Public Release Summary
on

Evaluation of the new active

FENHEXAMID

in the product

TELDOR 500 SC FUNGICIDE

National Registration Authority for Agricultural and Veterinary Chemicals

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FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the NRA works in close cooperation with advisory agencies, including the Department of Health and Aged Care (Chemicals and Non-prescription Drug Branch), Environment Australia (Risk Assessment and Policy Section), the National Occupational Health and Safety Commission (Worksafe Australia) and State departments of agriculture and environment.

The NRA has a policy of encouraging openness and transparency in its activities and of seeking community involvement in decision making. Part of that process is the publication of public release summaries for all products containing new active ingredients and for all proposed extensions of use for existing products.

The information and technical data required by the NRA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in the NRA's publications *Ag Manual: The Requirements Manual for Agricultural Chemicals* and *Ag Requirements Series.*

This Public Release Summary is intended as a brief overview of the assessment that has been completed by the NRA and its advisory agencies. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience thereby encouraging public comment.

More detailed technical assessment reports on all aspects of the evaluation of this chemical can be obtained by completing the order form in the back of this publication and submitting with payment to the NRA. Alternatively, the reports can be viewed at the NRA Library Ground Floor, 22 Brisbane Avenue, Barton, ACT.

The NRA welcomes comment on the usefulness of this publication and suggestions for further improvement. Comments should be submitted to the Executive Manager—Registration, National Registration Authority for Agricultural and Veterinary Chemicals, PO Box E240, Kingston ACT 2604.

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LIST OF ABBREVIATIONS AND ACRONYMS

ac	active constituent
ADI	Acceptable Daily Intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
bw	bodyweight
d	day
DAT	Days After Treatment
DT_{50}	Time taken for 50% of the concentration to dissipate
EA	Environment Australia
E_bC_{50}	concentration at which the biomass of 50% of the test population is impacted
EC_{50}	concentration at which 50% of the test population are immobilised
EEC	Estimated Environmental Concentration
E_rC_{50}	concentration at which the rate of growth of 50% of the test population is impacted
EUP	End Use Product
Fo	original parent generation
g	gram
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
h	hour
ha	hectare
Hct	Heamatocrit
Hg	Haemoglobin
HPLC	High Pressure Liquid Chromatography *or* High Performance Liquid Chromatography
id	intradermal
im	intramuscular
ip	intraperitoneal
IPM	Integrated Pest Management
iv	intravenous
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
kg	kilogram
K_{oc}	Organic carbon partitioning coefficient
L	Litre
LC_{50}	concentration that kills 50% of the test population of organisms
LD_{50}	dosage of chemical that kills 50% of the test population of organisms
LOD	Limit of Detection – level at which residues can be detected
LOQ	Limit of Quantitation – level at which residues can be quantified
mg	milligram
mL	millilitre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NDPSC	National Drugs and Poisons Schedule Committee
ng	nanogram
NHMRC	National Health and Medical Research Council
NOEC/NOEL	No Observable Effect Concentration Level
OC	Organic Carbon
OM	Organic Matter
po	oral
ppb	parts per billion
PPE	Personal Protective Equipment
ppm	parts per million
Q-value	Quotient-value

RBC	Red Blood Cell Count
s	second
sc	subcutaneous
SC	Suspension Concentrate
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration
TGAC	Technical grade active constituent
T-Value	A value used to determine the First Aid Instructions for chemical products that contain two or more poisons
µg	microgram
vmd	volume median diameter
WG	Water Dispersible Granule
WHP	Withholding Period

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INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of Teldor 500 SC Fungicide, which contains the new active constituent fenhexamid.

Fenhexamid is a new hydroxyanilide fungicide. It shows some locosystemic properties and inhibits the germ tube and mycelium. It does not inhibit spore germination. The biochemical mode of action is unknown and is under investigation, but appears to be different from that of all other known botryticides.

Responses to this public release summary will be considered prior to registration of the product. They will be taken into account by the NRA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

Written comments are invited and should be submitted by **31 May 2001,** addressed to:

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Applicant:

Bayer Australia Limited

Product details:

Teldor 500 SC Fungicide (Teldor) is a suspension concentrate formulation containing 500g/kg fenhexamid. The product will initially be marketed for the control of grey mould (*Botrytis cinerea)* on strawberries in all States.

The active constituent is manufactured by Bayer AG in Germany and the product will be formulated by that company in Germany and in Australia.

Applications have been made, or will be made, for registration of products containing fenhexamid for control of *Botrytis cinerea* and/or *Monilia spp* on strawberries, grapes, stone fruit, raspberries, currants, kiwifruit, tomatoes and various ornamentals in Europe, USA, Japan, Chile, Colombia, Ecuador, Israel, New Zealand, Peru, South Africa, Switzerland, Turkey and Venezuela.

CHEMISTRY AND MANUFACTURE

The product proposed for registration in Australia is a suspension concentrate formulation under the trade name Teldor 500 SC Fungicide.

The formulation storage stability and the physical and chemical properties of the formulated product and active constituent have been evaluated by the NRA and are considered acceptable.

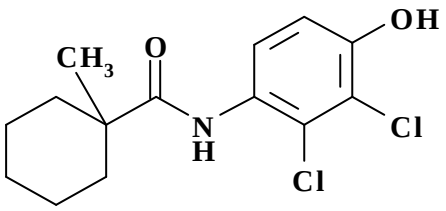
The source of Technical Grade Active Constituent to be used in the product has been approved by the NRA (Approval No 44462).

