Public Release Summary
on

Evaluation of the new active

FORCHLORFENURON

in the product

SITOFEX 10 EC PLANT GROWTH REGULATOR

Australian Pesticides and Veterinary Medicines Authority

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) 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 APVMA works in close cooperation with advisory agencies, including the xxxDepartment of Health and Ageing (Office of Chemical Safety), Department of the Environment and Heritage Australia (Risk Assessment and Policy Section and State departments of agriculture and environment.

The APVMA 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 APVMA 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 APVMA's publications *Manual of Requirement and Guidelines (MORAG).*

This Public Release Summary is intended as a brief overview of the assessment that has been completed by the APVMA 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 APVMA. Alternatively, the reports can be viewed at the APVMA Library First Floor, 22 Brisbane Avenue, Barton, ACT.

The APVMA welcomes comment on the usefulness of this publication and suggestions for further improvement. Comments should be submitted to the Program Manager Pesticides, Australian Pesticides and Veterinary Medicines Authority, 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
DEH	Department of Environment and Heritage
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
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
h	hour
ha	hectare
Hct	Heamatocrit
Hg	Haemoglobin
HPLC	High Pressure Liquid Chromatography *or* High Performance Liquid Chromatography
IPM	Integrated Pest Management
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 dquantified
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

INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of the product SITOFEX 10 EC PLANT GROWTH REGULATOR, which contains the new active ingredient forchlorfenuron. The product is proposed to be used for increasing berry size in table grapes.

Responses to this Public Release Summary will be considered prior to registration of the product. They will be taken into account by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

Copies of full technical evaluation reports on forchlorfenuron, covering toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the APVMA on request (see order form on last page). They can also be viewed at the APVMA library located at the APVMA offices, First Floor, 22 Brisbane Avenue, Barton, ACT, 2604.

Written comments should be received by the APVMA by **30 September 2005**.
They should be addressed to:

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Applicant:
Degussa AG

Product Details:
It is proposed to register SITOFEX 10 EC PLANT GROWTH REGULATOR containing 10 g/L of forchlorfenuron as an emulsifiable concentrate. The product will be imported fully formulated and packaged in 250 mL and 1 L containers.

SITOFEX 10 EC PLANT GROWTH REGULATOR is a member of the phenylurea chemical family. The product is absorbed by leaves, stem, cotyledon and germinated seeds. It promotes cell division, differentiation and development, it induces budding of callus and controls apical dominance, breaks dormancy of lateral buds and promotes germination, it delays the aging process and maintains chlorophyll in excised leaves, regulates the transport of nutrients and promotes fruit formation.

The rate of product use is 50 – 100 mL per 100 L of water. SITOFEX 10 EC PLANT GROWTH REGULATOR is proposed for registration in all States where table grapes are grown.

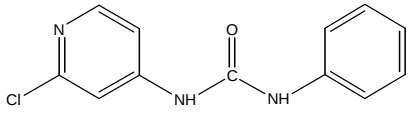
Formulations containing forchlorfenuron are currently registered as plant growth regulators to increase fruit size for table grapes, kiwifruit and various other fruits in Chile, Egypt, Israel, Mexico, New Zealand, South Africa, Turkey and the USA, with registration stated as pending in the European Union for use on kiwifruit.

CHEMISTRY AND MANUFACTURE

Manufacturing Site

The active constituent forchlorfenuron is manufactured by Rutgers Chemicals AG at Sandhofer Strabe 92, D-68305 Mannheim, Germany.

Chemical Characteristics of the Active Constituent

Common Name:	Forchlorfenuron
IUPAC Name:	1-(2-chloro-4-pyridyl)-3-phenylurea
CA:	*N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea
CAS No:	68157-60-8
Manufacturers Code:	SKW 20010, KT-30, CN-11-3183
Molecular formula	$C_{12}H_{10}ClN_3O$
Mol Wt.	247.7gmol^{-1}
Chemical Structure:	
Chemical Family	Phenylurea
Mode of Action	Absorbed by leaves, stem, cotyledon and germinated seeds. It promotes cell division, differentiation and development, it induces budding of callus and controls apical dominance, breaks dormancy of lateral buds and promotes germination, it delays the aging process and maintains chlorophyll in excised leaves, regulates the transport of nutrients and promotes fruit formation.

Physical and Chemical Properties of Pure Active Constituent and Technical Material

Melting Point	165 – 170 °C
Boiling Point	No data available
Temperature of Decomposition or sublimation	No data available
Relative density	1.44 at 21 °C
Vapour pressure	4.6×10^{-8} Pa at 25 °C 5.3×10^{-8} Pa at 27 °C 2.0×10^{-7} Pa at 50 °C 1.72×10^{-6} mm Hg at 25 °C
Volatility	Henry's Law Constant = 0.5 Pa × m^3 × mol^{-1}
Physical State, Colour	White to off-white crystalline powder
Odour	Odourless
Solubility in water, including effect of pH	Not very soluble in water. A forms homogeneous solution at 30 ppm, saturated concentration is 39 ppm. No stable pH was achieved for a 10 g/L aqueous dispersion (at 20 °C)
Solubility in Organic solvents (g/L at 21 °C)	Acetone 169.0 g/L Toluene 0.108 g/L Isopropanol 74.0 g/L Ethyl acetate 24.0 g/L Dichloromethane 1.0 g/L n-hexane 3×10^{-5} g/L
Partition co-efficient n-octanol/water	Log Pow = 3.2 at 20 °C, Pow shows no pH dependency in the pH range 4 to 10
Hydrolysis rate	Very stable in aqueous solutions at pH 5, 7, and 9
Photochemical degradation	Troposphere half life = 2.3 hours
Quantum Yield	No data available
Dissociation constant	pKa at 25 °C 2.5 (at 261 and 282 nm) and 12.2 (at 261 and 291 nm)
Stability in Air, photochemical degradation	Very stable

Flammability	Could not be ignited with a flame
Flash point	Is not self-ignitable
Explosive properties	Contains no moiety in its molecule, which could render it potentially explosive on theoretical grounds
Surface tension	Not considered as surface active
Oxidising properties	Contains no moiety in its molecule, which could exert oxidising properties on theoretical grounds

Summary of the APVMA's Evaluation of forchlorfenuron

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of forchlorfenuron (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. On the basis of the data provided, it is proposed that the following minimum compositional standard be established for forchlorfenuron:

Active constituent

Forchlorfenuron	Not less than 978 g/kg

Forchlorfenuron contains no toxicologically significant impurities present that require maximum specification limits.

PRODUCT

Distinguishing name:	*Sitofex 10 EC Plant Growth Regulator*
Formulation type:	Emulsifiable concentrate
Active constituent concentration:	10 g/L

Physical and Chemical Properties of the Product

Physical state:	Emulsifiable concentrate
Colour:	Reddish
Odour:	Alcoholic
Density or specific gravity:	0.84 at 20 °C
pH (1% solution):	7.78
Viscosity:	8 to 9 mPa at 20 °C
Flash point:	16 °C
Autoignition:	385 °C
Explodability:	Lower limit: 1.5 %(V), Upper limit 28 % (V)
Oxidising properties:	Non-corrosive
Storage stability:	Stable for approximately 3 years under normal conditions

Recommendations

Based on a review of the chemistry and manufacturing details provided by the applicant, the approval of forchlorfenuron manufactured by Rutgers Chemicals AG at Sandhofer Strabe 92, D-68305 Mannheim, Germany is supported.

Based on a review of the chemistry and manufacturing details provided by the applicant, registration of Sitofex 10 EC Plant Growth Regulator is supported.

TOXICOLOGICAL ASSESSMENT

The toxicological database for forchlorfenuron, consisting primarily of toxicological studies conducted in laboratory 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 may occur 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. Similarly, 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 adverse 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 (ADI and ARfD) at which no adverse health effects in humans are expected.

Toxicokinetics and Metabolism Studies

Rats given a single gavage dose of 100 mg/kg bw of ^{14}C-forchlorfenuron in corn oil absorbed it rapidly. About 70-80% of the dose was excreted in the urine, with the remainder in the faeces. The majority of the radioactivity in faeces was shown to be excreted in the bile. Therefore, absorption through the gastro-intestinal tract is virtually complete. Seven days after dosing, tissue residues accounted for less than 1% of the administered dose. The main metabolic pathways involve hydroxylation of the phenyl ring followed by sulfate conjugation.

Acute Studies

Forchlorfenuron has low oral toxicity in rats with an LD_{50} of 4940 mg/kg bw in male rats and 4899 mg/kg bw in females. It has low dermal toxicity (LD_{50} >2000 mg/kg bw) in rabbits and low inhalation toxicity (LC_{50}>3000 mg/m^3) in rats. It is non-irritating to rabbit skin and non-sensitising to guinea pig skin. Forchlorfenuron is a slight eye irritant in rabbits.

