Public release summary

On the evaluation of the new active Benzovindiflupyr in the product Elatus Ace Fungicide
APVMA product number 86310
JUNE 2019
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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 is 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 approval of the active constituent benzovindiflupyr and registration of the product ELATUS ACE 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 16 July 2019 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:

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

All personal information, and confidential information judged by the APVMA to be confidential commercial information (CCI)\(^1\) contained in submissions will be treated confidentially. Unless requested by the submitter, the APVMA may release a submission, with any CCI redacted, to the applicant for comment.

Written submissions on the APVMA’s proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Residues and Trade
Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

**Phone:** +61 2 6210 4701
**Email:** enquiries@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](https://www.apvma.gov.au).

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\(^1\) A full definition of "confidential commercial information" is contained in the Agvet Code.
1 INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for approval of the new active constituent benzovindiflupyr and registration of the product Elatus Ace Fungicide.

1.1 Applicant

Syngenta Australia Pty Ltd.

1.2 Purpose of application

Syngenta Australia Pty Ltd has applied to the APVMA for registration of the new product Elatus Ace Fungicide, containing 250 g/L propiconazole and 40 g/L benzovindiflupyr, as an emulsifiable concentrate.

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for approval of the new active constituent benzovindiflupyr and registration of the product Elatus Ace Fungicide.

1.3 Proposed claims and use pattern

Elatus Ace Fungicide is proposed for the control of certain fungal diseases in wheat and barley. It is applied at the first sign of disease. Depending on the disease being targeted, this may be during tillering or stem elongation. A repeat spray 21 to 28 days later may be required.

1.4 Mode of action

The active ingredients in Elatus Ace Fungicide have different modes of action on fungal pathogens and are in different resistance groups, Group 3 for propiconazole and Group 7 for benzovindiflupyr.

1.5 Overseas registrations

Elatus Ace Fungicide is currently registered in Argentina for use in barley and wheat. Registrations in Turkey and Uruguay (use in wheat and barley) are pending and there are plans to register Elatus Ace Fungicide in Brazil, Bolivia, and Paraguay for use in cereals.

100g/L benzovindiflupyr emulsifiable concentrate products are registered for use in Belgium, Bulgaria, Croatia, Czech Republic, Estonia, Finland, Germany, Ireland, Italy, Latvia, Lithuania, Slovenia, Sweden and United Kingdom for use in cereal crops such as barley, rye, triticale, wheat, oats and spelt. In Canada this formulation is registered for use in a large number of crops including barley and wheat and in the USA for a large number of crops including cereals.

A wettable granule formulation containing 150 g/kg benzovindiflupyr + 300 g/kg azoxystrobin is registered in Argentina, Bolivia, Brazil, Canada, Paraguay, USA and Uruguay for use predominantly in wheat, barley, soybean and corn.
2 CHEMISTRY AND MANUFACTURE

2.1 Active constituent

The active constituent benzovindiflupyr is a preventative fungicide belonging to the pyrazolcarboxamide chemical class.

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

<table>
<thead>
<tr>
<th>Table 1: Nomenclature and structural formula of the active constituent benzovindiflupyr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Common name (ISO):</strong></td>
</tr>
<tr>
<td><strong>IUPAC name:</strong></td>
</tr>
<tr>
<td><strong>Chemical abstracts name:</strong></td>
</tr>
<tr>
<td><strong>CAS registry number:</strong></td>
</tr>
<tr>
<td><strong>Molecular formula:</strong></td>
</tr>
<tr>
<td><strong>Molecular weight:</strong></td>
</tr>
</tbody>
</table>

Benzovindiflupyr technical is an off-white odourless powder with melting point at 145.7 °C. It is insoluble in water but soluble in common organic solvents. Benzovindiflupyr technical is hydrolytically stable with no degradation at pH, 5, 7, 9 for five days at 50 °C. It is also hydrolytically stable for 30 days at 25 °C. Key physicochemical properties are tabulated below.
<table>
<thead>
<tr>
<th>Physical form:</th>
<th>Solid (powder)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour:</td>
<td>White (99.4% w/w), off-white (97.7% w/w)</td>
</tr>
<tr>
<td>Odour:</td>
<td>Odourless (99.4% w/w), odourless (97.7% w/w)</td>
</tr>
<tr>
<td>Melting Point: purity 99.4% w/w</td>
<td>148.4 ± 0.5 °C</td>
</tr>
<tr>
<td>Melting point: purity 97.7%</td>
<td>145.7 °C</td>
</tr>
<tr>
<td>Boiling point:</td>
<td>Decomposition occurred, starting at 285 °C</td>
</tr>
<tr>
<td>Density (22.0 °C, technical active, purity 97.7%)</td>
<td>1.42 g/cm³</td>
</tr>
<tr>
<td>Relative density ($D_{420}^0$, pure active, 99.4%)</td>
<td>1.466</td>
</tr>
<tr>
<td>Surface tension (technical active, 90% of saturation concentration in water)</td>
<td>63.0 mN/m (20.0 °C)</td>
</tr>
</tbody>
</table>
| Particle size | Median: 6.05 μm  
d(10): 0.933 μm  
d(90): 54.8 μm |
| pH | 6.9 (1% w/v aqueous dispersion) |
| pKa | No dissociation constant (pKa) in the pH range 2.0–12.0 |
| Hydrolysis | Hydrolytically stable at pH 4, 5, 7, and 9 (in the dark, in sterile water, at 25 and 50 °C) |
| Aqueous photolysis | Sterile pH 7.0 0.01 M phosphate buffer  
$DT_{50}$ (summer sunlight, 30–50° N): 95.2 days  
$DT_{90}$ (summer sunlight, 30–50° N): 316.1 days  
Sterile natural water  
$DT_{50}$ (summer sunlight, 30–50° N): 10.4 days  
$DT_{90}$ (summer sunlight, 30–50° N): 34.6 days |
<p>| Atmospheric half-life (calculated degradation by hydroxyl radicals) | 2.37 hours |
| Vapour pressure (purity 99.4% w/w) | $3.2 \times 10^{-9}$ Pa at 25 °C |</p>
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Henry’s law constant (25 °C)</td>
<td>$1.3 \times 10^{-6}$ Pa m³/mol</td>
</tr>
<tr>
<td>n-Octanol/water partition coefficient (purity 99.4%)</td>
<td>log Pow = $4.3 \pm 0.3$ in purified water at 25 °C</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>0.98 mg/L at 25 °C</td>
</tr>
</tbody>
</table>
| Solubility in organic solvents at 25 °C (technical active, 97.7% purity) | Acetone: 350 g/L  
   Dichloromethane: 450 g/L  
   Ethyl acetate: 190 g/L  
   Hexane: 270 g/L  
   Methanol: 76 g/L  
   Octanol: 19 g/L  
   Toluene: 48 g/L |
| Flammability                                  | Not flammable                              |
| Auto-flammability                             | No ignition below the melting point         |
| Explosive properties                          | Not an explosive substance                 |
| Oxidising properties                          | Not an oxidising substance                 |
| Corrosion properties                          | Not corrosive to tinplate, galvanised sheet metal, sheet metal or stainless steel |
| Thermal stability                             | No exothermic events or weight losses between 25 and 200 °C |

On the basis of the chemistry data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for benzovindiflupyr:

<table>
<thead>
<tr>
<th>Constituent</th>
<th>Specification</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzovindiflupyr</td>
<td>benzovindiflupyr</td>
<td>960 g/kg minimum</td>
</tr>
</tbody>
</table>

### 2.2 Formulated product

The product will be formulated in various locations in Europe and Australia using benzovindiflupyr manufactured overseas. Tables 3 and 4 outline some key aspects of the formulation and physicochemical properties of the product. The manufacturing and quality control procedures, including compliance with the release specifications, are acceptable.
Table 3: Key aspects of the formulation of the product Elatus Ace Fungicide

<table>
<thead>
<tr>
<th>Distinguishing name:</th>
<th>Elatus Ace Fungicide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation type:</td>
<td>Emulsifiable concentrate</td>
</tr>
<tr>
<td>Active constituent concentration/s:</td>
<td>40 g/L benzovindiflupyr</td>
</tr>
<tr>
<td></td>
<td>250 g/L propiconazole</td>
</tr>
</tbody>
</table>

Table 4: Physicochemical properties of the product Elatus Ace Fungicide

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosity at 20 ºC:</td>
<td>109 mPa.s</td>
</tr>
<tr>
<td>Surface tension (3.75% w/v in pure water at 20ºC):</td>
<td>33.9 mN/m</td>
</tr>
<tr>
<td>pH value (1% v/v in water):</td>
<td>6.6</td>
</tr>
<tr>
<td>Persistent foaming:</td>
<td>0 mL</td>
</tr>
<tr>
<td>Emulsion stability (3.75% v/v, after 0.5 hours):</td>
<td>No cream, no oil</td>
</tr>
<tr>
<td>Safety properties:</td>
<td>Not corrosive, flammable or explosive</td>
</tr>
</tbody>
</table>

The applicant provided the results of accelerated stability testing conducted using samples stored in HDPE, fluorinated HDPE, HDPE/polyamide and PET packs (the proposed commercial container types). Testing of all key parameters for emulsifiable concentrate formulations was conducted. The results indicate that the formulated product is expected to be stable for at least two years when stored under normal conditions in the proposed commercial packaging.

2.3 Recommendations

The APVMA has evaluated the chemistry of the active constituent benzovindiflupyr and associated product Elatus Ace Fungicide, including the manufacturing process, quality control procedures, 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, approval of the active constituent benzovindiflupyr and the registration of the product Elatus Ace Fungicide are supported from a chemistry perspective.
3 TOXICOLOGICAL ASSESSMENT

3.1 Evaluation of toxicology

The toxicological data submitted on the active benzovindiflupyr was considered sufficient to determine its toxicology profile and to characterise the risk to humans. The data included metabolism studies, acute toxicity studies (active constituent and product), short-term toxicity studies (oral and dermal), long-term oral toxicity studies (including carcinogenicity), reproductive and developmental toxicity studies, genotoxicity studies, neurotoxicity studies (acute and repeat-dose), studies on metabolites and other information to address the human safety criteria. Reports by the European Food Safety Authority (EFSA, 2015) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR, 2013) for benzovindiflupyr were relied on, along with the underlying supporting data.

In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Findings of adverse effects in any one species do not necessarily indicate such effects might be generated in humans. From a conservative risk assessment perspective however, adverse findings in animal species are assumed to represent potential effects in humans, unless convincing evidence of species specificity is available. Where possible, considerations of the species specific mechanisms of adverse reactions weigh heavily in the extrapolation of animal data to likely human hazard. Equally, consideration of the risks to human health must take into account the likely human exposure levels.

