Agriculture Canada

Food Production
and Inspection Branch

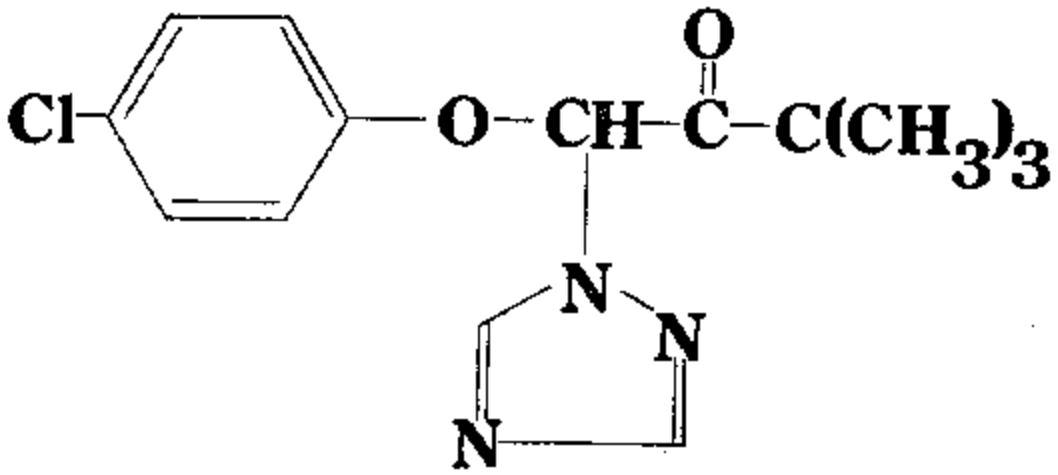
Pesticides Directorate

Direction générale,
Production et inspection des aliments

Direction des pesticides

Discussion Document D87-03

TRIADIMEFON



Fungicide

This bulletin is published by the Pesticide Information Division of the Plant Industry Directorate.
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FOREWARD

TRIADIMEFON

As part of the ongoing efforts to provide a summary of the data received and outline the regulatory action of the active ingredient triadimefon, a discussion document has been prepared. This document reflects input from specialists within Agriculture Canada and with key interdepartmental advisors. Based on the reviews of all available information and in consideration of wide ranging comments received, a regulatory decision has been made to extend a temporary registration, RESTRICTED use basis, for the formulated product Bayleton 50 WP.

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August 5, 1987

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TRIADIMEFON (BAYLETON 50 WP)

1. SUMMARY

The purpose of this document is to provide a summary of the data reviewed and outline the regulatory action on the active ingredient triadimefon.

The registration status of triadimefon represents an important ongoing regulatory issue particularly in regard to Intensive Cereal Management (ICM).

The ICM program is a new approach to growing cereals utilizing high yielding varieties (especially winter wheat) and strict applications of fertilizers and fungicides. Under ideal conditions, ICM represents a significant increase in yield and quality compared to traditional cereal-cropping practices and the use of fungicides like triadimefon, can account for a major portion of that increase.

Agriculture Canada, with the assistance of advisors from Environment Canada, Fisheries and Oceans Canada and Health and Welfare Canada, has completed a review of the data supporting triadimefon. Although the data base is modern, certain health and safety studies are not complete. For example, risks as a result of occupational exposure could not be identified due to the inadequacies of the studies submitted for exposure estimation under Canadian use situations. In light of the lack of data, growers are advised to use protective clothing in order to keep exposure to a minimum. In addition, enclosed packaging of the product (solupacs) contributes to reduced operator exposure during mixing and loading.

Consumer exposure to residues in food will be minimal, since residues of triadimefon and its metabolites on the harvested grain are expected to be below 0.1 ppm based on a 60-day preharvest interval. With reference to one of these metabolites, triazolyl alanine, there are still unresolved questions concerning the significance and extent of residues since triazolyl alanine has been shown to occur naturally at low levels in plants.

