipation studies are required. Such studies represent "worst case" scenarios and are useful to EFGWB in their review process. The submitted field dissipation study did provide enough information for us to conclude that no unreasonable adverse effects will likely result while a bare ground dissipation study is conducted.

Ecological effects data characterize dithiopyr as practically nontoxic to birds, based on acute and dietary data. It is also practically non-toxic to beneficial insects. Based on a supplementary freshwater invertebrate study, two freshwater fish studies, and a fish early life stage study, dithiopyr was determined to be "highly toxic" to aquatic organisms. Pesticide products containing dithiopyr must bear the following precautionary labeling: "This pesticide is highly toxic to fish."

Dithiopyr may be characterized as moderately toxic to aquatic invertebrates based on two supplementary acute studies with Daphnia magna. These studies do not meet EPA Guideline data requirement because the protocol for conducting these studies was not followed. Temperature of test solutions varied above 20° C and monitoring of the temperature of the solutions under study deviated from those required by acceptable protocol. Solvents were not appropriately used to maintain concentrations of dithiopyr adequate for testing to establish a doseage response curve necessary for determining a LC50 for this chemical. An acute freshwater invertebrate study (Guideline Ref. No. 72-2) using an appropriate solvent system must be submitted. Although the two Daphnia studies were supplementary and a third study is required, we can conclude that dithiopyr is moderately toxic and unreasonable adverse effects are not expected to occur while this study is repeated.

Acute LC50 estuarine and marine organisms studies (Guideline Reference No. 72-3) were not submitted in support of the registration of dithiopyr products. It is not entirely clear when these estuarine/marine acute studies are required. These studies are listed as conditionally required in 40 CFR Part 158.490, (wildlife and aquatic organism data requirement table). The factors which determine when these studies are required include whether (1) the product is directly applied to the estuarine or marine environment, or whether (2) the product will enter this environment in significant concentrations due to its expected use or mobility pattern. It appears that Monsanto and the Agency differ on whether the proposed use of dithiopyr would result in significant concentrations of the chemical in the estuarine environment. Monsanto claimed that the environmental fate studies did not indicate any significant concentration of dithiopyr or its metabolites would occur in estuarine or marine environments. Thus, the company did not submit the estuarine studies. Agency review of the available data indicate that dithiopyr is persistent in the aquatic environment and is highly toxic to freshwater fish, thus the estuarine studies are required. Whether the Agency could have

made this determination at the time of the new chemical screen (before officially reviewing the data) is questionable. The company believes that they made a good faith effort in determining whether these estuarine studies were required.

A major issue involved in the registration of dithiopyr for use in the culture of turf grasses is the lack of an avian reproduction study. Both the Ecological Effects Branch and the Environmental Fate and Ground Water Branch have characterized dithiopyr as a persistent pesticide that would require an avian reproduction study. Monsanto has agreed to conduct an avian reproduction study and has submitted a protocol for such a study. They have also indicated early observations on an avian reproduction study. Those observations indicated there were no adverse effects on quail and ducks as reflected in body weight gain and feed consumption or egg production at over 12 times the actual maximum measured residue of dithiopyr on grass treated at twice the label dose (based on a March 11, 1991 statement from Monsanto).

Ecological Effects Branch has indicated a number of factors as to why this is a major issue. Other than the fact that it is persistent, they have indicated that other factors involved with the proposed use of the pesticide add to this issue. These include season of application occurring during the time of normal bird reproduction, the lack of other chronic data for the chemical, and the fact that it represents new chemistry in the area of pesticides.

The following is a list of the pros and cons considered in the conditional registration of this new chemical without the required avian reproduction study:

Pros:

1. A rat reproduction study has been submitted and the Agency has concluded that dithiopyr does not interfere with normal reproductive performance in Sprague-Dawley rats at dietary levels of 25, 250 and 2500 ppm.
2. Monsanto certified, at the request of Anne Lindsay, that the study summaries listed below constitute a complete and accurate description of the toxicological findings of each study and that no treatment related oncogenic effects were observed. Monsanto certified that these studies revealed that liver toxicity is the principle outcome of chronic high dose exposure to dithiopyr.

