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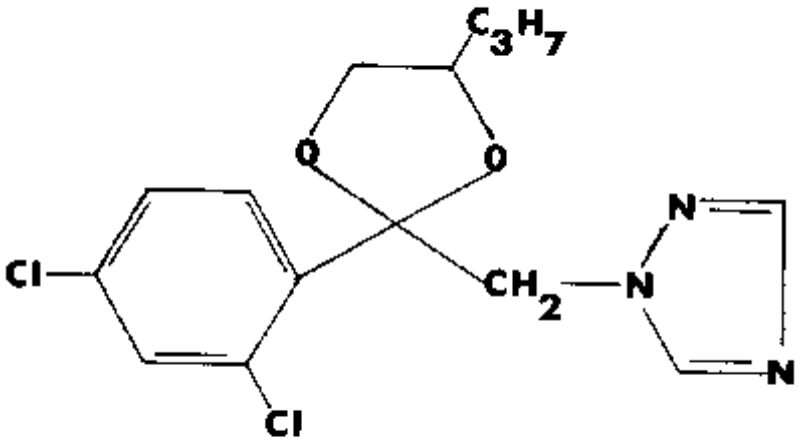
Direction générale, Production et inspection des aliments

Plant Industry Directorate

Direction de l'industrie des produits végétaux

Discussion Document D87-05

PROPICONAZOLE



Fungicide

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FOREWORD

PROPICONAZOLE

As part of the ongoing efforts to provide a summary of the data received and outline the regulatory action of the active ingredient propiconazole, 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 Class) for the formulated product Tilt 250 EC.

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PROPICONAZOLE (TILT 250)

1. SUMMARY

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

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

The ICM program is a new approach to growing cereals utilizing high-yielding varieties 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. The use of fungicides like propiconazole 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 propiconazole. 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.

Exposure of consumers to residues in food will be minimal. Residues of propiconazole and its metabolites containing the 2,4-dichlorobenzene moiety on harvested grain, are expected to be below 0.1 ppm when a 45-day interval is observed between application and harvest. With reference to the metabolite triazolyl alanine (TA), there are still unresolved questions concerning the significance and extent of its residues because TA has been shown to occur naturally in plants at low levels.

Propiconazole undergoes fairly slow microbial degradation in aerobic conditions in soil, sediment and water. Under anaerobic conditions, propiconazole will be persistent. A major degradation product of propiconazole also undergoes microbial degradation slowly. Photochemical transformation of propiconazole occurs in water but the rate of this process in natural waters is not known.

When applied at label rates, propiconazole is not expected to pose a direct hazard to wild birds or mammals, or terrestrial and aquatic invertebrates. Of concern is the high toxicity of propiconazole to some algal species. Because wetland areas are important habitats for wildlife, the integrity of wetland areas

must be maintained. A buffer zone of 15-m width should be used around all wetland areas so that propiconazole will not enter these sensitive ecosystems.

Based on a review of all available information and in consideration of wide ranging comments received, temporary registration (Restricted Class) was extended for Tilt 250 (P.C.P. No. 19346) on winter wheat, spring wheat and barley for 1987 under the following conditions:

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

b) The registrant was required to implement a training program for growers and dealers on the proper and efficient use of the product before the 1987 crop season.

c) Additional special labeling includes: "WARNING: safety data and registration of this product are under review. Directions for use and cautionary statements should be carefully followed."

d) A 45-day, pre-harvest interval for all cereals.

e) For ground application only.

2. PRODUCT CHEMISTRY

2.1 Pesticide Name

Common Name:	propiconazole
Trade Name:	Tilt
Chemical Name:	(RS)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
Empirical Formula:	$C_{15}H_{17}Cl_2N_3O_2$
CAS Registry No.:	60207-90-1