Based on a review of all available information and in consideration of wide ranging comments received, temporary registration, restricted class has been extended for Bayleton 50 WP (P.C.P. No. 18804) on winter wheat for 1987 under the following conditions:

1. A limited amount of material will be made available, i.e., only to those growers who utilize cereal management techniques for high yield and quality (ICM). This statement will be clearly outlined on the label.

2. Additional special labelling to include: "WARNING: Studies on the safety of this product for users and spray operators are not complete. Directions for use and precautionary statements should be followed carefully. Read the label before using."

3. Inclusion of a 60-day, preharvest interval for winter wheat.

4. For ground application only.

2. PESTICIDE NAME AND PROPERTIES

2.1 Pesticide Name

Trade Name:	BAYLETON
Research Number:	BAY MEB 6447
Common Name:	triadimefon
Chemical Name:	1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-butanone
CAS Registry No.:	43121-43-3

2.2 Physical and Chemical Properties (Technical):

Appearance:	White to tan crystals
Molecular Weight:	293.7
Melting Point:	72° - 78°C
Vapor Pressure:	$<10^{-6}$ millibar @ 20°C
Density:	1.22 @ 20°C
Solubility:	Water: 60 ppm @ 20°C Moderate solubility in most organic solvents except aliphatics
Stability:	Stable under normal storage conditions
Odor:	Mild
Octanol/Water Partition Coefficient:	972 @ 20°C

All aspects of the data on product chemistry have been reviewed and found acceptable. Standards, both analytical and technical grade, are acceptable and are available from the Laboratory Services Division, Agriculture Canada. Analysis for microcontaminants showed no evidence of dioxins or nitrosamines in the technical material.

2.3 Biological Properties

Bayleton (triadimefon) is a sterol-inhibiting fungicide. Sensitive fungi contain ergosterol as the principle sterol, the production of which is inhibited after the uptake of triadimefon, thus causing death of the target fungi. In addition, triadimefon is a systemic fungicide which is rapidly absorbed into young, actively growing plant tissues where it is translocated acropetally (upward) in the

vascular system of the plant. Some lateral translocation occurs by diffusion into cells adjacent to the vascular system. Basipetal (downward) translocation occurs only to a very slight degree. It has excellent preventive and curative activity on powdery mildew and rusts (leaf, stem and stripe).

3. USE HISTORY

In 1985, triadimefon was first used in Canada on winter wheat. Bayleton 50 WP was given a Temporary registration, RESTRICTED class. It was used only in the Maritimes; Ontario did not schedule the product in 1985.

In 1986, Bayleton was issued a Temporary registration, RESTRICTED class, for use on winter wheat and an Emergency registration for use in Alberta to control stripe rust on spring wheat. Ontario scheduled the product for use on hard red winter wheat only and required a permit for use.

For 1987, the Temporary registration, RESTRICTED class, allows use on winter wheat by those growers who utilize intensive cereal management techniques for high yield and quality.

Triadimefon has been registered in Europe for the past six years and in the United States for the last three years on a number of food crops including cereals.

4. REGULATORY ACTIONS

There has been continued effort by the registrant to update the data base of triadimefon and the review has proceeded accordingly. Based on these efforts, Agriculture Canada has renewed the temporary restricted class registration for triadimefon (Bayleton 50 WP) for winter wheat under the following conditions:

a) A limited amount of material will be made available i.e., only to those growers who utilize cereal management techniques for high yield and quality (ICM). This statement will be clearly outlined on the label.

b) Additional special labelling to include: "WARNING: Studies on the safety of this product for users and spray operators are not complete. Directions for use and precautionary statements should be followed carefully. Read the label before using."

c) Inclusion of a 60-day, preharvest interval for winter wheat.

d) For ground application only.