Active constituent

The chemical active constituent in Teldor is fenhexamid which has the following properties:

Common name (ISO):	Fenhexamid (proposed)
Chemical name:	1-methyl-cyclohexanecarboxylic acid (2,3-dichloro-4-hydroxy-phenyl)-amide (IUPAC)
CAS Registry Number:	126833-17-8
Empirical formula:	$C_{14}H_{17}Cl_2NO_2$
Molecular weight:	302.2
Physical form:	powder
Colour:	off-white
Melting point	153°C
Octanol/water partition coefficient:	log P_{OW} @25°C= 3.53(unbuffered), 3.62 (pH 5), 3.52 (pH 7), 2.23 (pH 9)
Vapour pressure at 30°C:	1.91-2.58X10^{-6}Pa

Structural formula:



Formulated product

Product name:	TELDOR 500 SC FUNGICIDE
Active content:	500g/kg fenhexamid
Formulation type:	Suspension concentrate
Density:	1.17 at 20°C

TOXICOLOGICAL ASSESSMENT

EVALUATION OF TOXICOLOGY

The toxicological database for fenhexamid, which consists primarily of toxicity tests conducted using animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Findings of adverse effects in any one species do not necessarily indicate such effects might be generated in humans. From a conservative risk assessment perspective however, adverse findings in animal species are assumed to represent potential effects in humans, unless convincing evidence of species specificity is available. Where possible, considerations of the species specific mechanisms of adverse reactions weigh heavily in the extrapolation of animal data to likely human hazard. Equally, consideration of the risks to human health must take into account the likely human exposure levels compared with those, usually many times higher, which produce effects in animal studies. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observable-Effect-Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

Toxicokinetics and Metabolism

In rats fenhexamid is rapidly absorbed from the gastro intestinal tract and rapidly excreted, mostly unchanged, primarily in the faeces but also in the urine. Repeated administration of fenhexamid did not alter its metabolism or toxicokinetics. Following oral administration to rats at 1000 mg/kg bw/day for 56 days, fenhexamid was undetectable in the blood, reflecting the rapid elimination and the absence of accumulation.

Acute Studies

Fenhexamid has low acute oral and dermal toxicity in rats and low oral toxicity in the mouse (LD50 > 5000 mg/kg bw in each case), low inhalational toxicity in rats (LC50 > 5057 mg/m^3), is not an eye or skin irritant in rabbits and is not a skin sensitiser in guinea pigs.

The product Teldor 500 SC Fungicide (50% ai) has low acute oral and dermal toxicity in rats (LD50 > 2500 and 4000 mg/kg bw respectively), is not a skin or eye irritant in rabbits and is not a skin sensitiser in guinea pigs.

Short-Term Studies

Fenhexamid has been administered to rats, orally at 100, 300 and 1000 mg/kg bw/day for 28 days, by inhalation at 12, 98 and 1093 mg/m^3 for 5 days (6 hours per day), or dermally at 1000 mg/kg bw for 6 hours/day for a 17 days over 3-weeks, without producing mortality or clinical signs, or any effects on body weight or food consumption, haematology, clinical chemistry, organ weights (except lungs), or gross or microscopic pathology. Slight increases in lung weights and a slight grey colouration of the lungs was seen in the inhalation study at the highest treatment level.

In a second inhalation study, rats were exposed to fenhexamid dust for 6 hours a day, for 4 weeks, at 10, 69 and 487 mg/m^3. At the highest exposure level animals gained slightly less weight, a slight decline in white blood cells was seen and, in males only, liver metabolic enzymes (P450 levels and aminopyrine -N-demethylase activity) were slightly reduced. Lung weights were increased in both sexes and heart weight was decreased slightly in males.

Microscopic changes were confined to slight changes in the lung and in the lymph nodes associated with the lungs (an increased incidence of bronchoalveolar proliferations and pigment laden alveolar macrophages, with an accumulation of macrophages in the lymph nodes of the lung).

Dogs administered fenhexamid orally at 100, 1000 and 10000 ppm in the diet (approximately 2.5, 25 and 250 mg/kg bw/day) for 28 days and rabbits treated on the skin with fenhexamid at 1000 mg/kg bw/day for 21 days, exhibited no adverse effects.

Studies with fenhexamid in mice have been performed at 100, 1000 and 10000 ppm in the diet (approximately 40, 350, 4200 mg/kg bw/day) for 14 weeks and 800, 2400, and 7000 ppm in the diet (approximately 250, 750, and 2200 mg/kg bw/day) for 2 years. In both studies effects of treatment were largely confined to the kidneys (decreased kidney weights, increased serum bilirubin and creatinine and in the 2 year study microscopic alterations to the proximal tubules of the kidney) and the liver (increased weight). At the highest doses used in the 14 week study the males ate more without gaining more weight and therefore had less efficient food utilisation, and had reduced glycogen content in liver cells. The NOEL in the 2 year study was 250 mg/kg/day.

Long-Term Studies

Fenhexamid has been studied in rats at treatment levels of 2500, 5000, 10000, 20000 ppm in the diet (approximately 200, 470, 1040 and 2820 mg/kg bw/day) for 90 days and at 500, 5000 and 20000 ppm in the diet (approximately 28, 300, and 2070 mg/kg bw/day) for 2 years. The efficiency of food utilisation was again decreased, this time in all treated animals in the 90 day study, and groups treated at 300 mg/kg bw/day in the 2 year study. Liver weights in the 90 day study were reversibly increased in all treated male groups and in the female group treated at 2820 mg/kg bw/day, together with some minor microscopic changes in this organ in females at this dose (focal Kupffer-cell proliferation and a condensed cytoplasm interpreted as a reduction of glycogen). Evidence of an increased rate of red blood cell turnover (increased bone marrow cellularity, splenic extramedullary haematopoiesis, immature red blood cells in the circulation) was seen at 300 mg/kg bw/day and above in the 2 year study. Males at 300 mg/kg bw/day and above had an increased growth of cells in the intestines (caecal mucosal hyperplasia) and at the highest dose slight microscopic changes were observed in the thyroid of both sexes (colloid alterations) and uterus (glandular hyperplasia). The NOEL in the 2 year study was 28 mg/kg bw/day.