Chemical class

Benzovindiflupyr is a broad spectrum foliar fungicide belonging to the pyrazole carboxamide class. The mode of action is an inhibitor of the succinate dehydrogenase generation mechanism of the citric acid cycle. Others in the succinate dehydrogenase inhibitor (SDHI) class approved in Australia are bixafen, fluxapyroxad, isopyrazam, penflufen, penthiopyrad and sedaxane. Technical benzovindiflupyr contains the enantiomers SYN546256 and SYN546527 at a ratio of 50:50. Both are fungicidally active.

Pharmacokinetics

Oral absorption of benzovindiflupyr was essentially complete (>80 per cent) following low dose (1 mg/kg bw) oral administration compared to IV administration in rats, and absorption was reduced at higher doses (~60 per cent at 40 mg/kg bw dose). Radioactivity associated with the administration of [14C]-benzovindiflupyr in rats was distributed widely with the highest levels detected in the liver with lower concentrations in the kidney and brown fat. It is extensively metabolised and rapidly eliminated, with the majority of radioactivity excreted in the faeces within 72 h. The major metabolites exceeding 10 per cent of the dose in rats were SYN546041 (approximately 26–56 per cent of the dose) and SYN546360 (approximately two–12 per cent of the dose). There was no evidence of accumulation or significant differences between sexes. Following a low dose, the terminal phase plasma half-life for administered radioactivity was 55 h in males and 28 h in females, and following a high dose 30 and 33 hours, respectively. Benzovindiflupyr was considered the only toxicologically significant compound.
Acute toxicity (active constituent)

Benzovindiflupyr is of moderate acute oral toxicity in rats (> 55 mg/kg bw LD$_{50}$ ≤ 175 mg/kg bw), low acute dermal toxicity (LD$_{50}$ > 2000 mg/kg bw) and of moderate acute inhalational toxicity (LC$_{50}$ > 560 mg/m$^3$). The active is classified as non-irritating to the skin of rabbits and moderately irritating to the eyes. It did not show skin sensitisier potential in a mouse local lymph node assay (LLNA).

Acute toxicity (product)

Based on submitted toxicological studies, the formulated product, Elatus Ace fungicide, containing 250 g/L propiconazole and 40 g/L benzovindiflupyr, has low acute toxicity in rats by the oral (> 550 LD$_{50}$ < 2000 mg/kg bw), dermal (LD$_{50}$ > 2000 mg/kg bw) and inhalation (LC$_{50}$ > 2000 mg/m$^3$) routes. The product was not a skin irritant but a moderate eye irritant and a skin sensitisier in mice (LLNA).

Repeat-dose toxicity

Following repeat-dosing, the liver was the primary target organ (hepatocellular hypertrophy, increased organ weight from 36/54 mg/kg bw/d in rats from 28/90 day studies, respectively) and reduced body weight/body weight gain (from 47/56 mg/kg bw/d in mice from 28/90 day studies, respectively; from 36/54 mg/kg bw/d in rats from 28/90 day studies respectively; from 375 mg/kg bw/d in dogs in a 13 wk study). In addition, colon/rectal hyperplasia was noted in mice (from 56 mg/kg bw/d from 90 day study).

Repeated dosing via the dermal route in rats did not demonstrate toxicity at the highest dose tested (1000 mg/kg bw/d five days/week for four weeks).

Chronic toxicity and carcinogenicity

Chronic studies in mice (diet; up to 29 mg/kg bw/d), rats (diet; up to 30 mg/kg bw/d) and dogs (capsule; up to 500 mg/kg bw/d) demonstrated benzovindiflupyr is not carcinogenic. Tumours noted in rodent studies were determined not to be relevant to humans. Harderian gland adenomas in mice were likely due to a low incidence in the control group; further, this is a rodent specific structure with no equivalent in humans. Thyroid follicular cell adenomas observed at the highest dose in rats were related to induction of a hepatic enzyme (uridine diphosphate glucuronol transferase (UDPGT)) that was unlikely to be of relevance to humans. Systemic effects noted in shorter term repeat-dose studies were reflected in longer studies, with liver effects (in rats from 27 mg/kg bw/d in a 104 week study, LOAEL), and reduced body weight/body weight gain (in rats from 27 mg/kg bw/d in a 104 week study) and colon/rectal hyperplasia was noted in mice (from 26 mg/kg bw/d from a 80 wk study study, LOAEL). Local but not systemic, gastrointestinal effects were noted in dogs (from 250 mg/kg bw/d in a 52 week study, NOAEL).

Reproductive and developmental toxicity

No reproductive toxicity of benzovindiflupyr was observed in a multi-generation reproduction dietary study in rats at doses up to 250 ppm for females and 600 ppm for males. The parental and offspring NOAEL was 100 ppm (equal to 6.8 mg/kg bw/d for F0 generation males during pre-pairing and 7.8 mg/kg bw/d for F1 males during pre-pairing) based on reduced body weight gain and food consumption, liver effects (adaptive/mild toxicity) and lower postnatal pup weights at 250 ppm in females (equivalent to 19.4 mg/kg bw/d for F0
generation females during pairing) and 600 ppm males (equal to 40.5 mg/kg bw/d for F0 generation males during pre-pairing). The NOAEL for effects on reproduction was the highest dose tested (250 ppm, approximately 17.5 mg/kg bw/d).

In oral gavage developmental toxicity studies in rats and rabbits, benzovindiflupyr was not teratogenic. In rats, the maternal and foetal NOAEL was 15 mg/kg bw/d based on clinical signs, reduced food intake and body weight in dams and reduced weight and delayed ossification in foetuses at doses toxic to dams. The developmental NOAEL was ≥ 30 mg/kg bw/d, the highest dose tested. In rabbits, NOAEL for maternal, foetal and developmental effects was ≥ 35 mg/kg bw/d, the highest dose tested.

Genotoxicity

Benzovindiflupyr was tested in a range of in vivo and in vitro assays for genotoxicity. No evidence for genotoxicity was observed in any test and it was concluded that benzovindiflupyr was unlikely to be genotoxic.

Neurotoxicity/immunotoxicity

Neurotoxicity studies in rats were conducted as a single oral gavage dose of up to 80 mg/kg bw/d and dietary dosing over 90 days at doses up to 38 mg/kg bw/d. It was concluded that benzovindiflupyr was not neurotoxic.

Benzovindiflupyr did not show immunotoxic potential in a 28 day immunotoxicity study in mice at doses up to 400 ppm (97 mg/kg bw/d) in the diet.

Mode of action (toxicology)

Benzovindiflupyr is a broad spectrum foliar fungicide belonging to the succinate dehydrogenase inhibitor (SDHI) pyrazole carboxamide class. These fungicides bind to the ubiquinone-binding site (Q-site) of fungal mitochondrial complex II, thereby inhibiting cellular respiration. As a class, these fungicides are highly selective for fungal mitochondrial complex II. Mammalian mitochondrial complex II are insensitive to the effects of these fungicides.

Toxicity of metabolites and/or impurities

Studies on three metabolites: SYN546039 (CSCD695908); SYN545720 (CSCD465008); and CSAA798670 (NOA449410) have been conducted. All three metabolites were less acutely toxic by the oral route in rats (LD₅₀ > 2000 mg/kg bw) than the parent compound, benzovindiflupyr. SYN546039 was negative in bacterial reverse mutation assay and the other two metabolites were also negative for genotoxicity (bacterial reverse mutation, in vitro cytogenetics and mammalian cell gene mutation (mouse lymphoma). SYN545720 and NOA449410 did not result in treatment related effects in 28 and 90 day dietary studies in rats (limit dose of 1000 mg/kg bw/d) or developmental effects in rabbits at the highest dose tested (1000 mg/kg bw/d and 250 mg/kg bw/d, respectively).
Reports related to human toxicity

The active, benzovindiflupyr, has been approved for a number of years overseas. No reports related to human toxicity were submitted to the APVMA and a search of the publicly available scientific literature did not reveal any relevant findings.

3.2 Health-based guidance values and poisons scheduling

Poisons standard

On 29 November 2018, the Delegate of the Secretary of the Department of Health published a final Scheduling decision to include benzovindiflupyr in Schedule 6 of the Poisons Standard with no exemptions or concentration cut-offs. The reasons for the decision was based on the toxicity profile (moderate acute oral and inhalational toxicity and moderate eye irritation).

Propiconazole is currently listed in Schedule 6 the Poisons Standard at concentrations greater than 20 per cent. Elatus Ace Fungicide containing 40 g/L benzovindiflupyr and 250 g/L propiconazole will be a Schedule 6 product.

Health-based guidance values

Acceptable Daily Intake (ADI)

The Acceptable Daily Intake (ADI) is that quantity of a chemical compound that can safely be consumed on a daily basis for a lifetime.

The ADI for benzovindiflupyr was established at 0.05 mg/kg bw/d. This was based on a NOAEL of 4.9 mg/kg bw/d for reduced body weight gain and liver toxicity (histological changes; increased incidences of eosinophilic foci of cellular alteration) at 27.4 mg/kg bw/d in a two-year rat study, with the application of an uncertainty factor of 100. This ADI was also supported by the NOAEL of 7.55 mg/kg bw/d in a mouse 80-week dietary study, with colon/caecum mucosal hyperplasia at 26.18 mg/kg bw/d.

Acute Reference Dose (ARfD)

The Acute Reference Dose (ARfD) is the maximum quantity of a chemical that can safely be consumed over a short period of time, usually in one meal or during one day.

The ARfD for benzovindiflupyr was established at 0.1 mg/kg bw. This was based on a NOAEL of 10 mg/kg bw for clinical observations (decreased locomotor activity at 1 h post-dosing and reduced forelimb grip strength in females at one hour post-dosing) and reduced body weight gain at 30 mg/kg bw in an acute neurotoxicity study in rats, with the application of an uncertainty factor of 100. This ARfD was also supported by the NOAEL of 15 mg/kg bw/d in a developmental toxicity study in rats with clinical signs (ataxia, decreased activity, hunched and prostrate posture and ruffled fur) at 30 mg/kg bw/d from treatment days six to 16.
3.3 Recommendations

Based on a review of the submitted toxicological data, the approval of the new active constituent benzovindiflupyr and registration of the product Elatus Ace Fungicide is supported from a human health perspective.
4 RESIDUES ASSESSMENT

As part of the residues assessment of benzovindiflupyr (Elatus Ace Fungicide), plant and animal metabolism studies, supervised residue trials for barley and wheat, animal transfer studies, analytical methodology, fate in storage and processing data, rotational cropping data and residues in trade information were considered.