- a. In a 1-year dog feeding study the NOEL was 0.5 mg/kg/day based on the increased deposition of brown pigment in the livers of the mid-dose animals (5.0 mg/kg/day).
 - b. In a rat oral chronic toxicity/oncogenicity study, dithiopyr displayed no carcinogenic potential under the conditions of exposure.
 - c. In a mouse oral chronic toxicity/oncogenicity study, dithiopyr displayed no carcinogenic potential under the conditions of exposure.
3. Monsanto has amended the use-pattern to limit exposure to avian species by reducing the dosage to 0.5 lb a.i. per acre and to a single annual application.
 4. Monsanto has agreed to institute a training program to make users and applicators of the end-use products aware of the potential environmental and ecological effects that may be associated with the use of this new turf herbicide. This training program will continue until adequate data are available to more clearly describe the potential environmental and ecological risks.

Cons:

1. This is the first product of a new class of chemical pesticides to be registered under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act as amended.
2. The use is at a time of year when avian reproduction normally takes place.
3. An avian reproduction study has not been submitted.

Chronic effects of dithiopyr are unknown. Its persistence and dissipation rates may result in accumulation in plant tissues and in soils. The following required data must be submitted as conditions for registration:

1. An acute aquatic invertebrate study using a solvent acceptable for testing and which maximizes solubility of dithiopyr. Two studies were submitted but were unacceptable due to solubility problems with them. These studies are not reparable.

2. Avian reproduction studies using an upland gamebird (bobwhite quail) and a waterfowl species (mallard duck).
3. Acute estuarine/marine studies using a solvent acceptable for testing and which maximizes solubility of dithiopyr. These studies are identified as follows:
 - o 96-hour LC₅₀ for an estuarine/marine fish
 - o 96-hour LC₅₀ for a shrimp species
 - o Either a 48-hour embryo larvae study or a 96-hour shell deposition study with oyster.No studies were submitted.
4. An aquatic invertebrate life-cycle study using a solvent acceptable for testing and which maximizes solubility of dithiopyr. No study was submitted.
5. Plant toxicity testing
 - o Seed germination/seedling emergence; vegetative vigor
 - o Aquatic plant growth

A mesocosm study may be required depending on the risk indicated by the data from the required studies.

During the period of time between conditional registration and EPA's receipt and review of the avian reproduction study, the following Environmental Hazard statement must appear on the end-use product labels:

Avian toxicology studies have shown low acute toxicity to birds; the potential for chronic effects is being evaluated. To reduce potential exposure to birds, do not apply this product in split applications; make only one application per season without exceeding dosages on this label. Avoid known bird nesting sites and sites where birds are actively feeding when applying this product.

All of the required product chemistry data: product identity/composition, analysis/certification of ingredient and physical/chemical characteristics have been reviewed and are acceptable.

PUBLIC INTEREST FINDINGS

Monsanto has submitted a statement of public interest for the use of dithiopyr in the culture of ornamental turf grasses. As a preemergence and postemergence selective herbicide, dithiopyr is described as follows for use in the culture of ornamental turf:

1. Its preemergent and early postemergent activity extends the window for application and reduces the need for retreatment. A single application will give season long control. It also allows selective application and is adaptable for use in integrated pest management programs in turf weed control.
2. It may supplant several existing registered turf herbicides that have been identified by this Agency as being problem pesticides, such as dacthal, trifluralin, benefin, etc.
3. Its effectiveness at 1/2 lb a.i./acre application per season will assure less exposure to applicators.
4. It has low mammalian toxicity and is not a skin sensitizer.
5. It has low potential for movement into groundwater.
6. Acutely, it is practically non-toxic to birds.