Sitofex® 10 EC Plant Growth Regulator has low oral (LD_{50}>2000 mg/kg bw), dermal (LD_{50}>2000 mg/kg bw) and inhalational (LC_{50}>5160 mg/m^3) toxicity in rats. It is a moderate eye and skin irritant in rabbits. There is evidence from guinea pig studies that it is a skin sensitiser.

Short-term Studies

A 28-day dietary range-finding study in rats (with forchlorfenuron dosage levels of 300, 1000, 3000 and 10000 ppm) found statistically significant decreases in food intake and body weight gain in the 10000 ppm group, and in body weight gain in the 3000 ppm group. There were no effects at lower dose levels.

A 28-day dietary range-finding study in dogs (with forchlorfenuron dosage levels of 150, 500, 2500 and 7500 ppm) found decreases in food consumption and overall body weight gain in dogs in the 7500 ppm dose group.

Subchronic Studies

In a 13-week range-finding study in mice (with forchlorfenuron dosage levels of 900, 1800, 3500 and 7000 ppm) a dietary concentration of 7000 ppm was associated with decreased food consumption in males, lower body weight gains in both sexes, and an increase in lymphocytic cell infiltration of the renal interstitium and pelvis in both sexes. The NOEL was 3500 ppm (609 mg/kg bw/d, males; 788 mg/kg bw/d, females).

In a 90-day dietary study in rats (with forchlorfenuron dosage levels of 200, 1000 and 5000 ppm), the test material tended to affect body weight gain in females at 5000 ppm. Increased liver weights were seen in males and females at 5000 ppm and in males at 1000 ppm. The NOEL was 200 ppm (16.2 mg/kg bw/d).

The only statistically significant effect observed in a 90-day dietary study in dogs given 50, 500 and 5000 ppm forchlorfenuron diets was increased cholesterol levels at 45 days at 5000 ppm. Males at 500 ppm and both sexes at 5000 ppm showed slightly decreased overall body weight gain. Absolute and relative liver weights were increased in 5000 ppm females. The NOEL was 500 ppm (16.8 mg/kg bw/d in males; 19.1 mg/kg bw/d in females).

A 13-week range-finding study in dogs (with forchlorfenuron dosage levels of 7500 and 10000 ppm) found that animals at 10000 ppm dose showed decreased defaecation. Food consumption in both test groups was reduced in a dose-related manner throughout the study. Dogs at the higher dose level lost weight during the trial, and at the lower dose weight gains were reduced. Mean red cell count, haemoglobin and haematocrit were below control levels in both test groups. Reticulocyte counts tended to be increased. Mean white cell counts in males at 7500 ppm and 10000 ppm were increased due to increased numbers of segmented neutrophils. Mean cholesterol values for all treated groups were elevated above control levels, without reaching statistical significance.

Chronic/Carcinogenicity Studies

A 18-month dietary carcinogenicity study in mice included forchlorfenuron dose levels of 10 and 1000 mg/kg bw/d. There were no carcinogenic effects of the test article at either test dose. Therefore the NOEL for carcinogenicity in this study was 1000 mg/kg bw/d. The dose level of 1000 mg/kg bw/d was associated with various systemic toxicological effects. These included lower food consumption, comparatively low body weights, increased kidney weights, some microscopic findings in the kidneys (e.g. increased incidence of tubular dilatation and brown pigment), increased incidence of A-cell hyperplasia of the adrenal cortex (in males), nasal fibro-osseous lesions (in females), splenic extramedullary haematopoiesis (in females) and atypical lymphoid hyperplasia of the thymus (in females). Some of the kidney abnormalities were also noted at the 10 mg/kg bw/d level but because of the high incidence of nephropathy in control animals they were considered to be of questionable toxicological significance.

In a 24-month dietary toxicity/carcinogenicity study in rats with 150, 2000 and 7500 ppm forchlorfenuron diets, there was no evidence of oncogenicity but a range of systemic effects were observed. Food consumption was decreased earlier in the study in the 2000 ppm and 7500 ppm groups. At the same dose levels, body weights were comparatively depressed. Decreased red blood cell counts in 7500 ppm males and increased MCH and MCV in 2000 and 7500 ppm males were observed early in the study. Increased reticulocytes were observed in the 7500 ppm group males throughout the study and in 7500 ppm females at 25 weeks. Platelet counts were increased in both sexes at 7500 ppm. White blood cell counts in the 7500 ppm group males and females were consistently elevated. In the 7500 ppm female group, serum potassium levels were elevated throughout the study and the specific gravity of the urine was decreased (with some indications of the latter effect in males as well). A major target organ was the kidney, with both macroscopic (e.g. white areas, renal cysts) and microscopic lesions (e.g. renal tubular dilatation, suppurative inflammation) being observed in the kidneys of rats at 7500 ppm and 2000 ppm. Therefore, a NOEL of 150 ppm (7 mg/kg bw/d, males; 9 mg/kg bw/d, females) was established for systemic toxicity. Since there was no evidence of oncogenicity, the NOEL for carcinogenicity was 7500 ppm (352 mg/kg bw/d, males; 518 mg/kg bw/d, females).

A one-year dietary toxicity study in dogs employed concentrations of forchlorfenuron of 150, 3000 and 7500 ppm. A diet of 7500 ppm forchlorfenuron led to depressed food consumption in both sexes and decreased body weights, especially in females. Females at 7500 ppm showed decreases in a range of haematological values throughout the study. Cholesterol levels were increased (although within the historical control range) in both sexes at 7500 ppm and 3000 ppm. There was a tendency for increased liver weights (not associated with any histopathology) among females in the 7500 ppm group. The NOEL was therefore 3000 ppm (87 mg/kg bw/d, males; 91 mg/kg bw/d, females).

Reproduction Study

Two generations of rats (with two litters each) were studied for parental and pup toxic effects by feeding diets containing 0, 150, 2000 or 7500 ppm forchlorfenuron. Parental toxicity in the F_0 and F_1 generations was exhibited at 7500 ppm by clinical signs, inhibition of body weight gain, reduced food consumption and kidney lesions. Parental toxicity was also observed at the 2000 ppm dose level with clinical signs and slightly reduced body weights and food consumption. Reproductive toxicity was exhibited at the 7500 ppm dose level with slightly reduced live litter sizes in the F_{2a} and F_{2b} litters.

Neonatal toxicity was evident at 7500 ppm with reduced pup body weights, reduced pup survival late in the lactation period, and an increased number of dead F_{1b} pups which had stomach or intestinal lesions and/or emaciation. Neonatal toxicity was also observed at 2000 ppm with slightly reduced pup body weights. The NOEL for parental toxicity was 150 ppm (9 mg/kg bw/d for males and 16 mg/kg bw/d for females). The NOEL for neonatal toxicity was 150 ppm (16 mg/kg bw/d). The NOEL for reproductive toxicity was 2000 ppm (115 mg/kg bw/d for males and 205 mg/kg bw/d for females).

Developmental Studies

Potential maternal and embryotoxic effects of forchlorfenuron were evaluated in a range-finding study in rats. Dosage levels of 0, 50, 125, 250, 500 and 1000 mg/kg bw/d were administered by gavage. Four adult rats died at 1000 mg/kg bw/d and one at 500 mg/kg bw/d and there were other signs of maternal toxicity at the higher dose. There was no evidence of embryotoxicity at the 50 to 500 mg/kg bw/d dose levels. Based on the results of this study, dosage levels of 0, 100, 200 and 400 mg/kg bw/d were selected for a definitive study.

Potential maternal, embryotoxic and teratogenic effects of forchlorfenuron were evaluated in a rat study with dose levels of 0, 100, 200 and 400 mg/kg bw/d administered by gavage. The test material produced clinical signs and effects on maternal body weight at 400 mg/kg bw/d. However there were no pathological changes at the scheduled necropsy of the dams. Mean foetal weight in the 400 mg/kg/day group was depressed, which was considered to be a secondary effect of maternal toxicity. Also, there was an increased incidence of foetuses with reduced ossification of ribs and sternebrae at 200 and 400 mg/kg bw/d, which was also considered to be a possible secondary effect of maternal toxicity. The pregnancy rate in this study was lower than optimal, and the author elected to repeat the study using the same dose levels, while noting that no evidence of teratogenicity was observed.

In the repeat study, potential maternal, embryotoxic and teratogenic effects of forchlorfenuron were evaluated in rats using dose levels of 0, 100, 200 and 400 mg/kg bw/d administered by gavage. Clinical signs were observed in the dams that were related to the test material at 200 and 400 mg/kg bw/d. Forchlorfenuron lowered maternal body weight gains statistically significantly at 400 mg/kg bw/d. There were no compound-related effects at the scheduled necropsy of the dams. Mean foetal body weight was decreased in the 400 mg/kg bw/d group, which was attributed to a secondary effect of maternal toxicity. The test material did not cause any foetal malformations. Retarded ossification of ribs and sternebrae was observed at 400 mg/kg bw/d. It was considered possible that such observations were a secondary effect resulting from maternal toxicity. Forchlorfenuron, therefore, exhibited maternal toxicity at 200 mg/kg bw/d, and was foetotoxic but not teratogenic at 400 mg/kg bw/d. The NOEL for maternal toxicity was 100 mg/kg bw/d and for foetotoxicity it was 200 mg/kg bw/d.