Elatus Ace Fungicide contains the existing active propiconazole in addition to benzovindiflupyr. The proposed use of propiconazole however is equivalent in application rate, timing, frequency and withholding periods to that approved in other currently registered products and no further consideration to propiconazole is required.

4.1 Metabolism

Metabolism studies were provided for spring wheat, tomatoes, soya beans, rotational crops, hen and goat. The metabolism and distribution of benzovindiflupyr was investigated in plants and animals using benzovindiflupyr labelled either in the phenyl ring or at the 5-position of the pyrazole ring.

Plants

In spring wheat, tomatoes and soya beans, parent compound represented the principal part of the residue in most crop commodities: 91–95 per cent Total Radioactive Residue (TRR) in tomato fruits, 84–87 per cent TRR in wheat grain, 81–84 per cent TRR in wheat straw and 89–103 per cent in wheat forage and hay, 67–72 per cent TRR in soya bean hay and 83–85 per cent TRR in soya bean forage. Parent represented 15-31 per cent TRR in soya bean seeds, in which a significant metabolite was SYN545720 (47 per cent TRR including conjugates) formed by cleavage between the pyrazole and phenyl rings combined with N-demethylation of the pyrazole moiety (either before or after cleavage). A significant metabolite in soya forage and hay was SYN546039 formed by mono hydroxylation on the alicyclic ring (9.2–12 per cent TRR including conjugates).

The metabolism of benzovindiflupyr was investigated in representative rotational crops (lettuce, spring wheat and turnip) from three consecutive rotations, after a single spray application of either phenyl or pyrazole labelled benzovindiflupyr was made onto the surface of bare soil. In rotational crops, parent benzovindiflupyr was the principal component in turnip roots (64–90 per cent TRR) and a significant component (6.5–38 per cent TRR) in the leafy parts of crops (immature and mature lettuce, turnip leaves, wheat forage, hay and straw). Significant metabolites were the cleavage products NOA449410 and SYN545720, together accounting for 34–73 per cent TRR in immature/mature lettuce and 24–26 per cent TRR in wheat forage, both at 90 and 300 day plant-back intervals. In wheat forage, wheat hay and wheat straw, SYN546206 (from N-demethylation of the pyrazole ring) and SYN546039 were frequently observed at >10 per cent TRR each, and occasionally approaching 20 per cent TRR each including conjugates.

Animals

The major compounds identified in goat and hen tissues, milk and eggs were parent and the metabolites SYN546039, SYN546422, SYN546041 and SYN546042 and their conjugates. Parent benzovindiflupyr was identified at 41–44 per cent TRR in goat fat, 24–25 per cent TRR in goat muscle, 7.5–13 per cent TRR in
goat kidney, 10–11 per cent TRR in goat liver and 5.5–7.3 per cent TRR in milk. In hen matrices it was detected in skin with fat at 38–42 per cent TRR, 3.3 per cent in muscle, 11–12 per cent TRR in egg white, 14 per cent TRR in egg yolk and <1 per cent TRR in liver.

The mono-hydroxylated metabolite SYN546039 and its conjugates was identified at levels of 22–50 per cent TRR in milk and goat tissues, 12–22 per cent TRR in egg yolks and whites and ≤5.2 per cent TRR in hen liver, muscle and skin with fat. The dihydroxylated metabolite SYN546422 and its conjugates was only found in goat and was identified at levels of 20–25 per cent TRR in milk, 16–19 per cent TRR in goat kidney and 1.5–8.9 per cent TRR in other goat tissues. The mono-hydroxylated demethylated metabolite isomers SYN546041 and SYN546042 were identified at levels of 11–13 per cent TRR and 6.6–12 per cent TRR in eggs, respectively, with each <4 per cent TRR in hen tissues and <9 per cent TRR in goat tissues and milk, except for goat kidney from pyrazole labelling at 10.5 per cent TRR.

4.2 Analytical methods and storage stability

Analytical methods

In the submitted Australian barley and wheat trials residues of benzovindiflupyr and its metabolite SYN546039 in grain and straw specimens were extracted with acetonitrile/ water. An aliquot of the crop extract was evaporated to remove the acetonitrile and HCl was added to the extract prior to liquid/liquid partitioning with hexane to separate residues of parent, which were analysed directly after evaporation and dissolution in acetonitrile/ water. The remaining acidic aqueous extract was heated to hydrolyse conjugates of SYN546039. The extracts were cooled, then cleaned-up using a polymeric SPE cartridge. The column eluates were then diluted with acetonitrile/ultra-pure water prior to final determination by LC–MS/MS. The limit of quantitation (LOQ) of the method was determined as 0.01 mg/kg, for each of parent and SYN546039 as individual analytes.

The method used for the determination of residues of parent benzovindiflupyr and its structurally related metabolites SYN546039 and SYN546422 in bovine tissues and milk (including skimmed milk and cream) involves homogenising samples with acetonitrile/water followed by a centrifugation step if required. Fat samples are dissolved in hexane and partitioned against acetonitrile/ water. For analysis of parent benzovindiflupyr, an aliquot is taken of the extract and diluted with water. For the determination of SYN546039 and SYN546422, an aliquot is diluted with water prior to removing the acetonitrile content by evaporation. The sample is then buffered with sodium acetate and conjugates of SYN546039 and SYN546422 are hydrolysed with β-glucuronidase by incubation. After hydrolysis, the sample is diluted with acetonitrile/ water and centrifuged by analysis. All samples are quantified by LC–MS/MS with LOQs of 0.01 mg/kg for parent and the metabolites. This method has also been validated for the determination of residues in hen eggs.

Studies detailing a number of other validated analytical methods for determining residues of benzovindiflupyr and its metabolites in plant and animal matrices, have also been submitted. It is noted that the multiple residue QuEChERS method is suitable for the determination of benzovindiflupyr parent in both plant and animal matrices.
Stability of the pesticide in stored analytical samples

The freezer storage stability of benzovindiflupyr was investigated in plant matrices. It was shown that residues of parent and SYN546039 are stable for at least 24 months in crop commodities representative of the high water (spinach), high acid (orange), high starch (wheat grain and potato), high protein (dry broad bean seed), high oil (soya bean seed) commodity groups as well as in wheat straw when stored at or below -18 °C. Residues of SYN546206 are stable for at least 22 months in crop commodities representative of the high water (spinach) and high starch (wheat grain, potato) commodity groups as well as in wheat straw when stored at or below -18 °C.

In the barley and wheat residue trials submitted, all samples were maintained under freezer conditions, (i.e. -18 °C) prior to analysis and tested within approximately 15 months of collection. This is acceptable for the purposes of the current application.

Storage stability data from the submitted dairy cow feeding study showed that residues of parent, SYN546039 and SYN546422 are stable in milk stored frozen for at least 62 days, in eggs for at least 56 days, in liver for at least 78 days and in muscle for at least 76 days.

4.3 Residue definition

Plant commodities

As parent benzovindiflupyr was shown to be a major component of the radioactive residues in both primary and secondary crops, the proposed residue definition for compliance and risk assessment for plant commodities is benzovindiflupyr.

Animal commodities

Benzovindiflupyr parent was found in every animal commodity in the goat and hen metabolism studies, although the levels in milk, eggs, mammalian offal and hen liver and muscle were low.

Apart from benzovindiflupyr, compounds observed in livestock commodities included the metabolites SYN546039, SYN546422 (goat only), SYN546041 and SYN546042. Since a significant part of these metabolites is present as conjugates, a hydrolysis procedure would be required to be able to measure these metabolites. The 2013 JMPR received toxicological data for the major metabolite, mono hydroxylated metabolite SYN546039, showing that this compound is at least 10 fold less toxic than parent. The other metabolites SYN546041, SYN546042 and SYN546422 based on the close structural similarity to SYN546039 were also considered to be at least 10 fold less toxic than the parent.

Parent compound can be determined in animal matrices using a multi-residue method.

The proposed enforcement and risk assessment residue definition for commodities of animal origin, is parent benzovindiflupyr, noting that the established residue definition for Codex and in overseas markets is also parent only.
4.4 Residues in food and animal feeds

Barley

In trials conducted in Australia/New Zealand and various countries in the EU, residues in barley grain after two applications at exaggerated rates, and conversion to predicted residues at commercial harvest after application at $1 \times$ the proposed application rate are, in rank order:

$<0.010$ (4), 0.011, 0.012, 0.013, 0.016, 0.018 (2), 0.019, 0.020 (2), 0.024, 0.027 (2), 0.028, 0.034, 0.045, 0.046, 0.058 and 0.12 mg/kg ($n=24$, Supervised Trial Median Residue (STMR) = 0.0185 mg/kg).

An MRL set at 0.2 mg/kg for GC 0640 Barley is considered appropriate for the proposed use of benzovindiflupyr on barley.

Wheat

In trials conducted in Australia/New Zealand and various countries in the EU, residues in wheat grain after two applications at exaggerated rates, and conversion to predicted residues at commercial harvest after application at $1 \times$ the proposed application rate are, in rank order:

$<0.010$ (23) mg/kg ($n=23$).

Although residues were all $<0.01$ mg/kg after scaling it is noted that two of the values from European trials were 0.008 mg/kg. A finite MRL set at 0.01 mg/kg for GC 0654 Wheat is therefore considered appropriate for the proposed use of benzovindiflupyr on wheat.

A harvest WHP of “Not required when used as directed” is appropriate for the proposed uses on barley and wheat, in conjunction with the following restraint:

“DO NOT apply after BBCH growth stage 69”.

Barley and wheat straw

Barley straw

In trials conducted in Australia, New Zealand and various countries in the EU, residues in barley straw on a dry weight basis after two applications at exaggerated rates, and conversion to predicted residues at commercial harvest after application at $1 \times$ the proposed application rate are, in rank order:

0.065, 0.12, 0.13, 0.17, 0.18, 0.19 (2), 0.20, 0.24, 0.27, 0.29, 0.31, 0.34, 0.35, 0.40, 0.45, 0.52 (2), 0.75, 0.87, 0.88, 1.21, 1.82 and 2.47 mg/kg ($n=24$, STMR = 0.325 mg/kg).

Wheat straw

In trials conducted in Australia, New Zealand and various countries in the EU, residues in wheat straw on a dry weight basis after two applications at exaggerated rates, and conversion to predicted residues at commercial harvest after application at $1 \times$ the proposed application rate are, in rank order:
0.11 (2), 0.13, 0.14 (2), 0.19, 0.25 (2), 0.31, 0.36 (2), 0.40, 0.47, 0.48, 0.53, 0.58, 0.67, 0.84, 0.99, 1.19, 1.22, 1.39 and 2.01 mg/kg (n=23, STMR = 0.40 mg/kg).