In dogs, fenhexamid was administered in the diet at 1000, 7000 and 50000 ppm (approximately 35, 240, and 1806 mg/kg bw/day) in a 90 day study and at 500, 3500 and 25000 ppm in the diet (approximately 17, 130, 935 mg/kg bw/day) in a 12 month study. In the 90 day study liver weight increased at 240 mg/kg bw/day and above. In both studies a slight anaemia (Heinz body), increased alkaline phosphatase levels and a lower body weight gain were observed in both sexes at higher doses. Adrenal weights were higher in females in the 12 month study at 130 mg/kg bw/day and above, which were accompanied by microscopic changes (intracytoplasmic vacuoles) in the adrenal cortex of these animals. An increase in the size of the cells in the outer layer of the adrenal glands (focal hypertrophy of zona fasciculata of the adrenal cortex) was observed in some males of the 12 month study at 935 mg/kg bw/day. The NOEL for dogs was 17 mg/kg bw/day in the 12 month study.

Lifetime carcinogenicity studies in mice and rats at doses of fenhexamid of up to 4200 and 2070 mg/kg bw/day respectively did not reveal any evidence of cancer or of cancer forming potential.

Reproduction and Developmental Studies

Treatment of 2 successive generations of rats, with fenhexamid in the diet at 100, 500, 5000 and 20000 ppm (approximately 5, 25, 250 and 1000 mg/kg bw/day) did not affect reproduction, but lower pup weights were observed whilst the pups were breast feeding at 250 mg/kg bw/day and above, extending into adulthood, and there was an increase in the number of pups of the first generation which died post weaning at 1000 mg/kg bw/day, attributed to their small size at weaning. Alkaline phosphatase levels (an enzyme which may leak from certain liver, kidney, placenta or bone cells if damaged) were slightly higher at 1000 mg/kg bw/day in both sexes in both generations. Liver weights were decreased in both 250 and 1000 mg/kg bw/day males of the first adult generation. Decreases were observed in kidney weights in adult females of the first generation at 1000 mg/kg bw/day and in both 250 and 1000 mg/kg bw/day adult males of the second generation. The NOEL for pup toxicity and non reproductive effects on the adults was 25 mg/kg bw/day.

Developmental toxicity studies in rats at 1000 mg/kg bw/day and rabbits at 100, 300 and 1000 mg/kg bw/day during the period of foetal organ development showed no evidence of malformation or teratogenicity in either species and no maternal toxicity in the rats. Rabbits dams treated at 300 mg/kg bw/day and above ate less and gained less weight, foetal development was slower at 1000 mg/kg bw/day only, and placental weights were lower at doses of 300 mg/kg bw/day and above. The NOEL was 100 mg/kg bw/day in rabbits.

Genotoxicity

Fenhexamid was not genotoxic in a range of tests which included; unscheduled DNA synthesis in rat hepatocytes *in vitro*, Ames tests covering *S.typhimurium strains* TA 98, 100, 1535, 1537, and *E.coli WP2 uvrA*, a chromosome aberration assay in cultured CHO cells, an *in vivo* mouse micronucleus test, and a mutagenicity assay in Chinese hamster V79 cells *in vitro*.

Special Studies

No evidence of acute neurotoxicity was observed following a single oral dose of fenhexamid to rats at up to 2000 mg/kg bw.

PUBLIC HEALTH STANDARDS

Poisons Scheduling

The National Drugs and Poisons Schedule Committee (NDPSC) considered the toxicity of the product and its active ingredients and assessed the necessary controls to be implemented under States' poisons regulations to prevent the occurrence of poisoning.

The NDPSC concluded that fenhexamid did not require inclusion in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Provisions for appropriate warning statements and first-aid directions on the product label were considered unnecessary.

NOEL/ADI

The ADI is 0.2 mg/kg bw/day based on a NOEL of 17.4 mg/kg bw/day in the one-year chronic dog study and using a 100-fold safety factor in view of the extensive data package.

METABOLISM AND TOXICOKINETICS ASSESSMENT

Fenhexamid metabolism studies in plants involved two or three direct applications of [phenyl-UL-^{14}C]-fenhexamid onto fruit (grapes, tomatoes and apples) at 10 to 14 day intervals. Fruit were harvested on the day of the last treatment, and 7 to 14 days post-treatment. Samples were analysed for their total radioactive residue (TRR) content and the composition of the TRR determined by HPLC, GC/MS, enzymatic and acid hydrolyses and proton NMR. The majority of the residue was located on the surface of the fruit. Characterisation of the residue revealed that parent compound was the major component of the residue (>80%) and that the extent of fenhexamid metabolism in plants is very limited. The small amount of metabolism that does occur in plants appears to involve either hydroxylation of the cyclohexyl ring in the 2- and 4- positions followed by conjugation with glucose or direct conjugation/glucosylation of the phenolic hydroxyl group of the parent fenhexamid.

The extent of fenhexamid translocation was also examined by applying radiolabelled fenhexamid to leaves located directly above and below untreated fruit. The leaves and untreated fruit were harvested 7 to 14 days post-treatment, and the TRRs determined. The results revealed that fenhexamid is not translocated from leaves to fruit.

In rats treated with low and high doses of ^{14}C-labelled fenhexamid (1 and 100 mg/kg bw, respectively), more than 97% of the oral dose was absorbed. The plasma levels peaked 5 to 10 minutes after dosing for the low dose and within 40 to 90 minutes for the higher dose. Fenhexamid excretion was rapid with more than 96% of the dose being excreted in the urine and faeces within 48 hours of dosing. Whole-body autoradiography experiments revealed that the radioactivity remaining in rats 48 hours post-treatment was primarily located in the gastrointestinal tract.

Analysis of the rat TRRs showed that the radioactivity was almost exclusively associated with the unchanged parent compound. The small proportion of material that was metabolised appeared to involve hydroxylation of the cyclohexyl ring in the 2-, 3- and 4- positions followed by conjugation with glucuronic acid.

The metabolism of fenhexamid in the lactating goat was qualitatively similar to that of the rat. Metabolism proceeded by conjugation of the aromatic group and via hydroxylation of the cyclohexyl ring. The major components of the residue identified in tissues and milk of the goat were fenhexamid, 4-OH fenhexamid, fenhexamid glucuronide and 4-OH fenhexamid glucuronide.