5. AGRONOMICS SUMMARY

Triadimefon is highly systemic. Trials indicate not only

protection from disease organisms, but also curative and eradicative properties after disease symptoms occur. At the proposed label rate (225-550 g Bayleton 50 WP/ha) triadimefon is particularly effective against powdery mildew (Erysiphe graminis) and effective against leaf, stem and stripe rust (Puccinia recondita, P. graminis and P. striiformis) on wheat. Triadimefon has been evaluated in Canada in replicated experiments since 1975 and under commercial scale research permit use since 1981.

Estimates of potential yield loss due to disease are as follows:

Disease	Cereal Disease Loss Potential (%)
Crown & root rot	15
Head diseases	20
Powdery mildew	30
Septoria/tan spot	20
Rusts	25
Viruses, etc.	10

The ranking of powdery mildew and the rusts as the number one and number two loss factors illustrates the importance of triadimefon as a control measure.

5.1 Powdery Mildew on Wheat

Erysiphe graminis, the causal agent of powdery mildew, is an obligate parasite of cereals and can cause up to 30 percent yield loss in wheat. In moist regions where wheat is grown under high fertilizer regimes, yield loss can be significantly greater. Such situations occur in the Maritimes and parts of Ontario and Manitoba. In over 15 research trials and several field scale demonstrations across Canada, Bayleton 50 WP has demonstrated excellent control of powdery mildew.

Effectiveness continued to be confirmed in 1986 in both replicated experiments and commercial scale comparisons. Direct yield response to Bayleton was measured under grower use conditions in 1986 in both winter wheat and spring wheat. In 10 locations in Ontario, yield response in soft white winter wheat averaged +10.7 percent (+7.1 bu/ac) and ranged from no response to +20.8 percent (+13.1 bu/ac). Although not registered for this use, research trials on spring wheat response in 11 locations averaged +14.7 percent (+6.1 bu/ac) and ranged from 0 to +32.9 percent (+13.2 bu/ac). The occasional absence of response was attributed to low disease incidence and/or late application.

5.2 Grower Reaction

Grower awareness of disease in cereals is increasing. In addition, the ability of growers to identify disease and

distinguish between the occasional disease symptom and an epidemic condition that requires treatment is also increasing. Growers point out that they need the product on hand for immediate use if they are to effectively utilize their management skills.

The use of specialized packaging for Bayleton 50 WP in 250 g water-soluble packets (solupacs) has been very well received. In addition to encouraging accurate rates of application the packets contribute to safe handling practices by reducing direct contact of the operator with the product during the mixing/loading operation.

5.3 Other Crops

At present Bayleton 50 WP is under active review for registration on cereals only. Serious consideration of use extension to fruit crops such as grapes must be held in abeyance pending further refinements of toxicological information and additional residue data to substantiate food crop applications closer to harvest. Additional uses will be considered for registration as soon as outstanding residue and toxicological questions can be resolved.

6. HEALTH AND WELFARE CANADA INPUT: TOXICOLOGICAL STUDIES

The following toxicology data base was submitted by Mobay in support of the registration of Bayleton 25 and 50 WP formulations for agricultural uses on diseases of wheat, barley, grapes and apples.

6.1 Acute toxicity

a)Technical grade triadimefon. Per oral (p.o.) studies in four mammalian species were evaluated: LD_{50} values ranged from 363 mg/kg body weight (bw) in female rats to 1071 mg/kg bw in female mice. Percutaneous administration of 2000 mg/kg in rabbits produced no observable adverse effects. The intraperitoneal LD_{50} value in rats was marginally lower than the oral values, 293 mg/kg bw in female rats.

In static and dynamic spray inhalation tests of 4-hour duration, using rats, rabbits and hamsters, adequately high dose levels were not achieved to establish an LC_{50}, 11 out of 20 mice died at 291 mg/m^3.

