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PRODUCT MANAGER, NO. R. Taylor (25)

PRODUCT NAME(S) MON 8437 HARNESS Herbicide

COMPANY NAME Monsanto Company

SUBMISSION PURPOSE Review data in support for EUP renewal and RD Action (temporary tolerance) for use on field and silage corn.

SHAUGHNESSEY NO.	CHEMICAL	% A.I.
121601	Acetochlor	81.15

EEB BRANCH REVIEW

MON 8437, Acetochlor (HARNESS Herbicide)

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

The Monsanto Agricultural Company has applied for an Experimental Use Permit (EUP) to conduct field testing with a new formulation of HARNESS Herbicide on field and silage corn.

100.2 Formulation information

ACTIVE INGREDIENT: 81.15%
2-chloro-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl) acetamide

INERT INGREDIENT: 18.85%

100.3 Application Methods, Directions, Rates

1. States, amounts, acreage

The following is a list of all states in which the pesticide will be used during the 1 year program. The maximum number of pounds of active ingredient proposed for shipment and the maximum acreage to be treated are indicated for each state.

STATE	POUNDS OF ACTIVE INGREDIENT	ACRES
IA	3600	1800
MN	3600	1800
SD	800	400

There are 100 plots total, each approximately 40 acres in area.

2. Directions for Application

HARNESS Herbicide will be applied in water or sprayable fluid fertilizer solutions in accordance with the labeled rates. Application is predominantly by ground broadcast, but may also be applied by center pivot irrigation or dry bulk fertilizer impregnation. Also, tank mixes with other herbicides are allowed. Specific herbicides listed on the label for tank mixing include Atrazine, Banvel, Bladex, 2,4-D, Roundup, Gramoxone, and Princep. An average of 2 lb ai/A, with a range of 1.5 - 3.0 lb ai/A will be applied. The EUP request indicated that application would be during early preplant, preplant incorporated, and preemergence stages of corn growth with only one application made on each plot. We note that the "Details of Proposed Program" section indicates

application at early preplant. However, the label does not contain directions for use for early preplant applications; therefore, the label must be modified to include this use or early preplant should be omitted from the EUP program.

100.4 Target Organisms

The target pests will include yellow nutsedge and a wide range of annual grasses and broadleaf weeds. See the "WEEDS CONTROLLED" section of the attached label for specific target pests.

100.5 Precautionary Labeling

Environmental Hazard: See attached label.

101 Hazard Assessment

101.1 Discussion

The maximum use rate of this product is 3 lb ai/A applied to conventional, reduced tillage and no-till systems between April and June. Only one treatment of this product may be applied to a labeled crop.

Data from EFGWB suggest that acetochlor is stable in aquatic systems with a hydrolytic half life greater than 24 months and is moderately to highly mobile in soil adsorption and column leaching studies. Microbial metabolism is a major pathway of degradation for acetochlor and acetochlor dissipates in < 3 days when applied to California sandy soil.
However, it may be stable on foliage since volatilization and photodegradation are negligible; in addition, it is absorbed primarily through the shoots of germinating seedlings and secondarily via the root system.

Terrestrial exposure

The following are the maximum expected residues that may be found on associated and adjacent foliage and invertebrates immediately after one 3.0 lb ai/A application (based on Hoerger and Kenaga, 1972):

SHORT RANGEGRASS	720 ppm
LONG GRASS	330 ppm
LEAVES AND LEAFY CROPS	375 ppm
FOLIAGE AND SMALL INSECTS	174 ppm
PODS CONTAINING SEEDS	36 ppm
FRUIT	21 ppm

Aquatic exposure

Aquatic exposure will occur via runoff and spray drift from ground applications. The following represents a scenario of runoff into a 1 acre pond from a 10 acre drainage basin.

3 lb ai x 0.05 (% runoff) x 10 A = 1.5 lb total runoff

Therefore, the EEC's for a one acre pond at the following depths are:

6 feet = 91.5 ppb or 0.0915 ppm

1 foot = 552 ppb or 0.552 ppm

6 inches = 1101 ppb or 1.101 ppm.

