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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 7 1990

MEMORANDUM

SUBJECT: Review of Dithiopyr-524-UGR, -UGN, -UGU-- in
Registration Standard Format.

FROM: *James W. Akerman*
James W. Akerman, Branch Chief,
Biological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Joanne Miller, PM-23
Fungicide-Herbicide Branch
Registration Division (H7505C)

Attached to this cover memorandum is the review of Dithiopyr herbicide as a technical product and for use on turf. The review is done in registration standard format. Also included are the DER's for the rainbow trout early life stage study and the 48-hour Daphnia study.

Attachment

240294
RECORD NUMBER

128994
Shaughnessey Code

REVIEW NUMBER

ECOLOGICAL EFFECTS BRANCH REVIEW

DATE: IN 7-13-89 OUT _____

FILE OR REG. NO. 524-UGR,-UGN,-UGU

PETITION OR EXP NO. _____

DATE OF SUBMISSION 1-31-89

DATE RECEIVED BY EFED 7-10-89

RD REQUESTED COMPLETION DATE 2-22-90

EEB ESTIMATED COMPLETION DATE 2-22-90

RD ACTION CODE/TYPE OF REVIEW 000- New Chemical

TYPE PRODUCT(S): I, D, H, F, N, R, S Herbicide

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. L. Schnaubelt (23)

PRODUCT NAME(S) Dithiopyr

COMPANY NAME Monsanto Agricultural Company

SUBMISSION PURPOSE Proposed registration of new chemical technical
and end-uses on turf

SHAUGHNESSEY CODE _____ CHEMICAL AND FORMULATION _____ % A.I. _____

ECOLOGICAL EFFECTS TOPICAL SUMMARIES

EFFECTS ON BIRDS

Three studies were received and evaluated under this topic. These studies were used in performing a hazard assessment.

<u>Author</u>	<u>MRID#</u>
Grimes and Jaber	406386-20
Grimes and Jaber	406386-21
Grimes and Jaber	406386-22

In order to establish the toxicity of dithiopyr (MON 15151, MON 15100) to birds, the minimum data required on the technical material are:

- An avian single-dose LD₅₀ with either one species of waterfowl, preferably the mallard, or one species of upland gamebird, preferably bobwhite (section 71-1); and

- Two avian dietary tests, one with a species of waterfowl, preferably the mallard, and one with a species of upland gamebird, preferably the bobwhite (section 71-2).

AVIAN ACUTE ORAL TOXICITY-TECHNICAL

The acceptable acute oral toxicity studies on dithiopyr are listed below.

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>MRID</u>	<u>Fulfill</u>	<u>Req.</u>
Mallard	91.5%	LD ₅₀ >2250 mg ai/kg	Grimes	'87	406389-20	yes	

AVIAN DIETARY TOXICITY-TECHNICAL

The acceptable avian dietary toxicity studies on technical dithiopyr are listed below.

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>MRID</u>	<u>Fulfill</u>	<u>Req.</u>
Mallard	91.5%	LC ₅₀ >5620 ppm ai NOEC=3160 ppm ai	Grimes	'87	406386-21	yes	
Bobwhite	91.5%	LC ₅₀ >5620 ppm ai NOEC=5620 ppm ai	Grimes	'87	406386-22	yes	

The guideline requirements for avian toxicity testing have been fulfilled. These tests indicate that dithiopyr is practically non-toxic to birds.

AVIAN REPRODUCTIVE STUDIES-TECHNICAL DITHIOPYR

Avian reproduction studies are required (section 71-4) for an end use product when birds may be subject to repeated or continuous exposure, the product is stable in the environment, stored or accumulated in plant or animal tissues, or reproduction in

terrestrial vertebrates may be adversely affected based on information from mammalian reproduction studies.

Environmental Fate and Groundwater Branch (EFGWB) has described dithiopyr as immobile in soil, with slow degradation time with half lives ranging from 336 days (in silt loam) to 900 days (volcanic ash). Based on this residue data, an avian reproduction test is required using the mallard duck and bobwhite quail.

PRECAUTIONARY LABELING

Based on the available information, no toxicity labeling for birds is needed.

EFFECTS ON FRESHWATER FISH

Three studies were evaluated under this topic. All studies were acceptable for use in a risk assessment.

<u>Author</u>	<u>MRID#</u>
Bowman, J.H.	406386-23
Bowman, J.H.	406386-24
McAllister, W.A.	410015-15

The minimum data required for establishing the acute toxicity to fish are the results from two 96-hour studies with the technical grade material. The studies should be performed on one cold water species (preferably rainbow trout) and one warm water species (preferably bluegill sunfish).

FRESHWATER FISH ACUTE TOXICITY-TECHNICAL

The acceptable fresh water fish acute toxicity studies on dithiopyr are listed below.

