Australian Government

Australian Pesticides and Veterinary Medicines Authority

Public Release Summary

on the evaluation of the new active folpet in the product Folpan 800 WG Fungicide

APVMA product number 93909

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This publication is available from the APVMA website.

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator responsible for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia. Before approving an active constituent and/or registering a product, the APVMA must be satisfied that the statutory criteria, including the safety, efficacy, trade, and labelling criteria, have been met. The information and technical data required by the APVMA to assess the statutory criteria of new chemical products, and the methods of assessment, must be consistent with accepted scientific principles and processes. Details are outlined on the APVMA website.

The APVMA has a policy of encouraging transparency in its activities and seeking community involvement in decision making. Part of that process is the publication of Public Release Summaries for products containing new active constituents. This Public Release Summary is intended as a brief overview of the assessment that has been conducted by the APVMA and of the specialist advice received from advisory agencies, including other Australian Government agencies and State departments of primary industries. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience to encourage public comment.

About this document

This Public Release Summary indicates that the APVMA is considering an application for registration of an agricultural or veterinary chemical. It provides a summary of the APVMA's assessment, which may include details of:

- the toxicology of both the active constituent and product
- the residues and trade assessment
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- efficacy and target crop or animal safety.

Comment is sought from interested stakeholders on the information contained within this document.

Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of Folpan 800 WG Fungicide should be granted. Submissions should relate only to matters that the APVMA is required, by legislation, to take into account in deciding whether to grant the application. These matters include aspects of public health, occupational health and safety, chemistry and manufacture, residues in food, environmental safety, trade, and efficacy and target crop or animal safety. Submissions should state the grounds on which they are based. Comments received that address issues outside the relevant matters cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 24 March 2026 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- a contact name
- the company or organisation name (if relevant)
- an email or postal address (if available)
- the date you made the submission.

Please note: submissions will be published on the APVMA website unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Case Management Team – Pesticides
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Phone: +61 2 6770 2300
Email: casemanagement@apvma.gov.au.

Further information

Further information can be obtained via the contact details provided above.

Copies of technical evaluation reports covering chemistry, efficacy and safety, toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the APVMA on request.

Further information on Public Release Summaries can be found on the APVMA website.

Introduction

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of the product Folpan 800 WG Fungicide, and approval of the new active constituent folpet.

Applicant

ADAMA Australia Pty. Limited

Purpose of application

ADAMA has applied to the APVMA for registration of the new product Folpan 800 WG Fungicide, containing 800 g/kg of the new active constituent folpet, as a water dispersible granule formulation.

Proposed claims and use pattern

The proposed product is for use as a preventative treatment for control of downy mildew, grey mould and powdery mildew in Grapes.

Mode of action

Folpet has a multi-site mode of action and is classified as a Group M4 fungicide, belonging to the class phthalimides.

Overseas registrations

Folpet is not a new active, being previously registered in Australia and is registered as both 800 g/kg WG and 500 g/L SC formulation in New Zealand, Canada, China, Japan and Europe.

Chemistry and manufacture

Active constituent

The active constituent folpet is manufactured overseas. Details of the chemical name, structure, and physicochemical properties of folpet are listed below (Tables 1 to 2).

Table 1: Nomenclature and structural formula of the active constituent folpet

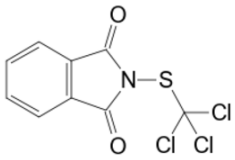
Common name (ISO):	Folpet
IUPAC name:	2-[(trichloromethyl)sulfanyl]-1*H*-isoindole-1,3(2*H*)-dione
CAS registry number:	133-07-3
Molecular formula:	$C_9H_4Cl_3NO_2S$
Molecular weight:	296.6 g/mol
Structural formula:	

Table 2: Key physicochemical properties of the active constituent folpet

<table>
<tr><td>Physical form:</td><td>Crystalline solid (Technical active - 95.7% purity, and purified active – 98.8% purity)</td></tr>
<tr><td>Colour:</td><td>Off white (Technical active - 95.7% purity), white (technical active - 98.8% purity)</td></tr>
<tr><td>Odour:</td><td>Faint-characteristic odour (Technical active - 95.7% purity)</td></tr>
<tr><td>Melting point:</td><td>179 – 180 °C (PAI- 99.6% purity)</td></tr>
<tr><td>Boiling point:</td><td>Not determinable, as test substance decomposes soon after melting</td></tr>
<tr><td>Vapour pressure, volatility</td><td>
<table>
<tr><td>EEC A.4</td><td>98.3%</td><td>Vapour pressure:
$p = 7.6 \times 10^{-6}$ Pa (20 °C)
$p = 1.5 \times 10^{-5}$ Pa (25 °C)
$p = 3.8 \times 10^{-4}$ Pa (50 °C)</td></tr>
<tr><td>USEPA 63-9</td><td>Not specified</td><td>$p = 2.1 \times 10^{-6}$ Pa (20 °C)
$p = 9.7 \times 10^{-5}$ Pa (35 °C)
$p = 4.5 \times 10^{-4}$ Pa (45 °C)</td></tr>
<tr><td></td><td></td><td>Henry's Law Constant: $H = 5.6 \times 10^{-3}$ $Pa.m^3mol^{-1}$
Calculated from vapour pressure: 1.5×10^{-5} at 25 °C;
solubility in water: 0.8 mg/L at 25 °C)</td></tr>
</table>
</td></tr>
<tr><td>Safety properties (technical active 96.0% purity):
Flammability and self -heating:
Explosive properties:
Oxidising properties:</td><td>
Not flammable; Does not self-ignite prior to melting.
Not explosive.
Not oxidizing</td></tr>
<tr><td>Solubility in water:</td><td>Solubility: (Technical active - 98.8% purity)
0.80 mg/L at 25 °C.
0.50 mg/L at 15 °C (pH 6.4).
after 28 h: max of 0.80 ppm folpet found.
after 49 h: max of 0.59 ppm folpet found.
Folpet decomposes in water.</td></tr>
<tr><td>Organic solvent solubility:</td><td>Results were determined at 25 °C (± 0.5 °C). (Technical active - 98.8% purity)
<table>
<tr><th>Solvent</th><th>Solubility [g/L]</th></tr>
<tr><td>Toluene</td><td>26.3</td></tr>
<tr><td>Carbon tetrachloride</td><td>6</td></tr>
<tr><td>Acetonitrile</td><td>19</td></tr>
<tr><td>methanol</td><td>3.1</td></tr>
<tr><td>acetone</td><td>34</td></tr>
<tr><td>n-octanol</td><td>1.4</td></tr>
<tr><td>Heptane</td><td>0.45</td></tr>
</table>
</td></tr>
</table>

Dissociation constant (PK_a):	Folpet is unlikely to dissociate in water because it does not contain protons that will dissociate at relevant pHs.
Octanol/water partition coefficient (Log K_{ow}/K_{OW}):	Partition coefficient at 25°C, (Technical active - 98.8% purity): 1279 (SD = 91, % SD = 7.1)
Spectra (UV/VIS, IR, NMR, MS):	molar extinction coefficients ε of folpet at different pH (max absorption). Neutral pH: 223.0 nm; ε [L/mol/cm]: 49 274.19 Acidic pH: 223.0 nm; ε [L/mol/cm]: 50 357.14 Alkaline pH: 222.5 nm; ε [L/mol/cm]: 19 060.40 The structure of folpet was determined by UV, IR, NMR and MS spectroscopic methods. These spectra and chromatograms are in accordance with the proposed structure.

Formulated product

The product *Folpan 800WG Fungicide* will be manufactured both in Australia and overseas. Tables 3 and 4 outline some key aspects of the formulation and physicochemical properties of the product.

Table 3: Key aspects of the formulation of the product Folpan 800WG Fungicide

Distinguishing name:	Folpan 800WG Fungicide
Formulation type:	Water Dispersible Granules (WG)
Active constituent concentration:	800 g/kg of folpet

Table 4: Physicochemical properties of the product Folpan 800WG Fungicide

Physical form:	Beige granules with a slight aromatic smell
PH:	pH 9.26 (1% aqueous suspension)
Relative density and bulk density:	pour density before compaction: 0.61 g/mL tap density after compaction: 0.68 g/mL
Stability of aqueous solution/dispersion:	stable at 0.15% (0.12% active ingredient in tap water up to 36 hours was found to be stable under the test conditions.
Safety properties:	Not explosive, no oxidizing properties and auto-ignition was not observed up to a maximum test temp of 402 °C.
Storage stability:	The active content and all of the physico-chemical properties of the formulation remained within product specification after storage at accelerated stability testing conditions. The product is expected to remain within the specifications for at least two (2) years when stored under normal conditions.

Recommendations

The APVMA Chemistry section has evaluated the chemistry of the active constituent folpet and associated product *Folpan 800WG Fungicide* including the manufacturing process, quality control procedures, physico-chemical properties, stability, batch analysis results and analytical methods, and found them to be acceptable. The available storage stability data indicate that the formulated product is expected to remain stable for at least two years when stored under normal conditions.

Based on a review of the chemistry and manufacturing details, the registration of *Folpan 800WG Fungicide*, and approval of the active constituent folpet are supported from a chemistry perspective.

Toxicological assessment

The submitted toxicological and toxicokinetics database for folpet was considered adequate to determine its toxicological hazard profile; acute toxicity, short-term, sub-chronic and chronic (including carcinogenicity) toxicity, genotoxicity (*in vitro* and *in vivo*), reproduction and developmental toxicity, endocrine studies, as well as mechanistic data were reviewed. Published studies, where appropriate, were also incorporated into the hazard assessment.

During the 1960-70s, many safety studies including those which underpinned the registration of folpet in overseas jurisdictions had been performed by 'Industrial Bio-Test Laboratories' (IBT), a testing laboratory known to have engaged in scientific misconduct and fraud (JMPR 1984). About a third of the unpublished safety studies (from a total of 90 studies), including the pivotal long-term repeat dose and reproduction toxicity studies submitted by the applicant were completed in the 1980s by laboratories other than IBT, to satisfy regulatory requirements for confidence in the validity of studies used to support the establishment of health-based guidance values (JMPR 1984) by other regulatory agencies (i.e., United States Environmental Protection Agency (US EPA) and the European Food Safety Authority (EFSA).

Evaluation of toxicology

Chemical class

Folpet belongs to the phthalimide chemical class and is also classified as a sulfenyl phthalimide fungicide and an organochlorine compound. Its ISO approved chemical name is N-(trichloromethylthio)phthalimide. Folpet is structurally similar to other fungicides from this chemical class currently approved in Australia e.g. Captan.

Toxicokinetics

The systemic bioavailability of folpet is zero. However, via the oral route folpet is efficiently converted pre-systemically to phthalimide and thiophosgene in the gastrointestinal tract. Phthalimide has a systemic bioavailability of >80%.

