7/21/80

EE BRANCH REVIEW

IN 7/3/80 OUT 7/18/80

FILE OR REG. NO. 241-EAR, -EAN

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED

DATE OF SUBMISSION

DATE SUBMISSION ACCEPTED

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

DATA ACCESSION NO(S). 099492

PRODUCT MGR. NO. G. LaRocca (15)

PRODUCT NAME(S) AMDRO Fire Ant Insecticide

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Full risk assessment of proposed conditional registration of fire ant use

CHEMICAL FORMULATION Tetrahydro-5,5-dimethyl-2(IH)-pyrimidinone-{3-[4-(trifluoromethyl)phenyl]-1-{2-[4-(trifluoromethyl)phenyl]ethenyl}-2-propenylidene}hydrazone 0.88%

Pesticide Name

AMDRO Fire Ant Insecticide

100 Pesticide Label Information

100.1 Pesticide Use

AMDRO is proposed for use in controlling the imported fire ant on pasture and range grass, grass hay, lawns, turf, and non-agricultural land.

100.2 Formulation Information

AMDRO 0.88%
Inert ingredients 99.12%
100%

INERT INGREDIENT INFORMATION IS NOT INCLUDED

AMDRO technical (92-97%) is mixed with [redacted] resulting in the 0.88% ai bait.

100.3 Application Methods

Label directions are as follows:

Apply when ants are active (typically when soil temperature is greater than 60°F) or consult your state experiment station or state extension service for proper timing of applications.

An effective fire ant insecticide must be slow acting so that it can be passed by the workers throughout the ant colony and eventually to the queen. AMDRO is a slow acting insecticide and is especially effective against the queen ant. Typically, in 2-4 weeks the queen and a number of ants are killed. Within 4-8 weeks a significant number of the ants die so that a visible reduction in mound activity is observed. Very large mounds may continue to be active for 4-6 months even though the queen is dead and no young are being produced. Retreatment after 4 months may be desirable under these circumstances.

BROADCAST APPLICATION

AMDRO fire ant insecticide should be applied with an applicator properly calibrated to assure accurate placement and proper dosage.

Sites	Rate lb.A	Application
Pasture and Range Grass, Grass Hay, Lawns, Turf and Nonagricultural lands	1.0 to 1.5 lb./A	Broadcast uniformly with ground equipment, or aircraft

INDIVIDUAL MOUND TREATMENT

Pasture and Range Grass, Grass Hay, Lawns, Turf and Nonagricultural lands: Use 1 tablespoon of bait for small mounds (less than 12" diameter) or 2 tablespoons for large mounds (greater than 12" diameter). The product should be uniformly distributed 6"-12" around the base of the mound.

100.5 Precautionary Labeling

The proposed label contains the caution:

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Avoid direct application to lakes, streams or ponds. DO NOT apply when weather conditions favor drift from target areas.

101 Physical and Chemical Properties

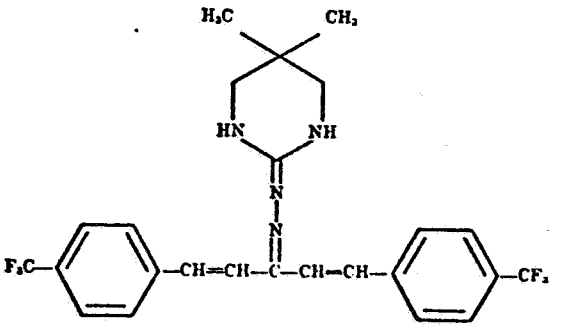
101.1 Chemical Name

Tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone {3-[4-(trifluoromethyl)phenyl]-1-{2-[4-(trifluoromethyl)phenyl]ethenyl}-2-propenylidene} hydrazone.

Previously referred to as:

1,5-bis(α,α,α-trifluoro-p-tolyl)-1,4-pentadien-3-one (1,4,5,6-tetrahydro-5,5-dimethyl)-2-pyrimidinyl)hydrazone.

101.2 Structural Formula



101.4 Trade Names

AMDRO
AC 217,300
CL 217,300

101.7 Solubility

AMDRO is insoluble in water and soluble in acetone, methanol, ethanol, isopropanol, and hot ethyl acetate.