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>MRID</u>	<u>Fulfill</u>	<u>Req.</u>
R. Trout	91.5%	LC ₅₀ =0.46 mg ai/l NOEC=0.19 mg ai/l	Bowman	'87	406386-23	yes	
B. Sunfish	91.5%	LC ₅₀ =0.47 mg ai/l NOEC=0.20 mg ai/l	Bowman	'87	406386-24	yes	

These studies show that dithiopyr is considered highly toxic to both species of fish.

FISH EARLY LIFE-STAGE-TECHNICAL

A fish early life-stage study is required when a product is applied directly to water or is expected to be transported to aquatic sites and 1) exposure of aquatic organisms will be continual or recurrent; or 2) the lowest LC₅₀ is 1 mg/l or less; or 3) the EEC in water is equal to or greater than 0.01 any LC₅₀; or 4) if the EEC is less than any LC₅₀ and the product has reproductive effects on or cumulative effects in, aquatic organisms or has a half-life in water greater than 4 days.

A rainbow trout early life-stage study was submitted, found acceptable, and is listed below.

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>MRID</u>	<u>Fulfill</u>	<u>Req.</u>
R. Trout	90.7%	NOEC=0.052 mg ai/l 0.056 mg ai/l < MATC < 0.12 mg ai/l	McAllister	'88	410015-15	yes	

PRECAUTIONARY LABELING

The following statement is required:

"This pesticide is highly toxic to fish."

EFFECTS ON AQUATIC INVERTEBRATES

Two studies were reviewed under this topic; however only one of them was acceptable for use in a risk assessment.

<u>Author</u>	<u>MRID#</u>
Forbis, A.D.	406386-25
Forbis, A.D.	410015-14

The minimum data required to establish the acute toxicity to freshwater invertebrates is a 48-hour aquatic study with the technical material. The test organisms should be first instar Daphnia magna or early instar amphipods, stoneflies, or mayflies.

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>MRID</u>	<u>Fulfill</u>	<u>Req.</u>
<u>D. magna</u>	97%	LC ₅₀ >5.6 mg ai /l	Forbis, A.D.	'85	406386-25	no	
<u>D. magna</u>	90.7%	LC ₅₀ >1.1 mg ai/l	Forbis, A.D.	'88	410015-14	no	

Dithiopyr may be characterized as moderately toxic to aquatic invertebrates. The guideline requirements have not been satisfied.

AQUATIC INVERTEBRATE LIFE-CYCLE

The Daphnia magna life cycle is required to support registration of an end use pesticide product if the actual or estimated environmental concentration in water is less than 0.01 of any LC₅₀ determined in acute testing for aquatic organisms required by 40 CFR 158.145 and if the pesticide is persistent in water.

Data from Environmental Fate and Ground Water Branch indicate that dithiopyr does not appreciably degrade in a 30 day period at 25° C in pH5 or pH7. The registrant has calculated a t_{1/2} of 2.9 years in pH9. Dithiopyr degraded in sterile, pH7 buffered water with a t_{1/2} of 62 hours.

Therefore, based on the available information, aquatic invertebrate life-cycle testing is required for full registration.

PRECAUTIONARY LABELING

No toxicity statement can be made at this time, data requirements must be fulfilled.

EFFECTS ON ESTUARINE AND MARINE ORGANISMS

No studies were evaluated under this topic.

Data on the acute toxicity to estuarine and marine organisms are required to support the registration of a pesticide intended for direct application to the estuarine or marine environment or if it is expected to enter this environment in significant concentration because of its expected use or mobility pattern.

Dithiopyr is proposed for use on turfgrass, which, in some cases, is grown near estuaries. A single direct application at the maximum rate of 1 lb. ai/acre would represent an EEC of 61 ppb in 6 feet of water. Based on the persistency in the aquatic environment (up to 2.9 years) and high toxicity of Dithiopyr for freshwater fish (LC₅₀'s 0.46-0.47 mg ai/l), this could pose a serious environmental hazard to estuarine or marine fish. Therefore, toxicity testing with estuarine and marine organisms are required. The requirements under this category (72-3) are the following:

- a 96-hour LC₅₀ for an estuarine fish
- a 96-hour LC₅₀ for mysid shrimp
- and either a 48-hour embryo larvae study or a 96-hour shell deposition study with oyster.

PRECAUTIONARY LABELING

No precautionary labeling statement can be determined at this time (estuarine and marine studies pending).

EFFECTS ON BENEFICIAL INSECTS

One study was evaluated under this topic and is acceptable for use in a risk assessment.

Author

Hoxter and Jaber

MRID#

406386-26

The minimum data requirement to establish the acute toxicity to honey bees is an acute oral LD₅₀ study with the technical material.

The following study is acceptable for use in a risk assessment.