RESIDUES ASSESSMENT

The applicant has provided plant and animal metabolism studies and crop residue studies in support of the registration of Teldor 500 EC Fungicide.

Residue definition and analytical method

The analytical method used for the determination of fenhexamid residues in agricultural commodities involves the following steps: (i) solvent extraction of the residue; (ii) purification of the extract (liquid-liquid partitioning and silica gel columns); and (iii) quantification of the fenhexamid residue using reverse-phase HPLC with electrochemical detection. Adequate recoveries were reported for fortified samples of strawberries as well as for the cattle commodities milk, liver, kidney, muscle and fat. The limit of analytical quantitation was 0.05 mg/kg for strawberries as well as for the cattle liver, kidney, muscle and fat. The limit of analytical quantitation for milk was 0.01 mg/kg.

The major component (> 80%) of fenhexamid residues in plants was identified as the parent compound, fenhexamid. Therefore, the plant metabolism studies and analytical methodology support a residue definition of "fenhexamid" as being appropriate and relevant. Such a definition is adequate to measure compliance with good agricultural practice.

Residue Trials

Strawberries

Residue trials with fenhexamid on strawberries were supplied from Australia, France, Italy, Spain, UK and Germany. Trials utilising either dilute[1] or low volume[2] sprays were provided. In general, residues following dilute application were higher than with low volume applications. Two dilute spray trials were conducted at 0.25-0.5× the proposed label rate, sixteen at 1-1.5× and nine at 2×.

For the low volume applications two trials were conducted at 0.5-1×, four at 2×, four at 3× and eight at 4× the proposed label rate. The seventeen maximum residue results from trials conducted at 1× - 1.5× the proposed maximum rate for strawberries harvested on or after the WHP of 0 days and in rank order (median underlined) were 0.19, 0.58, 0.66, 0.74, 1.0, 1.1, 1.1, 1.5, <u>1.5</u>, 1.8, 1.9, 1.9, 2.7, 3.7, 4.1, 4.8 and 5.6 mg/kg. At 2× and 4× the proposed maximum label rate the maximum residues at the WHP or longer were 0.53, 0.54, 0.55, 0.85, 1.2, 1.4, 1.8, 2.3, 3.9, 4.66, 6.4, 9.7 and 11 mg/kg for the 2× rate and 0.71, 0.75, 0.79, 0.81, 0.84, 0.97, 1.1, 1.5, 1.7, 1.7, 2.1 and 7.0 mg/kg for the 4× rate.

The data support an MRL of 10 mg/kg for strawberries when combined with a nil WHP. The supervised trial median residue (STMR) is 1.5 mg/kg (n=17) and the highest residue (HR) is 5.6 mg/kg.

[1] sprays were considered to be dilute applications when the spray volume was ≥ 1000 L/ha
[2] sprays were considered to be low volume applications when the spray volume was < 1000 L/ha

Animal feed commodities and animal MRLs

Strawberries and strawberry waste are unlikely to be fed to animals in significant quantities. It is not necessary at this stage to set animal commodity MRLs.

Storage stability

Fenhexamid residues were stable in homogenised grape, grape juice, raisin, raisin waste, peach, strawberry and tomato samples on storage at -18°C for periods up to 12 months. As the time between sampling and analysis in the residue trials was 2 to 8 months for the strawberry trials the residues determined are a true reflection of those present at sampling.

Processing

Processing data were presented strawberries. The processing factor for washing strawberries was 0.29 while the processing factor for making strawberry jam from washed strawberries was 0.28.

Maximum Daily Intake Calculations

The risk to human health from the use of fenhexamid is considered to be small. The chronic dietary risk is estimated by the national estimated daily intake (NEDI) calculation. The NEDI calculation shows that the intake is equivalent to 0.02% of the ADI for fenhexamid. As it is widely recognised this calculation is a gross overestimate of actual dietary intake, we conclude that the chronic dietary exposure is small and the risk is acceptable.

Amendments to the MRL Standard

The following amendments to the *MRL Standard* are recommended:

Table 1

Compound	Food	MRL (mg/kg)
Fenhexamid **DELETE:**		
	FB 0275 Strawberries	T5
ADD:		
	FB 0275 Strawberries	10

Withholding periods

The following WHPs are recommended in relation to the above MRL for Teldor 500 SC Fungicide:

Harvest:
Strawberries: Not required when used as directed.

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Overseas MRLs

Fresh strawberries are exported. Fenhexamid has not been evaluated by JMPR and no CODEX MRLs have been established. The applicant has provided the following information regarding tolerances in overseas markets.

Overseas MRLs for fenhexamid reported by the applicant and/or located in the USA Code of Federal Regulations

Country	Commodity	MRL (mg/kg)
Belgium	Cherry	5
	Currants	3
	Raspberry	3
	Strawberry	2
	Other plants	*0.05
France	Grape (table)	3
	Grape (wine)	2
	Wine	1
	Strawberry	3
	Tomato	1
Germany	Berries (others)	5
	Cherry	5
	Grape	3
	Plum	2
	Strawberry	3
	Tomato	1
Greece	Grape	3
	Strawberry	3
	Kiwi fruit	10
	Tomato	1
Japan	Citrus	5
	Large fruit (including peach)	1
	Small fruits (including grapes)	20
Spain	Grape	2
	Strawberry	3
South Africa	Grape	5
Switzerland	Cherry	2
	Grape	3
	Raspberry	3
	Strawberry	2
	Wine	1.5
USA	Almond, hull	2
	Almond, nut meat	0.02
	Grapes	4
	Plum (fresh prune)	0.5
	Prune (dried)	1
	Raisins	6
	Stone fruit, except plum (fresh prune)	6
	Strawberries	3

Potential risk to Australian Trade

The table below lists the major export markets for fresh strawberries.