It was observed that Bayleton technical (1) did not have any skin sensitization potential; (2) was a mild, reversible skin irritant; (3) and had no primary eye irritancy potential in rabbit studies.

b)Formulations. In per oral studies in rats, the LD_{50} values were observed to be 812 and 1470 mg/kg bw for males and females respectively using the 50 WP and in excess of 2500 mg/kg bw for both sexes for the 25 WP. There were no observed

adverse effects in rabbit percutaneous studies using 2000 mg/kg bw of the 50 WP or 5000 mg/kg bw of the 25 WP formulation. In a rat inhalation study (4 h) the LC_{50} was observed to be in excess of 3523 mg/m^3 for the 50 WP. In dogs, at 950 mg/kg bw, the 50 WP (p.o.) caused systemic effects in 50 percent of each sex; affected dogs survived with supportive therapy.

Skin sensitization study reports were not submitted. Neither formulation was observed to be a primary skin irritant in rabbits. The 50 WP was found to be a moderate, reversible eye irritant in rabbits; 25 WP caused mild, reversible eye irritation.

6.2 Short-term toxicity

In a 7-day rat feeding study, following a 14-day recovery period, fatty degenerative liver effects were observed at the lowest dose, 150 mg/kg bw. In a 12-week dietary study in rats a NOEL (No Observable Effect Level) was not established; the lowest dose tested was 50 ppm.

In a 30-day gavage study in rats NOEL's of 3 and 10 mg/kg for males and females respectively, were based on liver weight changes occurring at higher doses. In a following 28-day gavage study no adverse effects on liver morphology and function were observed at the highest dose tested, 25 mg/kg bw/day.

In inhalation studies, no adverse effects were observed in rats at 453.6 mg/m^3 exposed for 4 hours per day for 5 days. However in another study systemic effects were observed in rats given 307 mg/m^3 for 6 hours daily, 5 days per week for 3 weeks, the NOEL was 78.7 mg/m^3.

In a rabbit dermal study of 4 weeks duration, no systemic adverse effects were observed at 250 mg/kg bw, the highest dose level tested, but mild irritation was observed. In a 3-week rabbit study, 500 mg/kg bw caused severe irritation.

In a dog dietary study, a NOEL of 11.25 mg/kg bw/day for 13 weeks was determined for multiple systemic effects observed at higher doses.

6.3 Long-term toxicity and carcinogenicity

A long-term dietary study in rats was evaluated and found to be inadequate for determination of oncogenic potential. Additional information, relating to the utility of this study for chronic effects has been resubmitted but not yet evaluated.

An oncogenicity study in mice was deemed to be inadequate. A repeat study is underway and is scheduled for submission

in 1987. In a 2-year feeding study in dogs the NOEL was reported to be 330 ppm (dietary) based on multiple systemic effects, including hepatic effects at the next dose level, 2000 ppm.

6.4 Mutagenicity

In five mutagenicity studies triadimefon was not observed to have any mutagenic potential in a mouse micronucleus test at 2000 mg/kg bw; a mouse dominant lethal study, using a 10 mg/kg bolus oral dose; in an Ames test using S. typhimurium, a rec-assay with B. subtilis, a reversion assay with S. typhimurium and for DNA damage in E. coli.

6.5 Reproduction

Two reproduction dietary studies have been submitted, a three-generation (two-litter) study in rats and a two-generation (single litter) supplemental study in rats. In the first study, doses of 50, 300 and 1800 ppm were used and, in the second study, 50 and 1800 ppm. In the first study, complete reproduction failure occurred in the second generation (Fl) at the high-dose level. This effect was confirmed in the supplemental study in which significant (60%) fertility reduction was observed in the second generation (Fl). Cross mating of Fl high-dose males and control females confirmed that only the Fl males were affected. The only major systemic adverse effect other than fertility on Fl males was observed to be reduced weight gain. In utero exposure appears to be essential to the effect on fertility. There were no adverse reproductive effects at 50 and 300 ppm dose levels. Transient early depression of pup growth occurred in F2B and F3B litters at 300 ppm and in FlA and FlB litters at 1800 ppm. At 300 ppm splenic hematopoiesis was increased in male pups at weaning. For these reasons the 50 ppm dietary level was recommended as the NOEL.