The Biological and Economic Analysis Division (BEAD) reviewed Monsanto's public interest statement and the following are their conclusions:

Dithiopyr would provide preemergence crabgrass control when applied at the rate of 1/2 lb. a.i. per acre which is much less than alternatives such as DCPA, which is applied at the rate of 12 lb. a.i. per acre.

Dithiopyr would be applied only once per growing season and would provide season-long annual grassy weed control.

Dithiopyr has a wide window of application which is wider than alternatives, such as pendimethalin.

Dithiopyr, due to its efficacy from a single application would reduce the need for postemergence crabgrass herbicides, such as arsenicals.

Dithiopyr, due to its preemergence and postemergence activity, would allow turf managers to adopt a "wait and see" approach to reduce both the number of applications (both preemergence and follow-up at postemergence) and total amounts of herbicides used.

RECOMMENDATION

I recommend that you concur with the conditional registration of this new chemical herbicide for use in the culture of ornamental turf under Section 3(c)(7)(C) of the Act. The reasons behind this recommendation include:

- Adequate data have been submitted to the Agency, enabling us to conduct a risk assessment on this new chemical.
- Based on the available data and proposed use pattern, exposure to workers is not expected to be at a significant level
- Avian reproduction studies were not submitted, and therefore chronic wildlife effects have not been determined. However, Agency concerns about this data gap have been lessened because of the following:
 - a) Monsanto has revised the dithiopyr labels, reducing the application rate and limiting use of the pesticide to a single annual application.
 - b) Monsanto will initiate a training program to educate users of the pesticide on the potential ecological effects.
 - c) The dithiopyr labels are for professional turf applicator use only. This pesticide will not be available for homeowner use.
 - d) The conditional registration will have an expiration date.
- The Toxicology, Occupational and Residential Exposure, Environmental Fate and Ground Water, Registration Support and Ecological Effects Branches have raised no objections to these conditional Section 3 registrations.

The conditions for registration will be as follows:

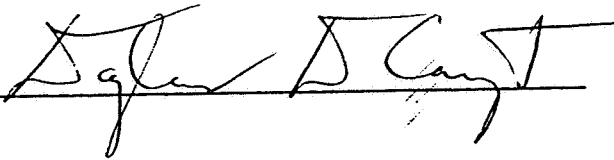
- That Monsanto Company will submit to the Agency all outstanding data requirements as listed in the Notice of Registration and submit the specified data according to the deadlines given in the Notice.

- o That Monsanto Company will institute a training program to make users and applicators of Dimension Turf Herbicide products aware of potential environmental and ecological effects that may be associated with this new turf herbicide. The potential risks of environmental and ecological hazards will be identified and measures to take to reduce such potential risks will be addressed in the training program. The training program will continue until adequate data are available to more clearly describe the potential environmental and ecological risks.

(Monsanto has already submitted their proposed training program. The program was examined in the Fungicide-Herbicide Branch and appears to be satisfy Agency concerns regarding educating users of dithiopyr.)

- o That the conditional registration will expire on July 31, 1994.

CONCUR:



DO NOT CONCUR

DATE:

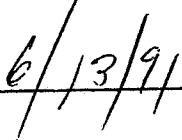


TABLE A

TOXICOLOGY

IV. Requirements (CFR 158.135):

Updated: March 7, 1991

Technical:

	Required	Satisfied
81-1 Acute Oral Toxicity	Y	Y
81-2 Acute Dermal Toxicity	Y	Y
81-3 Acute Inhalation Toxicity	Y	Y
81-4 Primary Eye Irritation	Y	Y
81-5 Primary Dermal Irritation	Y	Y
81-6 Dermal Sensitization	Y	Y
81-7 Acute Delayed Neurotox. (hen)	N	-
82-1 Subchronic Oral (rodent)	Y ¹	Y
82-1 Subchronic Oral (nonrodent)	N	-
82-2 21-Day Dermal	Y	Y
82-3 90-Day Dermal	N	-
82-4 90-Day Inhalation	N	-
82-5 90-Day Neurotoxicity (hen)	N	-
82-5 90-Day Neurotoxicity (mammal)	N	-
83-1 Chronic Toxicity (rodent)	N	-
83-1 Chronic Toxicity (nonrodent)	N	-
83-2 Oncogenicity (rat)	N	-
83-2 Oncogenicity (mouse)	N	-
83-3 Teratogenicity (rodent)	Y	Y
83-3 Teratogenicity (nonrodent)	Y	Y
83-4 Reproduction	N	Y
83-5 Chronic/Oncogenicity	N	-
84-2 Mutagenicity - Gene Mutation	Y	Y
84-2 Mutagenicity - Struct. Chrom. Aber.	Y	Y
84-2 Mutagenicity - Other Genotoxic Effect	Y	Y
85-1 General Metabolism	N	N ²
85-2 Dermal Penetration	N	N ³
86-1 Domestic Animal Safety	N	-

TABLE A cont.

IV. Requirements (CFR 158.135) (cont'd) Updated: March 7, 1991
Formulation:

	Required	Satisfied
<u>MON 15151 (12.6-13.5% a.i.)</u>		
81-1 Acute Oral Toxicity	Y	Y
81-2 Acute Dermal Toxicity	Y	Y
81-3 Acute Inhalation Toxicity	Y	Y
81-4 Primary Eye Irritation	Y	Y
81-5 Primary Dermal Irritation	Y	Y
81-6 Dermal Sensitization	Y	Y
<u>MON 15104(13.6% a.i.)</u>		
81-1 Acute Oral Toxicity	Y	Y
81-2 Acute Dermal Toxicity	Y	Y
81-3 Acute Inhalation Toxicity	Y	Y
81-4 Primary Eye Irritation	Y	Y
81-5 Primary Dermal Irritation	Y	Y
81-6 Dermal Sensitization	Y	Y
<u>MON 15159 (1.12% a.i.)</u>		
81-1 Acute Oral Toxicity	Y	Y
81-2 Acute Dermal Toxicity	Y	Y
81-3 Acute Inhalation Toxicity	Y	N ⁴
81-4 Primary Eye Irritation	Y	Y
81-5 Primary Dermal Irritation	Y	Y
81-6 Dermal Sensitization	Y	Y

Y - Yes; N - No; R - reserved, if tolerances are needed this study will be required.

1 The toxicology data base for MON-15100/MON-7200 technical grade dithiopyr supports the registration of dithiopyr for non-food crop use. This study is required in order to be consistent with the current requirements for reregistration under FIFRA 88.

2 A monkey metabolism study following intravenous administration of MON-15100 was acceptable. However, this study alone does not fully satisfy the toxicology Test Guidelines data requirement for metabolism because metabolism data from a single dose or repeat oral doses of MON-15100 was not generated.

3 This study is supplementary because the loss of 17 to 33% of the administered dose was not adequately accounted for and improper solvent (acetone) was used to wash unabsorbed test material from the skin.

4 A significant amount of respirable particles in this formulation may be derived by the rubbing action between particles during transport. Therefore, there may be a significant potential to become an inhalation hazard from inhaling these fine particles from this product. An acute inhalation study with MON-15159 is required prior to final registration of the product for general consumer use. See HED Doc 007787, dated Feb. 28, 1990. (This formulation is not one of the proposed dithiopyr products awaiting registration as discussed in the briefing memo).