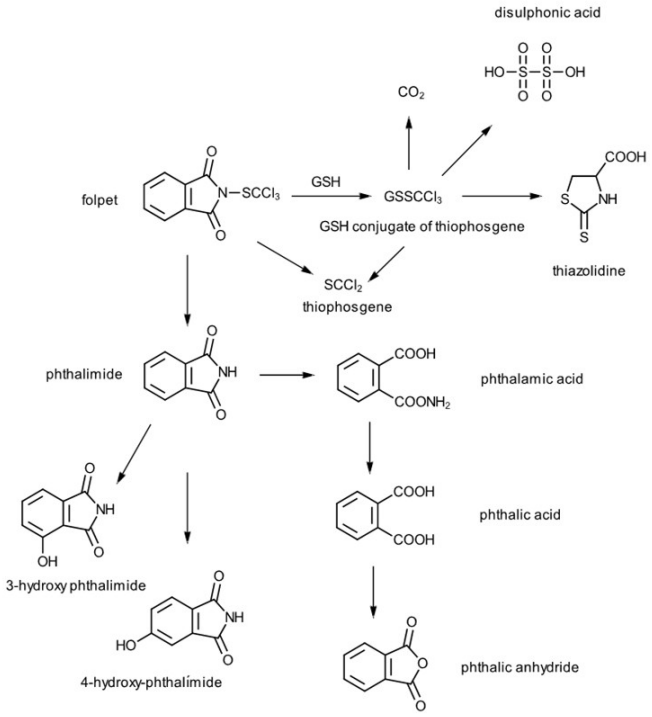
Folpet also undergoes rapid non-enzymatic conversion to phthalimide following dermal exposure resulting in no systemic folpet being observed. A conventional triple pack of absorption studies (ie., human/rat *in vitro* and rat *in vivo*) for the formulated product (Folpan 800 WG) showed absorption of phthalimide with human skin as 0.05% for the concentrate (800 g/kg) and 7.35% for folpet spray dilution (1.25 g/L).

In rats, following dosing with [^{14}C] radiolabelled folpet, radioactivity was distributed within the body of the treated animals at low concentration levels. Radioactivity, however, was not associated with parent compound, as folpet is converted to phthalimide pre-systemically. No accumulation of folpet or its metabolites was observed in the rat.

The most significant metabolic pathway involves cleavage of the trichloromethylthio- side chain of folpet to form highly reactive thiophosgene, which readily reacts with thiol groups in proteins. Removal of the side chain by hydrolysis or by detoxification mechanisms gives phthalimide, which is capable of hydroxylation in

the aromatic ring (demonstrated at the 3- and 4- positions). Phthalimide is further metabolised to phthalamic acid, which in turn may be converted to phthalic acid and phthalic anhydride. Derivatives of phthalimide are excreted predominantly in the urine mostly within 24 h of folpet administration and show no potential for accumulation.

Figure 1: Proposed metabolic pathway for folpet in rodents



Acute toxicity (active constituent)

The acute oral and dermal toxicity of folpet was classified low (oral LD_{50} 1950 mg/kg bw in rats and no deaths at limit dose of 2000 mg/kg bw and 5000 mg/kg bw, in dermal toxicity study in rats and rabbits, respectively). However, micronized folpet (dust) has moderate inhalational toxicity in rats when administered by the nose-only route (LC_{50} of 1080 mg/m^3). Additionally, folpet is classified as non-irritant to rabbit skin but as a severe eye irritant. Folpet has shown to have skin sensitisation potential in the Guinea-pig maximisation test.

Acute toxicity (product)

Acute toxicity studies with the product, Folpan 800WG Fungicide, demonstrated that its toxicity profile closely resembled that of the technical active constituent. The median lethal dose (LD/LC_{50}) is more than 2000 mg/kg bw following oral and dermal and inhalation exposure to rats. The irritancy potential of Folpan 800WG Fungicide to skin and eyes of rabbits can be classified as being moderate and severe, respectively. In the Guinea-pig maximisation test, Folpan 800WG Fungicide was shown to be a skin sensitiser. Owing to its use as a fungicide for many years overseas there are several published scientific reports confirming its skin sensitisation potential in occupational settings.

Repeat-dose toxicity

In repeat-dose oral studies in mice and rats, the gastrointestinal tract was the target organ. Toxicological effects at the site of contact, consistent with mucosal irritation (hyperkeratosis/acanthosis, oedema, ulceration) and regenerative responses (increased cell proliferation/hyperplasia, hypertrophy), were observed following several weeks of exposure. Gastrointestinal irritation was mainly observed in the stomach of rats and in the proximal region of the small intestine in mice. Dogs showed a different toxicity profile at low doses, with emesis and/or impaired bodyweight gain and changes in clinical chemistry parameters; at higher doses, additional targets of toxicity were the male reproductive organs, thyroid and lymphatic/hematopoietic systems. The lowest relevant oral No Observed Adverse Effect Level (NOAEL) was 300 mg/kg bw/day in a 13-week study in rats.

Excessive irritation in the repeat-dose dermal toxicity rat study at low levels of exposure precluded an assessment of systemic toxicity.

Acute and mode of action studies indicated that the thiophosgene released from inhaled folpet was likely to be highly reactive with mucous membranes and therefore cause portal-of-entry lesions in the airways. Although not submitted by the applicant, a repeat dose inhalation exposure study with the chemically related active constituent captan, available to the US EPA, Health Canada and EFSA, confirmed the presence of dose-related lesions in the larynx (eg., squamous metaplasia, squamous hyperplasia, vacuole degeneration of squamous epithelium). Lesions of the nasal mucosa, trachea and lungs were also evident at higher dose levels.

Chronic toxicity and carcinogenicity

In lifetime dietary toxicity studies in mice, folpet was irritating to the proximal region of the gastrointestinal tract (stomach, duodenum) with irritation also observed in the oesophagus; at higher dose levels, the jejunum and ileum were also targets of toxicity.

Chronic dietary administration to mice resulted in an increased incidence of hyperplasia, adenomas and adenocarcinomas of the small intestine (primarily in the duodenum), gastric ulceration and stomach papilloma. At higher doses, jejunal adenomas/adenocarcinomas were also observed. In rats, chronic dietary exposure to folpet resulted in irritation of the oesophagus (hyperkeratosis), as well as the non-glandular stomach (hyperkeratosis/acanthosis and ulceration/erosion) but did not produce an increase in the incidence of tumours of the gastrointestinal tract. In view of the fact that gastrointestinal irritation observed following oral exposure is attributable to the reactive metabolite thiophosgene, mechanistic assays with folpet and captan were informative in considering the carcinogenicity data. The data indicate that the neoplasms in the murine gastrointestinal tract are secondary to pronounced irritation and ensuing compensatory response. Pathology indicative of gastrointestinal irritation was not observed in the dog. The lowest relevant oral NOAEL was 9 mg/kg bw/day in a 2-year toxicity study in rats.

Reproductive and developmental toxicity

In dietary multigenerational reproductive toxicity studies in rats, maternal effects were consistent with other short-term dietary studies, with irritation of the gastrointestinal tract and reduced bodyweight gain observed.

Adverse effects on the reproductive system were not observed. Offspring toxicity was limited to reduced weight gain at maternally toxic doses. The lowest relevant oral reproductive NOAEL was 530 mg/kg bw/day.

Folpet was not a developmental or reproductive toxicant in multigeneration studies in rats, and prenatal developmental toxicity studies in the rat and rabbit.

Genotoxicity

In vivo genotoxicity assays with folpet, including a chromosome aberration assay, dominant lethal assays and a mouse spot assay were negative indicating a low likelihood of any mutagenic potential. Furthermore, an *in vivo* Comet assay with mouse duodenal cells was negative. The *in vitro* gene mutation assays gave mixed results, with positives mainly being observed in the absence of any metabolic activation. Mixed results were also noted in the *in vitro* chromosomal aberration assays. It seems likely that the attenuation or elimination of mutagenicity and clastogenicity *in vivo* is due to the presence of S-containing detoxification targets (such as glutathione) for the highly reactive thiophosgene. As a result, folpet is unlikely to represent a genotoxic concern.

Neurotoxicity

A sub-chronic neurotoxicity study on folpet did not reveal any evidence of neurotoxicity at a dose of 701 mg/kg bw/day.

Immunotoxicity

In addition to experimental data in guinea pigs which provides evidence that folpet has the potential to induce skin sensitisation, there are a few published studies which report immunological skin effects (ie., allergic reactions and dermatitis) in occupationally exposed workers.

Endocrine effects

Folpet was shown not to bind in a battery of *in vitro* endocrine receptor assays with mammalian cells or to influence pubertal development and thyroid function *in vivo* (rats).

Mode of action (toxicology)

The available data is consistent with an irritant mode of action on the duodenal villus epithelium resulting in an increased loss of villus cells and concomitant hyperplasia of the crypt epithelium, leading to benign and malignant tumour formation in the gastrointestinal tract. This mode of action appears to be a threshold phenomenon, requiring a high dose over a prolonged period. In rats, chronic dietary exposure to folpet resulted in irritation of the oesophagus (hyperkeratosis), as well as the non-glandular stomach (hyperkeratosis/acanthosis and ulceration/erosion) but did not produce an increase in the incidence of tumours of the gastrointestinal tract. No gastrointestinal irritation was observed in dogs.

Toxicity of metabolites and/or impurities

Available studies on folpet metabolites were limited. Phthalimide is the major mammalian metabolite of folpet. A developmental study in rabbits showed it did not exhibit any effects and was not acutely neurotoxic in rats at 1372 mg/kg bw. Phthalimide is also a major impurity (1%) but is discounted as being of toxicological concern as it is considered to have been tested in bioassays with folpet technical grade active constituent (TGAC) due to the rapid conversion of folpet to phthalimide. No *in vivo* studies on other metabolites were available for assessment.

The genotoxicity of the metabolites, phthalamic acid, phthalic acid and 2-cyanobenzoic acid, have been investigated and APVMA concludes these are unlikely to be genotoxic. In silico genotoxicity predictions show that the metabolites phthalamic acid and 2-cyanobenzoic acid were likely to be negative for mutagenicity and chromosome damage.

Considering the available genotoxicity data on similar compounds to phthalamic acid (compounds containing aromatic amides) and read across based on its close structural relationship to phthalic acid, it can be concluded that phthalamic acid is likely to be non-genotoxic.

Reports related to human toxicity

Owing to its use as a fungicide overseas there are several published scientific reports confirming folpet's skin sensitisation potential in occupational settings. In workers employed in a fungicide production plant who were potentially exposed to folpet, captan, phthalimide, tetrahdrophthalimide, perchloromethyl mercaptan, carbon tetrachloride, carbon disulfide, mercaptan, and chlorine, 48% reported eye problems (ie. burning, itching, and tearing of eyes) and 58% declared suffering from respiratory problems (i.e., dry throat, sore throat, coughing, wheezing, shortness of breath and difficulty breathing). Eye irritation was also reported in workers in an exposure monitoring trial on the use of a Folpet WG product for treating grape vines, as provided by the applicant.

Regarding potential human carcinogenicity, APVMA undertook a detailed evaluation of the data available in rats, mice and dogs for potential relevance to humans. It was concluded that although the postulated mode of action for duodenal tumours is biologically feasible for humans, there are two primary reasons this is seen as unlikely. Firstly, tumours were only seen in mice with a clear NOAEL of ~20 mg/kg bw/d. Secondly, evidence from dogs at higher doses than mice and rats, suggests that animal species without a forestomach may not be susceptible to the tumorigenic effects of the folpet hydrolysis product, thiophosgene. Therefore, humans are likely to be less susceptible to the cytotoxic and carcinogenic effects of folpet than rodents. Moreover, although the possibility of toxicity and carcinogenicity at extremely high-dose levels in humans cannot be excluded, such levels are very unlikely to arise from it use as a fungicide on grapevines.