Additional information explaining the cause of the reproductive failure at 1800 ppm has been received but not yet evaluated.

6.6 Teratology

Several studies were submitted to assess the developmental toxicity potential of triadimefon.

a) Rabbit. Two rabbit teratology studies have been submitted. Both were considered to have insufficient data to permit a complete evaluation of the teratogenic potential of triadimefon technical. Additional information, including methodology has been submitted. However, a reassessment of the study utility has not yet been undertaken.

b) Rat. Four rat teratology studies were submitted. An inhalation study was deemed to be unacceptable. In one rat study hydronephrosis was observed in all groups with a significant dose-related increase at 30 mg/kg bw/day and above. Minor and major malformations were observed in a second study at 50 mg/kg bw/day and above. In a third, earlier study a NOEL of 50 mg/kg bw/day was established for major malformations. For maternal toxicity, a NOEL of 10 mg/kg bw/day would be prudent for clinical observations including increased motor activity and for teratogenic effects, a NOEL of 25 mg/kg/day. Additional information has been submitted regarding hydronephrosis in rat fetuses which has not been fully assessed.

6.7 Occupational Exposure

The submitted studies do not allow adequate assessment of exposure potential at this stage of the evaluation. The following points are unresolved and must be addressed by the registrant before the usefulness of these studies for an exposure estimation under Canadian use situations can be established.

a) In a grape exposure study, patch and glove data were used to estimate dermal deposition and the triadimefon residues in urine were used to estimate the absorbed dose, following Bayleton use. Excretion data collected in this study and data from metabolism

and pharmacokinetic studies suggest that urinary monitoring of workers should have been carried out for a longer period following the final exposure. It was concluded, therefore, that the study findings represent an underestimate of urinary excretion and therefore also an underestimate of the absorbed dose. The registrant has not yet commented on this criticism of the study.

b) In a grain exposure study only,"outside" patch data were used to estimate dermal deposition of Bayleton. The assumption used in the calculation of the regional surface depositions was not reported nor was the method for estimation of hand deposition. Laboratory and field recovery efficiencies and analytical details were also not reported.

The study protocol required an application rate of only 125 g ai/ha using a 25 WP whereas the Canadian use recommends 275 g ai/ha using a 50 WP. Therefore, these studies are not useful for estimating exposure resulting from use of the Canadian product.

c) A dermal exposure study in rabbits using a single dose of 200 mg (^{14}C-labelled) 50 WP per animal was submitted.

The duration of exposure was 24 hours under occlusion patches. A description of the test material and the nature of the ^{14}C-labelling were not reported. The ranges of absorbed radioactivity were 2.8 to 6.7 percent in female rabbits and 7.9 to 17.3 percent in males. The authors' claim that the study represented a worst-case field exposure situation was not supported by evidence. Extrapolation to human exposure is difficult since rabbits are infrequently used for such studies, rats and monkeys being generally preferred test animals. The authors made no attempt to explain the relationship between their findings from a single dorsal skin application site, regional variations in dermal deposition and absorption in occupationally exposed humans. The study does not provide insight into the anticipated occupational exposure after Bayleton use.

7. HEALTH AND WELFARE CANADA INPUT: FOOD RESIDUE STUDIES

Triadimefon fungicide is metabolised in plants to triadimenol, KWG 1342 (4-(4-chlorophenoxy) -2,2-dimethyl -4-(lH-1,2.4-triazol-1-yl)-1,3-butandiole) and a number of minor metabolites. Triadimenol is the major metabolite of triadimefon. Total residues of triadimefon, triadimenol and KWG 1342 are not expected to exceed 0.05 ppm in grain harvested from winter wheat fields treated at 275g ai/ha at least 60 days before harvest.