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>MRID</u>	<u>Fulfill</u>	<u>Req.</u>
<u>Apis mellifera</u>	91.5%	LD ₅₀ =81 µg ai/bee	Hoxter, K.A. and Jaber, M.	'87	406386-26	yes	

Dithiopyr may be characterized as practically nontoxic to honey bees. The guideline requirement has been satisfied.

PRECAUTIONARY LABELING

Based on the above data, no toxicity statement is required.

PLANT PROTECTION

No studies were evaluated under this topic.

Because there are endangered plant species associated with commercial and residential turf use, non-target plant studies are required at this time.

I ECOLOGICAL EFFECTS PROFILE

TECHNICAL PRODUCT

A. Avian Studies

Grimes and Jaber (MRID# 406386-20) reported LD₅₀ values for the mallard duck of > 2250 mg ai/l. Grimes and Jaber (MRID# 406386-21,22) also reported dietary toxicity results of LC₅₀ > 5620 ppm ai. Dithiopyr may be characterized as practically nontoxic to birds on an acute oral and dietary basis.

B. Aquatic Studies

Freshwater Fish Bowman (MRID# 406386-23,24) conducted acute toxicity studies on rainbow trout and bluegill sunfish; LC₅₀ = 0.46 and 0.47 mg ai/l, respectively. McAllister conducted (MRID# 410015-15) a fish early life stage study; NOEC = 0.056 mg ai/l. The guideline requirements are satisfied for freshwater fish studies.

Freshwater Invertebrates There are no core studies under this topic. One study, categorized as supplemental, indicates the 48-hour LC₅₀, based on nominal concentrations is > 5.6 mg ai/l (Forbis, A.D.; MRID # 406386-25)

Estuarine and Marine Estuarine studies were not provided for review.

C. Non Target Plants

Non-target plant toxicity data are required at this time.

D. Mammal Data

Studies validated by Health Effects Division have indicated LD₅₀'s of 4100 mg/kg (male) and 3000 mg/kg (female) for the rat, and LD₅₀ > 5000 mg/kg for mice.

MANUFACTURING USE

The EEB does not perform a risk assessment on the manufacturing-use product.

II USES

Dimension (dithiopyr) is a selective herbicide for the preemergence and post emergence control of annual grasses and annual broadleaf weeds in established cool and warm season turfgrasses.

Type of Application	Max. use rate lb ai/acre	Times used
Turf Pre-emergent	.75	Mar-Apr
Early Post emergent	.75	May
Winter Annual	1.0	Sept

III ENVIRONMENTAL FATE INFORMATION

Data from Environmental Fate and Ground Water Branch indicate that dithiopyr does not appreciably degrade in a 30 day period at 25° C in pH5 or pH7. The registrant has calculated a t_{1/2} of 2.9 years in pH9. Dithiopyr degraded in sterile, pH7 buffered water with a t_{1/2} of 62 hours. Soil half lives range from 336 days in silt loam, 418 days in sandy loam, 490 days in clay and 900 days in volcanic ash.

IV RISK ASSESSMENT

a. Summary-Toxicity Data

The available information indicates that Dithiopyr:

1. Is practically non-toxic to birds
2. Is practically non-toxic to beneficial insects
3. Is no more than highly toxic to aquatic organisms.

b. Terrestrial

Maximum application rates of up to 1 lb ai/acre would be expected to yield the following residues:

short range grass	long grass	leaves & leafy crop	forage/ pods	fruit
240	110	125	58	7

Avian acute toxicity data available indicate LC₅₀ values are greater than 5620 ppm, far greater than the residues that would exist on forage and grass. An EEB Fate model was used to determine maximum and average residues on forage (insects) and short range grass with pre and post emergent applications. Residues were as high as 468 ppm with only two applications. With this current use rate, acute hazard to avian species appears low from the use of dithiopyr, but the persistency of this pesticide causes concern. Long term use of this product may cause an accumulation of the chemical in plant tissue or in soil. However, chronic effects to birds can not be determined at this time, since no chronic avian data have been submitted. Avian reproduction studies with the bobwhite and mallard must be conducted in order to complete the terrestrial risk assessment.

c. Aquatic

Exposure to aquatic organisms may occur through transport by runoff of applied material. The potential of spray drift from application close to water bodies should also be considered due to the high toxicity of dithiopyr to fish.

At maximum use rates for dithiopyr of 1.0 lb ai/A, the estimated concentration following direct applications are:

WATER DEPTH	EEC ppm
6 inches *****	0.734
1 foot *****	0.368
6 foot *****	0.061

Freshwater fish toxicity data available indicate LC₅₀ values (rainbow trout LC₅₀ = 0.46 ppm and bluegill sunfish LC₅₀ = 0.47) are greater than maximum expected residues in water that is at least 1 foot deep. However, in water that is less than one foot deep, which is common in golf courses, the maximum expected residues exceed the LC₅₀ for freshwater fish. Also, the NOEC values for the rainbow trout early life stage (0.056 ppm) is less than expected residues for all calculated water depths.