TABLE B

ENVIRONMENTAL FATE

<u>Environmental Fate Data Requirement</u>	<u>Required</u>	<u>Satisfied</u>
Degradation Studies-Lab		
161-1 Hydrolysis	Y	Y
161-2 Photodegradation in water	Y	Y
161-3 Photodegradation on soil	N	-1
Metabolism Studies-Lab		
162-1 Aerobic (Soil)	Y	Y
162-3 Anaerobic (aquatic)	Y ²	N
Mobility Studies		
163-1 Leaching, Adsorption/ Desorption	Y	Y
Dissipation Studies-Field		
164-1 Terrestrial	Y	N
164-2 Aquatic/sediment	N ³	-
Accumulation Studies		
165-4 In fish	Y	Y

- 1 The Environmental Fate data requirement table of Part 158.290 of 40 CFR, indicates that for terrestrial, non-food uses, the photodegradation on soil study is not required. Emil Regelman confirmed this for me on May 8, 1991.
- 2 This study is not normally required for terrestrial, non-food uses. However, EFGWB believes that useful information can be obtained on the persistence, movement and fate of dithiopyr.
- 3 Based on a reevaluation of the environmental fate of dithiopyr, EFGWB - Surface Water Section has determined that a pond water degradation study is not needed at this time.

TABLE C

ECOLOGICAL EFFECTS

Generic Data Requirements for Dithiopyr

Data Requirements	Required	Satisfied
Section 158.145 Wildlife and Aquatic Organisms		
71-1 Avian Acute Oral LD50	Y	Y
71-2 Avian Dietary LC50	Y	Y
a. waterfowl		
b. bobwhite		
71-3 Wild Mammal Toxicity	N ¹	-
71-4 Avian Reproduction		
a. waterfowl	Y	N
b. bobwhite	Y	N
71-5 Simulated/Actual Field Testing Terrestrial	N ²	-
72-1 Freshwater Fish LC50		
a. coldwater	Y	Y
b. warmwater	Y	Y
72-2 Freshwater Invertebrate	Y ³	N
72-3 Estuarine/Marine		
a. fish	Y ⁴	N
b. shrimp	Y ⁴	N
c. oyster	Y ⁴	N

TABLE C cont.

ECOLOGICAL EFFECTS

Generic Data Requirements for Dithiopyr

Data Requirement	Required	Satisfied
Section 158.145 Wildlife and Aquatic Organisms		
72-4 Fish Early Life Stage	Y	Y
72-2 Aquatic Invertebrate Life- Cycle	Y ⁵	N
72-5 Fish Full Life Cycle	N	-
72-6 Aquatic Organism Accumulation	N	-
72-7 Simulated or Actual Field Testing	N ⁶	-

- 1 Tests required only on a case-by-case basis when the toxicology data for evaluating hazards to human and domestic animals do not adequately address concerns pertaining to wild mammals.
- 2 Field Testing is not required at this time.
- 3 Freshwater invertebrate testing must be reconducted due to solubility and measurement problems.
- 4 Estuarine/Marine acute testing must be conducted for Turf use.
- 5 Fish and invertebrate chronic tests are required since Dithiopyr is persistent and would be used repeatedly throughout the season.
- 6 Field testing may be required, but this is dependent upon receipt and review of EFGWS's environmental fate review(s) and EEC's.

TABLE C cont.

ECOLOGICAL EFFECTS

Generic Data Requirements for Dithiopyr

Data Requirements	Required	Satisfied
Section 158.120 Plant Protection		
121-1 Target Area Phytotoxicity		
Tier 1 ¹		
122-1 Seed Germination/Seedling Emergence	N ¹	-
122-1 Vegetative Vigor Growth	N ¹	-
122-2 Aquatic Plant Growth	N ¹	-
Tier II		
122-1 Seed Germination/Seedling Emergence	Y	N ²
122-1 Vegetative Vigor	Y	N ²
122-2 Aquatic Plant Growth	Y	N ^{2,4}
Tier III		
124-1 Terrestrial Field Study	N ³	-
124-2 Aquatic Field Study	N ³	-

¹ Data are not required for herbicides.

² Endangered plant species concerns have been identified with this use.

³ Reserved pending results of Tier II

⁴ Only the algae Selenastrum capricornutum is required for this use.