2.2 Physical and Chemical Properties

Properties of the Pure Active Ingredient

Appearance:	yellowish clear viscous liquid
Density:	1.25 g/cm^3 at 20°C
Boiling point:	180°C at 0.1 mm Hg
Refractive index n_D20:	1.5468
Molar extinction coefficient:	220/11900, 225/11300, 268/350
Vapour pressure at 20°C:	1.0 x 10^{-6} mm Hg (= 1.3 x 10^{-4} Pa)
at 30°C:	3.6 x 10^{-6} mm Hg (= 4.8 x 10^{-4} Pa)
at 40°C:	1.1 x 10^{-5} mm Hg (= 1.5 x 10^{-3} Pa)
Volatility (SVC) at 20°C:	1.9 x 10^{-8} kg/m^3
Solubility in water at 20°C:	110 ppm
Solubility in organic solvents:	100% in methanol, isopropanol, acetone, methylene chloride, toluene, n-octanol; 6% in hexane
Partition coefficient hexane/water:	approx. 600 (calculated from solubility)
n-octanol/water:	4500 (determined by HPLC)
Hydrolysis:	no significant hydrolysis at each pH over 28 days at 70°C (of project report 07/80)
Thermal stability (DSC, 4°/min):	up to 320°C no exothermic reaction.
pKa value:	approx. 1 (very weak base)

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

Properties of the technical active ingredient

Appearance:	not yet specified
Odour:	very slight mild odour
Flammability:	non-flammable (closed-cup test negative up to 150°C)
Explosiveness:	non-explosive
Purity:	min. 88% (cis/trans isomers)
Analytical method:	gas chromatography (AW-88/3)

2.3 Biological Properties

Propiconazole is a systemic fungicide. The active ingredient is absorbed by the leaves and stems and is transported upward in the plant and into areas of new growth.

Propiconazole inhibits fungi by interfering with ergosterol biosynthesis, an essential part of the metabolism process in fungi.

3. USE HISTORY

Propiconazole has been registered in Europe for the past five years for use on many different crops, including cereals. In Canada, propiconazole was first registered on a temporary basis in 1986 for winter wheat and barley.

4. REGULATORY ACTIONS

During 1986, progress was made in the review of the database supporting propiconazole. Although the review is still not complete, some key points have been addressed. In addition, for 1987 the registrant conducted an education program both at the grower and dealer levels on the proper and efficient use of the product. Consequently, the temporary restricted class registration of propiconazole (Tilt 250E) for use on winter wheat and barley was renewed for 1987, and use on spring wheat was granted temporary registration. These registrations are for both eastern and western Canada.

The following are the conditions and limitations of the registration:

a) The registrant was required to implement a training program for growers and dealers on the proper and efficient use of the product before the 1987 crop season.

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

c) Additional special labeling includes "WARNING: safety data and registration of this product are under review. Directions for use and cautionary statements should be carefully followed."

d) A 45-day, pre-harvest interval for all cereals.

e) For ground application only.

5. AGRONOMICS SUMMARY

Tilt is a systemic fungicide for control of a broad spectrum of foliar diseases in wheat and barley.

5.1 Diseases Controlled

Wheat	Barley
Powdery Mildew	Powdery Mildew
Tan Spot	Rust
Leaf & Stem Rust	Scald
Stripe Rust	Net Blotch
Septoria Leaf Spot	Spot Blotch
Septoria Glume Blotch	Septoria Leaf Spot

5.2 Yield Increases*

	No. of Applications	Range	Average %
Eastern Canada			
Hard Red Winter Wheat	2	19-54	33
Hard Red Spring Wheat	2	17-32	24
Soft White Winter Wheat	2	10-18	14
Barley	1	3-31	16
Western Canada			
Soft White Wheat (irrigated)	1	0-62	18
Winter Wheat	1	0-56	19
Semi-dwarf Spring Wheat	1	0-29	10
Barley	1	0-43	17

*compared to check plots.

Tilt was shown to be economically advantageous on many of the test sites despite low grain prices. The economic payback from Tilt is greater in fields where a higher yield potential exists. Therefore, in fields where other good management practices are followed, the addition of a fungicide can provide improved returns to growers.