102 Behavior in the Environment

Reviews performed by Environmental Fate Branch (EFB) allow the following conclusions concerning the fate of AMDRO.

The half life of technical AMDRO under sunlight is 1 hour, and the half life of the bait product was 20-25 hours. A microbial degradation study indicated over 60% of the parent AMDRO remained after 1 month.

102.1 Soil

An aerobic soil metabolism study indicated more than 50% of the parent compounds remaining after 1 month, and 5 unidentified metabolites were formed. AMDRO (parent compound) has a field dissipation half-life of 18 hrs. AMDRO is immobile on sandy or silt loam.

102.2 Water

A hydrolysis study indicated that the half life of AMDRO was 3.6-5.2 days at pH 6.4. Four metabolites were detected. One (CL 98, 724) was named, but not identified any further.

102.3 Bioaccumulation

AMDRO has an Octanol/water coefficient of 206, which is rather low (DDT = 9,490). Low bioaccumulation factors of 50 and 100 were determined for channel catfish and mosquito fish, respectively vs. 1760 for mirex. Other bioaccumulation potentials observed were: algae-170 (vs. 5042 for mirex), snails-569 (vs. 15,320), and mosquito larvae-571 (vs. 1993).

In the channel catfish study, a bioaccumulation factor of 5480 was noted for algae in the last week of exposure, but no explanation was given.

A third fish bioaccumulation study which was found to be of questionable accuracy demonstrated a bioaccumulation factor in bluegills of 34,900. EFB felt that problems in the study probably accounted for this high value, and have required that the study be performed again. EEB also requires that the study in question be performed again, if the registrant's contention of low bioaccumulation potential is to be accepted.

102.4 Metabolites

Although it appears that the parent compound degrades rapidly in the field (as per EFB), studies which identify and determine the fate and persistence of the metabolites of AMDRO are not available. This information is necessary in order for EEB to complete an appropriate risk assessment for the proposed pesticide use. According to the Environmental Chemistry section (163.62) of the 1978 guidelines, the registrant is required to identify all metabolites comprising more than 10% of the initial application in degradation studies. Studies requiring this information include hydrolysis, photodegradation, aerobic soil metabolism, and field dissipation.

103 Toxicological Properties

103.1 References from Toxicology Branch

Rat acute oral LD_{50} = 1213 mg/kg (both sexes combined)

6-month dog feeding study
no effect level = .33 mg/kg/day

103.2 Minimum requirements

103.2.1 Avian Acute Oral LD_{50}

Mallard Duck
>2510 mg/kg - Technical (92%)
Core - Fink(1979) - in Acc.#098982

Bobwhite Quail
1828(983-3402) mg/kg - Technical (92%)
Core - Fink(1979) - in Acc.#098982

103.2.2 Avian Dietary LC_{50}

Mallard Duck
4355(2877-6592)ppm - Technical (92%)
Core - Fink(1979) - in Acc.#098982

Bobwhite Quail
1136(908-1420)ppm - Technical (92%)
Core - Fink(1979) - in Acc.#098982

103.2.3 Fish Acute LC_{50}

Rainbow Trout
0.16(.13-.19)ppm - Technical (92%)
Core - Schneider(1979) - in Acc.#098982

Bluegill Sunfish
1.7(1.4-2.1)ppm - Technical (92%)
Core - Seminara(1980) - in Acc.#099492

103.2.4 Aquatic Invertebrate Acute LC_{50}

Daphnia magna
1.14(.93-1.39)ppm - Technical (92%)
Core - Browne(1980) - in Acc.#099492

103.3.3 Toxicity to Beneficial Insects

According to laboratory tests conducted by E.L. Atkins of the University of California, AMDRO (tested as AC 217,300) is essentially non-toxic to bees.

104. Hazard Assessment

104.2 Likelihood of Adverse Effects to Non-Target Organisms

The proposed application rate for AMDRO is 1-1.5 lb/Acre. This is equivalent to .009-.013 lb ai/acre or 4-6g ai/acre.

Aquatic Hazard

A worst-case scenario can be calculated by assuming a direct application of AMDRO to water with all of the pesticide dissociating from the carrier and dissolving in six inches of water.