Health-based guidance values and poisons scheduling

Poisons Standard

Folpet is listed in Schedule 6 of the SUSMP with no cut-off to a lower schedule or other exceptions.

Health-based guidance values

Acceptable daily intake

An acceptable daily intake (ADI) for folpet has been established at 0.09 mg/kg bw/day, based on a NOAEL of 9 mg/kg bw/day observed in a two-year rat dietary exposure study. The NOAEL was based on hyperkeratosis and/or acanthosis of the non-glandular gastric mucosa at a Lowest Observed Adverse Effect Level (LOAEL) of 37 mg/kg bw/day. This NOAEL observed in the long-term rat study was supported by two other studies in other species having a similar value (i.e.,10 mg/kg bw/day). As there are no unique metabolites found in treated plants and animals considered to be of toxicological concern, the ADI only includes the parent compound (folpet).

Acute reference dose

An acute reference dose (ARfD) for folpet is considered to be unnecessary due to its low acute toxicity, the lack of evidence for any acute neurotoxicity, acute developmental toxicity (in the absence of maternotoxicity) or any other toxicologically relevant effect that might be attributable to a single dose or exposure.

Recommendations

The APVMA has evaluated the toxicology of the active constituent folpet (plus impurities) and the associated product Folpan 800 WG Fungicide and has no objections on human health grounds to the approval of the technical grade active constituent and registration of the product, when used in accordance with the proposed directions for use and adhering to the recommended safety directions.

For the protection of public health from dietary consumption of folpet residues in food, APVMA has established an acceptable daily intake ADI of 0.09 mg/kg bw/d, however an ARfD for folpet is considered unnecessary due to its low acute toxicity or any other toxicologically relevant effect that might be attributable to a single dietary exposure.

Residues assessment

Metabolism, analytical methodology, residue trial data, fate in storage and processing, and residues in trade information have been considered for folpet.

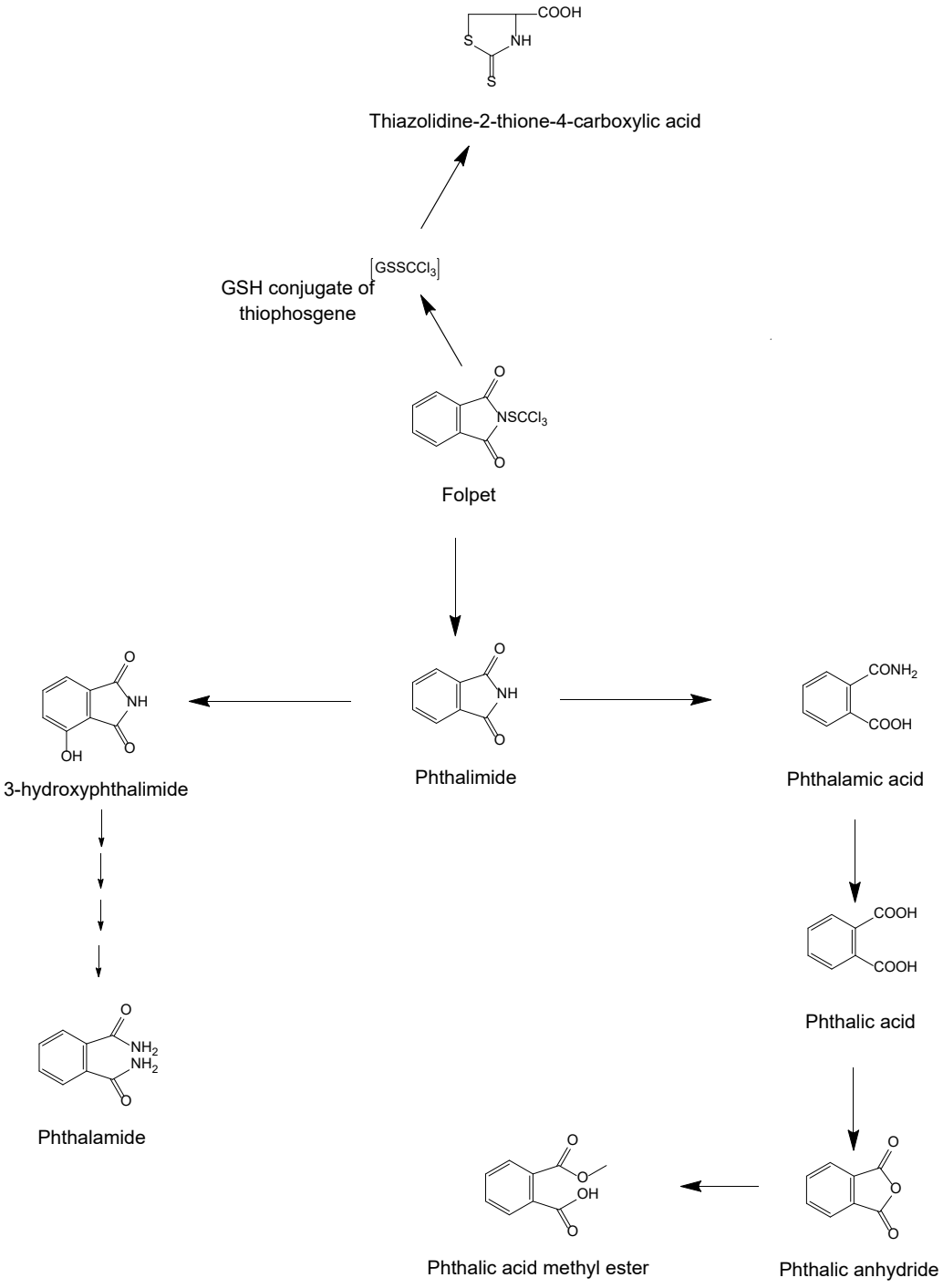
Metabolism

Animal commodities

Lactating goat metabolism studies were conducted with [trichloromethyl-^{14}C] and [U-phenyl-^{14}C] labelled folpet (applied for six days at 24 and 14 ppm in the diet respectively). The study conducted with [trichloromethyl-^{14}C] (TCM) labelled folpet investigated the distribution of the radioactive residues in the animal while an identification of the metabolic spectrum was performed in the study with the [U-phenyl-^{14}C] labelled compound. Parent folpet was extensively metabolised and excreted in faeces and urine and was not detected in milk or any edible tissue. Residues in milk and tissues from use of both labels were very low, representing less than 0.05 mg eq./kg except for the TCM label liver (0.25 mg eq./kg), kidney (0.16 mg eq./kg) and milk (0.18 mg eq./kg). The major metabolites in liver, kidney and milk were phthalimide and either phthalamic acid, phthalic anhydride or phthalic acid.

In the submitted poultry metabolism study, phenyl-^{14}C labelled folpet was fed to poultry at two dose levels. Due to the very low levels of residues observed in tissues (<0.05 mg eq./kg) identification was conducted in excreta. The major components of the residue were folpet at the high dose (approximately 10 ppm in the feed) with phthalic acid and phthalamic acid, and phthalic acid and phthalamic acid at the low dose (approximately 0.31 ppm in the feed). Phthalimide and phthalic anhydride were also observed at both doses.

Figure 2: Proposed metabolic pathway for folpet in poultry

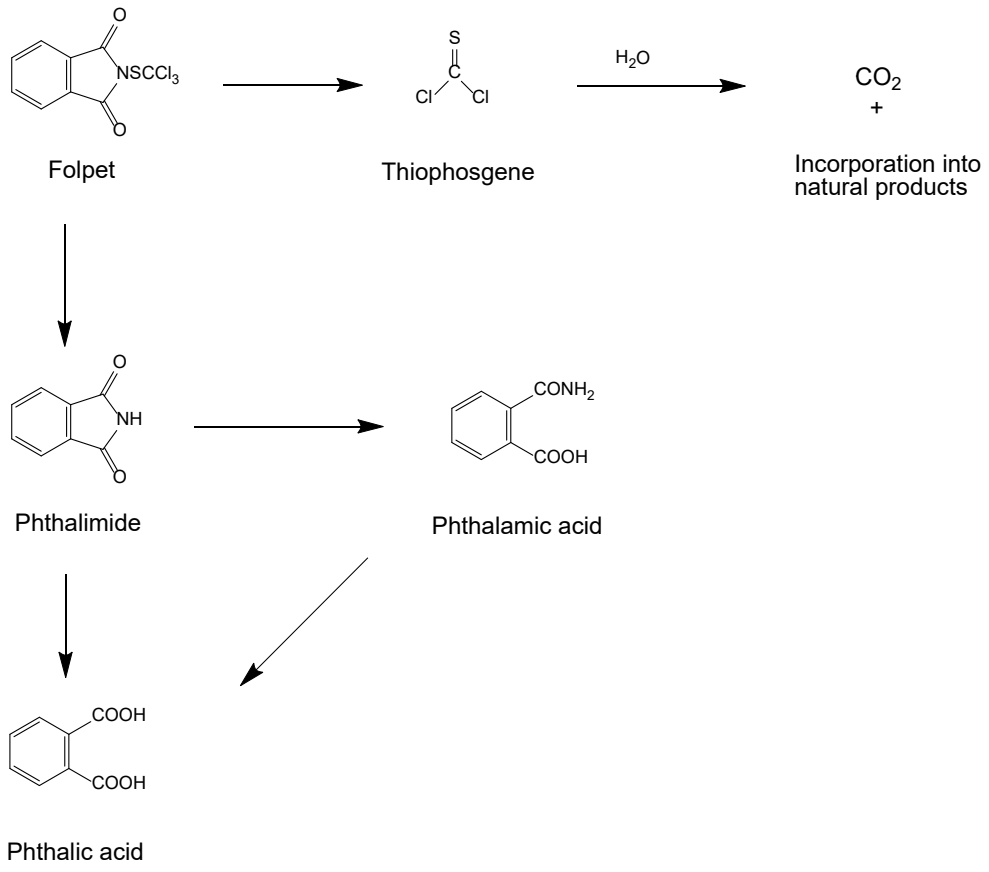


Plant commodities

The only plant metabolism study submitted to the APVMA was in grapes. This study with [^{14}C]-folpet labelled in the benzene ring (three applications at 1.35-1.58 kg a.i./ha at berry set, mid-berry and late berry stages) showed that folpet is degraded to phthalimide through release of the trichloromethylthio-sidechain. Phthalimide is further degraded to phthalic acid, phthalamic acid and related conjugates. Of the major compounds analysed in the fruit extracts, folpet, phthalimide and phthalic acid (free and conjugated) accounted for about 27% (2.0 mg eq./kg), 11% (0.81 mg eq./kg) and 47% of the TRR (3.58 mg eq./kg), respectively. Of the major compounds analysed in the leaf extracts, folpet, phthalimide and phthalic acid (free and conjugated) accounted for about 91% (266 mg eq./kg), 3% (8.8 mg eq./kg) and 2% (7.0 mg eq./kg) of the TRR, respectively.

Summary information concerning plant metabolism in other crops (avocado, tomato, potato and wheat) showed that the metabolism of folpet was similar although the individual metabolic pattern was dependent on the mode of application and the time elapsed between treatment and sampling. In crops having received a foliar application, the majority of the terminal residue was generally present as folpet, phthalimide and phthalic acid. In potato tubers and root-treated tomato plants the most important residues translocated between underground plant parts and upper plant parts were phthalic acid and phthalamic acid.