It is considered appropriate to establish an MRL at 3 mg/kg for AS 0081 straw and fodder (dry) of cereal grains, for the proposed uses of benzovindiflupyr on barley and wheat.

**Barley and wheat forage**

**Barley forage**

In trials conducted in various European countries, residues in barley forage on a dry weight basis, at nine to 11 days after two applications at exaggerated rates, and conversion to predicted residues after application at 1× the proposed application rate are, in rank order:

0.27, 0.40 (2), 0.47, 0.50, 0.67 (2), 0.77 (3), 0.90, 0.93, 1.17, 1.23, 1.30 (2), 2.17 and 2.73 mg/kg (n=18, STMR = 0.77 mg/kg).

**Wheat forage**

In trials conducted in various European countries, residues in wheat forage on a dry weight basis, at nine to 11 days after two applications at exaggerated rates, and conversion to predicted residues after application at 1× the proposed application rate are, in rank order:

0.24, 0.44, 0.56, 0.64 (2), 0.80, 1.0, 1.2, 1.4, 1.5, 1.0 (2), 1.7, 2.3, 2.4, 2.8 and 3.6 mg/kg (n=18, STMR = 1.46 mg/kg).

It is considered appropriate to establish an MRL at 7 mg/kg for AF 0081 Forage of cereal grains for the proposed uses of benzovindiflupyr on barley and wheat in conjunction with a grazing WHP of 10 days.

**Processed barley and wheat commodities**

Residues did not concentrate on processing to various barley commodities (pearl barley, brewing malt, beer, pot barley and barley flour). It is therefore unnecessary to establish separate MRLs for processed barley commodities.

Residues did concentrate on processing to various wheat commodities (coarse and fine bran, wholemeal flour, and gluten feed meal). However, as residues above 0.01 mg/kg are not expected in wheat grain from the use of benzovindiflupyr according to the proposed use pattern quantifiable residues are not expected to be present in these processed commodities. It is therefore unnecessary to establish separate MRLs for processed wheat commodities.

**4.5 Crop rotation**

The submitted field crop rotational studies show that after a single application of benzovindiflupyr to bare soil at 200 g a.i./ha (EC formulation) no residues were observed in rotational crops, except in one trial conducted in Southern Europe, at which residues were detected in wheat straw at a maximum of 0.014 mg/kg. As the
field rotational trials were conducted with an application rate 5× the proposed maximum seasonal rate (40 g a.i./ha), it is therefore considered unlikely that any following crops could take up residues at a detectable level.

4.6 Residues in animal commodities

Bioaccumulation potential

The $K_{ow}$ logP for benzovindiflupyr is 4.3 at 25°C and pH 6.6 indicating the potential for fat solubility and bioaccumulation in fat.

This is supported by the results of the benzovindiflupyr goat metabolism study which showed residues of parent at 0.031–0.040 mg/kg in fat in comparison with 0.008–0.017 mg/kg in muscle. In the cow feeding study after feeding at 16 and 32 ppm, parent was found in cream but not in the corresponding whole milk, and after feeding at 16 ppm residues were found in fat but not muscle. In the hen metabolism study, the partitioning of the parent compound into the fatty tissues is demonstrated with the highest levels of benzovindiflupyr found in egg yolks (0.022–0.024 mg/kg) and skin with fat (0.012–0.019 mg/kg).

Benzovindiflupyr is therefore considered to be fat soluble and the proposed mammalian and poultry meat MRLs have been designated “in the fat”.

Mammalian livestock

A feeding study was submitted showing the residues of benzovindiflupyr in milk and tissues after oral administration to lactating cows for 28 days at approximate concentrations in the feed of 0, 3.5, 16 and 32 ppm. No depuration data was provided.

Based on the wheat forage highest residue (HR) observation of 3.64 mg/kg (dry weight) and the barley forage HR residue observation of 2.73 mg/kg (dry weight) at a 9 to 11 day WHP, the anticipated dietary burden of benzovindiflupyr (beef and dairy cattle) was calculated. The estimated maximum dietary burdens of benzovindiflupyr for beef and dairy cattle resulting from the proposed uses are calculated to be 3.64 and 3.28 ppm respectively.

The results of the 3.5 ppm feeding level was considered relevant to the estimated maximum dietary burdens. Residues in cattle milk, muscle, fat, liver and kidney following a 3.5 ppm feeding level were <0.01 mg/kg.

Based on the predicted maximum residues, the following benzovindiflupyr MRLs are considered to be appropriate. The mammalian meat MRL will be established “in the fat” due to the moderately high partition coefficient which suggest the potential for bioaccumulation of residues of benzovindiflupyr.

Edible offal (mammalian): *0.01 mg/kg
Meat (mammalian) [in the fat]: *0.01 mg/kg
Milks: *0.01 mg/kg
Although residues concentrate in cream in comparison with milk, reflecting the fat solubility of benzovindiflupyr, no residues are expected in milk fats at the maximum dietary burden for dairy cattle. It is therefore not considered necessary to establish a separate MRL for milk fats at this time.

Poultry

In the submitted metabolism study laying hens were dosed at 16–20 ppm parent compound in the dry feed for 14 consecutive days. Maximum parent residues over the two labels were: 0.024 mg/kg in egg yolks, 0.004 mg/kg in egg whites, 0.019 mg/kg in fat, <0.001 mg/kg in liver and 0.001 mg/kg in muscle. The calculated dietary burdens for broilers, layers and turkeys of 0.0127, 0.0116 and 0.0054 ppm, respectively, (based on the barley and wheat grain STMR residue observations of 0.0185 and 0.01 mg/kg (wet weight) at harvest and wheat milled by-products residues of 0.01 mg/kg (based on no quantifiable residues observed in wheat grain)) are over 1000 times lower than the dose administered in the hen metabolism study (16–20 ppm). Therefore, no parent residues > 0.01 mg/kg are expected in egg yolks, egg whites and hen tissues. Accordingly, poultry commodity MRLs will be established at the LOQ.

PE 0112 Eggs: *0.01 mg/kg
PO 0111 Poultry, Edible offal of: *0.01 mg/kg
PM 0110 Poultry meat [in the fat]: *0.01 mg/kg

4.7 Spray drift

The draft label indicates that benzovindiflupyr should not be applied by aerial application, so therefore the potential for spray drift from ground application only was considered.

For ground application to barley and wheat at a maximum rate of 20 g a.i./ha and considering average deposition over 300m, APVMA’s standard scenario (High ground boom medium droplet) indicates that a no-spray zone is not required for application to barley or wheat for protection of international trade.

4.8 Dietary risk assessment

Estimated dietary intake

The chronic dietary exposure to benzovindiflupyr 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 benzovindiflupyr is equivalent to <5 per cent of the ADI.

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. The highest acute dietary intake was estimated at <1 per cent of the ARfD. It is concluded that the acute dietary exposure is acceptable.

The proposed use of propiconazole is equivalent in application rate, timing, frequency and withholding periods to that currently approved in wheat and barley and the estimated dietary intake for propiconazole remains unchanged.

4.9 Recommendations

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

Table 5: Amendments to the APVMA MRL Standard

<table>
<thead>
<tr>
<th>Amendments to Table 1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compound</strong></td>
<td><strong>Food</strong></td>
</tr>
<tr>
<td>ADD:</td>
<td></td>
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<tr>
<td>BENZOVINDIFLUPYR</td>
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<tr>
<td>GC 0640</td>
<td>Barley</td>
</tr>
<tr>
<td>MO 0105</td>
<td>Edible offal (mammalian)</td>
</tr>
<tr>
<td>PE 0112</td>
<td>Eggs</td>
</tr>
<tr>
<td>MM 0095</td>
<td>Meat (mammalian) (in the fat)</td>
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<td>ML 0106</td>
<td>Milks</td>
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<td>PO 0111</td>
<td>Poultry, edible offal of</td>
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<tr>
<td>PM 0110</td>
<td>Poultry meat (in the fat)</td>
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<td>GC 0654</td>
<td>Wheat</td>
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<th>Amendments to Table 3</th>
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<tr>
<td>BENZOVINDIFLUPYR</td>
<td>Benzovindiflupyr</td>
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<table>
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<th>Amendments to Table 4</th>
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<td><strong>Compound</strong></td>
<td><strong>Animal feed commodity</strong></td>
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<td>ADD:</td>
<td></td>
</tr>
<tr>
<td>BENZOVINDIFLUPYR</td>
<td></td>
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<tr>
<td>AF 0081</td>
<td>Forage of cereal grains</td>
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</table>
### Amendments to Table 1

<table>
<thead>
<tr>
<th>Compound</th>
<th>Food</th>
<th>MRL (mg/kg)</th>
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</thead>
<tbody>
<tr>
<td>AS 0081</td>
<td>Straw and fodder (dry) of cereal grains</td>
<td>3</td>
</tr>
</tbody>
</table>
5 ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

5.1 Commodities exported and main destinations

Wheat and barley are considered to be major export commodities\(^2\), as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated wheat and barley. Residues in these commodities resulting from the use of Elatus Ace Fungicide may have the potential to unduly prejudice trade.

Elatus Ace Fungicide contains the existing active propiconazole in addition to benzovindiflupyr. The proposed use of propiconazole however is equivalent in application rate, timing, frequency and withholding periods to that currently approved and no further consideration to propiconazole is required.

Barley and wheat

Australian exports of barley grain in 2017–18 totalled 404 kt (value $138 m). Australian exports of wheat grain in 2017–18 totalled 15,492 kt (value $4,672 m). The major exports for barley and wheat grain are\(^3\):

Table 6: Barley and wheat destinations

<table>
<thead>
<tr>
<th>Grain</th>
<th>Major destinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barley</td>
<td>Asia including China, Japan, Vietnam, Thailand, Rep. of Korea, Philippines and Taiwan; Middle East including United Arab Emirates and Kuwait</td>
</tr>
<tr>
<td>Wheat</td>
<td>Africa including Nigeria, Egypt, South Africa and Tanzania; Asia including Indonesia, Philippines, Vietnam, Rep. of Korea, China, Japan, Malaysia and Thailand; Middle East including Yemen, Kuwait, Iraq and United Arab Emirates; Oceania including New Zealand, Papua New Guinea and Fiji</td>
</tr>
</tbody>
</table>

5.2 Overseas registrations and approved label instructions

Elatus Ace Fungicide is currently registered in Argentina and there are plans to register this product in, Brazil, Bolivia, Paraguay, Turkey and Uruguay for use in wheat and barley.