In a study designed to establish dose levels for a definitive teratology study in rabbits, forchlorfenuron was administered orally by gastric intubation to groups of mated New Zealand White rabbits once daily from gestation day 6 to 18. Dosage levels of 0, 50, 125, 250, 500 and 1000 mg/kg bw/d were employed. Two dams in the 500 mg/kg bw/d group and four in the 1000 mg/kg bw/d group were found dead. One animal in each of the 125 and 250 mg/kg bw/d dose groups aborted. Decreased urination and defaecation was observed in most animals at 125 mg/kg bw/d and above. The test material also caused body weight loss during treatment at these dose levels. The mean numbers of viable foetuses, early and late resorptions and implantation sites were not affected by treatment at the 50 and 125 mg/kg bw/d dose levels. However, postimplantation loss was increased at the 250 and 500 mg/kg bw/d dose levels due to dams with total litter resorption. Based on these results, dose levels of 25, 50 and 100 mg/kg bw/d were chosen for a definitive teratology study in rabbits.

Potential maternal, embryotoxic and teratogenic effects of forchlorfenuron were evaluated following oral administration to three groups of 18 artificially inseminated New Zealand White rabbits once daily from gestation days 6 to 18. Dosage levels of 0, 25, 50 and 100 mg/kg bw/d were employed. The test material did not affect the survival of the dams but there were indications of maternal toxicity especially at the higher doses (50 and 100 mg/kg bw/d). Forchlorfenuron administration was associated with depressed body weights. No effect of the compound was observed at the scheduled necropsy of the dams. The test material had no foetotoxic or teratogenic effects. Therefore the NOEL for foetotoxicity and teratogenicity was equal to or greater than 100 mg/kg bw/d. The NOEL for maternal toxicity was 25 mg/kg bw/d.

Genotoxicity Studies

Forchlorfenuron was not mutagenic or clastogenic in cultured mammalian cell assays, and did not induce DNA damage in rat liver cells *in vivo* or *in vitro*. Using bacterial test systems, forchlorfenuron gave a slight positive result in 1 of 5 tester strains in an early experiment, but was clearly negative for mutation in all 5 strains in more recent experiments.

PUBLIC HEALTH STANDARDS

Poisons Scheduling

The National Drugs and Poisons Schedule Committee (NDPSC) considered the toxicity of the active ingredient, forchlorfenuron.

On the basis of its low level of toxicity, the NDPSC has included forchlorfenuron in Appendix B of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate First Aid Instructions and Safety Directions on the product label.

NOEL/ADI

The Acceptable Daily Intake (ADI) is that quantity of an agricultural compound, which can safely be consumed on a daily basis for a lifetime and is based on the lowest NOEL obtained in the most sensitive species. This NOEL is then divided by a safety factor, which reflects the quality of the toxicological database and takes into account the variability in responses between species and individuals.

The lowest NOEL obtained in the toxicological studies was 7 mg/kg bw/d in the two-year dietary study in rats. The major endpoint was kidney toxicity and altered renal function. A safety factor of 100 is considered appropriate in view of the extensive database for forchlorfenuron. Therefore, an ADI of 0.07 mg/kg bw/d was established.

Acute Reference Dose (ARfD)

The acute reference dose (ARfD) is the maximum quantity of an agricultural or veterinary chemical that can safely be consumed as a single, isolated, event. The ARfD is derived from the lowest single or short term dose which causes no effect in the most sensitive species of experimental animal tested, together with a safety factor which reflects the quality of the toxicological database and takes into account the variability in responses between species and individuals.

The acute oral toxicity study with forchlorfenuron was conducted with relatively doses (>4000 mg/kg bw). In other oral toxicity studies, there were no adverse effects as a result of a single or a few doses of forchlorfenuron. Therefore, it is considered that the establishment of an ARfD is unnecessary.

METABOLISM AND TOXICOKINETICS ASSESSMENT

Metabolism
Metabolism studies were provided for target plants (grapes, apples and kiwi fruit) and laboratory animals (rats).

Metabolism in Plants: The mode of action of forchlorfenuron is non-systemic, with the results from metabolism studies in grape vines, apple trees and kiwi vines demonstrating that the active constituent does not undergo any significant degree of translocation.

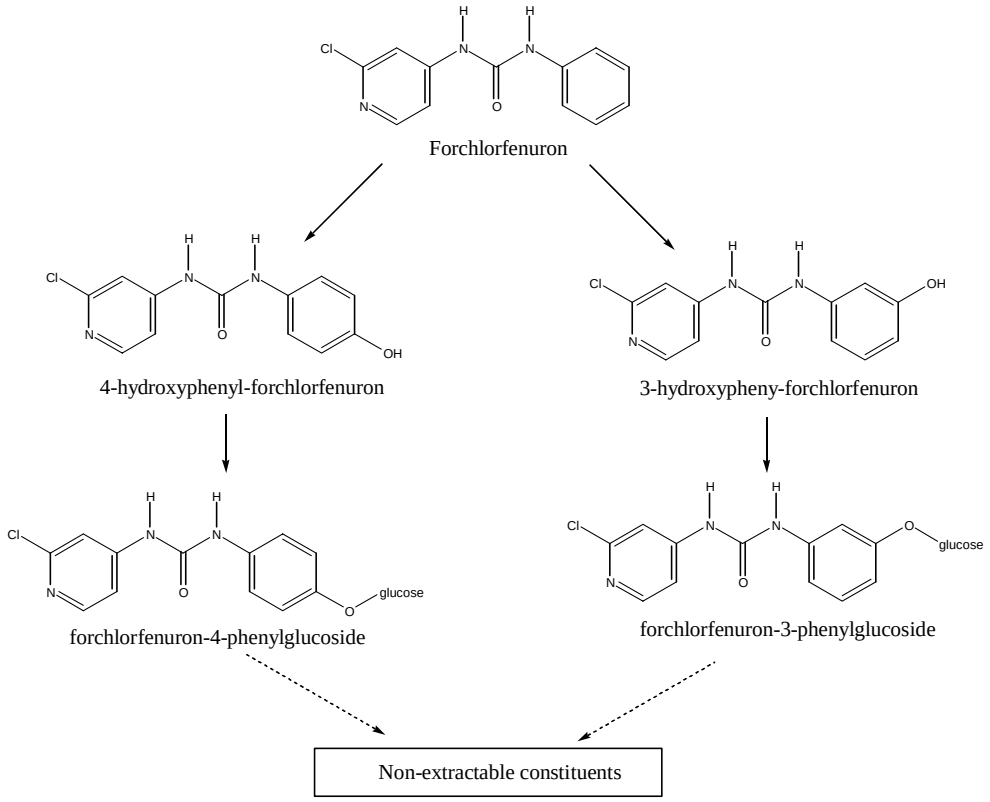
When grapevines were treated with a single application of 75 mg ^{14}C-forchlorfenuron/L, 85-92 % of the radioactive residues in leaves and berries at 0 or 1 day post treatment were able to be extracted using an organic solvent, with most of the radioactivity being identified as the parent forchlorfenuron. The applied radioactivity dissipated rapidly (half-life of ~2.5 days), with the levels of 3-hydroxyphenyl- and 4-hydroxyphenyl metabolites of forchlorfenuron increasing significantly during the first 4 days after treatment. Thereafter, the concentrations of forchlorfenuron and its metabolites declined steadily: the fraction of extractable radioactivity (comprising the parent compound plus metabolites with intact structures) decreased over time, while there was a concomitant increase in the levels of non-extractable radioactivity, which is indicative of the radioactivity being incorporated into plant tissues. At mature harvest (56 days after treatment), the level of radioactive residues in grapes declined from 0.57 mg equiv./kg to 0.04 mg equiv./kg, with 60 % of the terminal residues (0.025 mg equiv./kg) being non-extractable. The remaining extractable residues were composed of non-polar components (including forchlorfenuron and its metabolites with intact structures; 0.01 mg equiv./kg total) and more polar metabolites (0.004 mg equiv./kg) that were not identified owing to their very low concentrations.

When kiwi fruit vines were treated with a single application of 75 mg ^{14}C-forchlorfenuron/L, and mature fruit were harvested at 127 days after treatment, the radioactivity was primarily associated with the skin fraction of the kiwi fruit (2.45 mg equiv./kg), with residues in the fruit pulp being much lower (0.18 mg equiv./kg). Analysis of the extractable radioactive residues in kiwi fruit skin revealed that ~85 % of the residues were made up of the parent compound, indicating that the extent of metabolism of forchlorfenuron in the skin of treated fruit is minimal. In contrast, the forchlorfenuron that is absorbed into the pulp of the kiwi fruit undergoes a significant degree of metabolism, with only ~40 % of the extractable radioactive residues being identified as the parent forchlorfenuron. Characterisation of the extractable radioactive residues in kiwi (whole fruit) revealed that ~60 % of the radioactivity was associated with the parent compound, ~4 % was identified as the 3-hydroxyphenyl metabolite of forchlorfenuron, and the remainder was made up of a number of unidentified polar compounds, each of which comprised <5 % of the total extractable radioactive residues.