Freshwater aquatic invertebrate toxicity data available for dithiopyr indicate an LC₅₀ value of >5.6 ppm. However, chronic studies have not been submitted.

Information on environmental fate from EFGWB indicate a hydrolytic half-life of 2.9 years, as well as very high persistence in soil.

Based on the current guideline requirements, acute hazard to freshwater invertebrates appears low, but acute and chronic hazard for fish seems likely.

No toxicity data were available for marine organisms; therefore no assessment can be made.

c. Non-Target Plant Species

A risk assessment has not been completed for non target plants, no data have been submitted.

d. Endangered Species Considerations

SPECIES	LOWEST LC ₅₀	TRIGGER	MAX. EEC
Birds	5620 ppm	1/10 LC ₅₀ = 562 ppm	240 ppm
Fish	0.46 ppm	1/20 LC ₅₀ = 0.023 ppm	0.734 ppm
Aqu inverts	5.6 ppm	1/20 LC ₅₀ = 0.28 ppm	0.734 ppm

The above EEC's were calculated using 1 application of product; thus, they may be an underestimation of the actual EEC. Based on the available data dithiopyr seems to present minimal acute hazard to endangered birds.

The aquatic EEC is approximately 30x the endangered fish species acute trigger. Furthermore, this EEC is greater than the NOEC of 0.056 ppm for the rainbow trout early life stage study. The aquatic EEC also exceeds the endangered aquatic invertebrates trigger. Some endangered plant species have been identified to be associated with this use, however no plant toxicity data has been submitted.

In closing, a full assessment of effects to endangered species can not be made at this time because pertinent ecological effects and environmental fate data are not available. With submission and review of said data a formal consultation with the U.S. Fish and Wildlife Service (USFWS) will be initiated.

IV PRECAUTIONARY LABELING

a. Manufacturing Use

"This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your local State Water Board or Regional Office of the EPA"

b. End-Use Product

"This pesticide is toxic to fish. Drift or runoff may adversely affect aquatic organisms. Do not apply directly to water or wetlands (swamps, bogs, marshes, estuaries, and potholes). Do not contaminate water when disposing of equipment washwaters.

V. DATA REQUIREMENTS

Additional data are required before EEB can complete a full risk assessment of the proposed turf use. These data are:

1. An acute aquatic invertebrate study using a solvent acceptable for testing and which maximizes solubility of dithiopyr. A solvent control and measurements of all test concentrations during and at the end of the study are required.

2. Avian reproduction studies using an upland gamebird (bobwhite quail) and a waterfowl species (mallard duck). All test concentrations must be measured throughout the study.

3. Acute estuarine/marine studies using a solvent acceptable for testing and which maximizes solubility of dithiopyr. A solvent control and measurements of all test concentrations during and at the end of the studies are required. These studies are:

- 96-hour LC_{50} for an estuarine/marine fish
- 96-hour LC_{50} for a shrimp species
- Either a 48-hour embryo larvai study or a 96-hour shell deposition study with oyster

4. An aquatic invertebrate life-cycle study using a solvent acceptable for testing and which maximizes solubility of dithiopyr. A solvent control and measurements of all test concentrations during and at the end of the study are required.

5. Plant toxicity testing:

- Seed germination/seedling emergence; vegetative vigor
- Aquatic plant growth

Dependent upon the above, and receipt and review of EFGWB's environmental fate review(s) and aquatic EEC's^{1/}, EEB may require further data (e.g. mesocosm study).

^{1/} With completion of this new chemical registration standard EEB will be requesting aquatic EEC's from EFGWB.

Table A
Generic Data Requirements for Dithiopyr.

Data Requirement	Formulation ¹	Use Pattern ²	Does EPA Have Data to Satisfy this Data Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)	Time Period After EPA Notification to Report Required Data
Section 158.145 Wildlife and Aquatic Organisms						
71-1 Avian Acute Oral LD ₅₀	TGAI	B	yes	406386-20	no	
71-2 Avian Dietary LC ₅₀		B	yes	406386-21 406386-22	no	
a. waterfowl	TGAI					
b. bobwhite	TGAI					
71-3 Wild Mammal Toxicity	-	B	no ³	-	no	
71-4 Avian Reproduction		B		-		
a. waterfowl	TGAI		no		yes	
b. bobwhite	TGAI		no		yes	
71-5 Simulated/Actual Field Testing Terrestrial	TEP	B	no ⁴	-	no	
72-1 Freshwater Fish LC ₅₀		B				
a. coldwater	TGAI		yes	406386-23	no	
b. warmwater	TGAI		yes	406386-24	no	
72-2 Freshwater Invertebrate	TGAI	B	no	406386-25 410015-14	yes ⁵	
72-3 Estuarine/Marine		B		-		
a. fish	TGAI		no		yes ⁶	
b. shrimp	TGAI		no		yes ⁶	
c. oyster	TGAI		no		yes ⁶	