Major markets for Australian fresh strawberries

Importing country	1996/97 (tonnes)	1996/97 ($ 000)	1997/98 (tonnes)	1997/98 ($ 000)
Hong Kong	2219	5969	320	1512
Singapore	670	2189	274	1106
Malaysia	273	813	43	166
United Arab Emirates	167	802	155	782
United Kingdom	82	677	145	920
Thailand	92	348	1	7
Indonesia	112	347	38	68
Taiwan	132	323	0	0
Netherlands	14	169	26	273
Belgium-Luxembourg	16	166	8	113
Other	153	844	175	1085
Total	3930	12647	1185	6032

Most of the countries listed above do not have tolerances for fenhexamid in strawberries and the use of fenhexamid on strawberries destined for export to these markets could result in residue violations.

CODEX MRLs are often referenced in the case of international trade disputes arising from differences in domestic MRLs. Fenhexamid is a new compound and has not been reviewed by JMPR and no CODEX MRLs have been set. To date, relatively few fenhexamid MRLs have been established in Australia's major markets for fresh strawberries. The potential for finite residues in export commodities indicates a potential trade risk.

To minimise the risk to trade from the use of fenhexamid on strawberries, the company has included the following statement on the label:

"Export of Treated Produce:
Strawberry growers should note that suitable MRLs or import tolerances may not be established in all markets for strawberries treated with Teldor. If you are growing strawberries for export, please check with Bayer for the latest information on MRLs and export tolerances before using Teldor."

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Fenhexamid is not listed as a hazardous substance in the National Occupational Health and Safety Commission (NOHSC) *List of Designated Hazardous Substances.* Fenhexamid is determined to be a non-hazardous substance according to NOHSC criteria.

Fenhexamid has low oral, dermal and inhalational toxicity in rats. It is not a skin or eye irritant in rabbits and not a skin sensitiser in guinea pigs.

The product Teldor 500 SC Fungicide is a brown liquid suspension with a weak characteristic odour. The product demonstrated low oral and dermal acute toxicity. The oral LD_{50} was >2500 mg/kg in rats. The dermal LD_{50} was >4000 mg/kg in rats. The product is not a skin or eye irritant in rabbits or a skin sensitiser in guinea pigs.

Formulation, transport and storage

Fenhexamid TGAC will be imported and the product will be formulated and Australia. Some product will be imported fully formulated from Germany. Transport, storage and retail workers could only be exposed to fenhexamid or the products if packaging were breached.

End use

Teldor is proposed for control of grey mould (*Botrytis cinerea*) in strawberries. The product will be diluted with water and applied by hand held wands or tractor mounted boomspray. The application volume (spray) for hand held or boomspray is 500-1000 L/ha using l L of product. The concentration of fenhexamid in the working strength solution will be from 0.1% to 0.05% w/v. Teldor will be applied two to four times a year.

No worker exposure data were available to assess the risks of long term use of fenhexamid. The UK POEM was used by NOHSC to provide supplementary information on exposure during mixing/loading and application of Teldor. The results indicated that normal clothing is adequate for workers using Teldor.

Re-entry assessment

The draft label does not specify a re-entry period for any treated area. Based on the low toxicity and high dilution of the active in the product, NOHSC does not recommend any re-entry statement at this stage.

ENVIRONMENTAL ASSESSMENT

Environmental Exposure

Teldor is likely to have widespread use in the strawberry growing areas in all States of Australia. Following application any fenhexamid not captured by the crop is expected to become associated with the soil compartment under the plants or between the rows. Microbial metabolism is the primary mechanism for breakdown with photodegradation an important source of degradation of the metabolites formed. Environmental fate data are summarised below.

Hydrolysis

In sterile aquatic systems over the environmental pH range fenhexamid was stable to hydrolysis. Considering the hydrolytic stability determined under environmental pH and temperature conditions, it is not expected that hydrolytic processes will contribute to the degradation of fenhexamid in the environment.

Photolysis

Three studies investigating the photochemical degradation in water showed that solar radiation contributes to the degradation of fenhexamid in aquatic systems and also the elimination of residues of fenhexamid by means of mineralisation of the phenyl-ring. More than 14 degradation products or metabolite fractions were observed in the irradiated aqueous solution. The breakdown of the parent compound proceeded via dechlorination, stepwise hydroxylation and eventual cleavage of the phenyl-ring.

While degradation was rapid in the soil photolysis test it was concluded that the degradation of fenhexamid predominantly occurred through microbial degradation and not via photodegradation. However it can contribute to the elimination of metabolites and breakdown products of fenhexamid in the environment by means of mineralisation of phenyl-ring portions of such products in soil.

Degradation in soil and water

Aerobic soil metabolism

In four soils, fenhexamid was rapidly degraded and thoroughly metabolised under aerobic conditions. More than 13 degradates were formed and it was noted that no metabolite accumulated in soil. The maximum portion of a single metabolite was <6% of the applied radioactivity. All metabolites (except CO_2) reached their maximum concentration in soil in the first week after soil treatment and continuously declined until termination of the study. The short half-life (< 1 day) and continued breakdown of the metabolites give an extremely short environmental life.

Aquatic metabolism

The studies with fenhexamid in two different natural water/sediment systems showed that the compound is rapidly dissipated and thoroughly metabolised in an aquatic environment. The DT_{50} values of fenhexamid were calculated to be 2 and 15 days respectively referring to the entire system. More than 15 metabolites were formed, but no metabolite accumulated. No single metabolite or radioactive zone exceeded 10% of the applied radioactivity in the water and/or sediment. Fenhexamid

was fixed in the sediment with minor amounts in the water column. It continued to degrade to the final degradation product CO_2 with 100 day totals of between 5% and 12% of the total applied.

Mobility

Soil

The results of the adsorption/desorption studies in six soils with fenhexamid show strong adsorption as well as a low potential for desorption. The compound can be classified as a substance with moderate adsorption and low leaching potential.

Air

Based on the vapour pressure and the Henry Law Constant it can be concluded that significant volatilisation of fenhexamid is not to be expected. In addition, estimates of the chemical lifetime in the troposphere resulted in half lives < 1 day. According to these results, an accumulation of fenhexamid in the air and contamination by wet or dry deposition are not to be expected.