Because of the yield increases that Tilt has shown in over five years of testing, the following groups have made representations

to have fungicides made available:

Ontario Red Wheat Growers Association
Alberta Intensive Crop Producers
Maritime Farmers Council
Nova Scotia Winter Grain Marketing Board
Manitoba Crop Insurance Association

6. HEALTH AND WELFARE CANADA: TOXICOLOGY STUDIES

6.1 Acute Toxicity

Acute toxicity data submitted indicated that the technical and formulated material are of low acute toxicity. The acute hazard associated with use is that of irritation.

a. Technical

Oral (rat)	LD_{50} = 1517 (958-2291) mg/kg
(rat)	LD_{50} = 2233 (1809-2723) mg/kg (cis-isomer)
(rat)	LD_{50} = 1211 (807-2003) mg/kg (trans-isomer)
(mouse)	LD_{50} = 1490 (1138-1875) mg/kg
(rabbit)	LD_{50} = 1344 (1062-1710) mg/kg
Dermal (rat)	LD_{50} ¢ 4000 mg/kg
Inhalation	no study
Eye Irritation (rabbit)	minimal irritant
Skin Irritation (rabbit)	slight irritant
Sensitization (guinea pig)	no sensitizing potential
Intraperitoneal (rat)	LD_{50} = 508 (381-653) mg/kg

b. Formulations

	430 EC (360 EC)	250 EC	130 EC	(1.lE)
Oral (rat)		LD_{50}=1510 mg/kg(m) (1270-1800) LD_{50}=1100 mg/kg(f) (798-1520)	LD_{50}=2105mg/kg (1668-2750)	no study
Dermal (rabbit)		LD_{50} ¢ 5010 mg/kg	LD_{50}¢2500mg/kg	no study
Inhalation 4h. (rat)		LC_{50} ¢ 2.45 mg/L	LC_{50}=1.26 mg/L (1.08-1.65)	no study

Eye Irritation (rabbit)	mod. irr.	mod. irr.	mod.irr.
Skin Irritation (rabbit)	mod. irr.	marked irr.	severe irr.
Sensitization (guinea pig)	possible sensitizer	no study	non-sensitizer

6.2 Short-term Toxicity

a. Technical grade. In a 90-day dietary study in rats a NOEL of 240 ppm (approx. 12 mg/kg b.w./day) was observed with changes in body weight gain and clinical parameters at 1200 ppm and above.

A NOEL of 1250 ppm (approx. 35 mg/kg b.w./day which was the highest dose tested) was observed in dogs in a 3-month dietary study. A 12-month dietary study in dogs also resulted in a NOEL at the highest dose tested, 250 ppm (approx. 10 mg/kg b.w./day).

In a 21-day dermal study in rabbits, doses of 200 mg/kg b.w./day and above produced dermal irritation with animals showing clinical symptoms of poisoning at doses of 1000 mg/kg b.w./day and above.

Repeated airborne exposure of levels up to 0.191 mg/L for 90 days had minimal effects on the body weight gain of rats.

b. Formulated. In a 21-day dermal study in rabbits, doses of 30 mg/kg b.w./day and above of Tilt 430 EC produced dermal irritation. No NOEL was achieved for dermal irritation.

6.3 Long-term Toxicity and Carcinogenicity

In a long-term dietary study in rats with technical propiconazole, a NOEL of 100 ppm (approx. 3.6-4.6 mg/kg b.w./day) was established on the basis of reduced body weight gains at 500 ppm and above, and effects on the liver at 2500 ppm. The study did not indicate any evidence of tumor induction.

A long-term dietary study in mice demonstrated a significantly increased incidence of both benign and malignant hepatocellular tumors in the 2500 ppm males. No increase in tumors was observed in animals dosed at 100 and 500 ppm. The finding of increased hepatocellular tumors was only at dose levels at which disturbance of liver function

occurred, characterized by elevated enzyme activity, increased liver weight and non-neoplastic liver morphology (hepatocyte enlargement and fat deposition). There was an indication of increased multiplicity of hepatic neoplasias (which was determined at necropsy by grossly visible masses) and a shortening of the lifespan caused by the tumors. The lowest dose tested (100 ppm) was considered to be a NOEL for the study (approx. 14 mg/kg b.w./day).

6.4 Mutagenicity

Technical propiconazole did not demonstrate mutagenic potential in the following assays: Ames assay, nucleus anomaly test in Chinese Hamster, dominant lethal study in mice, host mediated point mutation assay with mouse lymphoma cells, unscheduled DNA synthesis test in human fibroblasts and rat hepatocytes and chromosome aberration assay in human lymphocytes.