Table A
Generic Data Requirements for Dithiopyr

Data Requirement	Formulation¹	Use Pattern²	Does EPA Have Data to Satisfy this Data Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)	Time Period After EPA Notification to Report Required Data
Section 158.145 Wildlife and Aquatic Organisms						
72-4 Fish Early Life Stage	TGAI	B	yes	410015-15	no	
72-2 Aquatic Invertebrate Life-Cycle	TGAI	B	no	-	yes ⁷	
72-5 Fish Full Life-Cycle	TGAI	B	no	-	no	
72-6 Aquatic Organism Accumulation	TGAI	B	no	-	no	
72-7 Simulated or Actual Field Testing	TEP	B	no	-	no ⁸	

¹ TGAI = Technical Grade of the Active Ingredient, TEP = Typical End-use Product

² A= Terrestrial, food crop; B= Terrestrial, non-food crop; C= Aquatic, food crop

³ Tests required only on a case-by case basis when the toxicology data for evaluating hazards to humans and domestic animals do not adequately address concerns pertaining to wild mammals.

⁴ Field Testing is not required at this time.

⁵ Freshwater invertebrate testing must be reconducted due to solubility and measurement problems.

⁶ Estuarine/Marine acute testing must be conducted for Turf use.

⁷ Fish and invertebrate chronic tests are required since Dithiopyr is persistent and would be used repeatedly throughout the season.

⁸ Field testing may be required, but this is dependent upon receipt and review of EFGWB's environmental fate review(s) and EEC's.

Table A
Generic Data Requirements for Dithiopyr

Data Requirement	Formulation¹	Use Pattern²	Does EPA Have Data to Satisfy this Data Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)	Time Period After EPA Notification to Report Required Data
Section 158.120 Plant Protection						
121-1 <u>TARGET AREA PHYTO-TOXICITY</u>	TEP	B	no³		no	
<u>TIER I³</u>						
122-1 Seed Germination/ Seedling Emergence	TGAI	B	no		no	
122-1 Vegetative Vigor	TGAI	B	no		no	
122-2 Aquatic Plant Growth	TGAI	B	no		no	
<u>TIER II</u>						
122-1 Seed Germination/ Seedling Emergence	TGAI	B	no		yes⁴	9 months
122-1 Vegetative Vigor	TGAI	B	no		yes⁴	9 months
122-2 Aquatic Plant Growth	TGAI	B	no		yes^{4,6}	9 months

Table A
Generic Data Requirements for Dithiopyr

Data Requirement	Formulation ¹	Use Pattern ²	Does EPA Have Data to Satisfy this Data Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)	Time Period After EPA Notification to Report Required Data
Section 158.120 Plant Protection						
<u>TIER III</u>						
124-1 Terrestrial Field Study	TEP	B	no		Reserved ⁵	
124-2 Aquatic Field Study	TEP	B	no		Reserved ⁵	

¹ Formulation: TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient; TEP=Typical end-use product.

² The use patterns are coded as follows: A=Terrestrial, food crop; B=Terrestrial, nonfood crop; C=Aquatic, food crop; D=Aquatic, nonfood crop; E=Greenhouse, food crop; F=Greenhouse, nonfood; G=Forestry; H=Domestic outdoor; and I=Indoor.

³ Data are not required for herbicides.

⁴ Endangered plant species concerns have been identified with this use.

⁵ Reserved pending results of Tier II.

⁶ Only the algae Selenastrum capricornutum is required for this use.

DATA EVALUATION RECORD

1. Chemical: MON-7200 (Dithiopyr)
2. Test Material: 90.7 % a.i.
3,5,-Pyridine-dicarbothioic acid, 2-(difluoromethyl)
-4-(2-methylpropyl)-6-(trifluoromethyl)-S,S-dimethyl ester.
3. Study Type: Acute Toxicity Study of Mon-7200 to Daphnia magna
4. Study ID: MRID NO. 410015-14
Forbis, Alan D. 1988. The acute toxicity of Mon-7200
to Daphnia magna. Unpublished study by Analytical Biochemistry
Laboratories, Inc. 7200 E. ABC Lane, Columbia, Missouri 65205.
5. Reviewed by: Cynthia Moulton
Biologist
EEB/EFED
Cynthia Moulton
3.5.90
6. Approved by: Norman Cook
Head Section II
EEB/EFED
Norman J. Cook
3.5.90
7. Conclusion: The study is classified as invalid and does not
satisfy guideline requirements. See reviewers discussion of the
test procedure for the discrepancies of the study.
8. Recommendations: This study needs to be redone using an
appropriate solvent (and a solvent control) to obtain an adequate
dose response curve.
9. Background: Proposed registration of new chemical
10. Discussion of Individual Tests: N/A.