The applicant indicated that 100g/L benzovindiflupyr emulsifiable concentrate products are registered for use in Belgium, Bulgaria, Croatia, Czech Republic, Estonia, Finland, Germany, Ireland, Italy, Latvia, Lithuania, Slovenia, Sweden and United Kingdom for use in cereal crops such as barley, rye, triticale, wheat, oats and spelt.

\(^2\) APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

\(^3\) www.agriculture.gov.au/abares/research-topics/agricultural-commodities/agricultural-commodities-trade-data#2018
In Canada this formulation is registered for use in a large number of crops including barley and wheat and in the USA for a large number of crops including cereals.

A wettable granule formulation containing 150 g/kg benzovindiflupyr + 300 g/kg azoxystrobin is registered in Argentina, Bolivia, Brazil, Canada, Paraguay, USA and Uruguay for use predominantly in wheat, barley, soybean and corn.

5.3 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. Benzovindiflupyr has been considered by Codex. The following relevant international MRLs have been established for benzovindiflupyr (Table 7).

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Tolerance for residues arising from the use of benzovindiflupyr (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Australia</td>
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<tr>
<td>Residue definition</td>
<td>Benzovindiflupyr (proposed)</td>
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<tr>
<td>Plant commodities</td>
<td></td>
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<tr>
<td>Barley</td>
<td>0.2 (proposed)</td>
</tr>
<tr>
<td>Wheat</td>
<td>0.01 (proposed)</td>
</tr>
<tr>
<td>Other cereal grains</td>
<td>*0.01</td>
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<tr>
<td>Animal commodities</td>
<td></td>
</tr>
<tr>
<td>Cattle fat</td>
<td></td>
</tr>
<tr>
<td>Cattle, edible offal</td>
<td></td>
</tr>
<tr>
<td>Cattle, kidney</td>
<td></td>
</tr>
<tr>
<td>Cattle, liver</td>
<td></td>
</tr>
<tr>
<td>Cattle, meat</td>
<td>*0.01</td>
</tr>
<tr>
<td>Cattle, meat by-products, except liver</td>
<td></td>
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<tr>
<td>Chicken, eggs</td>
<td>*0.01 (eggs—proposed)</td>
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<tr>
<td>Chicken, fat</td>
<td></td>
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<tr>
<td>Chicken, edible offal</td>
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</tbody>
</table>
## Table 1

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Tolerance for residues arising from the use of benzovindiflupyr (mg/kg)</th>
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<tr>
<td></td>
<td>Australia</td>
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<tr>
<td>Chicken, kidney</td>
<td>*0.01</td>
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<tr>
<td>Chicken, liver</td>
<td>*0.01</td>
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<tr>
<td>Chicken, muscle</td>
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<tr>
<td>Edible offal (mammalian)</td>
<td>*0.01 (proposed)</td>
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<tr>
<td>Mammalian fats (except milk fats)</td>
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<tr>
<td>Meat (from mammals other than marine mammals)</td>
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<tr>
<td>Meat (mammalian) (in the fat)</td>
<td>*0.01 (proposed)</td>
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<td>Milk</td>
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<td>Milk, fat</td>
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<td>Poultry fats</td>
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<tr>
<td>Poultry meat</td>
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</tr>
<tr>
<td>Poultry meat (in the fat)</td>
<td>*0.01 (proposed)</td>
</tr>
</tbody>
</table>

* Other than liver and kidney

No MRLs for benzovindiflupyr are established in China

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### 5.4 Potential risk to trade

#### Barley

An MRL at 0.2 mg/kg is proposed for barley. In the 24 trials conducted in Australia, New Zealand and Europe which were considered for the establishment of an MRL, the highest residue was 0.12 mg/kg and the STMR was 0.0185 mg/kg. In the three Australian trials the highest scaled residue was 0.013 mg/kg.

It is noted that Codex and major overseas markets have MRLs established at higher levels: Codex at 1 mg/kg, the EU, Korea, the USA and Taiwan at 1.5 mg/kg and Japan at 2 mg/kg and the potential risk to trade for these markets is low. However, a MRL has not been established in China.
Wheat

An MRL at 0.01 mg/kg is proposed for wheat. In the 23 trials conducted in Australia, New Zealand and Europe which were considered for the establishment of an MRL, all residues were <0.01 mg/kg although of these, two European trials showed scaled residues of 0.008 mg/kg. In the three Australian trials the observed residues, before scaling, after application at 8× the proposed application rate, were <0.003 (2) and 0.003 mg/kg.

MRLs are established overseas in major overseas markets (EU, Japan, Codex, the USA, Korea and Taiwan) at 0.1 mg/kg. It is considered that there is a low potential risk to trade as residues above the LOQ of 0.01 mg/kg are unlikely to occur.

Animal commodities

MRLs for animal commodities are proposed at the LOQ (0.01 mg/kg) so the risk to trade in animal commodities is considered to be low.
6 WORK HEALTH AND SAFETY ASSESSMENT

Elatus Ace Fungicide is to be applied using ground boom equipment. The product is restricted to two applications in any one season in the same field, with the duration of treatment expected to vary from one to 14 days depending on farm size, or up to 60 days for spray contractors. Exposure is expected to be medium to sub-chronic exposure.

6.1 Health hazards

Elatus Ace Fungicide has a low acute toxicity by the oral, dermal and inhalational routes. The product was not a skin irritant but was a moderate eye irritant and a skin sensitiser.

6.2 Occupational exposure

Exposure during use

Farmers and their employees, and contract sprayers will be the main users of the product. Workers may be exposed to the product when opening containers, mixing/loading, application, and cleaning up spills, maintaining equipment and entering treated areas.

The main routes of exposure to the product will be dermal and inhalational. In the absence of chemical-specific, worker exposure studies for Elatus Ace Fungicide, the US EPA Pesticides Handlers Database (PHED, 1998) was used to estimate worker exposure during mixing, loading and application activities. Propiconazole was considered the key driver for toxic effects from repeated exposure, based on its higher concentration in the product and its toxicity profile, in comparison to benzovindiflupyr. Risk mitigation measures were based on the acute toxicity profile of the product and the repeat dose exposure to propiconazole.

Acceptable margins of exposure (MOE) for mixing, loading and application by ground boom (open cab) were obtained when users of the product wear appropriate personal protective equipment (PPE).

Exposure during re-entry or rehandling

Farmers and their employees may be exposed to the dried product when they re-enter treated areas for inspection and farming activities. In the absence of chemical-specific, worker exposure studies for Elatus Ace Fungicide, the US EPA Occupational Pesticide Re-entry Exposure Calculator (OPREC, 2016) was used to estimate exposure during activities associated with re-entering treated areas. The risks associated with re-entering a treated area were considered to be low. To allay concerns associated with skin sensitisation a re-entry statement (outlined below) has been recommended.

6.3 Public exposure

Elatus Ace Fungicide is not intended for use by the general public or in the areas accessible by the general public.
6.4 Recommendations

Elatus Ace Fungicide, an emulsifiable concentrate (EC) formulation containing 40 g/L benzovindiflupyr and 250 g/L propiconazole for the control of certain fungal diseases of wheat and barley, is supported from a human health perspective. Elatus Ace Fungicide can be used safely if handled in accordance with the instructions on the product label.

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

First aid instructions

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126; New Zealand 0800 764 766.

Safety directions

Harmful if swallowed or inhaled. Will irritate the eyes. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. Do not inhale. 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 and face shield or goggles. When using the prepared spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves. If product in eyes, wash it out immediately with water. Wash hands after use. After each day’s use, wash gloves, face shield or goggles and contaminated clothing.

Re-entry statement

Do not allow entry into treated areas until spray has dried. If prior entry is necessary wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day’s use.
7 ENVIRONMENTAL ASSESSMENT

In assessing the environmental risks associated with the use of Elatus Ace Fungicide, a full suite of environmental fate and toxicity data were provided for technical benzovindiflupyr, a solo EC formulation of benzovindiflupyr, and several of its metabolites. A full suite of environmental toxicity data were also provided for the Elatus Ace Fungicide formulation. In the absence of formulation toxicity data in the case of aquatic plants, combination toxicity of benzovindiflupyr and propiconazole was estimated assuming additive toxicity.

7.1 Fate and behaviour in the environment

Soil

Benzovindiflupyr is considered to be stable to sunlight and no metabolites were produced during the test exceeding 10 per cent of applied. In irradiated soils, the half-life in summer sunlight ranged from 298 (dry soil) to 501 days (moist soil). No degradation was observed in dark controls.

The degradation of benzovindiflu pyr in dark, aerobic laboratory soil was very slow in a range of studies provided with different incubation periods (120–365 days) and different temperatures (20°C and 30°C). Only one major metabolite was formed, which was the desmethyl metabolite SYN546206 (5.6 per cent at 365d and increasing). DT50 values for benzovindiflupyr determined by SFO extended beyond the study period and all exceeded 500 days (geomean DT50 908 days, five soils).

To further examine the mechanisms involved in degradation of benzovindiflu pyr in soil, an exploratory study was carried out with intact soil cores. Untreated soil cores were collected from the trial site in Georgia, USA and radiolabelled benzovindiflu pyr was applied to the soil surface. The treated cores were incubated in the laboratory under one of three sets of conditions: (1) in the dark, (2) under a diurnal light/dark cycle with simulated natural sunlight, (including the UV wavelengths that support photolysis), or (3) under a diurnal light/dark cycle with fluorescent light (providing photosynthetically active radiation which maintains the growth of soil photoautrophs, but without UV wavelengths). Benzovindiflu pyr was degraded slowly in the soil cores incubated in the dark. However, degradation was considerably more rapid in both the light/dark conditions. Under these conditions, levels of bound residues increased slowly, reaching maxima of 8.9-17 per cent AR after 35–53 days. NOA449410 (pyrazole acid, metabolite common to fluxapyroxad) was the only major metabolite (max 12 per cent at 53 days). The DT50 in the dark samples was 349 days while those in the other two light/dark test systems were 35–36 days. The rate and pattern of degradation observed in the soil cores was similar for the soils incubated under the simulated natural sunlight and under the photosynthetically active radiation. This indicates that degradation under realistic conditions is via biological processes rather than photolysis as this process would not have occurred under the photosynthetically active radiation. Furthermore, as the degradation rates were similar despite the seven-fold difference in light intensities in the non-UV range for the two light sources (502 W/m2 for the simulated natural sunlight and 72 W/m2 for the photosynthetically active radiation), the rate of degradation in soil does not appear to be influenced by light intensity over this range. This is supported by the finding that benzovindiflu pyr is also degraded by cultures of algal species representative of those found widely in field soils.
The degradation of benzovindiflupyr under anaerobic laboratory soil conditions was also slow. No major metabolites were formed. Evolved carbon dioxide reached a maximum value of 0.4 per cent AR at 120 days. Bound residues reach a maximum of 7.5 per cent AR at 90 DAT. The DT$_{50}$ was >1000 days.