When apple trees were treated with a single application of 75 mg ^{14}C-forchlorfenuron/L, and mature fruit were harvested at 114 days after treatment, approximately 62 % of the radioactive residues were associated with the apple pulp (including skin) (0.029 mg equiv./kg), with the apple core fraction containing ~30 % of the radioactive residues (0.014 mg equiv./kg). Residues in apple juice were very low (0.004 mg equiv./kg) relative to the whole fruit. In the apple pulp and core fractions, the parent forchlorfenuron was the major residue component, comprising ~20 % of the extractable radioactivity in apple pulp, and ~46 % of the extractable radioactivity in apple cores. A number of minor metabolites were also detected in the different apple fractions, but none of these components made up more than 5 % of the extractable radioactivity.

Conclusion: Overall, the extent of absorption and metabolism of forchlorfenuron in grape vines and apple trees appears to be quantitatively higher than that observed in kiwi vines. However, on a qualitative basis, the routes of metabolism in the different plant species appear to be comparable (see figure below for the proposed metabolic pathway for forchlorfenuron in plants). On the basis of these metabolism studies, it is concluded that the residue definition for forchlorfenuron should be the parent compound, *per se*.

Metabolism of forchlorfenuron in plants



Metabolism in animals: When radiolabelled forchlorfenuron was orally administered to rats, it was rapidly and extensively (~100 %) absorbed from the gut of treated rats: 65-85 % of the absorbed dose was associated with urine, tissues and expired air. A further 20 % of the absorbed drug was secreted in the bile, and was eliminated via the faeces. Once absorbed, forchlorfenuron is rapidly eliminated from the body, with 44-70 % of the dose being excreted in urine within 48 hours of administration (estimated urinary half-life of 14 hours), and a further 13-28 % of the administered dose being recovered in faeces from treated rats within the same timeframe (estimated faecal half-life of 16 hours).

The metabolism of forchlorfenuron in rats primarily involves hydroxylation of the phenyl ring. Formation of the sulfate conjugate of hydroxyl-forchlorfenuron occurred rapidly, allowing for excretion in the urine. Hydroxy-forchlorfenuron was eliminated via the faeces. Additional hydroxylation and other modifications of the hydroxyl moieties (eg methylation, glucuronidation) also occurred, but to a limited extent. The metabolic pathways for forchlorfenuron mainly involved modifications of the phenyl ring, with only a limited amount of modification occurring at the chloropyridinyl ring.

Overall, <2 % of the orally administered dose was retained in the rat carcass at 7 days post-treatment. The levels of radioactivity in rat tissues at 7 days post-treatment with 100 mg ^{14}C-forchlorfenuron/kg bw were 0.1-0.8 mg equiv./kg in kidney, 0.2-1.2 mg equiv./kg in liver, and 0.03-0.45 mg equiv./kg in fat. Thus, the relative rank order of radioactive residues in rat tissues was: liver > kidney > fat. The composition of the tissue residues was not determined, owing to their relatively low levels.

Conclusion: A single metabolism study in rats is not considered adequate to elucidate the metabolic pathways for forchlorfenuron in target animals. However, given that table grapes are unlikely to be fed to animals at any significant levels, the limited number of metabolism studies is considered adequate.

Analytical methods

Details were provided for the validated analytical methods used to determine forchlorfenuron residues in grapes (berries). Briefly, the methodology involves extracting forchlorfenuron residues from homogenised fruit samples using methanol or methanol/water (1:1, v/v), followed by clean up using

liquid/liquid partitioning techniques. The forchlorfenuron content of the purified extracts is determined using a reverse phase HPLC method with UV detection at 265 nm. Residue concentrations are determined using an external standard calibration curve. The limit of quantitation (LOQ) for forchlorfenuron residues in grapes is 0.001 mg/kg. The method would be suitable for regulatory surveillance and monitoring purposes.

Storage stability
Data were provided to demonstrate that forchlorfenuron residues in fruit matrices (grapes) are stable for at least 24 months, when samples are stored frozen (<-10 ^{o}C).

Residue definition
The available metabolism data in plants (grapes, kiwifruit and apples) support a residue definition of parent compound *per se* for forchlorfenuron. Adequate analytical methodology was provided for the determination of forchlorfenuron residues in plant matrices. Therefore, the residue definition for forchlorfenuron will be set as the parent compound *per se*, for the purposes of dietary assessment and regulatory monitoring.

It is noted that there were insufficient metabolism data in animals to determine whether the parent compound is the appropriate residue definition for forchlorfenuron residues in animal commodities. This issue will need to be revisited if, in the future, it is intended that forchlorfenuron be registered for use in crop(s) that are significant animal feed commodities.

RESIDUES ASSESSMENT

Residue trials

Details were provided details of three Australian residues trials (two in Victoria and one in NSW) conducted using forchlorfenuron on table grapes. Additionally, details of two trials conducted in Southern Greece were provided, along with the summary results for 17 Chilean trials and 6 Japanese trials. In all trials, grapevines were treated with forchlorfenuron when the grape berries were 4-8 mm in diameter.

The results from Australian and overseas residues trials, where grapevines were treated with forchlorfenuron at 1-2.5× the maximum proposed Australian label rate, show that residues of forchlorfenuron in grapes at mature harvest are all below the limit of quantitation of the analytical methods. Indeed, in the majority of cases, residues were non-detectable (below the LOD). The "worst-case" residues scenario is considered to be the Chilean trial with the shortest period between application and harvest, where grapes were treated with forchlorfenuron at the 1× rate at 38 days before mature harvest: four of the five residue results were reported to be 0.005 mg/kg (ie below the LOQ of 0.01 mg/kg, but above the LOD of 0.001 mg/kg), and the fifth result was <0.001 mg/kg.

Based on the residue data provided with the submission, it is concluded that an MRL of *0.01 mg/kg (at or about the method LOQ) would adequately cover the occurrence of forchlorfenuron residues in table grapes. A harvest WHP of "Not required when used as directed" is also considered appropriate in relation to the application timing stated on the draft label.

Processing studies

The proposed use pattern for forchlorfenuron involves treatment of table grapes only. Table grapes are not typically processed into dried fruit, but are consumed as the fresh fruit. Consequently, consideration of forchlorfenuron residues in processed/dried fruit is unnecessary.

Animal feeds

As indicated above, the proposed use pattern for forchlorfenuron involves treatment of table grapes only, and table grapes are not typically processed. Therefore, neither the grapes themselves, nor grape pomace/processing by-products, are significant animal feed commodities. Consequently, there are no entries recommended for Table 4 of the *MRL Standard*.

Animal commodity MRLs

No animal transfer studies were provided in the registration package. However, as indicated above, table grapes are not a significant animal feed commodity. Therefore, no animal commodity MRLs are required for forchlorfenuron.

In the absence of any animal commodity MRLs, it is considered appropriate to set a grazing restraint for treated vineyards. Data from the metabolism studies with grapevines revealed that the applied radioactivity dissipated rapidly, with the half-life of forchlorfenuron in grape leaves and berries being conservatively estimated at 2.5 days. Assuming the dissipation of forchlorfenuron residues in non-target plants (exposed through overspray) parallels that in grapevines, then residues at 38 days post-treatment (ie the shortest period between application and harvest; equivalent to 15 half-lives) are likely to be non-detectable (<0.01 % of the original residue level). Thus, the following grazing restraint is considered appropriate:

> *DO NOT graze treated vineyards or cut treated areas for stockfeed until after completion of grape harvest.*

Bioaccumulation potential

Forchlorfenuron has an octanol/water partition coefficient (log P) of 3.3 at 20 ^{o}C (pH 4 to 10). The FAO Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed (FAO, Rome, 1997, p40) states that when the log P value exceeds 4, the compound would generally be designated as fat soluble. Under this definition, forchlorfenuron would not be considered fat soluble. This conclusion is supported by the results of the rat metabolism study, where the relative rank order of radioactive residues in rat tissues was: liver > kidney > fat.

Spray drift
Sitofex® 10 EC Plant Growth Regulator is not for aerial application. Additionally, the available data indicate that the potential for forchlorfenuron to bioaccumulate in animal tissues/fat is very low. Therefore, further consideration of the spray drift aspects of the current application is not warranted.

Estimated dietary intake
The chronic dietary intake (NEDI) risk for forchlorfenuron has been assessed. The ADI for forchlorfenuron has been set at 0.07 mg/kg body weight/day, based upon a NOEL of 7 mg/kg bodyweight/day, with a 100-fold safety factor. The NEDI for forchlorfenuron is equivalent to <0.1 % of the ADI. With respect to the acute dietary exposure (NESTI) estimate, the Office of Chemical safety (OCS) has determined that an Acute Reference Dose (ARfD) is not necessary for forchlorfenuron. It is concluded that the level of dietary exposure to forchlorfenuron residues in table grapes is acceptably low.