Figure 3: Proposed metabolic pathway for folpet in plants



Analytical methods and storage stability

A number of suitable analytical methods and validations for the analysis of folpet and its metabolites in animal and plant matrices were submitted. The performances of the methods were verified by concurrent recoveries, which were generally within the boundaries of 70-110%.

In Australian table and wine grape trials conducted in 2014, residues of folpet and phthalimide were extracted with ethyl acetate. Instrumental analysis was conducted by GC/MS. The limit of quantification (LOQ) of the method was determined as 0.01 mg/kg for folpet and phthalimide in the grape specimens (whole table grapes, wine grapes and processing portions; dried grapes, pomace, juice and wine).

In another Australian study, residues of folpet, phthalimide, phthalamic acid and phthalic acid were extracted with trifluoroacetic acid in water and methanol, followed by analysis by LC-MS/MS. The LOQ of the method was determined as 0.05 mg/kg in wine and table grapes and in processed fractions (dried grapes, pomace, juice and wine).

A number of other validated analytical methods were referred to for the determination of residues of folpet and metabolites in plant matrices, using various techniques, with LOQs of 0.01-0.05 mg/kg.

Details of an analytical method were also submitted for the determination of residues of folpet and metabolites in animal matrices using LC-MS/MS, with LOQs of 0.01 mg/kg for folpet and 0.05 mg/kg for phthalimide, phthalic acid, phthalic anhydride and phthalamic acid.

Storage stability studies were submitted which indicated that folpet and phthalimide are stable in grapes for at least 12 and 13 months respectively, under frozen storage conditions. Another study showed no decline of folpet residues in various fruit and vegetable matrices for periods ranging from 29-176 days. A further study investigated the frozen storage stability of folpet and its metabolites in animal commodities over periods of up to 2 months for eggs, cow muscle, fat and liver and up to 10 days in milk.

Residue definition

Animal commodities

A dairy cow feeding study was submitted which showed the magnitude of residues of folpet and its metabolites (phthalimide, phthalic acid, phthalic anhydride and phthalamic acid) in samples of milk and tissues (muscle, fat, liver and kidney) of dairy cows following multiple oral administration of folpet. The folpet test item was administered orally at exaggerated dose levels of 36 ppm, 104 ppm and 364 ppm. At the lowest level in the feeding study (36 ppm), no residues of parent folpet or folpet metabolites except for phthalimide were detected in milk samples, while only residues of phthalimide (in muscle and fat), phthalic acid (in fat) and phthalamic acid (in liver and kidney) were found in tissue samples. It is noted that this feeding level is significantly higher than the estimated mammalian dietary burden resulting from consumption of grape pomace which is the only animal feed from the proposed use on grapes.

OECD guidelines indicate that the only potential feed for poultry from the proposed use on grapes is from the feeding of grape pomace to turkeys at up to 20% of the diet.

The major compounds observed in animal metabolism studies were phthalimide and phthalamic acid. Noting that quantifiable residues of folpet and its metabolites are not expected in poultry eggs or tissues and also not in the milk and tissues of livestock, from the proposed use on grapes, a default residue definition of folpet, is considered to be appropriate for commodities of animal origin for enforcement. The sum of parent folpet and phthalimide and expressed as folpet, is considered to be the appropriate residue definition for commodities of animal origin for dietary risk assessment.

Plant commodities

In the submitted metabolism study in grapes, the proposed crop in the current evaluation, parent folpet was the major identified component of the residue in fruit. It is noted that in the submitted residues studies folpet was usually the highest observed residue in grapes. Parent folpet is therefore considered to be the appropriate residue definition for commodities of plant origin for enforcement. This is the residue definition for enforcement in most overseas markets.

The submitted abiotic degradation studies indicated that under hydrolytic conditions typical of those occurring during processing the major recovered compounds were phthalimide and phthalic acid. The importance of phthalimide residues in processed commodities is reinforced by the results of the three submitted Australian wine grape trials conducted in 2014 or 2021-2022, in which residues of folpet and phthalimide were determined after five applications of folpet at approximately 1 and 1.5 or 2× the proposed rate. Although finite residues of both folpet and phthalimide were detected in all samples of grape berries taken at 7, 14, 28-29 and 35 DALA after application at both 1 and 2×, all wine samples from processing of the grapes taken at 29 DALA showed finite phthalimide residues but no quantifiable residues of folpet. This result was also observed in a French processing trial conducted in 2008. It is therefore considered appropriate to include phthalimide as a component of the risk assessment definition for folpet.

Phthalic acid, which was a major component observed in the metabolism studies was also observed to be an important component of the residue in grapes and processed fractions in the submitted Australian processing studies but will not be considered for inclusion in the risk assessment definition due to its natural presence in the environment.

The sum of parent folpet and phthalimide and expressed as folpet, is therefore considered to be the appropriate residue definition for commodities of plant origin for dietary risk assessment, noting that phthalimide is covered by the ADI for folpet and that there are no residues of toxicological concern.

Residues in food and animal feeds

Data from the submitted Australian and European studies were considered for MRL estimation for grapes.

Grapes

The Australian dataset suitable for MRL estimation is, in rank order (wine grapes in bold): 2.41, 3.12, 3.85, 3.94, **4.31**, **4.56**, **4.82** and **4.91** mg/kg (STMR = 4.13 mg/kg, n = 8). The OECD MRL calculator estimates an MRL of 15 mg/kg.

The combined Australian *and European* dataset suitable for MRL estimation is, in rank order: ***1.2***, ***1.7***, ***2.0***, ***2.2***, 2.41, 3.12, 3.85, 3.94, **4.31**, **4.56**, **4.82** and **4.91** mg/kg (STMR = 3.49 mg/kg, n = 12). The OECD MRL calculator estimates an MRL of 10 mg/kg.

A folpet MRL of 10 mg/kg for FB 0269 Grapes is considered appropriate to cover residues in grapes arising from the proposed use in conjunction with the proposed 7 days harvest WHP.

Dried grapes

Data from the submitted Australian and European processing studies were considered for MRL estimation for dried grapes.

The highest processing factor was 3.2×. Based on the highest residues (HR) in grapes (4.91 mg/kg), the highest estimated residue value (HR-P) in dried grapes is 15.7 mg/kg. An MRL at 20 mg/kg is recommended for DF 0269 Dried grapes (= currants, raisins and sultanas).

Wine

The available processing factors (all <1) indicate that folpet residues do not concentrate in wine, so it is not necessary to establish a separate MRL.

Juice

The available processing factors (all <1) indicate that folpet residues do not concentrate in juice, so it is not necessary to establish a separate MRL.

Grape pomace

Data from the submitted Australian and European processing studies were considered for MRL estimation for grape pomace.

The highest processing factor for dry grape pomace is 5.6×. Based on the HR in wine grapes (4.91 mg/kg), the highest estimated residue value (HR-P) in dry grape pomace is 27.5 mg/kg. An MRL at 30 mg/kg is recommended for AB 0269 Grape pomace, dry.

Crop rotation

Grapes are not a rotational crop, so no consideration of crop rotation is necessary.

Residues in animal commodities

There is the possibility of targeted grazing of understory vegetation in vineyards by sheep and other animals. In Australia sheep may graze in vineyards between the completion of harvest and budburst. The Applicant has proposed a grazing restraint of ‘DO NOT graze vineyards or orchards after application’. Noting that there

is no proposed use in orchards, a grazing restraint of 'DO NOT graze treated vineyards' is considered to be more appropriate for the proposed use on grapes.

Residues may be found in grape pomace, which may contribute up to 20% of the diet for beef and dairy cattle and 20% of the diet for turkeys.

Cattle

The estimated maximum dietary burden of folpet for beef and dairy cattle, resulting from the proposed use on grapes (based on a diet of 20% grape pomace) was calculated to be 1.30 ppm.

A feeding study was submitted showing the residues of folpet in milk and tissues following administration to dairy cows.

The proposed residue definition for compliance for animal commodities is folpet. The results of the submitted feeding study (highest observed residues of folpet after feeding at 36 ppm) were considered to predict residues in milk and tissues.

The estimated maximum residues of folpet in milk and tissues after feeding at the calculated maximum dietary burden of 1.30 ppm (beef and dairy cattle), after extrapolation from the observed maximum residues after feeding dairy cattle for 28 days at 36 ppm, are as follows:

Cattle

Feeding level (ppm)	Milk	Muscle	Liver	Kidney	Fat
		Folpet (mg/kg)			
36 – feeding study	<0.01	<0.01	<0.01	<0.01	<0.01
1.30 – beef and dairy, estimated burden	<0.01	<0.01	<0.01	<0.01	<0.01
Recommended MRLs	*0.01 (milks)	*0.01 (meat)	*0.01 (offal)		-

LOQ of folpet = 0.01 mg/kg

Quantifiable residues of folpet are not expected to occur in mammalian animal commodities as a result of the proposed use. It is appropriate to establish mammalian animal commodity MRLs at the LOQs of folpet in the analytical method. The following MRLs are therefore recommended:

MO 0105	Edible offal (mammalian)	*0.01 mg/kg
MM 0095	Meat (mammalian)	*0.01 mg/kg
ML 0106	Milks	*0.01 mg/kg

Poultry

The estimated maximum dietary burden of folpet for turkeys, resulting from the proposed use on grapes (based on a diet of 20% grape pomace) was calculated to be 1.30 ppm.

No feeding study was submitted showing the residues of folpet in eggs and tissues following administration to poultry. As OECD guidelines do not consider that grape pomace is a possible animal feed for poultry layers (or broilers) consideration of residues in eggs is not necessary. In the absence of a feeding study, the results of the submitted laying hen metabolism study (highest observed TRRs after feeding at 0.31 and 10 ppm), were therefore considered to predict residues in tissues.

The proposed residue definition for compliance for animal commodities is folpet. The estimated maximum residues of folpet in tissues after feeding at the calculated maximum dietary burden of 1.30 ppm (turkeys only), after interpolation from the highest observed TRRs in liver, muscle (breast and thigh) and fat (subcutaneous, abdominal and renal) after feeding laying hens for 7 days at 0.31 and 10 ppm, are as follows:

Poultry - turkeys

Feeding level (ppm)	Liver	Muscle TRR as parent equivalents (mg/kg)	Fat
10 - laying hens metabolism study	0.0276	0.0446 (breast)	0.011 (renal)
0.31 - laying hens metabolism study	0.0016	0.003 (breast)	0.0008 (renal)
1.30 – turkeys, estimated burden	0.004	0.007	0.002
Recommended MRLs	*0.01 (offal)	*0.01 (meat)	-

Quantifiable residues of folpet are not expected to occur in poultry animal commodities as a result of the proposed use. It is appropriate to establish poultry animal commodity MRLs at the respective LOQs of folpet in the analytical method. The following MRLs are recommended:

PE 0112	Eggs	*0.01 mg/kg
PM 0110	Poultry meat	*0.01 mg/kg
PO 0111	Poultry, edible offal of	*0.01 mg/kg

Dietary risk assessment

The chronic dietary exposure to folpet is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/ temporary uses of the chemical and the mean daily dietary consumption data derived primarily from the 2011-12 National Nutritional and Physical Activity Survey. The NEDI calculation is made in accordance with WHO Guidelines and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for folpet is equivalent to <10% of the ADI.