Information on the dissipation of benzovindiflupyr in soil under European field conditions is available from six dissipation trials, four located in Northern Europe and two located in Southern Europe. The decline of residue levels in the 0–10 cm soil depth was not associated with any significant increase in residue levels in the 10–20 and 20–30 cm depth increments (only trace levels could be found in a few instances which were close to the limit of quantification). No major metabolites were formed. Dissipation kinetics were well described by SFO kinetics for three sites, with DT$_{50}$ values ranging 163–336 days (DT$_{90}$ values 542–1117 days). For three other sites, biphasic models were more appropriate to describe the dissipation of benzovindiflupyr, with DT$_{50}$ values ranging <1 to 43 days (DT$_{90}$ 784 to >1000 days). Similar results were found in four US trials in terms of mobility where several applications were made and residues assessed under bare soil conditions. DT$_{50}$ values determined by SFO ranged from 183 to 660 days. A further non-guideline field dissipation study in the US showed a DT$_{50}$ of 29 days. Based on 11 field dissipation results, the geomean DT$_{50}$ was 438 days.

Standard batch equilibrium test results were available for eight soils in two studies. The soils tested had a range of 0.31–3.25 per cent organic carbon and the KF values ranged from 10–178 L/kg (mean 1/n 0.94). The data show a reasonable correlation between soil sorption and organic carbon. Based on a regression analysis, a KF value of 37 L/kg was derived for a soil with one per cent organic carbon.

**Water**

Benzovindiflupyr was shown to be stable to hydrolysis. Photodegradation of benzovindiflupyr in water resulted in DT$_{50}$ 44 days (buffered water) and DT$_{50}$ 5.0 days (natural water). The equivalent degradation rates in summer sunlight at 30–50°N were DT$_{50}$ 95 days (buffered water) and DT$_{50}$ 10 days (natural water). Degradation in the dark control samples was not observed. In the natural water experiment, NOAA449410 and SYN508272 (pyrazole amide, metabolite common to fluxapyroxad) were formed and reached maximum levels of 36 per cent and 24 per cent AR by 15 days, respectively.

The behaviour of benzovindiflupyr in two water/sediment systems was investigated under several different incubation conditions. Under dark conditions, benzovindiflupyr was persistent in the whole system with geomean DT$_{50}$ values of 559 days (aerobic) and 663 days (anaerobic). Movement from the water column sediment was relatively fast with geomean DT$_{50}$ values of 27 days (aerobic) and 31 days (anaerobic). Under more realistic exposure conditions with algae or aquatic plants in the water/sediment systems and with the provision of light, degradation was significantly faster (geomean water DT$_{50}$ 5.1–12 days, geomean whole system DT$_{50}$ 54–154 days). In non-modified systems, no metabolites produced exceeded 10 per cent AR. However, in those systems modified with algae or macrophytes, SYN546039 (formed by mono hydroxylation on the alicyclic ring) was the most significant metabolite formed, reaching 16 per cent AR in systems containing algae and 20 per cent AR in systems containing macrophytes.

Benzovindiflupyr is not readily biodegradable.
Air

Using standard modelling methodology, benzovindiflupyr is predicted to have an atmospheric DT$_{50}$ of 2.4 hours based on 12 hours of sunlight per day. Because of this, its low vapour pressure and the calculated Henry’s law constant, benzovindiflupyr is unlikely to be transported long or short distances in the air.

7.2 Effects and associated risks to non-target species

Terrestrial vertebrates

Benzovindiflupyr is considered to be highly toxic to wild mammals (LD$_{50}$ 55 mg ac/kg bw, *Rattus norvegicus*). A solo EC formulation of benzovindiflupyr was less toxic (LD$_{50}$ >200 mg ac/kg bw, *Rattus norvegicus*). Following long-term dietary exposure in a two-generation reproduction study, reduced food consumption, body weights, and body weight gains was observed in parental and F1 generations at pre-pairing doses as low as 19 mg ac/kg bw/d (lowest NOAEL 6.8 mg ac/kg bw/d, *Rattus norvegicus*). No relevant metabolites have been identified for consideration in the risk assessment for mammals; the toxicity of any metabolites are considered to be covered by the toxicity studies on benzovindiflupyr.

Based on data available on three test species, benzovindiflupyr is considered to be moderately toxic to birds (lowest LD$_{50}$ 1315 mg ac/kg bw, *Colinus virginianus*). A solo EC formulation of benzovindiflupyr was also available (LD$_{50}$ >100 mg ac/kg bw, *Colinus virginianus*). Benzovindiflupyr was not toxic to birds when administered in the diet (LD$_{50}$ >1168 mg ac/kg bw/d, two species). Following long-term dietary exposure in a one-generation reproduction study, reduced adult female body weight, egg production and offspring body weights were observed as low as 85 mg ac/kg bw/d (NOAEL 25 mg ac/kg bw/day, *Anas platyrhynchos*). No adverse effects were observed in *Colinus virginianus* at the highest dose tested (NOAEL 54 mg ac/kg bw/d).

Based on formulation toxicity data on Elatus Ace Fungicide, combined residues of benzovindiflupyr and propiconazole are considered to be moderately toxic to mammals (LD$_{50}$ 585 mg acs/kg bw, *Rattus norvegicus*) and have low toxicity to birds (LD$_{50}$ >595 mg acs/kg bw, *Colinus virginianus*). When consider the mouse is a more sensitive species to propiconazole, a predicted LD$_{50}$ of 243 mg acs/kg bw was derived for a ‘sensitive mammal species’ for regulatory purposes. Based on available toxicity data and assuming additive toxicity, and the LD$_{50}$ for birds was predicted to be 2440 mg acs/kg bw.

Risks of benzovindiflupyr to terrestrial vertebrates were determined to be acceptable at the screening level, which assumed direct exposure to maximum possible cumulative concentrations in dietary items. Similarly, risks of combined residues of benzovindiflupyr and propiconazole were determined to be acceptable at the screening level, which assumed direct exposure immediately after application.

Although benzovindiflupyr has high potential to partition to fat (log $K_{ow}$ 4.3), a food chain assessment indicated that any accumulated residues in earthworms or fish, for example, will not reach levels harmful to predators. Risks of biomagnification were also determined to be low due to lack of bioaccumulation in mammalian tissue. In addition, benzovindiflupyr was shown to not bioconcentrate in fish.
Aquatic species

Benzovindiflupyr is considered to be very toxic to fish (lowest LC$_{50}$ 0.0035 mg ac/L, *Cyprinus carpio*, five species tested), aquatic invertebrates (lowest LC$_{50}$ 0.056 mg ac/L, *Mysidopsis bahia*, three species tested) and algae (lowest E$_{C_{50}}$ 0.55 mg ac/L, *Skeletonema costatum*, four species tested). Benzovindiflupyr was not toxic to aquatic plants at the limit of solubility (E$_{C_{50}}$ >0.88 mg ac/L, *Lemna gibba*). The toxicity of benzovindiflupyr does not appear to be significantly modified when in an EC formulation (LC$_{50}$ 0.0047 mg ac/L, *Oncorhynchus mykiss*; EC$_{50}$ 0.027 mg ac/L, *Daphnia magna*; E$_{C_{50}}$ 0.27 mg ac/L, *Pseudokirchneriella subcapitata*). Following long-term exposure to benzovindiflupyr, reduced growth was observed in fish fry at 0.0018 mg ac/L (NOEC 0.00095 mg ac/L, *Pimephales promelas*), reduced reproduction was observed in aquatic invertebrates at 0.015 mg ac/L (lowest NOEC 0.0074 mg ac/L, *Mysidopsis bahia*, two species tested), and reduced adult survival was observed in sediment dwellers at 8.7 mg ac/kg dry sediment (lowest NOEC 4.1 mg ac/kg dry sediment, *Chironomus riparius*, two species tested).

The metabolites SYN546039, NOA449410 and SYN508272 were significantly less toxic than benzovindiflupyr to fish (LC$_{50}$ 2.4 mg/L, >100 mg/L and >100 mg/L versus LC$_{50}$ 0.0091 mg ac/L), aquatic invertebrates (EC$_{50}$ 5.2 mg/L, >0.88 mg/L, >100 mg/L and >100 mg/L versus EC$_{50}$ 0.085 mg ac/L, *Daphnia magna*), and algae (E$_{C_{50}}$ >6.4 mg/L, 36 mg/L and >100 mg/L versus E$_{C_{50}}$ 0.27 mg ac/L$^4$, *Pseudokirchneriella subcapitata*).

Benzovindiflupyr was shown to not bioconcentrate in a standard fish study with a whole fish BCF (lipid normalised at steady state) of 123 L/kg and a growth-corrected depuration half-life of 0.54 days.

Based on formulation toxicity data on Elatus Ace Fungicide, combined residues of benzovindiflupyr and propiconazole are considered to be very toxic to fish (LC$_{50}$ 0.053 mg acs/L, *Oncorhynchus mykiss*), aquatic invertebrates (EC$_{50}$ 0.18 mg acs/L, *Daphnia magna*) and moderately toxic to algae (E$_{C_{50}}$ 3.2 mg acs/L). Toxicity and risks of the formulation to fish were attributed to benzovindiflupyr due to its high toxicity. When considering mysid shrimp are more sensitive to propiconazole, a predicted EC$_{50}$ of 0.15 mg acs/L was derived for a ‘sensitive aquatic invertebrate species’ for regulatory purposes. Based on available toxicity data, toxicity of combined residues to aquatic plants are expected to comparable to algae.

Risks of benzovindiflupyr to algae and aquatic plants were determined to be acceptable at the screening level, which assumed direct exposure to maximum possible cumulative concentrations in water and sediment. Similarly, risks of combined residues of benzovindiflupyr and propiconazole to algae and aquatic plants were determined to be acceptable at the screening level, which assumed direct exposure immediately after application.

Runoff risks of benzovindiflupyr to fish and aquatic invertebrates were determined to be acceptable without mitigation; however, a restraint is required to minimise runoff risks of propiconazole. Spray drift risks of benzovindiflupyr and combined residues to fish and aquatic invertebrates were determined to be acceptable with a mandatory no-spray zone of 10 metres (using standard drift curves for high ground boom and a medium spray quality).

$^4$ EC formulation result is presented since an endpoint could not be established at the limit of solubility for the technical product
The following protection statement has been recommended due to the high toxicity of benzovindiflupyr to aquatic species.

**PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT**

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

**Bees**

Benzovindiflupyr is not toxic to bees (oral LD$_{50}$ >109 µg ac/bee; contact LD$_{50}$ >100 µg ac/bee). No sub-lethal effects were observed. The solo EC formulation of benzovindiflupyr was slightly more toxic (oral LD$_{50}$ 38 µg ac/bee; contact LD$_{50}$ 36 µg ac/bee). Sub-lethal effects such as apathetic and moribund bees were noted at doses as low as 12 µg ac/bee in both oral and contact tests (NOEL 6.8 µg ac/bee).

Based on formulation toxicity data on Elatus Ace Fungicide, combined residues of benzovindiflupyr and propiconazole are also considered to have low toxicity to bees (oral LD$_{50}$ 114 µg acs/bee; contact LD$_{50}$ 87 µg acs/bee).

Risks of benzovindiflupyr and combined residues of benzovindiflupyr and propiconazole to bees were determined to be acceptable at the screening level, which assumed direct exposure to maximum possible concentrations on treated foliage, pollen and nectar.

**Other non-target arthropods**

Available toxicity data on solo EC formulations of benzovindiflupyr indicate relatively low toxicity to other beneficial (predatory and parasitic) arthropods. Tier 1 laboratory tests investigating toxicity of fresh-dried residues on inert (glass) substrate for the standard indicator species indicated LR$_{50}$ values of 432 g ac/ha (Typhlodromus pyri) and 89 g ac/ha (Aphidius rhopalosiphi). Extended laboratory tests on natural (foliage) substrate indicated respective LR$_{50}$ values of >600 g ac/ha and 283 g ac/ha.

In tier 1 glass plate tests, the LR$_{50}$ values for Elatus Ace Fungicide were 75 g acs for predatory arthropods (Typhlodromus pyri) and 23 g acs/ha for parasitic arthropods (Aphidius rhopalosiphi). Available data on the individual active constituents suggests that the formulation toxicity is driven by propiconazole for predatory arthropods and is ‘more than additive’ for parasitic arthropods.

Risks of benzovindiflupyr to beneficial non-target arthropods were determined to be acceptable at the screening level, which assumed direct exposure to maximum possible cumulative concentrations on treated foliage. Higher tier tests are not available to refine the assessment and therefore Elatus Ace Fungicide is not considered to be compatible with IPM utilising beneficial arthropods.

**Soil organisms**

Benzovindiflupyr is considered to be moderately toxic to soil macro-organisms (LC$_{50corr}$ 203 mg ac/kg dry soil for technical product, LC$_{50corr}$ 35 mg ac/kg dry soil for solo EC formulation, *Eisenia fetida*). Following long-term exposure to benzovindiflupyr (technical product or solo EC formulation), reduced rates of reproduction were observed at concentrations as low as 10 mg ac/kg dry soil (NOEC 7.8 mg ac/kg dry soil).
Benzovindiflupyr did not affect soil processes such as carbon and nitrogen mineralisation at the maximum rate tested (NOEC 1.4 mg ac/kg dry soil for technical product; NOEC 1.3 mg ac/kg dry soil for solo EC formulation).

The soil metabolite NOA449410 is not considered to be toxic to soil macro-organisms (LC₅₀ >1000 mg/kg dry soil, 
Eisenia fetida). Following long-term exposure, NOA449410 did not adversely affect soil macro-organisms (NOEC 5.3 mg/kg dry soil, 
Eisenia fetida) or soil microbial function (NOEC 0.37 mg/kg dry soil).

Based on formulation toxicity data on Elatus Ace Fungicide, combined residues of benzovindiflupyr and propiconazole are considered to be moderately toxic to soil macro-organisms such as earthworms (LC₅₀ >290 mg acs/kg dry soil, 
Eisenia fetida). Based on available toxicity data and assuming additive toxicity, the LC₅₀ for earthworms was predicted to be 307 mg acs/kg dry soil. Following long-term exposure to Elatus Ace Fungicide, reduced reproduction rates were observed at 28 mg acs/kg dry soil (NOEC 15 mg acs/kg dry soil, 
Eisenia fetida, two species tested). Elatus Ace Fungicide had no effect on soil processes such as carbon and nitrogen mineralisation at the maximum soil concentration tested (NOEC 2.7 mg acs/kg dry soil).

Risks of benzovindiflupyr to soil organisms were determined to be acceptable at the screening level, which assumed direct exposure to maximum possible cumulative concentrations in soil. Similarly, risks of combined residues of benzovindiflupyr and propiconazole were determined to be acceptable at the screening level, which assumed direct exposure immediately after application.

**Non-target terrestrial plants**

Benzovindiflupyr is not considered to be phytotoxic based on pre- and post-emergent toxicity testing of a solo EC formulation on six crop species (ER₂₅ >100 g ac/ha; ER₅₀ >100 g ac/ha).

Tier II dose-response tests were performed with Elatus Ace Fungicide on six standard plant test species in both seedling emergence and vegetative vigour test systems. Assessments made on phytotoxicity symptoms indicated no phytotoxicity to plants exposed prior to emergence (pre-emergent: ER₂₅ >290 g acs/ha, ER₅₀ >290 g acs/ha). Some phytotoxicity (ie, >25 per cent impact) was observed in plants exposed post-emergence in their early growth stage. Generally, at 116 g acs/ha, phytotoxic symptoms were either not apparent or only minor (post-emergent: ER₂₅ >116 g acs/ha, ER₅₀ >290 g acs/ha). At an application rate of 145 g acs/ha, the product is not expected to result in phytotoxicity or adverse effects on plant growth.

Considering a lack of phytotoxicity at environmentally relevant rates, risks of benzovindiflupyr and Elatus Ace Fungicide to non-target terrestrial plants are considered to be acceptable.

**7.3 Recommendations**

In considering the environmental safety of the proposed use of Elatus Ace Fungicide, the APVMA had regard to the toxicity of the active constituent and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems.

Based on the outcome of the risk assessment, the APVMA is satisfied that the use of the product when used according to instruction, would not be likely to have an unintended effect that is harmful to animals, plants, or things or to the environment.
8 EFFICACY AND SAFETY ASSESSMENT

8.1 Proposed product use pattern

The purpose of the application is to register Elatus Ace Fungicide containing 250 g/L propiconazole and 40 g/L benzovindifupyr, a protectant fungicide for the control of foliar diseases in wheat and barley. The two active ingredients in Elatus Ace Fungicide have different modes of action on fungal pathogens and are in different fungicide resistance groups, three and seven respectively.

8.2 Efficacy and target crop safety

Elatus Ace Fungicide was evaluated for efficacy and crop safety on wheat and barley in ninety field trials between 2014 and 2017 in Queensland, NSW, Victoria, South Australia and Western Australia, and multiple field trials globally.

Efficacy and crop safety data were generated using various formulations of Elatus Ace Fungicide. This included the proposed formulation and variant formulations containing 250 g/L propiconazole and 40 g/L benzovindifupyr and other variant formulations containing 100 g/L benzovindiflupyr and 250 g/L propiconazole. The formulation variants were found to be bioequivalent to each other and the proposed Elatus Ace Fungicide formulation.

Australian industry standards, including registered products containing prothioconazole (210 g/L), tebuconazole (210 g/L), propiconazole (250 g/L), azoxystrobin (250 g/L), epoxiconazole (125 g/L), prothioconazole (150 g/L), and bixafen plus tebuconazole (75 g/L and 430 g/L) were compared to Elatus Ace Fungicide for efficacy and crop safety.

Elatus Ace Fungicide was applied to foliage at 250, 500 and 1000 mL/ha (0.5, 1 and 2x proposed label rate) in water volumes of 90 to 120 L/ha. In most trials, two applications were made at an interval of about 21 days.

Assessments of efficacy and crop safety included disease incidence and severity, percentage control, green leaf area, lodging, reflectance (NDVI), dry weight, moisture and protein content, crop yield and visual phytotoxicity from seven days after treatment to crop maturity. Upper, middle and lower parts of the crop canopy and specific areas of the plant were assessed according to the disease and characteristic symptoms.

Crop safety was assessed during efficacy trials on multiple cultivars of wheat and barley. Twenty wheat, cultivars, used in efficacy and crop safety trials including durum and APH varieties EGA Gregory, Lancer, Chara, Scout, Yitpi, Cosmi, Mace, Bolac, Revenu, Cobra, Trojan, Scepter, Magenta, Justica, H45, NNNNN, Corack. Fourteen barley varieties were evaluated including the major varieties for commercial malting production in Australia, Bass, Hindmarsh, Compass, La Trobe, Spartacus, Stirling, Granger and Commander.

The field trials used valid trial design, scientific methodology and assessment parameters, with multiple replicates, and untreated controls. Results were analysed using standard statistical procedures (ANOVA and LSD).
Efficacy

Efficacy was assessed against the following diseases:

- yellow leaf spot in wheat (*Pyrenophora tritici-repentis*)
- septoria tritici blotch in wheat (*Zymoseptoria tritici*)
- glume blotch in wheat (*Parastagonospora nodorum*)
- powdery mildew in wheat (*Blumeria graminis f.sp. tritici*)
- stripe rust in wheat (*Puccinia striiformis*)
- leaf rust in wheat (*Puccinia triticiana*)
- stem rust in wheat (*Puccinia graminis f.sp. tritici*)
- eyespot in wheat (*Oculimacula yallundae*)
- spot form net blotch in barley (*Pyrenophora teres f. maculata*)
- net form net blotch in barley (*Pyrenophora teres f. teres*)
- ring spot in barley (*Pyrenophora semeniperda*)
- scald in barley (*Rhynchosporium secalis*)
- powdery mildew in barley (*Blumeria graminis f.sp. hordei*)
- leaf rust in barley (*Puccinia hordei*)
- ramularia leaf spot in barley (*Ramularia collo-cygni*).

Elatus Ace Fungicide provided good disease control equal to, or superior to, currently registered fungicides commonly used in Australia for the control of yellow leaf spot, *Septoria tritici* blotch, glume blotch, powdery mildew, stripe rust, stem rust, leaf rust, spot form net blotch, net form net blotch, and scald. Elatus Ace Fungicide also provided strong suppression of eyespot, ringspot and ramularia.

Applied to wheat cv Lancer, Elatus Ace Fungicide (proposed formulation) resulted in 78 per cent control of yellow leaf spot at 29 days after treatment two, at a crop stage of BBCH71, compared to 75 per cent for the tank mix formulation containing 100 g/L benzovindiflupyr plus 250 g/L propiconazole, with 73 per cent control for the industry standards when applied alone. Elatus Ace Fungicide provided effective control of yellow leaf spot, equivalent to the industry standards and the tank mix formulation containing 100 g/L benzovindiflupyr plus 250 g/L propiconazole. In terms of efficacy against yellow leaf spot, all formulation variants were determined to be bioequivalent.