11. Materials and Methods:

a. Test Animals - First instar Daphnia magna from an in-house ABC Laboratories culture.

b. Test System - 250 ml beakers were used as test chambers, each with 200 ml of daphnid culture/test water. The vessels were kept at 20 + 2 C in a 16 hour daylight photoperiod. An initial range finding experiment was conducted using 10 Daphnia each in nominal concentrations of 0.01, 1.0, 5.0, and 10 mg/l. From the results of this study, five treatment concentrations plus a control in duplicate with ten Daphnia per beaker were used for the definitive bioassay.

The temperature, dissolved oxygen, and ph were measured in the control, and the low, middle, and high concentrations at 0 and 48 hours.

c. Dosing - Static bioassay using nominal concentrations, no solvents were used. Analysis of test levels was made at 0-hour and 48 hours; $\bar{x} \pm \text{s.d.}$ recovery was $12 \pm 0.89\%$.

d. Design - A control and five nominal concentrations (in duplicate) were used; 1.3, 2.2, 3.6, 6.0, and 10 mg/l. Mean measured values for these levels were: 0.17, 0.29, 0.45, 0.72 and 1.1 mg/l, respectively.

e. Statistics - The LC50 value was determined by transferring percent mortality into probit values.

12. Reported Results:

The 48-hour LC50 >1.1 mg/l for 90.7% ai. MON 7200 and first instar D. magna.

13. Study Authors Conclusion:

"The 24- and 48-hour LC50 values were both > 1.1 mg/l."

The study was conducted following the intent of the Good Laboratory Practice Regulations and the final report was reviewed by ABC Laboratories Quality Assurance Unit.

14. Reviewers Discussion and Interpretation of the Study:

a. Test Procedures - The following discrepancies in the study were noted:

- The recommended test temperature for *Daphnia* is 20 C. The temperature reported by study authors was 20 + 2 C (cited also in previous review 7-25-88).

- Temperature should be measured continuously (hourly) in at least one test vessel during the entire study period. If temperature is controlled by a waterbath, measurements can be recorded every six hours. In this study test vessels were kept in a "controlled area"; however, temperature was recorded only at 0 and 48 hours (cited also in previous review on 7-25-88).

- The percent recovery of the spiked samples was 96 + 4.0%, the percent recovery of the test samples was 12 + 0.89%. According to the ASTM Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians, "if measured concentrations of toxicant is more than 30% higher or lower than the concentration calculated from the composition of the stock solution and the calibration of the metering system, identification of the cause may provide useful information about the operation of the metering system or the properties of the toxicant". There was no explanation given in the study report as to the cause of the deviation of 84% between the spiked and test samples. However, since a solvent was not used in preparing the definitive test levels, but acetone was used on the spiked samples, we conclude this accounts for the percent recovery differences.

- The authors of the study conclude that the LC50 for MON 7200 to *Daphnia magna* is > 1.1 mg/l. However there was no mortality in 3 of 5 treatment levels and 10 % mortality in the 2 highest concentrations. A dose response curve can not be determined from these data. The study authors conclude that the LC50 is greater than its water solubility of 1.1 mg/l (as calculated by study authors; Monsanto specifies solubility as 0.7 mg/l), based on nominal concentrations. First, an LC50 value of > 1.1 mg/l is unacceptable because this estimate includes the moderately toxic to practically nontoxic range. Second, a solvent may have been used to dissolve appropriate amounts of the test substance, up to 10 mg/l, as established by the initial range finding experiment, to show a valid dose response. Previous studies involving MON 7200 reviewed on 7-25-88; *Salmo gairdneri* and *Lepomis macrochirus* acute static tests utilized the solvent dimethylformamide (DMF). Also the supplemental *Daphnia magna* study used Acetone as a solvent.

4.

b. Statistical Analysis - Because the reviewer considers the study invalid, a statistical analysis was not performed on the data.

c. Discussion/ Results - The study was inconclusive and did not provide a valid LC50 value of MON 7200 on Daphnia magna.

d. Adequacy of Study

1) Classification: Invalid

2) Rationale: Major discrepancies (see reviewers discussion of test procedures) detract from the validity of the study.