Recommendations
The following amendments to the *MRL Standard* are recommended in relation to the proposed use of *Sitofex® 10 EC Plant Growth Regulator*.

Table 1

Compound	Food		MRL (mg/kg)
ADD:			
Forchlorfenuron	FB 0269	Grapes	*0.01

Table 3

Compound	Residue
ADD:	
Forchlorfenuron	Forchlorfenuron

The following withholding periods are required in conjunction with the above MRLs:

WITHHOLDING PERIODS

HARVEST (grapes) NOT REQUIRED WHEN USED AS DIRECTED

GRAZING DO NOT GRAZE TREATED VINEYARDS OR CUT TREATED AREAS FOR STOCKFEED UNTIL AFTER COMPLETION OF GRAPE HARVEST

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Destination and value of exports

Total exports of table grapes in 2002/2003 were 39,752 tonnes valued at approximately $95.4 million (The Australian Horticultural Statistics Handbook, 2004). The five largest export markets for Australian table grapes in 2002/2003 are shown below:

Rank (by $ value)	Importing country	Volume, tonnes	Value, $AUS million
1	Hong Kong	15,055	36.4
2	Malaysia	6,273	14.4
3	Indonesia	5,842	13.0
4	Singapore	5,256	12.8
5	Thailand	2,241	6.2
Total	**--**	***39,752***	***95.4***

Comparison of Australian MRLs with Codex Alimentarius Commission (Codex) and overseas MRLs

To date, no Codex MRLs have been established for forchlorfenuron in any edible commodities. Similarly, MRLs/tolerances have not been set for forchlorfenuron in grapes by any of the major importing countries (Hong Kong, Malaysia, Indonesia, Singapore and Thailand). In contrast, the USA has set a tolerance of 0.03 mg/kg for forchlorfenuron in grapes; Israel has set an MRL of 0.01 mg/kg; and Spain has set an MRL of 0.05 mg/kg.

Potential risk to Australian export trade

It is concluded that the use of forchlorfenuron in the new product, *Sitofex® 10 EC Plant Growth Regulator*, would not constitute an undue risk to Australia's export trade in table grapes, since the levels of residues in grapes from treated vines are expected to be non-detectable (<0.01 mg/kg).

Label Statements - Export Trade Advice

In line with Part 5B of the Ag Requirements Series: *Overseas Trade Aspects of Residues in Food Commodities*, it is recommended that the following export trade advice statement be included on the product label:

EXPORT HARVEST INTERVAL (EHI): Not required when used as directed.

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Health hazards

Forchlorfenuron has low acute oral, dermal and inhalation toxicity in rats. It is non-irritating to rabbit skin and non-sensitising to guinea pig skin. Forchlorfenuron is a slight eye irritant in rabbits. Forchlorfenuron is not on the NOHSC Hazardous Substances Information System. Based on the submitted information, forchlorfenuron is not classified as a hazardous substance, in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances.*

Sitofex 10EC Plant Growth Regulator is an emulsifiable concentrate formulation. Sitofex 10EC Plant Growth Regulator is of low acute oral, dermal, and inhalation toxicity in rats. It is a moderate eye and skin irritant in rabbits. There is some evidence that it is a slight skin sensitiser. Sitofex 10EC Plant Growth Regulator is classified as a hazardous substance, in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances,* with risk phrases R36 and R38.

Formulation, packaging, transport, storage and retailing

The product will be formulated in Germany and imported as packaged for sale in 250 mL and 1 L high density polyethylene (HDPE) containers. Transport workers, store persons and retailers will handle the packaged product and could become contaminated if the packaging were breached.

Use and exposure

Sitofex 10EC Plant Growth Regulator is intended for increasing berry size in table grapes. Farmers and contract workers will use the product. Contract workers will be exposed to Sitofex 10EC Plant Growth Regulator repeatedly. The draft label recommends a maximum application rate of 100 mL/100 L (0.01% EUP; 0.001% forchlorfenuron). The product can be applied by using a knapsack as directed to spray the young fruit or bunches with a spray volume in the range of 500 L/ha (500 mL product/ha) or overall spray on the whole vines by means of a mist blower (air blast method) with a spray volume of around 1000 L/ha (1000 mL product/ha).

Workers may become contaminated with the product during mixing, loading, spraying, cleaning up spills, maintaining equipment and when entering treated areas. The main routes of exposure to the product will be dermal and inhalation, though ocular exposure may also occur. Workers may also be exposed to spray mist.

The main acute hazards associated with Sitofex 10EC Plant Growth Regulator are skin and eye irritation and also skin sensitisation. During application, the most concentrated spray will contain up to 0.01% product. At this concentration, the risk of skin and eye irritation and of skin sensitisation is low. Therefore, cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves, and face shield or goggles are recommended when opening the container and preparing spray to protect against skin irritation/sensitisation and eye irritation.

There were no worker exposure studies on forchlorfenuron or Sitofex 10EC Plant Growth Regulator available for assessment. Therefore, exposure models (UK Predictive Operator Exposure Model & the Pesticide Handler Exposure Database Surrogate Exposure Guide) were used to estimate repeated worker exposure to Sitofex 10EC Plant Growth Regulator during mixing/loading and application.

These estimates in conjunction with toxicology data demonstrated that the use of clothing, gloves, and face shield or goggles is required when opening the container and preparing spray.

Entry into treated areas

Workers entering treated areas can be exposed to product residues, photodegradates and degradation products during crop management activities.

Using the US Occupational Post-Application Risk Assessment Calculator (US Policy 003.1) and based on the toxicity profile and use pattern of Sitofex 10EC Plant Growth Regulator, OCS (OHS) concluded that workers re-entering treated areas will not be at risk. Therefore, OCS (OHS) does not recommend a re-entry statement.

Recommendations for safe use

Users should follow the instructions and Safety Directions on the product label. Safety Directions include the use of cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves, and face shield or goggles when opening the container and preparing spray.

Information provision

Material Safety Data Sheet (MSDS)

Degussa AG has produced a MSDS for Sitofex 10EC Plant Growth Regulator. This should contain information relevant to Australian workers, as outlined in the NOHSC National Code of Practice for the Preparation of MSDS. Employers should obtain the MSDS from the supplier and ensure that their employees have ready access to it.

Conclusion

The registration of forchlorfenuron in Sitofex 10EC Plant Growth Regulator at 10 g/L as an emulsifiable concentrate formulation, for use on table grapes, is supported on the grounds that the product when used according the proposed label instruction would not pose an undue hazard to the safety of people exposed to it during its handling.

Sitofex 10EC Plant Growth Regulator can be used safely if handled in accordance with the instructions on the product label and any other control measures described above. Additional information is available in the product MSDS.

ENVIRONMENTAL ASSESSMENT

Environmental fate summary

Forchlorfenuron, as Sitofex 10 EC, is to be used to increase the fruit size of table grapes with application either as a directed spray to the young fruit or bunches using a water based spray volume of 500 L/ha or as an overall spray on the whole vines by a mist blower (air blast spraying) with spray volumes of about 1000 L/ha. Application is as a fine mist with avoidance of runoff and formation of drip points on the grapes. The proposed use rate is 50 to 100 mL Sitofex 10 EC/100 L of water, equivalent to a maximum concentration of 10 g forchlorfenuron/1000 L or 10 g forchlorfenuron/ha. There is only one application per season.

Hydrolysis and photolysis

The vapour pressure and Henry's Law Constant of forchlorfenuron indicate that it is relatively non-volatile from dry or moist surfaces or from water but with its water solubility (39 mg/L) indicative of moderate solubility. Hydrolysis and aqueous photolysis have not been identified as significant degradation routes for forchlorfenuron in the environment. Forchlorfenuron on the surface of soils is unlikely to undergo significant degradation as a result of exposure to sunlight.

Aerobic and anaerobic soil metabolism

When ^{14}C radiolabelled forchlorfenuron was added to a sandy loam soil at nominal concentration of 10 μg forchlorfenuron/g soil and maintained under aerobic conditions, forchlorfenuron made up 55% of the initial measured dose after twelve months with no other identifiable residue found. Approximately 10% of the applied radioactivity was mineralized over the twelve months with bound residues making up 24% of the initial measured dose at that time. Forchlorfenuron was stable under laboratory conditions with an aerobic soil half-life of 578 days calculated based on first order degradation kinetics. The primary path of degradation was formation of bound but unchanged residues.