6.5 Reproduction

The initial 2-generation (1-litter) dietary study in rats indicated excessive toxicity at 5000 ppm as evidenced by increased mortality. Despite other shortcomings, this study suggested that levels of 400 and 2000 ppm were maternally toxic. A repeat 2-generation (2 litters/generation) dietary study with the technical material resulted in treatment-related effects on parental animals (liver histopathology) at 500 and 2500 ppm, and on progeny (pup weight changes and liver hypertrophy) at 2500 ppm. Thus, the NOEL was set at 100 ppm, equivalent to 5 mg/kg b.w./day.

6.6 Teratology

In an oral rat study, no teratogenicity was observed at the highest dose level of 300 mg/kg b.w./day but maternal toxicity was evident. Delayed fetal ossification at 100 mg/kg b.w./day resulted in a NOEL of 30 mg/kg b.w./day. In the oral rabbit study, no teratogenic effects were observed, the NOEL of 90 mg/kg b.w./day being based on maternal toxicity at 180 mg/kg b.w./day.

6.7 Other Toxicology Studies

A rat study was submitted on the "tumor promoting" ability of propiconazole using gamma glutamyl transpeptidase (GGT) as a histochemical marker for altered hepatocytes. The results of the experiment suggested promoting ability of propiconazole but did not preclude its potential for tumor induction. However, it should be noted that the long-term bioassay in the rat was negative with respect to liver tumors.

Repeated oral administration of propiconazole to rats in doses of 20-320 mg/kg for 14 days, demonstrated a

treatment-related effect on increased relative liver weights which was accompanied by proliferation of the smooth endoplasmic reticulum and pronounced metabolizing enzyme activity.

Oral metabolism studies in rats with radio-labeled material indicate rapid urinary (2/3) and fecal (1/3) excretion within 24 hours with negligible quantities in expired air. Recovery was almost complete by six days with the highest residual being found in the liver, blood, kidneys and lungs. Several metabolites are excreted but are presently unidentified.

6.8 Occupational Exposure

The registrant has submitted exposure studies conducted with the U.S. formulation of propiconazole. These studies have been reviewed and recent comments from the registrants have been considered in the overall assessment of the occupational exposure potential.

A total of three studies were submitted. Two of these involved the ground application of Tilt 3.6E (American formulation) by ground boom sprayers. The third study involved aerial application of Tilt 3.6E to rice and was therefore not considered.

The two ground application studies have been used to represent the Canadian use of Tilt 250 EC but do not represent the proposed use of Banner 130 EC which is applied repeatedly at 14 to 21-day intervals to small areas of turf.

The study design of the ground application studies was to monitor dermal deposition on workers during mixing/loading/spraying and clean-up with and without protective gloves and face mask. In one study, urinary samples were taken to measure excretion of propiconazole. The activity of eight workers in each study was limited to one mixing/loading cycle with a small amount of product. The pesticide was then applied by a different worker to 2.5 to 3 acres.

Environmental Health Directorate (EHD) has concluded that these studies are not adequate for predicting occupational exposure under Canadian use conditions. EHD considers the small amount of the pesticide used for the exposure trials as well as the very short mixing/loading and application times to be unrepresentative of typical use conditions. The measured dermal deposition values are therefore an unreliable basis for extrapolation to a full work day exposure.

The study is further encumbered by the lack of field recovery data. The recently submitted storage stability data do not fully compensate for this deficiency.

The urinary excretion levels measured in one study did not correlate with the exposure levels in the different workers and were considered to be useful only as a confirmation that exposure had occurred.

7. HEALTH AND WELFARE CANADA: FOOD RESIDUE STUDIES SUMMARY

Propiconazole fungicide is metabolised in plants to a range of metabolites containing the 2,4-dichlorobenzene moiety. Total residues of propiconazole and 2,4-dichlorobenzene moiety are not expected to exceed 0.1 ppm in grain harvested from wheat and barley fields treated at 125 grams a.i./ha up to growth stage 55 or no closer than 45 days before harvest.

Propiconazole and its triazole ring containing metabolites also react with -alanine in plants to form triazolyl alanine. Other triazole rings containing fungicides, such as triadimefon, triadimenol, bitertanol, etc. may also form triazolyl alanine. Questions concerning the significance and extent of triazolyl alanine residues in treated crops are still under consideration.