It is concluded that the chronic dietary exposure to folpet is acceptable.

The acute dietary exposure is estimated by the National Estimated Short Term Intake (NESTI) calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR with 97.5th percentile food consumption data derived primarily from the 2011-12 National Nutritional and Physical Activity Survey. NESTI calculations are conservative estimates of short-term exposure (24 hour period) to chemical residues in food.

An ARfD for folpet was considered unnecessary by the APVMA and therefore an acute exposure assessment is not required.

Recommendations

The following amendments are required to be made to the APVMA MRL Standard (Table 5).

Table 5: Amendments to the APVMA MRL Standard

Amendments to Table 1			
Compound		**Food**	**MRL (mg/kg)**
Add:			
Folpet			
DF	0269	Dried grapes (= currants, raisins and sultanas)	20
MO	0105	Edible offal (mammalian)	*0.01
PE	0112	Eggs	*0.01
FB	0269	Grapes	10
MM	0095	Meat (mammalian)	*0.01
ML	0106	Milks	*0.01
PM	0110	Poultry meat	*0.01
PO	0111	Poultry, edible offal of	*0.01

Amendments to Table 3	
Compound	**Residue**
Add:	
Folpet	Commodities of plant and animal origin for enforcement: Folpet Commodities of plant and animal origin for dietary exposure assessment: Sum of folpet and 1,2-benzenedicarboximide (phthalimide), expressed as folpet

Amendments to Table 4			
Compound		**Animal feed commodity**	**MRL (mg/kg)**
Add:			
Folpet			
AB	0269	Grape pomace, dry	30

Assessment of overseas trade aspects of residues in food

Commodities exported and main destinations

Grapes (including dried grapes) and wine are considered to be major export commodities[1], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated grapes. Residues in these commodities resulting from the use of *Folpan 800 WG Fungicide* may have the potential to unduly prejudice trade.

Australian exports of table grapes totalled 107.3 kt (value $478.4 m) for the year ending June 2024. The major export markets for fresh table grapes in that period included China, Indonesia, South Korea, the Philippines, and Vietnam.[2]

Australian exports of dried grapes totalled 3.0 kt (value $15.9 m) for the year ending June 2024.[3]

Australian exports of wine totalled 635 ML ($2,318 m) in the 2023-2024 fiscal year. The major export markets for wine in the year ending June 2024 included the United Kingdom, China, the USA, Hong Kong, Canada, New Zealand, Singapore, Malaysia, Netherlands, Japan, Denmark and Malaysia.[3]

Overseas registrations and approved label instructions

The Applicant indicated that folpet products are registered overseas (European Union, Canada and New Zealand) for use on grapes and other crops.

Comparison of Australian MRLs with Codex and international MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. CXLs are primarily intended to facilitate international trade and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Folpet has been considered by Codex. The following relevant Codex CXLs and international MRLs have been established for folpet (Table 6).

Table 6: Proposed Australian and current international plant commodity MRLs for folpet

Country	Residue definition for compliance with MRLs	Grapes MRL (mg/kg)	Dried grapes MRL (mg/kg)
Australia (proposed)	*Folpet (proposed)*	*10 (proposed)*	*20 (= currants, raisins and sultanas) (proposed)*

[1] APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B)
[2] Australian Horticulture Statistics Handbook Fruit 2023/24, https://www.horticulture.com.au/growers/help-your-business-grow/research-reports-publications-fact-sheets-and-more/australian-horticulture-statistics-handbook/
[3] Agricultural Commodity Statistics 2023, https://www.agriculture.gov.au/abares/research-topics/agricultural-outlook/data#_2023

Country	Residue definition for compliance with MRLs	Grapes MRL (mg/kg)	Dried grapes MRL (mg/kg)
Canada[4]	Folpet	25	25 (currants)
China[5]	Folpet	10	40 (raisins)
Codex[6]	Folpet	10	40
Codex – outcomes of 2024 JMPR periodic review evaluation of folpet[7]	*Folpet*	*10 (withdraw)* *15 (wine grapes)*	*40 (withdraw)*
EU[8]	Sum of folpet and phthalimide, expressed as folpet (R)	6 (table grapes) 20 (wine grapes)	-
Japan[9]	Folpet	10	40 (raisins)
Korea[10]	-	5.0	-
New Zealand[11]	Folpet (for plant commodities)	25	30 (black, red, white currants)
USA[12]	Folpet	50.0	80.0 (raisins)

Potential risk to trade

Grapes

It is proposed to establish a folpet MRL for FB 0269 Grapes at 10 mg/kg. A Codex MRL is established for grapes at the same level to that proposed, although the 2024 JMPR recommended withdrawal of this MRL and the establishment of an MRL for wine grapes at 15 mg/kg. MRLs are established in many overseas markets at the same (China and Japan) or higher levels (the EU for wine grapes at 20 mg/kg, Canada and New Zealand at 25 mg/kg and the USA at 50 mg/kg) to that proposed. Although it is noted that the EU has

[4] Health Canada, *Government of Canada Maximum residue limits search*, Government of Canada Health Canada website, accessed 1 May 2025.
[5] United States Department of Agriculture Foreign Agricultural Service, *China: Maximum Residue Limits for Pesticides in Foods, Global Agricultural Information Network report*, 24 August 2021, accessed 1 May 2025.
[6] Food and Agriculture Organisation of the United Nations (FAO), *Codex Alimentarius: 41 - Folpet* , FAO website, accessed 1 May 2025.
[7] Food and Agriculture Organisation of the United Nations (FAO), Outcomes of 2024 JMPR periodic review evaluation of folpet.
[8] European Commission, *EU Pesticide residue(s) and maximum residue levels (mg/kg)*, European Commission website, accessed 1 May 2025.
[9] Japanese Food Chemistry Research Promotion Foundation, *Table of MRLs for Agricultural Chemicals*, JFCRPF website, accessed 1 May 2025.
[10] Ministry of Food and Drug Safety Korea, *Pesticide MRLs for agricultural commodities*, FSK website, accessed 1 May 2025.
[11] Ministry for Primary Industries, *Maximum Residue Limits for Agricultural Compounds*, New Zealand Government Ministry for Primary Industries website, accessed 1 May 2025.
[12] Electronic Code of Federal Regulations, *Tolerances and Exemptions for Pesticide Chemical Residues in Food*, eCFR website, accessed 1 May 2025.

an established MRL for table grapes at 6 mg/kg, as the major export markets for fresh table grapes are China, Indonesia, South Korea, the Philippines and Vietnam, and the highest sum of residues (folpet + phthalimide as folpet equivalents, the EU residue definition) in table grapes from the Australian trials was 4.16 mg/kg, the overall risk to trade in grapes is considered to be low.

Dried grapes

It is proposed to establish a folpet MRL for DF 0269 Dried grapes (= currants, raisins and sultanas) at 20 mg/kg. Given that a Codex MRL is established for dried grapes at 40 mg/kg (proposed to be withdrawn by the 2024 JMPR) and MRLs are established for raisins in many overseas markets at higher levels (in China and Japan at 40 mg/kg and the USA at 80 mg/kg), and for currants in Canada at 25 mg/kg, the overall risk to trade in dried grapes is considered to be low.

Wine

The available processing factors indicate that folpet residues do not concentrate in wine, so it is not necessary to establish a separate MRL. The proposed folpet MRL for Grapes at 10 mg/kg will therefore also apply to wine. In three Australian processing trials conducted at GAP, no quantifiable residues of parent folpet were observed in any wine sample at both 1× and 1.5 or 2× the proposed application concentration. Similarly, no residues of folpet were observed in wine samples from six French processing trials conducted at exaggerated concentrations.

Noting that the proposed residues definition for enforcement for plant commodities is folpet, the same as in most other overseas markets, and that no residues of folpet were observed in the samples of wine from the processing trials, the overall risk to trade in wine is considered to be low.

Although it is noted that the EU has an established MRL for wine grapes at 20 mg/kg, as the highest sum of residues (folpet + phthalimide as folpet equivalents, the EU residue definition) in wine from the Australian trials was 5.19 mg/kg, the overall risk to trade in grapes to the EU is also considered to be low.

Animal commodities

Quantifiable residues are not expected in milk or animal tissues through consumption of animal feeds from treated crops. MRLs for animal commodities are proposed at the LOQ of folpet (0.01 mg/kg) to account for the proposed uses of folpet.

Animal commodity MRLs are not currently established for folpet in many overseas markets. Codex MRLs are proposed in animal commodities at the LOQ for folpet of 0.01 mg/kg, while MRLs for animal commodities are established at 0.05 mg/kg in both the European Union and New Zealand, which have a residue definition for compliance for animal commodities of folpet + phthalimide, expressed as parent folpet. It is therefore considered that residues should be below the LOQ for folpet of 0.01 mg/kg and below the LOQ for phthalamide of 0.05 mg/kg in animal tissues to mitigate a risk to the international trade of animal tissues.

A mammalian transfer study has been submitted with the current application. Dosing with folpet at 36 ppm in the dairy cow feeding study did not result in quantifiable residues of folpet in any tissue. Dosing with folpet at 36 ppm gave a highest phthalimide residue of 0.053 mg/kg (0.11 mg/kg as parent equivalents) in fat. At the

calculated maximum dietary burden of 1.30 ppm, quantifiable residues of phthalimide are therefore also not expected to occur in mammalian animal commodities as a result of the proposed use. As quantifiable residues of folpet and phthalimide are not expected, the risk to Australia's export trade in animal commodities is considered to be low.

It is noted that by-products such as grape pomace would not normally be fed within 60 days of slaughter for export without declaration.

The Applicant has proposed the following risk mitigation statement which is considered appropriate and acceptable:

EXPORT TRADE ADVICE – TREATED CROPS:

Treated crop commodities destined for export may require extra time being allowed between application and harvest to be accepted in some export markets. Before using FOLPAN 800 WG on crops destined for export it is essential to consult your exporter or ADAMA Australia Pty Ltd. and/or your industry body about any potential trade issues and their management.

Work health and safety assessment

Folpan 800 WG Fungicide containing folpet at 800 g/kg in a water dispersible granule formulation is intended for use as a fungicide on grapes. The formulated product will be available in 1 kg – 20 kg HDPE/PE (plastic) bags. Folpan 800 WG is intended for professional use and will be applied mechanically by a vertical sprayer (e.g., airblast).

Folpan 800 WG Fungicide, once diluted in water (125 g/100 L), will be applied at a maximum rate of 1.25 kg/ha, with at least 7 days between applications up to a maximum of five occasions per calendar year. A work rate of 30 ha/d (75 acres/d) was used as a conservative default in the work health and safety assessment.

The main routes of exposure will be dermal and inhalation exposure during mixing, loading and application and dermal exposure during re-entry activities. Incidental ocular exposure may also occur. The pattern of occupational exposure is considered to be of short-term duration.

Health hazards

The results of acute studies on Folpan 800WG Fungicide indicate it has low toxicity following oral, dermal and inhalational exposure. However, published data has shown that majority of the droplets (>75%) of the spray applied to grapes via airblast were under 5 µm (mean 3.7 µm), therefore able to reach the mucous membranes of pulmonary passages through inhalation by the occupational sprayers, and causing cytotoxicity. The product is therefore classified as harmful by inhalation. Folpan 800WG Fungicide has also been shown to possess severe eye and moderate skin irritation potential and is a skin sensitiser in the Guinea-pig maximisation test.