^{14}C-radiolabelled forchlorfenuron was added to a sandy loam soil at a nominal concentration of 10 μg forchlorfenuron/g soil and maintained initially under aerobic conditions for thirty days and then anaerobically, following flooding by water, for sixty days. Only a little degradation occurred under the aerobic conditions, with extractable residues comprising 91% of the initial measured ^{14}C dose after thirty days with 82% being forchlorfenuron. At that time thirteen percent of the initial measured ^{14}C dose was present as bound residues with one percent of the initial measured ^{14}C dose present as volatile residues. After sixty days under anaerobic conditions, 62% of the initial measured ^{14}C dose was extractable with forchlorfenuron making up 70% of this material. Bound residues had increased to 31%, and cumulative volatile residues to 1.5%, of the initial measured ^{14}C dose. First order degradation kinetics based on the concentrations of extracted parent gave a half-life of 347 days for forchlorfenuron in soil under aerobic conditions and of 226 days under anaerobic conditions. Degradation of the forchlorfenuron was considered to be mainly through formation of bound residues with low levels of mineralisation also occurring. While caution is required in interpreting the results because the half-lives calculated were longer than the length of the study, the data show that forchlorfenuron will be persistent in soils.

A literature report on the fate of forchlorfenuron on grapes and in soil stated that three soils fortified at 10 mg forchlorfenuron/kg and then maintained at either air dry or field capacity moisture levels for 60 days, had DT50s of 37 days (an organic carbon rich clay soil) to 121 days (a loamy sand soil) with air dried soils. In soils at field moisture capacity, the DT50s were much shorter, 15 (a clay) to 46 (a loamy sand soil) days. These values contrast to those reported previously but were carried out under poorly defined conditions.

Aerobic and anaerobic soil/water metabolism

Aerobic and anaerobic soil/water metabolism studies were not presented. However, the anaerobic soil study showed that forchlorfenuron could be expected to persist in anaerobic soil/water systems, being mainly associated with the sediment phases but with some desorption from the soil and movement into the water column possible.

Mobility in soils

In an adsorption/desorption study using radiolabelled forchlorfenuron and four soils (silt loam, clay, sandy loam and sand), the Kd(ads) determined ranged from 2.1 (sand) to 40 (clay), equivalent to Koc values of 852 to 3320. Kd(des) values ranged from 4.3 (sand) to 47 (clay), or as Koc values, 1708 to 3941. Forchlorfenuron was seen to be of low mobility in the silt loam, the sandy loam and the sand (Koc between 500 and 2000) and of slight mobility in the clay (Koc between 2000 and 5000). These values would also indicate that forchlorfenuron in waterbodies should adsorb to sediment rather than staying in the water column.

Field dissipation

No field dissipation or soil accumulation studies were presented. Modelling based on a single application per year and using the reported half-lives in aerobic and anaerobic soils of, respectively, 578 and 226 days, shows the maximum soil concentration (5 cm soil profile, soil density 1.4 g/cm^3) under a best case scenario is ~0.02 mg forchlorfenuron/kg soil and, for a worst case scenario, 0.04 mg forchlorfenuron/kg soil.

Bioconcentration

Experiments with juvenile bluegill sunfish indicated low bioconcentration potential with the Bioconcentration Factor in whole fish being 6.1 after 28 days. Residue concentrations decreased rapidly in the depuration phase, being non-quantifiable (<0.077 mg/kg) after three days.

Environmental toxicity summary

Effects on avian species

Forchlorfenuron was slightly toxic to bobwhite quail in a single oral dose acute study, with an LD50 estimated to be greater than 2250 mg/kg bw. The 5-day dietary studies in bobwhite quails and in mallard ducks similarly showed that forchlorfenuron was practically nontoxic to the test species, with LC_{50} values estimated to be greater than 5620 ppm in both cases.

Effects on aquatic organisms

Acute toxicity studies on bluegill sunfish (*Lepomis macrochirus*) and rainbow trout (*Oncorhynchus mykiss*) determined that forchlorfenuron is moderately toxic to fish, with 96 LC50s of 8.8 mg/L and 9.2 mg/L, respectively. One or more sublethal effects such as quiescence, dark colouration, erratic swimming, laboured respiration, and loss of equilibrium were observed at concentrations down to 2.6 mg/L in rainbow trout, therefore establishing a NOEC at 1.6 mg/L.

A chronic study in fish demonstrated a slight toxic effect of forchlorfenuron. Mortality in juvenile rainbow trout exposed to 5.0 mg/L forchlorfenuron over 28 days was 67%, when compared to fish in control treatments. Hypoactivity and discolouration were also observed in surviving fish exposed to 5.0 mg/L. Trout maintained at lower concentrations did not exhibit mortality or significantly reduced growth rates when compared to controls. Therefore, the 28 d NOEC was set at 2.0 mg/L.

Forchlorfenuron is considered moderately toxic to *Daphnia* according to a 48 h acute test, and very slightly toxic to *Daphnia* in a chronic test over 21 days. The 48 h EC50 was 8.0 mg/L (95% C.I. = 6.3-12 mg/L). Sublethal effects such immobilisation were noted at concentrations of 5.1 mg/L and therefore the 48 h NOEC was set at 2.9 mg/L. In a longer exposure over 21 days, most Daphnids died after 3 days of exposure to 5.0 mg/L forchlorfenuron, although survival was not significantly affected at other concentrations. The 21 d EC50 for parental survival was between 2 and 5 mg/L. The 21 d EC50 for reproduction (IC50) was >2mg/L. The 21 d LOEC was 5 mg/L, and the 21 d NOEC was 2 mg/L.

Cultures of the alga *Selenastrum capricornutum* were adversely affected by exposure to concentrations of 1.8 mg/L forchlorfenuron and above. A 23% reduction in growth was observed in cultures exposed to 3.2 mg/L forchlorfenuron. The 72 h EbC50 was estimated to be 3.3 mg/L for growth inhibition, and a 72 h ErC50 of 5.3 mg/L was calculated for growth rate reduction. Forchlorfenuron is therefore moderately toxic to algae. The NOEC was 1.0 mg/L.

The active constituent will not be used directly in the environment. Instead, the formulated product, Sitofex, will be used to increase fruit size of grapes. Sitofex contains forchlorfenuron at a concentration of approximately 1%. The studies that have directly tested the toxicity of Sitofex on aquatic organisms are summarised below.

The 96 h LC50 for rainbow trout exposed to Sitofex was calculated to be 160 mg/L. Sublethal effects such as hypoactive swimming were noted at concentrations of 100 mg/L Sitofex. Therefore, the NOEL was given as 63 mg/L. Accordingly, Sitofex is considered practically nontoxic to fish but on an active constituent basis, the 96 h LC50 = 1.6 mg/L, assuming no effect of other constituents, and is rated as moderately toxic.

A static test in which *Daphnia magna* were exposed to Sitofex over 48 hours estimated that the 48 h LC_{50} was 348 mg/L. Acute immobilization was noted at concentrations of 320 mg/L and therefore the 48 h NOEC was set at 180 mg/L. Sitofex is therefore practically nontoxic to Daphnia. However, on an active constituent basis, the 48 h LC50 = 3.5 mg/L, assuming no effect of other constituents, and rated as moderately toxic.

The formulated product, Sitofex, is classified as harmful to algae. When *S. capricornutum* cultures were exposed to Sitofex, the 96 h EbC50 was estimated to be 27 mg/L (growth inhibition), the ErC50 was estimated to be 74 mg/L (growth rate reduction) and the NOEC was 5.6 mg/L. Sitofex itself is therefore slightly toxic to algae. Because this value is for Sitofex, which contains the active constituent at a concentration of 1%, the 96 h EbC50 for forchlorfenuron would be 0.27 mg/L for growth inhibition. Accordingly, forchlorfenuron would be classified as highly toxic to algae.

Effects on terrestrial beneficial invertebrates

Forchlorfenuron was found to be slightly toxic to honeybees in an acute contact test. There was 4% mortality in newly emergent honeybees (*Apis mellifera*) exposed to 25 μg/bee forchlorfenuron over 2 days, comparable to that evident in bees exposed to control treatments. The authors estimated the LD_{50} to be greater than 25 μg/bee, the highest dose tested, while the NOEC was set at 25 μg/bee.

Similarly, another study that investigated the effect of forchlorfenuron on adult honeybees in contact, respiration, and feeding tests, found no mortalities of bees according to treatment over 24 hours. Therefore, the LD_{50} was considered to be greater than 100 μg/bee, the highest concentration tested in the feeding trial. However, this was a non-standard test and was not used in the risk assessment.

Forchlorfenuron was not toxic to earthworms (*Eisenia fetida)* over 14 days, when maintained in artificial soil. Because no mortality occurred in treatments ranging from 75-1000 mg forchlorfenuron/kg artificial soil, an LD_{50} could not be calculated. Although there was a trend for decreased body weights at higher concentrations, this was not statistically significant. The authors concluded that the NOEC was greater than 1000 mg/kg artificial soil. Reproduction and growth of earthworms were also measured over 8 weeks of exposure to very low levels of forchlorfenuron. No adverse effects were noted according to treatment and therefore the 8-week NOEC was estimated to be 0.3 mg/kg dry artificial soil, the highest concentration tested.

The toxicity of the formulated product, Sitofex, containing forchlorfenuron at a concentration of approximately 1%, was also tested on several beneficial insect species. At field rates of 30 g forchlorfenuron/ha, the effects of Sitofex overall were found to be minimal. The proposed rate for the Australian product is 100 mL/100 L at 1000 L water/ha. Therefore, the proposed Australian rate is approximately 10 g forchlorfenuron/ha.