Bioaccumulation

Exposure in bioaccumulation testing resulted in quick uptake. However, when exposure ceased, the residues were depurated very quickly with a half-life of less than 1 day. The mean bioconcentration factor based on the total radioactive residue (active ingredient and metabolites) for whole fish has been determined as 159 in the first bioconcentration study. In the second study which characterised the total radioactive residues demonstrated that greater than 50% of the radioactivity applied can be attributed to the parent compound fenhexamid. A new BCF value was estimated to be about 80.

Soil accumulation

The potential for soil accumulation is a function of the mobility and speed of degradation in the soil. The low mobility and short half life in soil (< 1 day) shown by fenhexamid would lead to a low potential to accumulate.

Environmental Toxicity

Birds

Fenhexamid has low toxicity to birds. An acute LD_{50} of >2000 mg ai/kg body weight was determined for bobwhite quail. The dietary LC_{50} for this species and for mallard duck was determined as greater than 5000 mg ai/kg diet. The NOEC for reproduction in the bobwhite quail was 2074 mg ai/kg diet, and the LOEC was determined as >2074 mg ai/kg diet based on the observation of adults and their offspring.

Effects on aquatic organisms

Acute toxicity testing in fish has shown a moderate toxicity for fenhexamid. In 96-hour flow through studies with rainbow trout and bluegill sunfish, LC_{50} values of 1.24 and 3.17 mg/L (respectively) were determined. In a 96 day rainbow trout early life stage toxicity test conducted with fenhexamid, the lowest NOEC was determined to be 101 mg/L based on the most sensitive end point (time to swim-up), indicating moderate toxicity.

Testing on *Daphnia magna* with fenhexamid resulted in a 48-hour EC_{50} value of > 18.8 mg/L, indicating slight toxicity. In a 21-day semistatic reproduction study, the NOEC was determined as 1.0 mg/L, confirming the slight toxicity.

Algae, represented by *Scenedesmus subspicatus* and *Selenastrum capricornutum*, are not particularly sensitive to fenhexamid. In a standard 72-hour static test, an EC_{50} value (based on growth rate) of >26.1 mg/L was established for *Scenedesmus subspicatus*, and in a standard 120-hour test a value of 8.43 mg/L was established for *Selenastrum capricornutum*. This represents slightly and moderately toxicity respectively.

Effects on bees and other arthropods

Acute toxicity studies on honey bees in the laboratory gave LD50 values of > 188 (contact) and >97.7 (oral) µg ai/bee. Fenhexamid therefore exhibits practically no toxicity.

Ground dwelling predators, as represented by the rove beetle *Aleochara bilineata*, proved to be not susceptible to Teldor with either of the application rates (0.75 or 2.0 kg ai/ha). The number of emerging progenies was also not reduced. Therefore, Teldor spray treatments are not expected to have any adverse effects on ground dwelling arthropods under field conditions.

Laboratory testing on larvae and adults of the seven-pointed ladybird, *Coccinella septempunctata*, also revealed no effects from Teldor treatments at rates of 0.6, 1.2 and 4.0 kg product/ha. Accordingly, no adverse effects are anticipated on foliage dwelling predators under the proposed agricultural use conditions.

Testing for effects of Teldor on the predatory mite *Typhlodromus pyri* under laboratory conditions led to the conclusion that a risk of adverse effects under field usage conditions can be excluded. There were no statistically significant differences observed in percent mortality between the control and the two treatment rates (2 and 4 kg product/ha).

Tests carried out on a representative sample of Australian predatory mites and a range of beneficial arthropods found no effect at 0.75 the proposed field rate but some slight reduction in survival at 7.5 times proposed field rate There is no expectation of injury to these tested species following field use of fenhexamid.

Testing on parasitoids, as represented by *Aphidius rhopalosiphi*, has also been performed with Teldor at rates of 0.3, 1.0 and 2.0 kg ai/ha. There were no significant effects. In conclusion, parasitoids as represented by *Aphidius rhopalosiphi*, will not be impacted by a spray treatment with Teldor up to an application rate of 4.0 kg product/ha.

From the results in the laboratory and the field it can be concluded that a slight risk on non-target arthropod populations may occur at excessively high use rates (10X), but is not anticipated at label rates of Teldor and proposed application schedules.

Effects on earthworms and soil micro-organisms

The LC_{50} of fenhexamid for the earthworm *Eisenia fetida* was determined to be greater than 957 mg ai/kg dry wt substrate, indicating low toxicity.

The laboratory studies performed with fenhexamid concerning effects on the soil micro-organism C- and N-cycles reveal that at double the proposed application rate, 1 kg ai/ha, and even with the 10-fold overdose, fenhexamid will have no influence on microbial

mineralisation processes in field soils. Furthermore, fenhexamid has shown low bactericidal activity, and a risk to biological sewage treatments is not anticipated.

Phytotoxicity

No specific tests were submitted as an evaluation of the potential for phytotoxicity to non-target species but due to the proposed use as a fungicide on strawberries, fenhexarnid would not be expected to adversely effect off target plants at normal use rates.

Environmental Hazard

It is proposed that fenhexamid will be applied no more than 7-10 days apart with only two successive sprays before a rotation fungicide is used. An application rate of 500 g ai/ha fenhexamid is recommended on the label with application to fruit, leaves and stems. The strawberry plants are typically grown on raised rows covered by plastic mulch. This mulch would intercept the spray and a residue would form that could be washed to the adjoining inter-row space by subsequent rainfall or overhead irrigation. Laboratory studies on photolysis and soil metabolism indicate that the breakdown of fenhexamid on the soil will proceed quickly. Fenhexamid is unlikely to accumulate in high concentrations in the soil.