Assuming a maximum rate of 1.5 lb/A (.013 lb ai/A), a concentration of 9.9 ppb would result in 6 inches of water. This concentration is less than 1/10 of the LC_{50} of the most sensitive aquatic species tested (Rainbow trout, LC_{50} = .16 ppm). On the the basis of this calculation, it would appear that AMDRO would not present an acute exposure hazard to aquatic organisms. No information is available on the long term effects of AMDRO to aquatic organisms, so it is impossible to assess the hazard of chronic exposure at this time.

Avian Hazard

Since the bobwhite-AMDRO LC_{50} is 1828 mg/kg, an approximate LD_{50} can be calculated for a typical songbird:

LD_{50} for a 60 gram songbird $= \frac{LD_{50} \times \text{body wt.}}{\% \text{ ai}}$

$= \frac{1828 \text{ mg/kg} \times .06\text{kg}}{.0088}$

$= 12.5$ g/bird

The maximum application rate of 1.5 pounds/Acre is equivalent to 16 mg of bait per sq. ft. One square foot of treated rangeland will contain, therefore, $\frac{16\text{mg}}{12.5\text{ g}}$, or approximately 0.1% of a typical songbird LD_{50}. The bird would have to eat all the bait falling on 780 sq ft to ingest an LD_{50} dose. Since the toxicant available per sq ft is so much less than 1/5 the avian LD_{50}, little acute hazard to birds would be anticipated.

The acute hazard to small mammals would be similar to that predicted for birds, based on the similarity in rat and quail oral LD_{50} values.

Hazard - Conclusion

Although the hazard from acute exposure to AMDRO appears to be minimal, there are still some aspects of hazard that cannot be assessed at this time. The lack of information concerning the long-term effects of AMDRO and the lack of information on AMDRO metabolites make it impossible to complete a risk assessment for chronic hazards based on the data available. Studies required before the hazards that can be fully assessed are outlined in sec. 104.5

104.3 Endangered Species Considerations

Until sufficient information is submitted to enable a hazard assessment, the possible effects of AMDRO on endangered species cannot be evaluated.

104.5 Additional Data Required

As mentioned above in section 104.2, the lack of long-term studies makes it difficult to assess the hazard of AMDRO on a long-term basis. Since the potential area for use of AMDRO

involves such large acreage, EEB feels it is important to gain a more detailed understanding of the effects of AMDRO to non-target organisms. Since AMDRO will also be applied by air, there is a high probability that small bodies of water may be exposed to full applications of the pesticide. According to the 1978 guidelines (163.72-4(a)), fish embryo-larvae and aquatic invertebrate life-cycle studies are indicated.

Points indicating necessity of fish embryo larvae study.

1. LC_{50} is less than 1 mg/l
2. Estimated concentration is greater than 1% of the LC_{50}.

Point 1 above also indicates the necessity of an aquatic invertebrate life-cycle study.

One of the important properties affecting the efficacy of AMDRO is the slow-acting nature of the pesticide. In light of this, it is important to have some indication of the toxicity to non-target organisms after longer exposures, and the studies mentioned above would meet this requirement.

As mentioned in sec. 102.3, EEB supports EFB in their requirement that the bluegill bioaccumulation study be repeated.

The need for information on metabolites of AMDRO is outlined in Sec. 102.4. Required information includes identification of the metabolites from hydrolysis, photodegradation, aerobic soil metabolism, and field dissipation studies. In addition, information on the fate and persistence of these metabolites is required.

107 Conclusions

107.3 Environmental Hazards Labeling

The environmental hazard section of the label should be modified to include the caution:

> "Keep out of lakes, ponds, or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

107.4 Data Adequacy Conclusions

The six basic studies required by subpart E of the guidelines have been received and are acceptable in support of registration.

107.5 Data Requests

The following studies are required before EEB can perform a complete hazard assessment:

1. A fish embryo-larvae study.
2. An aquatic invertebrate life-cycle study.
3. Re-performance of the bluegill bioaccumulation study.
4. Information on AMDRO metabolites and their persistence and fate from hydrolysis, photodegradation, aerobic soil metabolism, and field dissipation studies.

Rationale for these requirements is provided above, in Sections 102 and 104.

107.7 Recommendations

EEB objects to the proposed registration of AMDRO on the grounds that it is impossible to make a complete hazard assessment since data pertinent to potential chronic hazards are lacking.

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