101.2 Likelihood of Adverse Effects to Non-target Organisms

It appears that one application of HARNESS Herbicide would have minimal adverse acute effects on birds and mammals. The maximum expected residues on foliage and insects are lower than the LC_{50} for bobwhite and mallard (LC_{50} > 5620 ppm and NOEL = 1780 ppm for both) and below the LD_{50} for the rat (2953 mg/kg) and bobwhite (1567 mg/kg)[1]. However, the HED has identified that acetochlor is a carcinogenic risk to mammals, affecting the liver and sinus areas. A rat reproduction NOEL and LEL of 500 ppm and 1500 ppm respectively, were also determined. Chronic data are not available for evaluating long term risk to birds, these data are needed to do so. EEB has chronic avian concerns primarily because acetochlor is a carcinogen to mammals. In addition, available data suggest acetochlor is persistent: e.g. negligible photodegradation. EEB concludes, therefore, that minimal chronic risks appear likely to mammals and birds under the conditions of the EUP. However, to support further EUPs and/or registration, and to more adequately address EEB's chronic avian concern, avian reproduction studies are required.

It seems that Acetochlor would also have minimal acute effects on Daphnia magna and bluegill sunfish (LC_{50} = 14 mg/L and 1.3 mg/L, respectively) but rough Aquatic EEC's exceed the LD_{50} for rainbow trout (0.42 mg/L) at pond depths less than 6 feet. Also, a "no observed effect level" (NOEL) for rainbow trout could

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[1]When converted to a 1-day LC50 value:i.e.,
ppm x food cons./body wgt. = mg/kg/day
rat: ppm x .05 = 2953 mg/kg/day
ppm = 59060
quail: ppm x 8.9% = 1567 mg/kg/day
ppm = 17607 ppm

4

not be determined as mortality occurred at all levels tested. Also, a MATC could not be obtained from the trout fish early life stage test, because no pesticide-related adverse effects occurred. Also, the percent viability in the control groups did not exceed 34%. Given that acetochlor has a very long aquatic half life, adult and young rainbow trout will likely be adversely impacted by the use of this chemical. Acute toxicity data for marine and estuarine organisms have not been submitted, but are not required to support this EUP request. However, to support future EUP's or a full section 3 registration on corn, all estuarine and marine data must be submitted as well as a valid fish early life stage test and an invertebrate life-cycle study.

101.3 Endangered Species

SPECIES	TOXICITY	FACTOR	TRIGGER
BIRDS	5620 ppm	/10	562 ppm
	17,607 ppm[3]	/10	1761 ppm
MAMMALS	2953 mg/kg	/10	295 mg/kg
	59,060 ppm[3]	/10	5906 ppm
FISH	0.42 mg/l	/20	0.021 mg/l
AQU. INVERTEBRATES	14 mg/l	/20	0.7 mg/kg

[3] One-day LC_{50} values converted from LD_{50} values.

It appears that acetochlor would have minimal adverse acute effects on endangered birds and mammals. Maximum expected residues on short range grass (720 ppm) do not exceed 1/10th of the one day mammalian LC_{50} value (1761 ppm), and although 720 ppm exceeds the avian dietary trigger of 562 ppm, adverse acute effects on birds are not anticipated because: (1) the LC_{50} value in the mallard and bobwhite quail dietary studies was actually 5620 ppm; (2) no mortality occurred at the 5620 ppm level; and (3) the NOEC was 1780 ppm based on reduced body weight gain and food consumption at 3160 ppm. Chronic studies have not been completed for birds; therefore, chronic effects can not be adequately assessed for birds. As for mammals, it is noted that acetochlor is a carcinogen, affecting the liver and sinus areas. A rat reproduction NOEL and LEL of 500 ppm and 1500 ppm, respectively, were also determined. Because of the limited acreage and one application/season, chronic effects to birds and mammals in the three states shown for the EUP are unlikely.

The endangered freshwater fish and aquatic invertebrates triggers have been greatly exceeded, plus data are incomplete to assess chronic hazard to aquatic organisms. The Higgin's Eye Pearly Mussel and the Pallid Sturgeon are aquatic endangered species that occur in Iowa, Minnesota, and/or South

5

Dakota. The Higgin's Eye Pearly Mussel is found mainly in the Ohio and Mississippi River systems where currents run fast enough to scour the area and thus would minimize possible adverse effects. The Pallid Sturgeon is a recently listed fish species found in the Missouri River in Iowa and South Dakota. Since very little is known about this species and the potential toxicity effects that may incur from the use of this chemical, acetochlor may not be used in the following counties (from personal communications with Larry Turner, EPA):

IOWA -- Fremont, Harrison Mills, Monona, Pottawattamie, and Woodbury

SOUTH DAKOTA -- Brule, Buffalo, Campbell, Charles Mix, Clay, Carson, Dewey, Gregory, Hughes, Lymann, Potter, Stanley, Sully, Union, Walworth, and Yankton.