8. ENVIRONMENT CANADA: ENVIRONMENTAL STUDIES

8.1 Summary

Evaluation of the submitted data supports the following opinion. Propiconazole undergoes fairly slow microbial degradation in aerobic conditions in soil, sediment and water. Under anaerobic conditions propiconazole will be persistent. A major degradation product of propiconazole also undergoes microbial degradation only slowly. Photochemical transformation of propiconazole occurs in water but the rate of this process in natural waters is not known.

When applied at label rates, propiconazole is not expected to pose a direct hazard to wild birds or mammals, or terrestrial and aquatic invertebrates. Of concern is the high toxicity of propiconazole to some algal species. Because wetland areas are important habitats for wildlife, the integrity of wetland areas must be maintained. A buffer zone of 15-m width should be used around all wetland areas so that propiconazole will not enter these sensitive ecosystems.

8.2 Environmental Chemistry and Fate

The solubility of propiconazole in water at 20°C is llO mg/L, the octanol-water partitioning coefficient is 4500, and the vapour pressure is 1.3×10^{-4} Pa ($=10^{-6}$ mm Hg). The air-water distribution ratio or Henry's Law constant is very low: volatilisation of propiconazole from wet substrates will be

low. Hydrolysis of propiconazole in water does not occur under environmentally-relevant conditions.

Propiconazole is strongly adsorbed to most soils. In laboratory leaching studies on four soil types (sandy soil, sand, silty loam and sandy loam) propiconazole did not move past the 30-cm zone with most of the material remaining in the top 10 cm.

Laboratory studies of the degradation of propiconazole have shown that, although photochemical degradation of the compound will occur in water, the major route of degradation under aerobic conditions in soils and sediments or in natural waters in darkness, will be microbial. The initial half-lives (50% decline times) of propiconazole in these laboratory studies ranged from several weeks to a few months: some of the transformation products (in particular 1,2,4-triazole) formed during these experiments have half-lives in that same range. Under anaerobic conditions no microbial degradation was found. There is no definitive evidence concerning the rate of photochemical degradation of propiconazole in natural waters: the persistence of the parent compound and its major transformation products in such compartments is, therefore, unknown.

Studies of the dissipation of propiconazole in field plots on a silt loam soil confirm the laboratory finding that propiconazole itself remains in the upper layers of the soil. The question of possible leaching of the transformation product 1,2,4-triazole to greater depths is unresolved in the absence of both laboratory studies of its leaching potential and monitoring of its occurrence in the field. However, the behaviour of 1,2,4-triazole in extraction procedures for soil samples suggests that it would be strongly retained by soil under environmental conditions.

Propiconazole is formulated as an emulsifiable concentrate for spray application to the crop. There is, therefore, a potential for contamination by spray drift of sensitive environments (wetlands, surface waters) near treated areas. Since propiconazole will be retained by adsorption in the surface soil on which it falls, it could be transported from a treated area on particulate matter in runoff water. The amount of propiconazole that reaches the soil surface will depend on the growth stage of the crop to which it is applied and on the weather (especially rainfall) in the period soon after application. In clear weather and with a well-developed stand most of the sprayed fungicide will be intercepted by the plants and will dissipate by evaporation or by absorption and metabolism in the plant. Early rainfall may sufficiently wash off the applied fungicide onto the soil so as to necessitate the recommended re-application.

8.3 Environmental Toxicology

Wild Birds. The acute toxicity of propiconazole to birds is low. The acute oral LD_{50} to 5-day-old Peking ducks was greater than 6000 mg/kg. The acute oral LD_{50} to adult Japanese quail was found to be 2223 mg/kg.

Exposure of birds through ingestion of contaminated food is unlikely to cause mortality. When fed levels in the diet of up to 1000 mg/kg for five days, no mortalities of 5-day old Peking ducks occurred. Similarly, no mortality of adult Japanese quail occurred when fed 1000 mg/kg diet for five days.

Effects on avian reproduction are not expected. Studies on avian reproduction showed the no-effect levels to be high, at 300 mg/kg for the Mallard duck and 1000 mg/kg for the Bobwhite quail.

Field studies on birds have not been done. Given the low toxicity of propiconazole to birds, field studies on avian impacts seem unwarranted.

Wild Mammals. No wild mammals were tested. Propiconazole is of low toxicity to the laboratory mammalian species tested. The acute oral LD_{50} values ranged from 1344 to 1517 mg/kg for mice, rats and rabbits.