Terrestrial Fauna

The potential residues from a spray of fenhexamid on strawberries at the label rate of 500 g/ha result in initial residues of 107 ppm in short grass, 60 ppm on leaves and leafy crops and 6 ppm on fruit and large insects

Estimated concentrations resulting from a diet exclusively based on feed contaminated to this extent (which is highly unlikely) are 50 ppm and 19 ppm for quail and mallard duck, respectively. For both bobwhite quail and mallard ducks, these worst case concentrations are well below the 23 week dietary exposure NOEC >2074 ppm, for quail. Fenhexamid used in accordance with label recommendations is not likely to present a hazard to birds ingesting these residues. Acute or chronic toxicity to mammals is also highly unlikely from the proposed use in strawberry crops.

Testing for effects on a range of beneficial arthropods resulted in no effect at 75% of the proposed label rates and slight effect at 7 times the proposed rate. It was concluded that with the proposed use pattern in strawberry crops, significant direct toxicity is unlikely to arise to most non-target terrestrial invertebrate species.

Fenhexamid has been found to have low toxicity to the earthworm species *Eisenia foetida* (14 d LC_{50} > 957 mg ai per kg soil). As the level in the top 10 cm of the soil at 500 g/ha would equal 0.35 mg ai per kg soil, use of the product as proposed is unlikely to present a hazard to earthworms.

Aquatic fauna

A screening level assessment that considers the effects of spray drift (or runoff), estimated to provide 10% of the concentration that would arise from overspray, predicts an environmental concentration of 33.35 µg/L in 15 cm water from an application rate of 500 g ai/ha. For the most sensitive aquatic species tested this is less than 10 % of the lowest acute LC_{50}, indicative

of low hazard. With a direct overspray a marginal hazard may exist, however, if no dissipation is assumed.

Bioaccumulation studies show that the chemical is quickly taken up by the test species but just as quickly depurated on removal from exposure. A bioconcentration factor below the level of concern was calculated.

Terrestrial and aquatic flora

As there is no indication of crop phytotoxicity from use in a range of crops at specified application rates, it appears unlikely that phytotoxicity should arise from direct overspray of fenhexamid or spray drift onto native plants.

Algae are not particularly sensitive to fenhexamid. In a standard 72-hour static test, an EC_{50} value (based on growth rate) of >26.1 mg/L was established for *Scenedesmus subspicatus,* and in a standard 120-hour test a value of 8.43 mg/L was established for *Selenastrum capricornutum.* This represents a wide safety margin compared with likely levels above.

Tests of up to 10 times the label rate have shown no effect on soil microflora. Under normal conditions of use, fenhexamid would not be expected to affect carbon turnover or cause long term detrimental effects on the turnover of nitrogen in soils.

Conclusions

Fenhexamid is a representative of a new chemical group of fungicidally active chemicals that exhibit narrow spectrum of activity. The moderate effects on non target organisms and short half life in the environment on exposure to microbial activity in the soil or aquatic environment indicates a low hazard.

Environment Australia believes that low hazard to the environment exists provided the label recommendations are adhered to and principles of good agricultural practice are followed.

EFFICACY AND SAFETY ASSESSMENT

Justification for use

Grey mould (*Botrytis cinerea)* can have a significant impact on strawberry production and can develop further during storage and cause substantial spoilage of fruit.

There is a high level of dicarboximide resistance throughout the major growing areas, and currently registered products have other disadvantages including phytotoxicity in hot weather, lack of compatibility with other products, long withholding periods and skin irritancy.

Teldor 500 Sc Fungicide contains fenhexamid, a new hydroxyanilide fungicide. It shows some locosystemic properties and inhibits the germ tube and mycelium. It does not inhibit spore germination. The biochemical mode of action is unknown and is under investigation, but appears to be different from that of all other known botryticides.

It is not cross-resistant to all other known botryticides and should therefore play an important role in resistance management programs. Teldor is expected to replace or take the pressure off the dicarboximide group so growers can alternate with their base protectant programs and use Teldor as a strategically applied product.

Proposed use pattern

The directions for use proposed to be included on the product label are as follows:

Crop	Disease	Rate	Application	Critical Comments
Strawberries	Grey mould	1 L/ha	Use where spray volume is less than 1000 L/ha. Do not apply volumes less than 500 L/ha	Reduce background levels of disease by removing plant debris and rotted fruit. If conditions favour grey mould development, apply Teldor at 7 to 10 day intervals. Do not apply more than 2 successive sprays of Teldor before switching to a fungicide of a different group.
		100 mL/100L	Use where spray volume exceeds 1000 L/ha	

Evaluation of efficacy and safety

Efficacy

The results of six field trials and one laboratory study were submitted in support of the claim for use of the product to control grey mould in strawberries.

In initial *in vitro* screening work conducted by the Queensland Department of Primary Industries, fenhexamid was highly effective against Rovral (iprodione) resistant and Rovral sensitive strains of *Botrytis cinerea.*

The field trials were conducted at Nambour, Qld and Silvan, Vic over several years. The trials involved Teldor at a range of rates compared to standard treatments Euparen 500WG, Rovral 250 SC and, in 1 trial only, Captan 800 WG, at their registered rates, and untreated controls.

Trial designs, experimental conditions and analysis of trial results were suitable. Generally there was no significant difference between the various rates of Teldor and the registered products in the major parameter percentage of fruit showing grey mould infection. In all trials the treatments gave significantly lower percentages of fruit having grey mould than the untreated controls.

The data support that the product will be effective when used as proposed for the control of grey mould of strawberries.

Phytotoxicity

The results of three field trials were presented in which the safety of frequent high rate applications of Teldor was assessed. Two trials were conducted at Silvan, Vic and one at Nambour, Qld.

In the two Victorian trials, use at up to double the proposed label rate on 6 occasions in the early fruiting period did not show any significant leaf scorch compared to untreated controls. In the Queensland trial, use at from twice to 16 times the label rate, in a series of 4 sprays over the flowering and fruiting period, did not produce any symptoms of phytotoxicity to the foliage or fruit.

The data shows that the product, when used as directed, does not have any adverse effect on strawberries.