Occupational exposure

Exposure during use

APVMA undertook exposure modelling for mixer/loaders (M/L) and applicators (A) using the US EPA Occupational Pesticide Handler and Post-application Exposure Calculator (2021). At an application rate of 1.25 kg/ha (1 kg a.c/ha) and a work rate of 30 ha/d, margins of exposure (MOEs) for M/L were acceptable wearing single layer clothing and gloves. For airblast application (open cab tractor), MOEs were acceptable for single layer clothing and washable hat and gloves, which provided an acceptable combined (M/L/A) MOE of >300.

PPE for acute effects also requires eye protection during M/L and respiratory protection during open cab application. The PPE determined for M/L/A can be found in the recommended safety directions (See below).

Exposure during re-entry or rehandling

APVMA undertook an assessment of re-entry exposure using the US EPA Occupational Pesticide Post-application Exposure Calculator (2021). At an application rate of 1 kg a.c/ha (0.89 lb a.c/acre), using a NOAEL of 10 mg/kg bw/d and dermal absorption factor of 0.05% (concentrate), MOEs were acceptable for

all maintenance activities in wine and table grapes on Day 0 (day of spraying). However, due to the acute hazard profile of the product, re-entry is not recommended until the spray has dried.

Public exposure

The product is intended for professional use only. Therefore, risks for users are not relevant for the general public.

Exposure to bystanders through drift of spray is considered separately in the spray drift risk assessment section.

Exposure to folpet residues is possible from ingestion of residues in grapes treated with Folpan 800WG Fungicide. APVMA Residues has established a maximum residue limit (MRL) in grapes to ensure the established ADI is not exceeded.

Recommendations

The following first aid instructions, safety directions and precautionary statements are recommended for the product label.

First aid instructions

First Aid Instruction Code	Instruction
a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766.
s	If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

Safety directions

Harmful if inhaled. May irritate the nose and throat. Will irritate the skin. Will damage eyes. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. Do not inhale dust or spray mist. When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, elbow-length chemical resistant gloves and face shield or goggles. If applying by closed cab tractor wear cotton overalls buttoned to the neck and wrist (or equivalent clothing). If applying by open cab tractor, wear cotton overalls buttoned to the neck and wrist and a washable hat, gauntlet length chemical resistant gloves and a disposable mist facemask covering mouth and nose. Wash hands after use. After each day's use, wash gloves, face shield or goggles and contaminated clothing.

Precautionary statements

DO NOT apply by aerial spraying.

DO NOT allow bystanders to come into contact with the spray cloud.

DO NOT enter treated areas until the spray has dried. If prior entry is necessary wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), a washable hat and elbow-length chemical resistant gloves. Clothing must be laundered after each day's use.

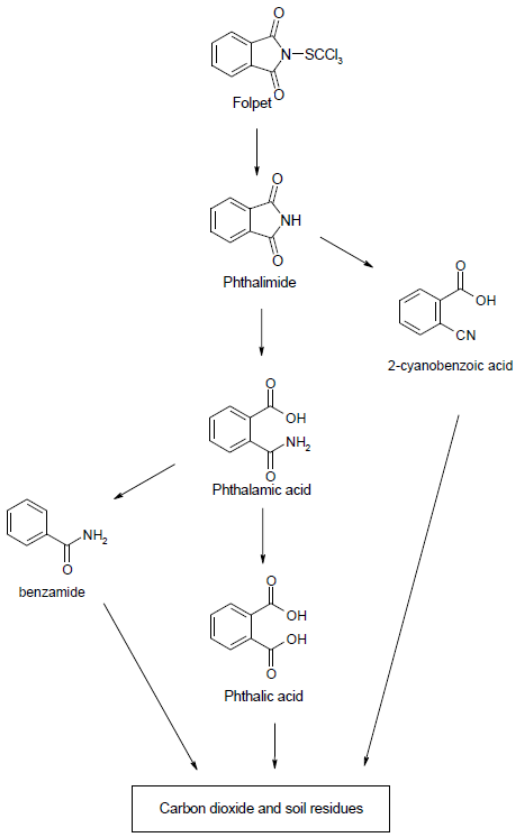
Environmental assessment

Fate and behaviour in the environment

Soil

In soil laboratory incubations under aerobic conditions in the dark, folpet exhibited low persistence, forming the major metabolites phthalimide (max. 65% AR), phthalamic acid (max. 17% AR) and phthalic acid (max. 17% AR), all of which exhibited very low to low persistence. Folpet degradation was pH dependent with degradation being faster at higher soil pH. Mineralisation to carbon dioxide accounted for 36–91% AR after 30 days, and formation of bound residues accounted for 13-29% AR. In a laboratory soil photolysis experiment, light enhanced folpet degradation, but novel transformation products were not identified. Folpet exhibited low mobility in soil, while phthalimide exhibited medium soil mobility. Adsorption was not pH dependent. The proposed aerobic degradation pathway in soil is shown in Figure 4.

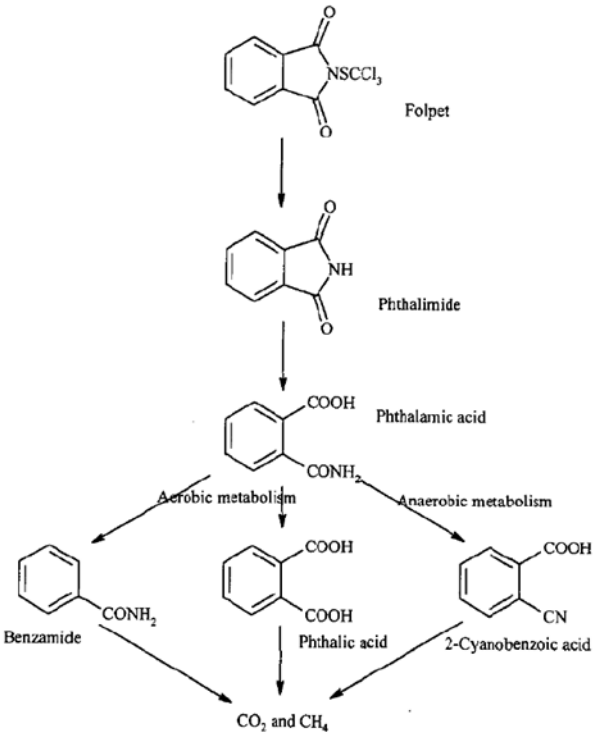
Figure 4: Proposed degradation pathway of folpet in soil



Water

Folpet rapidly hydrolyses in water and the rate of hydrolysis rapidly increases with pH. The overall impact of irradiation on the dissipation of folpet in water, which is largely governed by hydrolysis, is considered negligible. In laboratory incubations in dark aerobic natural water/sediment systems, folpet exhibited very low persistence, forming the major metabolites phthalimide (max. 32% AR), phthalamic acid (max. 13% AR), phthalic acid (max. 41% AR), 2-cyanobenzoic acid (max. 40% AR) and benzamide (max. 10% AR), all of which remained largely in the water phase and exhibited low persistence. The bound residue in the sediment accounted for 9.0-26% AR after 100 days, and mineralisation of accounted for 55–80% AR. The proposed degradation pathway of folpet in water/sediment systems is shown in Figure 5.

Figure 5 Proposed degradation pathway of folpet in water/sediment



Air

Based on its vapour pressure, folpet may be considered as potentially semi-volatile from plant surfaces. In two monitoring studies in France where folpet is used as a fungicide in vineyards, wheat and apples, folpet was frequently detected in the ambient air. The authors postulated that folpet might be associated with particles in the air resulting in medium-range transport. Nevertheless, folpet would not be subject to gas

phase transport over large distances, due to rapid indirect photochemical degradation. Negligible deposition of folpet from vapour drift is predicted beyond the treatment area.[13]

Effects and associated risks to non-target species

Terrestrial vertebrates

Folpet has low toxicity to mammals (LD_{50} >2000 mg ac/kg bw, *Rattus norvegicus*). In the rabbit developmental toxicity studies, the ecologically relevant effect was incomplete ossification of pups at 30 mg ac/kg bw/d (NOEL 20 mg ac/kg/bw/d, *Oryctolagus cuniculus*). The effect was considered to be species-specific, and therefore the ecologically relevant endpoint from the rat two-generation reproduction study can be used for higher tier assessment of non-lagomorph species (NOEL 60 mg ac/kg bw/d based on reduced adult body weight, food consumption and pup weight at 263 mg ac/kg bw/d).

Folpet has low toxicity to birds (LD_{50} >2510 mg ac/kg bw/d, *Colinus virginianus*). Following dietary administration in reproductive toxicity tests, reduction in hatchlings body weight was observed at 100 mg ac/kg diet (lowest NOEC 78 mg ac/kg bw/d, two species).

The acute assessment assumed that animals obtained 100% of their diet from the treatment area, while the chronic assessment assumed that animals obtain 50% of their diet from the treatment area for 21 days after the last application. Exposure estimates also considered chemical-specific dissipation on the different food items (foliar DT_{50} 14 days, arthropod DT_{50} 3.5 days, default DT_{50} 10 days for remaining food items). The higher tier (non-lagomorph) endpoint was considered in the assessment of risks to native rodents. Based on these considerations, the assessment concluded acceptable risks to birds and mammals. As a result, no protection measures are required for terrestrial vertebrates.

The log P_{ow} 3.1 for folpet indicates a high potential for bioaccumulation. As bioaccumulation processes are slow, a chronic assessment was conducted for the following scenarios: (1) food chain from earthworm to earthworm-eating vertebrates; (2) food chain from fish to fish-eating vertebrates; and (3) biomagnification in terrestrial food chains. The food chain assessment indicated that any accumulated residues in earthworms or fish will not reach levels harmful to predators under the proposed conditions of use. In the mammalian toxicokinetic studies, folpet was widely distributed in tissues, but it did not show any potential for accumulation as it was rapidly excreted and extensively metabolised. In addition, the fish toxicokinetic studies found no evidence of tissue accumulation with rapid depuration (CT_{50} <1 day). Therefore, it is considered that there will be no biomagnification along the food chain.

Aquatic species

Folpet has high toxicity to fish (geomean LC_{50} 0.034 mg ac/L, three species) and aquatic invertebrates (lowest EC_{50} 0.020 mg ac/L, *Daphnia magna*), and moderate toxicity to algae (E_rC_{10} 0.083 mg ac/L, *Raphidocelis subcapitata*) and aquatic plants (EC_{50} 7.5 mg ac/L, *Lemna minor*). The major metabolites

[13] Based on Exposure Via Air (EVA3) model (rev2h) available at: https://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/zul_umwelt_eva_prog-EN.xlsm?__blob=publicationFile&v=3

phthalimide, phthalamic acid, phthalic acid, 2-cyanobenzoic acid and benzamide are over 1000-fold less toxic to aquatic species than the parent substance.

Following long-term exposure to folpet, reduced growth of fish fry was observed at 0.018 mg ac/L (NOEC 0.011 mg ac/L, *Pimephales promelas*). No reliable chronic toxicity studies are available with aquatic invertebrates; however, folpet is not stable in water and chronic exposure is of low relevance.