Propiconazole also has low dermal toxicity to rats and rabbits, the acute dermal LD_{50}'s being 4000 mg/kg and ¢5010 mg/kg, respectively.

The data suggest that propiconazole is not embryotoxic or teratogenic to rats or rabbits.

Studies using ^{14}C-labelled propiconazole demonstrated that intragastrically dosed rats can readily metabolize this compound. It was shown that 53-67% and 28-46% of the residues were excreted via the urine and feces, respectively. Only low levels of radioactivity were detected in body tissues at 144 hours after dosing. A similar pattern of excretion and accumulation was observed in lactating goats.

Wild mammals have the potential of being exposed dermally, through inhalation and orally (chronic dietary). When applied at field rates, it is not expected that wild mammals will be at risk due to exposure to propiconazole.

Amphibians and Reptiles. No data are available to evaluate the risk to amphibians and reptiles from the use of propiconazole.

Aquatic Invertebrates. Propiconazole is not acutely toxic to Daphnia magna: the 48-h EC_{50} (immobilization) of the

technical material is 11.5 mg/L. The formulated product, Tilt 430 EC, has a higher level of toxicity than the technical material, the 48-h LC_{50} being 1.34 mg a.i./L. The metabolite, 1,2,4-triazole, is considerably less toxic than the parent compound, the acute 24-h EC_{50} being 900 mg/L.

When applied at field rates (125 g a.i./ha), propiconazole itself is not expected to be directly toxic to Daphnia magna either through acute or chronic exposure.

Terrestrial Invertebrates. Under the conditions tested, propiconazole does not appear to be toxic to terrestrial invertebrates. Following a 7-day exposure to foliage treated at 4 times the proposed label rate, four species of beneficial insects (Anthocoris nemorum, Coccygonymus turionellae, Coccinella septempunctata and Chrysopa carnea) showed no observable deleterious effects.

Earthworms suffered no mortalities during exposure for 28 days to sandy loam soil containing 20 mg propiconazole/kg soil. The formulation tested was WP lO, however, which is different from those proposed for use in Canada. In a study of exposure for 14 days to 1,2,4-triazole in an artificial soil substrate, the NOEL was 100 ppm. Bioaccumulation of propiconazole by the earthworm was not studied.

Test results from exposure of bees to technical propiconazole suggest that this compound is of low toxicity, but no data are available from similar studies for comparative purposes.

When applied at field rates, propiconazole is not expected to be acutely toxic to terrestrial invertebrates.

Soil microbial systems. Judged on the basis of measurements of the production of $C0_2$ under laboratory conditions, propiconazole at concentrations ranging much above those relevant to field-use had no significant deleterious effects on soil microorganisms in two clay loam soils amended with alfalfa meal. Similar absences of significant effects were found in soils amended with either cellulose, protein, or starch.

There were no significant effects on the soil nitrification process as measured by the conversion of ammonium ion to nitrate, and at realistic concentrations of propiconazole in the upper 5 cm of soil, no effects were found on either the rate of nitrogen fixation by Rhizobium trifolii or root nodulation of white clover.

The transformation product 1,2,4-triazole caused no environmentally significant interference with mineralization ($C0_2$ production) in two soils amended with alfalfa meal.

Plants. The effects of technical propiconazole on the growth of four species of algae were tested, and propiconazole was found to be highly toxic. The 11-day EC_{10} for three species of algae and the 9-day EC_{10} for a fourth species (Selenastrum capricornutum) were:

26 g/L for Navicula seminulum (a freshwater diatom);
18 g/L for Skeletonema costatum (a marine diatom);
6.8 mg/L for Anabaena flos-aquae (a blue-green alga); and
0.72 mg/L for Selenastrum capricornutum (a freshwater green alga)

These results suggest that propiconazole is an extremely effective algicide.

Data on the toxicity of the formulated product to algae are not available, but were requested early in 1985.

In the data submitted, differing experimental conditions make it difficult to compare the toxicity of the metabolite 1,2,4-triazole with that of the parent compound. In the one available study of the metabolite, algal growth inhibition was measured over 5 days only, and on a species whose sensitivity to propiconazole is unknown. The 5-day EC_{10} for Scenedesmus subspicatus was about 1 mg/L.