Triadimefon and its triazole ring-containing metabolites also react with -alanine in plants to form triazolyl alanine. Other triazole ring-containing fungicides, such as triadimenol, propiconazole, bitertanol, etc., may also form triazolyl alanine. Limited available data indicate that residues of triazole alanine may range from 0.1-2.0 ppm in crops after treatment with triadimefon, depending on the treatments and the number of years after application. However, naturally occurring background levels of 0.01-0.05 ppm triazolyl alanine also occur in untreated cereal crops. Questions concerning the significance and extent of triazolyl alanine residues are still under consideration.

8. ENVIRONMENTAL PROTECTION SERVICE AND CANADIAN WILDLIFE SERVICE OF ENVIRONMENT CANADA INPUT:
SUMMARY OF ENVIRONMENTAL ASPECTS

Triadimefon persists to the extent that it has a reported half-life of a few weeks to a few months in soil: its primary metabolite is triadimenol (the active ingredient of Baytan) which is more persistent. More data are needed to define the persistence and the potential mobility. Additional information is also needed concerning possible effects in birds, demonstrated toxicity in aquatic organisms, and effects on wildlife habitat (especially in wetlands).

8.1 Environmental Chemistry and Fate

The solubility of triadimefon in water at 20°C is 60 ppm, and its octanol-water partitioning coefficient is 972. Triadimefon is readily adsorbed to all soil types including sand, loam, and silty clay. Neither triadimefon nor its primary metabolite, triadimenol, is very readily leached from soils. The vapour pressure of triadimefon is low and volatilization will also be low.

Triadimefon is somewhat persistent in soil to the extent that it has a reported half-life of a few weeks to a few months. The primary metabolite, triadimenol (which is also a fungicide in its own right) is more persistent, having a half-life in soil of at least some months. Further field soil dissipation studies under Canadian conditions are warranted to define the accumulation and depth of penetration of triadimenol in the soil profile with repeated use of Bayleton.

Triadimefon or its transformation product, triadimenol, is unlikely to enter sensitive aquatic systems through leaching. Although they could enter as a result of erosion, the most likely route of contamination is through spray drift of Bayleton. Triadimenol has been shown to be more persistent than triadimefon in sediment as well as in soil.

8.2 Environmental Toxicology

a) Wild birds. The toxicity of triadimefon to wild birds is low. No mortalities of adult mallard ducks were observed when dosed with 4000 mg/kg bw of the technical material. The eight-day dietary LC_{50} is between 4640 and 10000 mg/kg diet for bobwhite quail. No mortalities of mallard ducks were observed at 10000 mg/kg diet.

Although the manufacturer has indicated that studies on the effects of triadimefon on reproduction of bobwhite quail and mallard ducks have been done, these studies have not been received for evaluation. Baytan, a major degradation product of triadimefon, was evaluated for reproductive effects on bobwhite quail. The compound was fed for 10 weeks prior to laying and throughout a 13-week laying period at concentrations of 0, 20, 100 and 500 mg/kg diet. No effects were observed on adult survival, body weight, feed consumption, egg cracking, fertility, viability, hatching, chick survival and chick weight at 0 and 14 days. A 15 percent reduction in egg production at the highest dose level indicated maternal toxicity.

Exposure to triadimefon is unlikely to be acutely toxic to wild birds. Effects due to chronic exposure through ingestion of contaminated grain cannot be fully evaluated as the studies on the effects of the active ingredient on avian reproduction have not been received.

b) Wild mammals. Triadimefon technical was not highly toxic to laboratory rats, mice, rabbits or dogs. Acute oral LD_{50} values ranged from 363-568 mg/kg for rats, 989-1071 mg/kg for mice, 500 mg/kg for rabbits and 500 mg/kg for dogs. No wild mammals were tested.