Survivorship of larval lacewing *Chrysoperla carnea* Steph was unaffected by exposure to residues of Sitofex at field application rates. However, mean larval hatching rate of eggs laid by females reared in the presence of Sitofex was significantly less than hatching rate of eggs laid by female in control treatments. Taking both survivorship and reproduction into account, the reduction in beneficial capacity caused by exposure to Sitofex was calculated to be 15%. Therefore, Sitofex was classified as harmless to *C. carnea*.

Sitofex had little effect on mortality and food consumption in the wolf spider *Paradosa* spec. (*Araneae, Lycosidae*) when tested over two weeks. Similarly, survival of parasitic wasps *Aphidius rhopalosiphi* was found to be unaffected by exposure to Sitofex at field rates, as was their ability to parasitise aphids.

However, residues of Sitofex, when applied to glass plates at field application rates, were found to be slightly harmful to predatory mites, *Typhlodromus pyri*, by causing a 36% reduction in beneficial

capacity over two weeks. The reduction was predominantly driven by a reduction in reproductive output after exposure to Sitofex.

Forchlorfenuron at concentrations of 0.04 and 0.2 mg/kg soil dry weight was found to have little effect on the activity of soil microflora when tested over 56 days. There were statistically significant differences in respiration rates in soils treated with forchlorfenuron from control soils. Nevertheless, because the deviation between the control soil and that treated with forchlorfenuron did not exceed 25% on any day tested, the impact of forchlorfenuron on soil microflora is considered negligible.

While no terrestrial phytotoxicity studies were presented, a US EPA report on forchlorfenuron noted that 62 g forchlorfenuron/ha (~6X the proposed Australian rate) applied to ten terrestrial plant species resulted in 0 to 17% inhibition of seed emergence.

Environmental risk summary

- **Birds and mammals**

Exposure at the time of application could occur by birds and mammals eating contaminated insects, weeds, seeds, etc. in the treated vineyards and adjacent areas. Estimated concentrations resulting in a diet exclusively based on feed contaminated to this extent are ~1 ppm for quail (assuming a diet of 30% small insects and 70% grain), ~0.39 ppm for mallard duck and 1 ppm for rats. These worst case concentrations are well below (Risk Quotient Q<0.1) the 5-day dietary LC50 values for the two bird species and the calculated dietary LC50 for the rat. Consequently, forchlorfenuron used in accordance with label recommendations is not likely to present an acute or dietary risk to birds, or based on the toxicity data for the rat, to mammals from ingestion of forchlorfenuron residues.

- **Aquatic organisms**

Contamination of a shallow (15 cm deep), static waterbody with direct overspray at the maximum application rate of 10 g forchlorfenuron/ha is calculated to give a notional concentration in the water of 6.7 µg/L, which presents an acceptable risk to fish, aquatic invertebrates, algae and duckweed. Consequently, a downwind buffer distance is not indicated as necessary and aquatic species should be adequately protected from spray drift arising from the ground application provided the draft label's requirements that strategies to minimise spray drift are employed and application is not made under conditions likely to result in spraydrift onto waterbodies. Based on rainbow trout and daphnid studies and the low application rates, chronic toxicity is unlikely to be of risk to aquatic species even though there may be some persistence in the water column and sediment. Modelling of runoff of forchlorfenuron indicated that risk to aquatic species would be acceptable.

- **Risk to non-target invertebrates and micro-organisms**

The data package provided in support of the use of Sitofex on table grapes showed that Sitofex exposure was unlikely to have significant adverse effects on beneficial insects such as the wolf spider, lacewing and the parasitic wasp. Sitofex was slightly harmful to the predatory mite, *Typhlodromus pyri*, causing reduced reproduction. *T. pyri* is a predator of spider mites in grapes. Therefore, the proposed use of Sitofex may lead to adverse effects on this beneficial species, particularly as this mite has a very low dispersal tendency. However, given that the study tested effects at application rates of 30 g forchlorfenuron/ha, which is 3 times the rate currently proposed for the Australian product, the risk is currently considered acceptable for the aforementioned classes of beneficial insects.

- **Native vegetation**

Although no plant phytotoxicity studies were presented, an estimate of risk was made based on a reported EC25 value for seedling emergence. This showed risk was acceptable with respect to this parameter. Because of the proposed use on grapes and the knowledge that use on kiwifruit, apples, pears, almonds etc. has been considered, phytotoxicity to native vegetation would not be expected.

Conclusion

DEH has considered the available data with attention given to the potential risk to avian, aquatic and beneficial species and also to plant phytotoxicity. The label instructions with respect to spraying so that drift and runoff from the treated grapes are minimised and avoiding spraying when rain is expected, plus the single application at the low maximum use rate of 10 g forchlorfenuron/ha, results in the conclusion that use of Sitofex 10 EC Plant Growth Regulator in accordance with the recommendations for its use would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

EFFICACY AND SAFETY ASSESSMENT

Justification for use:

For a number of tablegrape varieties, and in particular seedless varieties, it is necessary to achieve larger berry size to meet the customer specifications, and to achieve premium returns. Sitofex 10 EC is a plant growth regulator that has been found to be effective in increasing berry size of seedless varieties of tablegrapes that are known not to respond to applications of gibberellic acid. Berry size of seedless tablegrapes is generally increased by a number of gibberellic acid (GA) at the times of flowering and fruit set. With some cultivars this may have a deleterious effect on bud initiation for the following year, and on post harvest berry shatter. It has been found that a similar increase in berry size can be achieved with a single application of forchlofenuron to Thompson Seedless, which is the predominant seedless variety.

Degussa AG, a company based in Trostberg, Germany, has supplied information on the use of Sitofex® 10 EC Plant Growth Regulator in 6 trials in tablegrape vines, in Victoria. The varieties include Red Globe, Menindee Seedless and Thompson Seedless. Trials have also been conducted in South Australia and in other countries. The 5 trials vine trials in Victoria and New South Wales were conducted by Degussa AG, in collaboration with Agchem Pty Ltd and Chemicare Consulting & Training Services.

The information supplied justifies the use of Sitofex® 10 EC Plant Growth Regulator for various tablegrape varieties, including Thompson Seedless, Menindee Seedless and Red Globe.

The availability of this product will provide significant potential benefits to Australian tablegrape growers. This is because when the product is registered growers will have a management tool available to improve the consumer-desired qualities in their marketed produce. Also, Australian growers will be able to compete more effectively in the marketplace with other tablegrape produce that is imported from countries where forchlorfenuron is registered. These additional potential benefits provide further justification for registration of the product.

Adequacy of data as it relates to:

Trial design:

Adequate data are supplied regarding trial design, number of replicates and treatments applied in each case. Of the six trials, one was of a split block design, one was an exploratory trial and four were of a randomised block design.. The chemical was applied in liquid form by standard vineyard spray equipment. All trials included appropriate controls.

Experimental conditions:

Adequate data are supplied with regard to experimental conditions, particularly in terms of application timing and the inclusion of standard growth regulator treatments of gibberellic acid. Timing of growth regulators to vines is critical to ensure favourable results and this is supported by the data provided for each trial.

Analysis and interpretation of data:

The interpretation and analysis of the data for the various trials which included the table grape varieties, Menindee Seedless, Thompson Seedless and Red Globe is adequate. The individual trials were conducted between 1991 - 1992 and 2003 – 2004. The assessments for each of the trials were carried out individually including the conclusions. In all cases the analysis and interpretation of the trial data is adequate to support the conclusions in the application.

Trial validation:

All trials provide relevant information regarding the person/s responsible for conducting the trials, as well as the location and dates. All tablegrape variety trials were conducted between 1991 and 2004 and are relevant to this application.

Applicability of trial data to use under commercial conditions:

All trials were conducted under commercial situations. The trial data presented is most applicable to the use of Sitofex 10 EC under commercial conditions. The treatment application in all cases was by the use of commercial vineyard spray application equipment.

Claims

Data supporting claims

The efficacy data presented supports the use of Sitofex 10 EC for the specified tablegrape varieties. The data supports claims that when applied alone in individual trials when berry size ranged between 4 mm and 8 mm in diameter had no effect on berry size, weight or maturity. The data also supports the claims that when Sitofex 10 EC is applied in combination with GA there was a further increase in berry size, berry weight, bunches per vine and yield per vine. However, there was a slight delay in maturity.

Wording of claim:

The general wording of the claims is acceptable and complies with ongoing industry standards for the culturing programs for tablegrapes. The data clearly shows the effects with Sitofex 10 EC when used alone and when used in conjunction with gibberellic acid products. Highly professional persons who have developed high levels of skills and background with vineyard production conducted all trials. The data presented, and in the style in which it was presented supports the wording of the claim.

Directions for use

It is considered that adequate information is provided for the directions for use of Sitofex 10 EC for application on Thompson Seedless, Red Globe and Menindee Seedless tablegrapes. The general instructions clearly define the product, along with the application rates and application timing for best results.