3) Repairability: none

15. Completion of One-Liner:

February 26, 1990

DATA EVALUATION RECORD

1. Chemical: MON-7200 (Dithiopyr)
2. Test Material: 90.7 % a.i.
3,5,-Pyridine-dicarbothioic acid, 2-(diflouromethyl)
-4-(2-methylpropyl)-6-(triflouromethyl)-S,S-dimethyl ester.
3. Study Type: Early Life Stage Toxicity of MON-7200 to Rainbow Trout (Salmo gairdneri) in a Flow-Through System
4. Study ID: MRID NO. 410015-15
McAllister, W.A. 1988. Early life stage toxicity of MON-7200 to rainbow trout (Salmo gairdneri) in a flow-through system. An unpublished study by Analytical Bio-Chemistry Laboratories, Inc. 7200 E. ABC Lane, Columbia, Missouri 65205.
5. Reviewed by: Cynthia Moulton
Biologist
EEB/EFED
Cynthia A. Moulton
3.5.90
6. Approved by: Norman Cook
Head Section II
EEB/EFED
Norman J. Cook
3.5.90
7. Conclusion: The study is scientifically sound and meets the guideline requirements for a fish early life stage test. Based on significant adverse effects on survival and growth, the no observed effect concentration was 0.056 mg/l and the lowest observed effect concentration was 0.12 mg/l. The maximum allowable toxic concentration (MATC) of MON 7200 (90.7% a.i.) for rainbow trout was estimated to be >0.056 mg/l and <0.12 mg/l.
8. Recommendations: N/A
9. Background: Proposed registration of new chemical
10. Discussion of Individual Tests: N/A.

11. Materials and Methods:

a. Test Animals - Trout eggs used for the initiation of the definitive test were obtained from Mt. Lassen Trout Farm (U.S. D.I. disease free cert.) in Red Bluff, California. Unfertilized eggs were shipped by air freight under refrigerated conditions. Eggs were slowly acclimated from approx 6.5 C to 10 C, then thoroughly mixed. They were then rinsed with control water 4 times then covered again with water and allowed to water harden before distribution to the test system incubation cups.

b. Test System - A two-liter proportional diluter system described by Mount and Brungs (1967) with a Hamilton Model 420 Syringe dispenser, was used for the intermittent introduction of a dimethylformamide solution of MON7200 to four replicate test chambers per concentration. The test system dilution water was obtained from uncontaminated deep well water part of which was passed through a reverse osmosis system then blended back to a total hardness of 40 to 50 mg/l (as CaCO₃) and a pH of approximately 8.0.

The inside dimensions of the glass test aquaria measured 15.6 x 30.7 cm with a water depth of 25 cm. This yields an approximate replicate chamber volume of 12 liter. Water was delivered to the replicated chambers at an average rate of 81.5 replicate/day, an amount sufficient to replace the replicate volume 6.8 times per day. The test aquaria was immersed in a water bath held at approximately 10 C and the light intensity at the surface was 147 +29.8 foot candles.

c. Dosing - The study included the following five concentrations; 0.06, 0.12, 0.23, 0.46, 0.96, plus a control and solvent control. The average measured concentration for each treatment group was 0.024, 0.056, 0.12, 0.20, 0.41, respectively. The solvent used in the study was DMF.

d. Design - The definitive study was initiated by distributing several impartially selected newly fertilized rainbow trout eggs at a time into successive incubator cups in each of the 4 replicate exposure aquaria (note: 30 eggs/cup; 120 eggs/concentration). In addition, 50 eggs were placed in each of the 4 control replicates. Egg mortality was recorded daily. After 11 days, 200 eggs were set aside for viability (fertility success). When hatching commenced, the number of eggs hatched in each incubation cup was recorded daily until hatching was completed. The 60 day post-hatch growth period began on study day 38 (study length = 98 days). On day 40, the number of fry per replicate was reduced to 15; on day 45 they were released into the growth chambers. Feeding began on day 49, initially the fry were fed live brine shrimp nauplii and ground salmon starter was added to the diet on day 57. On study day 74, standard length of the fry was determined by the photographic method of McKim and Benoit (1971).

At test termination, all surviving fish were sacrificed and measured for standard length, blotted, and weighed.

Water quality parameters of temperature, dissolved oxygen, conductivity, and pH were measured on days 0, 1, 7, and every 7th day thereafter.

e. Statistics - Continuous data were assessed by ANOVA techniques for nested design experiments in a manner similar to that described by McClave, et. al. (1981). If significant effects due to concentration were determined by the ANOVA calculations, Tukey's HSD comparison test was used to determine those treatment levels having responses significantly different from control response.

12. Reported Results:

The significant effects that occurred in the treatment test concentrations when compared to the control were reduced survival in test levels 4 and 5 and a reduction in both weight and length in levels 3 and 4. The behavior/physical effects that were noted in the lower test levels did not indicate enough of an effect for a sufficient duration to be judged affected. Therefore, based on the data for this 60-day post-hatch rainbow trout early life stage toxicity study, the Maximum Acceptable Toxicant Concentration (MATC) is 0.082 mg/l MON7200.

13. Study Authors Conclusion:

"... limits for MON7200 were estimated to be the mean measured concentrations of 0.056 mg/l and 0.12 mg/l. The MATC, defined as the geometric mean of the lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) is 0.082 mg/l MON7200."

The study was conducted following the intent of the Good Laboratory Practice Regulations and the final report was reviewed by ABC Laboratories Quality Assurance Unit.