On the basis of estimates of exposure following recommended application rates on wheat, triadimefon is not expected to pose an acute toxic hazard to wild animals.

c) Amphibians and Reptiles. No data are available for evaluation of risk to amphibians and reptiles.

d) Aquatic Organisms. The acute toxicities of the technical and formulated product (50 WP) to aquatic invertebrate species are moderate. The 48-h LC_{50} (static water test) to Daphnia is 1.6 - 11.3 mgai/L for the technical and 16 mg ai/L for the formulated product. The no-effect concentration of the formulated product was 5.6 mg/L.

Studies on the acute toxicity of triadimefon suggest that crayfish are less sensitive to the compound than Daphnia, having a 96-h LC_{50} of 104 mg/L. The reliability of these results is questionable because the nominal concentrations were not confirmed analytically and are above the water solubility of the compound.

If spray drift at rates recommended for use of Bayleton on wheat should deposit on water, chronic exposure to triadimefon and triadimenol could affect aquatic organisms, especially those living in or on the sediment.

e) Terrestrial Invertebrates. No effect on numbers of earthworms was observed after 10 days in soil containing triadimefon at 50 mg/kg soil.

Studies on selected soil microorganisms showed varied species sensitivity. Growth of one of the five species of bacteria and actinomycetes tested was inhibited at two ppm triadimefon in soil, and growth of one of the four species of fungi was inhibited at 10 ppm.

No effects on soil nitrification or denitrification have been observed.

At application rates recommended for use, triadimefon concentrations of at least l ppm in soil can be expected to occur. Some populations of soil microorganisms could potentially be affected.

f) Wildlife Habitat Considerations. There is evidence for

effects on plant growth at low concentrations. Growth of soybean plants was significantly reduced (60% decrease in shoot length, 21% decrease in plant fresh weight) relative to controls following continuous irrigation for 4 weeks with a 0.5 mg/L solution of triadimefon. No data are available on the phytotoxicity of triadimefon to aquatic plants. Because triadimefon could reach aquatic systems such as prairie sloughs, the impact on aquatic plants and subsequently on wi1d1ife wetland habitat needs to be defined. These data are still outstanding.

9. FISHERIES AND OCEANS CANADA INPUT:
FISH AND FISH HABITAT STUDIES

Technical triadimefon exhibits slight-to-moderate toxicity to fish with acute LC_{50} values of 10 mg/L (95% confidence interval 9.7 to 12 mg/L) for bluegill, 14 mg/L (95% confidence interval 12 to 16 mg/L) for rainbow trout, 15 mg/L (95% confidence interval 13 to 17 mg/L) for channel catfish and 10 to 50 mg/L for goldfish. The 50 WP formulation has LC_{50} values for fish of 12 mg ai/L (95% confidence interval 11 to 14 mg/L) for bluegill, and 12 mg ai/L (95% confidence interval 10 to 14 mg/L) for rainbow trout.

Using growth rate as the criterion, the no-effect level for larval rainbow trout was 40.6 g/L. A concentration of 890 g/L caused significantly higher mortalities of larvae than in controls.

The accumulation factor of triadimefon in channel catfish is 7.6 at 10 g ai/L water concentration and 6.5 at 100 g ai/L water concentration based on experiments using ^{14}C labelled compound. Concentrations in the fish increased during the first two hours only and depuration was rapid with 87% decrease in ^{14}C activity during the first five hours of withdrawal. Only 4 percent of the initial activity remained after seven days of withdrawal.

At recommended application rates, with no spray reaching water bodies directly, there appears to be little concern about deleterious effects on fish. However, if a water body 0.5 metre deep were to receive a complete overspray, the concentration in the water would be 55 g/L, which is above the No Effect Level for fish larvae. If concentrations over 55 g/L were to persist, some effects on growth might be expected. However, fish deaths would be highly unlikely.

Because of the long half-lives possible for triadimefon and triadimenol in soil, water, and sediment and the low concentrations at which there are detrimental effects on fish larvae, monitoring studies of soil and water bodies near treatment areas appear warranted.

Please direct all inquiries regarding triadimefon to Dr. Adrian Carter, Associate Director, Plant Disease Control Section.