Ten applications of a WG formulation of folpet was applied to an outdoor freshwater microcosm at nominal concentrations ranging 10-1000 µg ac/L in 7-day intervals. The community contained zooplankton, macro-invertebrates, emergent insects, phytoplankton and aquatic macrophytes. Zooplankton was the most sensitive group with pronounced effects on the copepod *Diaptomus* sp. at 30 µg ac/L, but the total period of effects was <8 weeks. Therefore, the NOEAEC was set at 30 µg ac/L, which is the basis of the aquatic RAL 10 µg ac/L (after application of assessment factor 3). No direct effects on phytoplankton community or on the distribution of four tested macrophytes were observed.

Runoff risks of folpet were determined to be acceptable under a realistic worst-case scenario (50% crop interception with 50% wash-off to clay-dominated Queensland soil profile). General runoff restraints are advised to avoid a runoff event soon after application (i.e., within 3 days).

Spray drift risks to aquatic species (natural aquatic areas) are considered in the spray drift risk assessment section.

Bees

Folpet has low toxicity to adult bees by contact exposure (LD_{50} >166 µg ac/bee, *Apis mellifera*) and oral exposure (LD_{50} >185 µg ac/bee, *Apis mellifera*). In an 8-day repeated dietary exposure study on bee larvae, increased mortality was observed at 5.0 µg ac/bee (NOEL 2.9 µg ac/bee, *Apis mellifera*).

Both nectar and pollen of grapes are considered attractive to bees and so exposure to bee brood was considered. Folpet has low water solubility and poor leaf penetration; therefore, residues in nectar and pollen are not expected when applications occur outside of the flowering period. Acceptable risks to bee brood could be concluded assuming bees forage in grapes treated during the flowering period. No protection or risk mitigation measures are considered necessary for bees.

Spray drift risks to bees (pollinator areas) are considered spray drift risk assessment section.

Other non-target arthropods

Following exposure to fresh-dried residues of a representative WG formulation of folpet on glass plates, LR_{50} values were >16000 g ac/ha for the indicator species of predatory arthropods (*Typhlodromus pyri*) and 457 g ac/ha for the indicator species of parasitic arthropods (*Aphidius rhopalosiphi*)[14]. Under extended laboratory (natural substrate) conditions, LR_{50} values were >5250 g ac/ha for predatory foliar arthropods (*Typhlodromus*

[14] An additional species of parasitic wasp was also tested on glass plates, but was less sensitive (LR_{50}/ER_{50} >530 g ac/ha, *Trichogramma cacoeciae*)

pyri, Coccinella septempunctata, Chyrsoperla carnea) and 996 g ac/ha for the parasitic wasp (*Aphidius rhopalosiphi*). The LR_{50} for the ground beetle on quartz sand was >660 g ac/ha (*Poecilus cupreus*).

The risk assessment assumes exposure to fresh-dried residues within the treatment area immediately after the last (fifth) application. Based on the extended laboratory tests (natural substrate), acceptable risks could be concluded for predatory arthropods. Higher-tier aged residue testing on the most sensitive parasitic arthropod species (*Aphidius rhopalosiphi*) suggests that responses are highly variable and acceptable impacts can be observed at field-relevant rates on day 0 (i.e., <50% effect on survival and reproduction at 3380 g ac/ha). Based on all available information, it is concluded that risks to beneficial arthropods used in integrated pest management systems are low under the proposed use conditions and no protection statements are considered necessary.

Soil organisms

Folpet has low toxicity to soil macro-organisms such as earthworms (LC_{50corr} >500 mg ac/kg dry soil, *Eisenia fetida*). Following long-term exposure to a representative WG formulation of folpet, reduced reproduction was observed at concentrations as low as 17 mg ac/kg dry soil (lowest $NOEC_{corr}$ 6.4 mg ac/kg dry soil, *Eisenia fetida*). Folpet did not impact soil processes such as nitrogen transformation at exaggerated soil concentrations (NOEC 21 mg ac/kg dry soil). No adverse effects on soil organisms were observed following exposure to the major soil metabolites phthalimide, phthalamic acid, and phthalic acid at concentrations exceeding field-relevant rates.

Acceptable risks could be concluded for soil organisms under a worst-case scenario of cumulative exposure to multiple applications without crop interception. No protection measures are considered necessary for soil organisms.

Non-target terrestrial plants

Available data on a representative WG formulation of folpet to 10 crop plant species indicate no phytotoxicity following either pre- or post-emergent exposure at the limit rate tested (ER_{25} >4000 g ac/ha).

Non-target plants are defined as non-crop plants located outside the treatment area, for which spray drift is considered the primary route of exposure. Spray drift risks to non-target terrestrial plants (vegetation areas) are considered spray drift risk assessment section.

Recommendations

The following protection statements are recommended based on the outcome of the environmental risk assessment. Spray drift risks are considered in the spray drift risk assessment section.

> Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers. To protect aquatic species from runoff, DO NOT apply if heavy rains or storms are forecast within 3 days. DO NOT irrigate to the point of water runoff from the treatment area for at least 3 days after application.

Efficacy and safety assessment

Proposed product use pattern

The proposed new product, Folpan 800 WG Fungicide, is a fungicide for use in wine, table and dried grapes, containing 800 g/kg of the active Folpet. Product is to be applied using vertical sprayer application at the rate of 125 g/100 L and 1000 L of spray ha. The label claims preventative control of the following diseases when used as part of a spray and in conjunction with other products.

- grey mould (*Botrytis cinerea*)
- downy mildew (*Plasmopara viticola*)
- powdery Mildew (*Uncinular necator*)

Efficacy and target crop/animal safety

Efficacy

Efficacy was assessed in 24 Australian trials and 92 overseas trials. The proposed diseases were all present in Australian trials. All but one trial applied the product 3 to 7 times in succession with no alternation of mode of action which is contrary to the label instructions. Trials were designed with 3-4 replicates per trial in a complete block design with ANOVA statistical analysis, followed by an appropriate post hoc test. Disease presence and severity in all trials were scored based on visual assessment. Disease pressure varied depending on the disease but was generally low to moderate except for downy mildew where artificially inoculated trials were used resulting in a high disease pressure.

Trials demonstrated an effect of treatment with use of the proposed product reducing both incidence and severity of the disease. For powdery mildew trials showed up to 50% reduction in disease when used alone and a 97-99% reduction when used as part of a spray program.

For grey mould, treatment using Folpan 800 alone, maintained the disease pressure at the initial low infestation rate, while untreated plots increased significantly. However, overall disease pressure remained low. No grey mould developed in spray program trials.

For downy mildew, applicant included artificially inoculated trials where treatment reduced incidence by up to 70% when Folpan 800 was applied alone. In trials where the product was applied as part of a coordinated spray program incidence was reduced by 90 to 95%.

Data provided supports use as a preventative fungicide as part of a spray program.

Crop safety

All trials conducted in Australia, showed no visible phytotoxicity or adverse growth effects on Grape crops when assessed visually. Folpan 800 WG is considered safe including 2x label rate (250 g/100 L). No

phytotoxic effects were observed on grapes during its growth at either flowering or budburst in Australia. As the rate for all diseases is equivalent crop safety can be satisfied for use against all diseases.

Resistance management

Folpet is a group M04 fungicide with multi-site activity. Currently Captan is the only other active approved for use in Australia with this mode of action. Resistance risk is reduced by the multi-site action of this product and the label includes instruction to use Folpan 800 as part of a spray program and in conjunction with alternate modes of action. Sufficient label instructions are provided.

Recommendations

Trial data provided confirmed efficacy and crop safety for the proposed product, when used according to label directions i.e. applied at 125 g/100 L to grapevines for the preventative control of the diseases downy mildew, grey mould, and powdery mildew as part of a fungicide spray program.

Spray drift assessment

Regulatory Acceptable Levels (RALs) were established using the APVMA Spray Drift Assessment Tool (SDRAT), or Spray Drift Management Tool (SDMT), by each risk area, in order to calculate the appropriate spray drift buffer zones for Folpan 800 WG Fungicide.

Human health

Application of Folpan 800WG Fungicide by a vertical sprayer may lead to unintended bystander exposure via chemical spray drift. This may be in the form of a single random exposure or repeat exposures of residents who reside adjacent to areas being treated with the product. Bystander exposure assessment does not consider bystander contact with airborne spray drift but rather the risks from landed residues.

Regulatory acceptable levels were determined using toddler on turf models for 1–2 and 2–3 year old children.

The following inputs and application parameters were used in the tool:

Model input parameters	
Body weight	11 kg (1-2 years old)
Body weight	15 kg (2-3 years old)
Transfer coefficient	49000 (1-2 years old)
Transfer coefficient	60000 (2-3 years old)
NOAEL[15]	10 mg/kg bw/d
Dermal absorption factor (DAF)[16]	7% (Fraction = 0.07)
RAL in g ac/ha	541 (1-2 years old)
Product application details	
Application method	Groundboom
Active constituent concentration	800 g/kg
Max application rate (product)	3.125 L/ha

[15] The NOAEL of 10 mg/kg bw/d was determined in a rabbit developmental study 24-month rat dietary study. Folpet is non-enzymatically metabolised pre-systemically to phthalimide in the GI tract prior to absorption. The systemic bioavailability of folpet is zero, but is >80% for phthalimide, the main metabolite of folpet. Therefore, gastrointestinal (GI) absorption adjustment is not necessary.

Risks from spraying activities were estimated using the APVMA Spray Drift Risk Assessment Tool (2023) at an application rate of 1.25 kg/ha. Results indicated that no buffer zones are required for vertical spraying of vines (canopies 2 metres or less).

Residues and trade

The proposed use on grapes involves a spray concentration of 125g product/100L (100g a.i./100L) and applied as 1000 L of spray/ha. The Applicant has not proposed statements in relation to spray drift.

Animal commodity MRLs are not currently established for folpet in many overseas markets. Codex MRLs are proposed in animal commodities at the LOQ for folpet of 0.01 mg/kg, while MRLs for animal commodities are established at 0.05 mg/kg in both the European Union and New Zealand, which have a residue definition for compliance for animal commodities of folpet + phthalimide, expressed as parent folpet. It is therefore considered that residues should be below the LOQ for folpet of 0.01 mg/kg and below the LOQ for phthalamide of 0.05 mg/kg in animal tissues to mitigate a risk to the international trade of animal tissues.

A mammalian transfer study has been submitted with the current application. Dosing with folpet at 36 ppm did not result in quantifiable residues of the parent folpet in any tissue. Dosing with folpet at 36 ppm gave a highest folpet + phthalimide residue of 0.12 mg/kg (as parent equivalents) in fat.

For residues of folpet and phthalimide (as parent folpet) to be at the European Union LOQ (0.05 mg/kg), the maximum feeding level or Regulatory Acceptable Level (RAL) is 15 ppm.

If this Regulatory Acceptable Level for folpet and the proposed spray parameters are used in the APVMA Spray Drift Risk Assessment Tool (SDRAT), no buffer zones are required for livestock areas and the protection of international trade.

Environment

The RAL for the protection of natural aquatic areas is 10 µg ac/L based on the outdoor freshwater microcosm NOEAEC 30 µg ac/L (transient effects on the copepod *Diaptomus* sp.) and an assessment factor of 3. Based on this RAL and the proposed use of Folpan 800 WG Fungicide, buffer zones of 10 metres are required for the protection of natural aquatic areas.