14. Reviewers Discussion and Interpretation of the Study:

a. Test Procedures - The following discrepancies in the study were noted:

- The test system dilution water was not sterilized or tested for pesticides, heavy metal, or other contaminants before the initiation of the study.

- The pH of the dilution water was approximately 8.0 (not fluctuating more than + 10%), recommended pH is 7.2 - 7.6.

4.

b. Statistical Analysis - The statistical analysis conducted by the study author was appropriate.

c. Discussion/ Results - The most sensitive indicator of MON 7200 toxicity (among the toxic endpoints used in the study) were fry survival and growth. Larval survival was reduced significantly at 0.20 mg/l and adverse growth effects were significant at 0.012 mg/l. Sublethal behavior/physical effects occurred at all treatment levels.

The study author reports the maximum allowable toxic concentration (MATC) to be the geometric mean of the no observed effect level (NOEL) and the lowest observed effect level (LOEL). EEB considers the range of these two values to be a more adequate representation of the MATC. Therefore, based on these data, the MATC for MON 7200 (at 90.7 % a.i.) is estimated to be >0.056 mg/l and <0.12 mg/l. The no observed effect level is 0.056 mg/l.

d. Adequacy of Study

1) Classification: Core

2) Rationale: The discrepancies noted in the reviewers discussion do not significantly detract from the study.

3) Repairability: N/A

15. Completion of One-Liner:

February 26, 1990

LITERATURE CITED

McClave, J.T., J.H. Sullivan, and J.G. Pearson. 1981. Statistical analysis of fish chronic toxicity data. IN Aquatic Toxicology and Hazard Assessment: Fourth Conference. ASTM STP 737. American Society for Testing and Materials.

McKim, J.M. and D. A. Benoit. 1971. Effect of long-term exposure to copper on survival, reproduction and growth of brook trout (Salvelinus fontinalis). J. Fish. Res. Bd. Canada 28:655-662.

CHEMICAL

CASSELL#

881C	2,4,5-Trichlorophenoxyacetic acid, alkyl*amine salt *(tridecylamine salt) CAS: 53404-85-6 SHA: 082012
881L	2,4,5-Trichlorophenoxyacetic acid, alkyl* ester *(C3H7-C7H9)
881M	2,4,5-Trichlorophenoxyacetic acid; amyl ester CAS: 120-39-8 SHA: 082051
881NN	2,4,5-Trichlorophenoxyacetic acid, butoxyethoxypropyl ester
881N	2,4,5-Trichlorophenoxyacetic acid, 2-butoxyethyl ester CAS: 2545-59-7 SHA: 082053
881O	2,4,5-Trichlorophenoxyacetic acid, butoxypropyl ester or propylene glycol butyl ether ester CAS: 1928-48-9 SHA: 082055
881P	2,4,5-Trichlorophenoxyacetic acid, butyl ester CAS: 93-79-8 SHA: 082056
881H	2,4,5-Trichlorophenoxyacetic acid, N,N-diethylethanamine salt CAS: 53404-86-7 SHA: 082038
881E	2,4,5-Trichlorophenoxyacetic acid, dimethylamine salt CAS: 6369-97-7 SHA: 082019
881F	2,4,5-Trichlorophenoxyacetic acid, N,N-dimethylinoleylamine salt CAS: 53404-88-9 SHA: 082037
881G	2,4,5-Trichlorophenoxyacetic acid, N,N-dimethylethyleylamine salt CAS: 53404-89-0 SHA: 082020

CHEMICAL

CASSELL#

Trichloronitromethane

214

878A 2,2,2-Trichloro-N-(pentachlorophenyl)acetimidoyl chloride (CA)

Bay 58733

CAS: 3583-63-9

SMA: 478200

879 2,4,5-Trichlorophenol

CAS: 95-95-4

SMA: 064210

880C 2,4,6-Trichlorophenol

CAS: 88-06-2

SMA: 064212

880 2,4,5-Trichlorophenol, 2,6-bis((dimethylamino)methyl)cyclohexanone salt

CAS: 53404-83-4

SMA: 064211

880A 2,4,5-Trichlorophenol, potassium salt

CAS: 35471-43-3

881 2,4,5-Trichlorophenoxyacetic acid

2,4,5-T

Dacamine

Fence Rider

Trinoxol

Esteron 245

CAS: 93-76-5

SMA: 082001

881B 2,4,5-Trichlorophenoxyacetic acid, alkyl*amine salt *(dodecylamine salt)

CAS: 53404-84-5

SMA: 082011

881D 2,4,5-Trichlorophenoxyacetic acid, alkyl*amine salt *(tetradecylamine salt)

CAS: 53535-37-8

SMA: 082013

Dithiopyr Science Review

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- _____ Identity of the source of product ingredients.
- _____ Sales or other commercial/financial information.
- _____ A draft product label.
- _____ The product confidential statement of formula.
- _____ Information about a pending registration action
- FIFRA registration data.
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