LABELLING REQUIREMENTS

The draft label proposed for the product is as follows:

READ SAFETY DIRECTIONS

Teldor® 500 SC Fungicide

Active Constituent: 500 g/L FENHEXAMID

GROUP	J	FUNGICIDE

For the control of grey mould on strawberries

1 Litre
5 Litres
10 Litres
20 Litres

Directions for use

Crop	Disease	Rate	Application	Critical Comments
Strawberries	Grey mould	1 L/ha	Use where spray volume is less than 1000 L/ha. Do not apply volumes less than 500 L/ha	Reduce background levels of disease by removing plant debris and rotted fruit. If conditions favour grey mould development, apply Teldor at 7 to 10 day intervals. Do not apply more than 2 successive sprays of Teldor before switching to a fungicide of a different group.
		100 mL/100L	Use where spray volume exceeds 1000 L/ha	

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION

WITHHOLDING PERIOD: STRAWBERRIES: NOT REQUIRED WHEN USED AS DIRECTED

Bayer Australia Limited emergency contact
1 800 033 111
Australia wide, 24 hours

Bayer Australia Limited
875 Pacific Highway
Pymble NSW 2073
Telephone (02) 9391 6000

General Instructions

Resistance management recommendation/strawberries
Do not apply more than two successive sprays of Teldor before changing to a fungicide from a different group.

Fungicide Resistance Warning

GROUP	J	FUNGICIDE

For fungicide resistance management Teldor is a Group J fungicide. Some naturally occurring individual fungi resistant to the product and other Group J fungicides may exist through normal genetic variability in any fungal population. The resistant individuals can eventually dominate the fungal population if these fungicides are used repeatedly. These resistant fungi will not be controlled by this product and other Group J fungicides, thus resulting in a reduction in efficacy and possible yield loss. Since the occurrence of resistant fungi is difficult to detect prior to use, Bayer Australia Limited accepts no liability for any losses that result from failure of this product to control resistant fungi.

Mixing
Prior to pouring, shake container vigorously, then add the required quantity of Teldor 500 SC to water in the spray vat while stirring or with agitators in motion.

Export of Treated Produce
Strawberry growers should note that suitable MRLs or import tolerances may not be established in all markets for strawberries harvested from Teldor treated plants. If you are growing strawberries for export, please check with Bayer for the latest information on MRLs and export tolerances before using Teldor.

Protection of Wildlife, Fish, Crustaceans and Environment
DO NOT contaminate streams, rivers or waterways with the chemical or used containers. DO NOT spray across open bodies of water.

Storage and Disposal
(1 litre label)
Store in the closed, original container in a cool, well ventilated area. Do not store for prolonged periods in direct sunlight. Rinse container before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. Dispose of at a local authority landfill. If no landfill is available, bury the container below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.
(other pack sizes)
Store in the closed, original container in a cool, well ventilated area. Do not store for prolonged periods in direct sunlight. Triple or preferably pressure rinse container before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush or puncture and bury empty containers in a local authority landfill. If no landfill is available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.

Safety Directions
When opening the container and preparing spray, wear elbow-length gloves. After each day's use, wash gloves. Wash hands after use.

First Aid
If poisoning occurs contact a doctor or Poisons Information Centre (131126).

For further information refer to the Material Safety Data Sheet for the product.

Liability
This product must be used strictly as directed. Bayer Australia Limited may not be liable for loss or damage arising from failure to follow directions for use.

Teldor® is a registered trademark of Bayer AG, Germany MN
 NRA Approval Number 50670/

GLOSSARY

Active constituent	The substance that is primarily responsible for the effect produced by a chemical product.
Acute	Having rapid onset and of short duration.
Carcinogenicity	The ability to cause cancer.
Chronic	Of long duration.
Codex MRL	Internationally published standard maximum residue limit.
Desorption	Removal of an absorbed material from a surface.
Efficacy	Production of the desired effect.
Formulation	A combination of both active and inactive constituents to form the end use product.
Genotoxicity	The ability to damage genetic material
Hydrophobic	Water repelling
Leaching	Removal of a compound by use of a solvent.
Log P_{ow}	Log to base 10 of octonol water partioning co-efficient.
Metabolism	The conversion of food into energy
Photodegradation	Breakdown of chemicals due to the action of light.
Photolysis	Breakdown of chemicals due to the action of light.
Subcutaneous	Under the skin
Toxicokinetics	The study of the movement of toxins through the body.
Toxicology	The study of the nature and effects of poisons.

Suggested further reading

Felton, J.C., Oomen, P.A. & Stevenson, J.H. 1986, 'Toxicity and hazard of pesticides to honeybees: harmonisation of test methods', *Bee World*, vol. 67, no. 3, pp. 114-24.

Goring, C.A.I. et al. 1975, 'Principles of pesticide degradation in soil', in *Environmental Dynamics of Pesticides*, edited by R. Haque and V.H. Freed, Plenum Press, New York, pp 135-72.

Matthews, G.A. 1992, *Pesticide Application Methods*, 2nd ed., Longman, London.

National Registration Authority for Agricultural and Veterinary Chemicals 1996, *Ag Manual: The Requirements Manual for Agricultural Chemicals*, NRA, Canberra.

National Registration Authority for Agricultural and Veterinary Chemicals 1997, *Ag Requirements Series: Guidelines for Registering Agricultural Chemicals*, NRA, Canberra.

National Registration Authority for Agricultural and Veterinary Chemicals 1996, *MRL Standard: Maximum Residue Limits in Food and Animal Feedstuffs*, NRA, Canberra.

National Registration Authority for Agricultural and Veterinary Chemicals 1997, *Ag Labelling Code—Code of Practice for Labelling Agricultural Chemical Products*, NRA, Canberra.

NRA PUBLICATIONS ORDER FORM

To receive a copy of the full technical report for the evaluation of fenhexamid in the product Teldor 500 SC Fungicide, please fill in this form and send it, along with payment of $30, to:

David Hutchison
Agreicultural & Veterinary Chemicals Evaluation Section
National Registration Authority for Agricultural and Veterinary Chemicals
PO Box E240
Kingston ACT 2604

Alternatively, fax this form, along with your credit card details, to:
David Hutchison at (06) 6272 3218.

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