Safety to target and non-target species

Sufficient information is provided in relation to safety to target and non-target species. When Sitofex 10 EC is used in accordance with the proposed label directions, phytotoxicity is very unlikely for the target crop. If spray drift was directed toward non-target crops, the only effect would be to increase fruit size and / or weight for the non-target crop. Therefore there would be no issues with safety to non-target crops.

Compatibility with good agricultural practice

The evidence provided with the data in the application, along with the background and purpose for use of Sitofex 10 EC adequately addresses the residue issues. It is also considered that there are no other issues of incompatibility in relation to standard agricultural practice.

Conclusions

This application contains much evidence as to the efficacy of Sitofex 10 EC in increasing berry size and berry weight of grapes when used in combination with gibberellic acid during the early stages of grape berry sizing. The trial results were summarised adequately, particularly with the trials conducted in the Sunraysia district.

Data compiled in the tables in each case was easy to follow and interpret.

Current trends with the tablegrape industry, particularly with regard to customer specification requirements provide an ever-increasing need to produce larger berried grapes with increased shelf life. There is a need for the registration of such products, as Sitofex 10 EC, which will assist the industry in achieving the required specifications. The industry must continue to explore the use of such products to improve the position in the global market.

The information provided in this application gives substantial evidence to justify the use of Sitofex 10 EC in the situations described. It is therefore recommended that the submission for registration of this product be accepted on the grounds that the product can be effective when used in accordance with the proposed label instructions.

LABELLING: The proposed product label follows:

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Sitofex® 10 EC

Plant Growth Regulator

ACTIVE CONSTITUENT: 10 g/L FORCHLORFENURON

For Increasing Berry Size
in Table Grapes

IMPORTANT: READ THE ATTACHED
BOOKLET BEFORE USE

250 mL, 1L

Manufactured by:
DEGUSSA AG
Dr.-Albert-Frank Strasse 32
83308 Trostberg
GERMANY

Distributed by:
Maliky Distributors (Mildura) Pty Ltd
P O Box 1199, Mildura Vic 3502
Lot 2 Melaleuca Street, Buronga NSW 2739
FF: 1800 815 503 T: (03) 5021 3303
E: maliky@bigpond.com
www.maliky.com.au

APVMA Approval No. 58566/250/ , 58566/1/

® Registered trademark of Degussa AG

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

DO NOT contaminate streams, rivers or waterways with the chemical or used containers.

STORAGE AND DISPOSAL

FLAMMABLE – Keep away from flames and heat.

Store in the closed, original container in a cool (below 20^0C), dry place out of the reach of children. Do not store in direct sunlight.

Triple or preferably pressure rinse containers 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

Will irritate the eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin.

If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use.

When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves and face shield or goggles.

After each day's use, wash gloves, face shield or goggles and contaminated clothing.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

MATERIAL SAFETY DATA SHEET

For additional information, refer to MSDS.

CONDITIONS OF SALE

Although this remedy has been extensively tested under a large variety of conditions, the registration holder does not warrant that it will be efficacious under all conditions because the action and effect thereof may be affected by factors such as abnormal climatic and storage conditions; quality of dilution water; compatibility with other substances not indicated on the label as well as by the method, time and accuracy of application. The registration holder furthermore does not accept responsibility for damage to crops, vegetation, the environment or harm to man or animal or for lack of performance of the remedy concerned due to failure of the user to follow the label instructions or to the occurrence of conditions which could not have been foreseen in terms of registration. Consult the supplier or registration holder in the event of any uncertainty.

FLAMMABLE
LIQUID
3

UN No. 1170
ETHANOL SOLUTION
(ETHYL ALCOHOL SOLUTION)
PG II

In a transport emergency dial 000, Police or Fire Brigade.

DOM
Batch No.

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Sitofex® 10 EC

Plant Growth Regulator

ACTIVE CONSTITUENT: 10 g/L FORCHLORFENURON

For Increasing Berry Size
in Table Grapes

This booklet is part of the label.
Read before use.

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www.maliky.com.au

APVMA Approval No. 58566/

DIRECTIONS FOR USE

RESTRAINT: DO NOT apply by air.

CROP	RATE	CRITICAL COMMENTS
TABLE GRAPES Thompson Seedless Menindee Seedless Red Globe	50 - 100 mL per 100 L water	Apply at 4 to 6 mm berry size.

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

WITHHOLDING PERIOD:

HARVEST (GRAPES): NOT REQUIRED WHEN USED AS DIRECTED.

GRAZING: DO NOT GRAZE TREATED VINEYARDS OR CUT TREATED AREAS FOR STOCKFEED UNTIL AFTER COMPLETION OF GRAPE HARVEST.

EXPORT HARVEST INTERVAL (EHI): NOT REQUIRED WHEN USED AS DIRECTED.

GENERAL INSTRUCTIONS

SITOFEX is a very active plant growth regulator (phenylurea type cytokinin) that increases fruit size of table grapes. As the active ingredient forchlorfenuron acts through increasing cell number and cell size by exhibiting direct influence on the fruit and as forchlorfenuron is not translocated in plant tissue (e.g. from treated leaves to fruit), it is sufficient to spray only the fruit by direct application. Directed spray to the young fruitlets and airblast spraying to fruitlets and leaves are equivalent with respect to efficacy.

SITOFEX increases berry size in table grapes when sprayed onto the small berries when they have reached 4 - 6 mm diameter. Higher rates of SITOFEX may change berry shape to a more spherical form.

Gibberellic Acid

Good berry thinning is essential when using SITOFEX. Therefore, gibberellic acid (GA3) thinning sprays should be done at full rates. Optimum berry size is obtained when using SITOFEX in addition to a standard GA3 programme.

Mixing

Thoroughly clean out spray container with clean water. Use correct measuring device and do not mix more than is needed. To prevent foaming and ensure adequate mixing, add part of water to spray tank, then product, mix and add remaining water. Agitate whilst mixing and applying.

Compatibility

SITOFEX is not compatible with insecticides, fungicides, herbicides, surfactants or other adjuvants and should therefore not be used in tank mixtures with these products. SITOFEX can be used in a tankmix with gibberellic acid.

Application

SITOFEX can be applied as:

- Directed spray to the young fruit or bunches, with spray volumes in the range of 500 L/ha (single fruit treatment). Spray volume depends on crop load, spray equipment used, nozzle type and spray pressure. Bunches have to be thoroughly wetted. Formation of drip points must be avoided.

- Overall spray on the whole vines by means of a mist blower, etc (eg, air blast spraying), with spray volumes of around 1,000 L/ha depending on vine height, spacing of vines and equipment used (nozzle type and size etc.).

Apply as a fine mist. Complete coverage of the fruit is essential and all bunches have to be wetted thoroughly. Apply at a volume of between 500 and 1,000 L water per hectare on established vines. Use proportionally less on younger vines. The required water volume may be determined by applying different test volumes, using different settings on the sprayer, from industry guidelines or expert advice.

The required spray volume will change and the sprayer set up and operation may also need to be changed as the crop grows.

Avoid run-off and formation of drip-points, which may lead to unwanted marks/rings on the berry skin. Apply preferably during the morning or late afternoon hours. Avoid the midday heat. Avoid spraying if rain is expected.

As SITOFEX is not systemic and applications are made some weeks before new bud formation occurs, SITOFEX cannot directly influence crop load in the following year. However, with the use of SITOFEX, the productive requirements of the treated plants are increased. For this reason, it is important to adjust fruit load, nutritional state and water balance of the plants accordingly.

Apply SITOFEX **after** termination of post bloom shatter period as otherwise SITOFEX may increase fruit set.

PROTECTION OF CROPS, NATIVE AND OTHER NON-TARGET PLANTS

DO NOT apply under weather conditions, or from spraying equipment, that may cause spray to drift onto nearby susceptible plants/crops, cropping lands or pastures.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

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STORAGE AND DISPOSAL

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In a transport emergency dial 000, Police or Fire Brigade.

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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.
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.

References

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National Registration Authority for Agricultural and Veterinary Chemicals 2001, *Ag Labelling Code—Code of Practice for Labelling Agricultural Chemical Products*, APVMA, Canberra. (See footnote below)

Footnote:
Updated versions of these documents are available on the APVMA website http://www.apvma.gov.au.

APVMA PUBLICATIONS ORDER FORM

To receive a copy of the full technical report for the evaluation of forchlorfenuron in the product Sitofex 10 EC Plant Growth Regulator, please fill in this form and send it, along with payment of $30 to:

David Hutchison
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
Kingston ACT 2604

Name (Mr, Mrs, Ms, Dr)_____

Position _____

Company/organisation _____

Address _____

Contact phone number (___) _____

I enclose payment by cheque, money order or credit card for $_____

Make cheques payable to 'Australian Pesticides and Veterinary Medicines Authority'.

___ Bankcard ___ Visa ___ Mastercard

Card number _____/_____/_____/_____ Expiry date ...../...../.....

Signature_____ Date _____