Also, since acetochlor is a herbicide, the chemical should not be used in counties where endangered plants are located. In addition to the above counties the following counties should not be included in this EUP program:

IOWA -- Adair, Allamakee, Black Hawk, Bremer Buena Vista Butler, Cherokee, Clark, Clay, Clayton, Delaware, Dickinson, Dubuque, Emmet, Guthrie, Howard, Jackson, Kossuth, Lucas, Osceola, Story, Warren, and Winneshiek.

MINNESOTA -- Brown, Clay, Cottonwood, Goodhue, Jackson, Mowere, Norman, Polk, Renville, Rice, and Rock.

101.4 Adequacy of Toxicity Data

Eight studies with Acetochlor were submitted by Monsanto for review under the current EPA guidelines. The following table indicates the status of each.

Study Type	Author/Date	Guidelines Satisfied
Avian Single Dose LD_{50}: 1567.1 mg a.i/kg Bobwhite	Fink WL-80-003 1980	yes
Avian Dietary LC_{50}:>5620 ppm Bobwhite	Fink WL-79-361 1980	yes
Avian Dietary LC_{50}:>5620 ppm Mallard	Fink WL-79-362 1980	yes
Static Acute LC_{50}: 14 mg/kg Daphnia magna	AB-79-079 Forbis and Thompson 1979	yes

Acute Bluegill Sunfish LC_{50}: 1.3 mg/l	Griffen and Thompson 1981 AB-81-181	yes
Acute Bluegill Sunfish LC_{50}: ---	Griffen and Thompson 1979 AB-79-078	no
Acute Rainbow Trout LC_{50}: 0.42 mg/l	Forbis and Thompson 1979 AB-79-077	yes
Fish Early Life Stage Rainbow Trout MATC: unknown	Altshul 1983 BN-82-276	no

From the results of the review of the above studies and the discussion given in section 101.2, the following studies are required for section 3 registration as well as future EUP requests:

- (2) 71-4 avian reproduction studies with bobwhite quail and mallard.

- (1) 72-4 Fish Early Life Stage study with the Rainbow Trout.

- (1) 72-4 Invertebrate life cycle study with Daphnia magna.

- (3) 72-3 Estuarine and marine toxicity studies (shrimp, mollusc, fish). (Required for all corn use patterns.)

- Tier II nontarget plant testing is necessary because Acetochlor controls both grasses and broadleaf weeds and may be applied through center pivot irrigation systems. EEB considers center pivot irrigation to be an aerial application and drift is a primary concern. The following data are required;

123-1 Seed Germination/ Seedling Emergence,
123-1 Vegetative Vigor,
123-2 Aquatic Plant Growth with all of the following:
Selenastrum capricornutum
Lemna gibba
Skeletonema costatum
Anabaena flos-aquae
a freshwater diatom.

In addition to the above, further data may be required depending on the results of the above and review of a complete environmental fate package: e.g. aquatic mesocosm study.

101.5 Adequacy of Labeling

The precautionary labeling statement should be modified to read as follows:

This pesticide is toxic to fish. Do not apply directly to water or wetlands. Do not contaminate water when disposing of equipment washwaters.

103 Conclusions

The EEB has completed a risk assessment of HARNESS Herbicide (Acetochlor) and has determined that birds and mammals should not be adversely affected from the use of this chemical under the conditions of the EUP. Risk to aquatic organisms may be substantial but the limited acreage involved in the EUP and one time application are mitigating factors. However, because of federally listed endangered species concerns with the Pallid Sturgeon and endangered plants, this product may not be used in the counties indicated in section 101.3 of this review. Further, the label submitted for review did not contain directions for use for early preplant applications; therefore, the label must be modified to include this use or early preplant should be omitted from the EUP program. EEB has noted several data requirements in section 101.4 of this review that must be completed before section 3 registration or future EUP's are granted for Acetochlor.

Cynthia Moulton
Biologist
EEB/EFED

Cynthia A. Moulton
2.27.91

Norman J. Cook
Head Section 2
EEB/EFED

Norman J. Cook
02.28.91

James W. Akerman
Branch Chief
EEB/EFED

3/6/91