If a pond less than 1 m in depth is directly oversprayed at the label rate of 125 g a.i./L, an initial concentration of propiconazole greater than 12 g/L could be expected in the pond water. The persistence of propiconazole in the water column is not known. In addition, the current label states that the compound should be reapplied if rainfall occurs within two hours of spraying. It is thus expected that the use of propiconazole near aquatic systems could result in levels in the water that would adversely affect algal communities.

Only one study is available to evaluate the risk to aquatic vascular plants from the use of propiconazole. The 14-day EC_{50} to Lemna gibba was estimated to be 9 mg/L. Although it appears that aquatic macrophytes are less sensitive than algae to propiconazole, such an extrapolation is difficult to make on the basis of one species, whose sensitivity relative to other species is undefined. Lemna is also known to respond differently when exposed through a spray rather than through solution.

No data are available to evaluate the risk to terrestrial plants from the use of propiconazole. Data produced during company phytotoxicity screens were requested in January 1985, but no data have been received to date.

Wildlife Habitat Impact Assessment. Wetland areas are important habitats for several forms of wildlife. To maintain our wildlife resources, it is important that the

integrity of wetland habitats be maintained. Wetland areas could potentially receive propiconazole through direct spray or drift. Direct spray of propiconazole at label rates is expected to affect algal communities

deleteriously, but it is difficult to assess the long-term impacts to various consumer levels, of a kill or species shift in the primary producer level. Protection of aquatic habitats from the risk presented by the use (and especially by aerial application) of propiconazole near surface waters requires that a buffer zone of 15-m be specified.

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

The 96-h LC_{50} to bluegill sunfish of the 430 EC formulation of proprioconazole and rainbow trout ranged from one to five mg a.i./L. For Daphnia magna, the 48-h LC_{50} of the active ingredient alone was about 11.5 mg/L. For the 430 EC formulation the 48-h LC_{50} was about 3.2 mg/L (1.3 mg/L of a.i). Either one of the other ingredients in the formulation is more toxic to D. magna than the active ingredient, or there is an additive or synergistic effect between the active ingredient and one or more of the other ingredients. The reasons for the observed differences should be investigated.

The normal application frequency is annual or bi-annual, although repeat applications must be made in the event of precipitation within 2 hours of the original application. The recommended app1ication rate is 125 g a.i./ha. Accumulation factors which would lead to concerns regarding fish as food are not seen as being a problem unless unusually high use frequencies occur. Accumulation rates in bluegill sunfish exposed to 1 mg/L of the radioactively tagged active ingredient resulted in bioconcentration rates of 24 times over a 28-day period. Once the fish were moved to uncontaminated waters total depuration was achieved in 14 days.

The active ingredient is somewhat persistent with a half-life in soils of 70 days at 20°C. Simulated pond studies (25°C) with the parent compound indicated a half-life of 70 days in water and sediment with an extended half-life of 100 days toward the end of the experiments.

There might be concerns if aerial applications were carried out without strict enforcement of buffer zones or if direct overflights of shallow water bodies were to occur. The current label strictly forbids aerial application.

Regarding the major metabolite (1,2,4-triazole): the 96-hr LC_{50} for trout is 760 mg/L, the 5 day EC_{50} for algae is 6.3 mg/L, and the 24 hr EC_{50} for Daphnia magna is 900 mg/L. Laboratory studies of its degradation in soils (25°C) indicated a half-life of 14 weeks.

Neither the parent compound nor the major metabolite penetrate soils deeply and thus little if any ground water contamination would be expected. Detectable levels of both active ingredient and the triazole metabolite were seldom observed chemically below the 5-cm soil depth. It was only with the use of radiochemical tracers that the presence of either was noted below 20 cm.

Expected concentrations in aquatic habitats are understandably unpredictable from both the data presented and the actual use of the product. Strict adherence to instructions on the label should minimize the chances of the active ingredient reaching fish habitat.

Therefore, the use of the Tilt 430 EC formulation is acceptable to Fisheries and Oceans Canada at this time. However, another formulation currently termed 250 EC, has been suggested by the proponent. Because the formulations are so different, this Department will require further data on Tilt 250 EC.

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

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