RAL for the protection of pollinator areas is 27667 g ac/ha based on the acute contact LD_{50} >166 µg ac/bee (*Apis mellifera*), assessment factor of 2.5, and conversion factor of 1000 / ExpE 2.4. Based on this RAL and the proposed use of Folpan 800 WG Fungicide, no buffer zones are required for the protection of pollinator areas.

The RAL for the protection of vegetations areas is 2000 g ac/ha based on the ER_{25} >4000 g ac/ha following pre- or post-emergent exposure of ten crop plant species and an assessment factor of 2. Based on this RAL and the proposed use of Folpan 800 WG Fungicide, no buffer zones are required for the protection of vegetation areas.

Table 7: Summary of RALs for Folpan 800 WG Fungicide

Sensitive area	Regulatory Acceptable Level	
	Level of active	Units
Bystander	541	g/ha
Livestock	15	ppm
Aquatic	10	µg/L
Pollinator	27667	g/ha
Vegetation	2000	g/ha

Buffer zones calculated by the SDRAT or SDMT, using the above RALs, were incorporated into the Folpan 800 WG label spray drift instructions (see *Labelling requirements* below).

Labelling requirements

POISON

KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Folpan®800 WG

Fungicide

ACTIVE CONSTITUENT: 800 g/kg FOLPET

GROUP	M4	FUNGICIDE

***A preventative treatment for control of Downy mildew, Powdery mildew and Grey mould in Grapes as shown under the directions for use*.**

Formulation type: Water Dispersible granule (WG)

adama.com **CONTENTS: 1 kg - 1000 kg**

RESTRAINTS
DO NOT apply by aircraft.
DO NOT apply if heavy rains or storms that are likely to cause runoff from treated areas are forecast within 3 days.
DO NOT irrigate to the point of water runoff from the treatment area for at least 3 days after application.
DO NOT apply more than five applications per season in grapes.

SPRAY DRIFT RESTRAINTS
Specific definitions for terms used in this section of the label can be found at apvma.gov.au/spraydrift

DO NOT allow bystanders to come into contact with the spray cloud.
DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The advisory buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.
DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.
DO NOT apply if there are surface temperature inversion conditions present at the application site during the time of application. These conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.
DO NOT apply by a vertical sprayer unless the following requirements are met:

- spray is not directed above the target canopy
- the outside of the sprayer is turned off when turning at the end of rows and when spraying the outer row on each side of the application site
- for dilute water rates up to the maximum listed for each type of canopy specified, minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for vertical sprayers') are observed.

Buffer zones for vertical sprayers					
Type of target canopy	**Bystander areas**	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**	**Livestock areas**
Grapevines	Not required	10 metres	Not required	Not required	Not required

DIRECTIONS FOR USE
Apply Folpan® 800 WG as a part of preventative fungicide spray program to control Downy mildew, Grey mould and Powdery mildew.

Crop	DISEASE	Rate	Critical Comments
Grapes	Downy mildew (*Plasmopara viticola)*	**Dilute spraying 125 g/100L** **Concentrate spraying** Refer to the Mixing/Applications section	Folpan® 800 WG is a multi-site fungicide with a preventative mode of action. Apply preventatively from budburst as a part of downy mildew protectant spray program, with 10-14 day spray interval. When the conditions favour disease development use the shorter spray interval. Apply to point of run-off.
	Grey mould *(Botrytis cinerea)*		Apply in a preventative spray program from early flowering until pre-harvest. Apply to point of run-off. Folpan® 800 WG can be used in conjunction with a systemic Botrytis product to assist with resistance management.
	Powdery Mildew *(uncinular necator)*		Incorporate Folpan® 800 WG as part of a season long spray programs in support of sulfur or other single-site Mode-of-Action (MoA) treatments. Folpan 800 WG should be used as part of a powdery mildew preventative program.

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

WITHHOLDING PERIODS:

HARVEST
Grapes: DO NOT HARVEST FOR 7 DAYS AFTER APPLICATION

GRAZING

TREATED CROPS ARE NOT TO BE GRAZED OR FED TO ANIMALS.
DO NOT GRAZE VINEYARDS AFTER APPLICATION.

EXPORT TRADE ADVICE – TREATED CROPS:
Treated crop commodities destined for export may require extra time being allowed between application and harvest to be accepted in some export markets. Before using FOLPAN 800 WG on crops destined for export it is essential to consult your exporter or ADAMA Australia Pty Ltd. and/or your industry body about any potential trade issues and their management.

GENERAL INSTRUCTIONS
FUNGICIDE RESISTANCE WARNING

GROUP M4 FUNGICIDE

For fungicide resistance management FOLPAN® 800 WG Fungicide is a Group M4 fungicide. FOLPAN 800 WG Fungicide contains folpet a protectant fungicide from the phthalimide chemical group with multi-site activity. For best results, thorough coverage of the crop prior to the onset of infection is recommended as FOLPAN 800WG Fungicide has activity against very early stages of infection such as spore germination. For best results use in a program with other fungicide mode of action groups and or mixed with other fungicide mode of action groups. Some naturally occurring fungi resistant to the product and other Group M4 fungicides may exist through normal genetic variability in any fungal population. The resistant individuals can eventually

dominate the fungal population if FOLPAN® 800 WG or other Group M4 fungicides are used repeatedly. These resistant fungi will not be controlled by this product or other Group M4 fungicides, thus resulting in a reduction in efficacy and possible yield loss.
Since occurrence of resistant fungi is difficult to detect prior to use, ADAMA Australia accepts no liability for any losses that may result from the failure of this product to control resistant insects. Folpan 800WG may be subject to specific resistance management strategies. For further information contact your local supplier, ADAMA Australia or local agricultural department agronomist.

MIXING
Add the required amount of product to the 70% filled spray tank with the agitator in operation. Fill the tank with water and continue agitation during spraying and after a stoppage. Do not leave mixture in tank overnight. Rinse out spray tank, pumps and nozzles at the end of the day.

APPLICATION
Ground application

Dilute Spraying - Grapes
Use a sprayer designed to apply high volumes of water up to the point of run-off and matched to the crop being sprayed.
Set up and operate the sprayer to achieve even coverage throughout the crop canopy. Apply sufficient water to cover the crop to the point of run-off. Avoid excessive run-off. The required water volume may be determined by applying different test volumes, using different settings on the sprayer, from industry guidelines or expert advice. Add the amount of product specified in the Directions for Use table for each 100 L of water. Spray to the point of run-off. The required dilute spray volume will change and the sprayer set up and operation may also need to be changed, as the crop grows.

Concentrate Spraying:
Use a sprayer designed and set up for concentrate spraying (that is a sprayer which applies water volumes less than those required to reach the point of run-off) and matched to the crop being sprayed. Set up and operate the sprayer to achieve even coverage throughout the crop canopy using your choses water volume. Determine an appropriate dilute spray volume (see Dilute Spraying above) for the crop canopy. This is needed to calculate the concentrate mixing rate. The mixing rate for concentrate spraying can then be calculated in the following way.
Examples only

1. Dilute spray volume as determined above: For example 1000L/ha
2. Your chosen concentrate spray volume: For example 500 L/ha
3. The concentration factor in this example is: 2X (i.e 1000L÷ 500 L = 2)
4. If the dilute label rate is 125 g/100L, then the concentrate rate becomes 2 x 125 that is 250 g/100L of concentrate spray.

The chosen spray volume, amount of product per 100 L of water and the sprayer set up and operation may need to be changed as the crop grows. DO NOT use at a concentration rate higher than that specified in the Critical Comments as crop safety has not been assessed.
For further information on concentrate spraying, users are advised to consult relevant industry guidelines, undertake appropriate competency training and follow industry Best practices.

PRECAUTIONS
Do not apply using spraying equipment carried on the back of the user.

Re-entry Period

Do not allow entry into treated areas until the spray has dried. When prior entry is necessary wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), a washable hat and elbow-length chemical resistant gloves. Clothing must be laundered after each day's use.

Tank mix compatibility

If FOLPAN 800WG is to be mixed with other products, the physical compatibility of the mixture should be tested prior to use. For information of tank mix compatibility please contact Adama Australia. Physical compatibility testing to be carried out and a compatibility guide to be produced.

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
Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.

STORAGE AND DISPOSAL
Store in the closed, original container in a cool, well-ventilated area. DO NOT store for prolonged periods in direct sunlight.

Single-rinse or shake remainder into spray tank. DO NOT dispose of undiluted chemicals on site. Puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, dispose of empty container or unused product in compliance with relevant local, state or territory government regulations. DO NOT burn empty containers or product.

SAFETY DIRECTIONS
Harmful if inhaled. Will damage eyes, will irritate skin and may irritate the nose and throat. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow length chemical resistant gloves, washable hat and face shield or goggles. If applying by closed cab tractor wear cotton overalls buttoned to the neck and wrist (or equivalent clothing). If applying by open cab tractor, wear cotton overalls buttoned to the neck and wrist and a washable hat, gauntlet length chemical resistant gloves and a disposable mist facemask covering mouth and nose. Wash hands after use. 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 131126.
If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor'.

Acronyms and abbreviations

Shortened term	Full term
ACCS/ACMS	Advisory Committee for Chemicals Scheduling/Advisory Committee for Medicines Scheduling
ac	Active constituent
ADI	Acceptable daily intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	Active ingredient
ARfD	Acute reference dose
BBA	Biologische Bundesanalstalt fur Land – und forstwirschaft
bw	Bodyweight
CT_{50}	Time taken for 50% clearance of chemical from animal tissue
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
EI	Export interval
EGI	Export grazing interval
ESI	Export slaughter interval
EUP	End use product
ExpE	Exposure estimate
F_0	Original parent generation
g	Gram
GAP	Good Agricultural Practice

Shortened term	Full term
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GVP	Good Veterinary Practice
h	Hour
ha	Hectare
Hct	Heamatocrit
Hb	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
Log K_{OW}	Log to base 10 of octanol water partitioning co-efficient, synonym P_{OW}
LOQ	Limit of quantitation – level at which residues can be quantified
mg	Milligram
mL	Millilitre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet

Shortened term	Full term
NEDI	National Estimated Daily Intake
NESTI	National Estimated Short-Term Intake
ng	Nanogram
NHMRC	National Health and Medical Research Council
NOEAEC	No observed ecologically adverse effect concentration
NOEC/NOEL	No observable effect concentration level
NOAEL	No observed adverse effect 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
RAL	Regulatory Acceptable Level
RBC	Red blood cell count
REI	Re-entry interval
s	Second
sc	Subcutaneous
SC	Suspension concentrate
SDMT	Spray Drift Management Tool
SDRAT	Spray Drift Risk Assessment Tool
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
TGAC	Technical grade active constituent
µg	Microgram
vmd	Volume median diameter

Shortened term	Full term
WG	Water dispersible granule
WHP	Withholding period

Glossary

Term	Description
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 a material from or through 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	Repels water
Leaching	Removal of a compound by use of a solvent
Metabolism	The chemical processes that maintain living organisms
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

JMPR (1984). Folpet. Pesticide residues in food report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues 1984 Rome, 24 September - 3 October 1984.