Elatus Ace Fungicide (proposed formulation) applied to barley at the proposed label rate in an Argentinian trial in 2017, resulted in 96 per cent control of ramularia at 32 days after a single application. Greater than 90 per cent control of ramularia was achieved in most international trials for the range of formulation variants.

Consistently, where disease was moderate to high, all formulation variants provided significant control of fungal diseases on wheat equal or superior to Australian industry standards. Significant yield increase was recorded in many trials as a result of disease control with excellent green leaf retention.
Applied to Barley cv Bass, the tank mix formulation containing 100 g/L benzovindiflupyr plus 250 g/L propiconazole, resulted in significant yield improvements of 0.8 t/ha over the untreated control, and disease control equal or superior to the registered industry standards. The same formulation resulted in 96 per cent disease control at 10 days after the second application (applied at 19 days interval) at BBCH77, compared to 52 per cent and 27 per cent disease control for industry standards. In this trial, treatments had a mean yield of 2.61 t/ha compared to 1.86 t/ha for the untreated control and 1.68 and 1.9 t/ha for the industry standards.

Elatus Ace Fungicide (all formulation variants) consistently provided significant control of fungal diseases on barley and was superior, or equal to, the industry standards. Significant yield increase in barley was recorded in many trials as a result of disease control.

International trials in Russia, Argentina, Turkey, Croatia, Poland and Romania using the proposed Elatus Ace Fungicide formulation, and the other formulation variants used in Australian trials, resulted in control equal to, or superior to, industry standards for the same fungal diseases of wheat and barley evaluated in Australian trials.

**Crop safety**

Elatus Ace Fungicide applied twice at an interval of two months at 100 L/ha and at the proposed and double label rate to wheat and barley cultivars including Triticum cvs NNNNN, Cobra, Corack, Scepter, Hordeum cvs, Compass, LaTrobe and Spartacus, resulted zero phytotoxicity at all assessments up to 20 days after the last application. Some formulation variants tested, were not safe to wheat and barley cultivars, however, the proposed formulation of Elatus Ace Fungicide was safe with no significant phytotoxicity recorded in trials.

The crop safety of Elatus Ace Fungicide was confirmed on multiple barley and wheat cultivars in efficacy and specific crop safety field trials. Where minor phytotoxicity was recorded, all formulations including the industry standards had similar results.

**8.3 Recommendations**

Elatus Ace Fungicide containing 250 g/L propiconazole and 40 g/L benzovindifupyr applied at the proposed recommended label rate, was determined to be efficacious for all pathogens evaluated (control and suppression) and safe for wheat and barley cultivars.

90 trials were conducted in the major cropping regions in five states over four growing seasons, and internationally, providing comprehensive data to support crop safety.

Trial data confirmed efficacy and crop safety on wheat and barley and equal or superior control of pathogens to industry standards, therefore, the registration of Elatus Ace Fungicide is supported.
9 LABELLING REQUIREMENTS

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

Elatus Ace
Fungicide

ACTIVE CONSTITUENTS: 40 g/L BENZOVINIFLUOPYR
250 g/L PROPICONAZOLE

GROUP 3 7 FUNGICIDE

Controls certain fungal diseases of Wheat and Barley as specified in the Directions for Use

5 to 20 LITRES

Syngenta Australia Pty Ltd
Level 1, 2-4 Lyonpark Road, Macquarie Park NSW 2113

In a transport emergency dial 000, Police or Fire Brigade
For specialist advice in an emergency only, call 1800 033 111 (24 hours)

APVMA Approval No: 86310/115394
Item number
DIRECTIONS FOR USE

Restraints:
DO NOT apply with aircraft
DO NOT apply if rain is expected within 48 hours to avoid runoff
DO NOT apply more than 2 applications of ELATUS ACE (or any other Group 7 fungicide) in any one season on the same paddock
DO NOT apply after BBCH growth stage 69

Spray Drift Restraints
DO NOT apply with spray droplets smaller than a MEDIUM spray droplet size category according to nozzle manufacturer specifications that refer to the ASAE S572 Standard or the British Crop Production Council guideline

DO NOT apply when wind speed is less than 3 or more than 20 kilometres per hour, as measured at the application site

DO NOT apply during surface temperature inversion conditions at the application site

Users of this product MUST make an accurate written record of the details of each spray application within 24 hours following application, and must KEEP this record for at least 2 years. The spray application details that must be recorded are:
1 date with start and finish times of application
2 location address and paddock(s) sprayed
3 full name of this product
4 amount of product used per hectare and number of hectares applied to
5 crop or situation and weed or pest
6 wind speed and direction during application
7 air temperature and relative humidity during application
8 nozzle brand, type, spray angle, nozzle capacity and spray system pressure measured during application
9 name and address of person applying this product.
(Additional record details may be required by the state or territory where this product is used.)

Mandatory No-Spray Zones
DO NOT apply if there are aquatic and wetland areas including aquacultural ponds, surface streams and rivers within 10 metres downwind from the application area

<table>
<thead>
<tr>
<th>Crop</th>
<th>Pest</th>
<th>Rate</th>
<th>Critical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barley</td>
<td>Scald (Rhynchosporium secalis)</td>
<td>500 mL/ha</td>
<td>Spray at the first sign of disease during the tillering stage. A repeat spray 21 to 28 days later may be required. Ensure thorough coverage of stems and leaves.</td>
</tr>
<tr>
<td></td>
<td>Spot form net blotch (Pyrenophora teres f. maculata)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Net form net blotch (Pyrenophora teres f. teres)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Ring spot (Pyrenophora semeniperda)</td>
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<tr>
<td></td>
<td>Powdery mildew (Blumeria graminis f.sp. hordei)</td>
<td>500 mL/ha</td>
<td>Spray at the first sign of disease, typically this may be during stem elongation. A repeat spray 21 to 28 days later may be required. Ensure thorough coverage of stems and leaves.</td>
</tr>
<tr>
<td></td>
<td>Leaf rust (Puccinia hordei)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Ramularia leaf spot (Ramularia collo-cygni)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Crop | Pest | Rate | Critical Comments
---|---|---|---
Wheat | 1 Stripe rust *(Puccinia striiformis)* Powdery mildew *(Blumeria graminis f.sp. tritici)* | 500 mL/ha | Spray at the first sign of disease. Depending on the disease being targeted, this may be during tillering or stem elongation. A repeat spray 21 to 28 days later may be required. Ensure thorough coverage of stems and leaves.
 | 2 Stem rust *(Puccinia graminis f.sp. tritici)* Septoria tritici blotch *(Zymoseptoria tritici)* Leaf rust *(Puccinia triticiana)* Glume blotch *(Parastagonospora nodorum)* Yellow leaf spot *(Pyrenophora tritici-repentis)* | | |
Suppression of Eyespot *(Oculimacula yallundae)* | 500 mL/ha | Apply at GS31 in combination with a plant growth regulator program such as Moddus® Evo Yield and Quality Enhancer and Errex 750 Plant Growth Regulator for disease suppression. Ensure water volume and coverage is sufficient for the product to reach the base of the tillers.

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

WITHHOLDING PERIODS
*Harvest*: NOT REQUIRED WHEN USED A DIRECTED
*Grazing*: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 10 DAYS AFTER APPLICATION

GENERAL INSTRUCTIONS

SHAKE WELL BEFORE OPENING

Mixing
ELATUS ACE Fungicide is an emulsifiable concentrate that mixes readily with water. Fill the spray tank to one quarter full. Add ELATUS ACE and continue adding water to make up to the final spray volume. Agitate while mixing and spraying.

When tank mixing, wettable powder or water dispersible granule formulations should be added to the tank first followed by suspension concentrates (flowables), water soluble salts then ELATUS ACE or other emulsifiable concentrate formulations. Maintain thorough agitation during mixing and application. Agitate tank mixes vigorously if allowed to stand. Note: Tank mix spray solutions should NOT be left standing in the vat overnight.

Application
DO NOT apply with aircraft.
Use a nozzle delivering spray quality in the medium spray range, with a minimum of 70 L/ha of water volume up to 150 L/ha. Ensure complete coverage of all leaves and stems is obtained. The object of spraying is to keep the upper 2 to 3 leaves green and functioning through grain filling stage.
Compatibility
ELATUS ACE is compatible with a range of commonly used fungicides, insecticides, herbicides and fertilizers. Always consult your Syngenta representative before mixing ELATUS ACE with other products. As formulations of other manufacturers’ products are beyond the control of Syngenta and water quality varies with location, all mixtures should be tested prior to mixing commercial quantities.

Fungicide Resistance Warning

ELATUS ACE Fungicide contains two different groups of fungicides, benzovindiflupyr is a member of the SDHI group of fungicides and propiconazole is a member of the DMI group of fungicides. For fungicide resistance management ELATUS ACE is both a Group 7 and a Group 3 fungicide. Some naturally occurring individual fungi resistant to ELATUS ACE and other Group 7 and/or Group 3 fungicides may exist through normal genetic variability in any fungal population. The resistant individuals can eventually dominate the fungi population if these fungicides are used repeatedly. These resistant fungi will not be controlled by ELATUS ACE and other Group 7 and/or Group 3 fungicides, thus resulting in a reduction in efficacy and possible yield loss. Since the occurrence of resistant fungi is difficult to detect prior to use, Syngenta Australia Pty Ltd accepts no liability for any losses that may result from the failure of ELATUS ACE to control resistant fungi.

PRECAUTION

Re-entry Period
DO NOT allow entry into treated areas until spray has dried. If prior entry is necessary, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day’s use.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

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

INTEGRATED PEST MANAGEMENT

Toxic to beneficial arthropods. Not compatible with integrated pest management (IPM) programs utilising beneficial arthropods. Minimise spray drift to reduce harmful effects on beneficial arthropods in non-crop areas.

STORAGE AND DISPOSAL

Store in the closed, original container in a cool, well ventilated area. DO NOT store for prolonged periods in direct sunlight. Triple or preferably pressure rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty container to an approved waste management facility. If an approved waste management facility is available, bury the empty container below 500 mm in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots in compliance with relevant local, state or territory government regulations. DO NOT burn empty containers or product.

SAFETY DIRECTIONS

Harmful if swallowed or inhaled. Will irritate the eyes. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. Do not inhale. 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 and
- face shield or goggles.
When using the prepared spray, wear
- cotton overalls buttoned to the neck and wrist (or equivalent clothing) and
- elbow-length chemical resistant gloves.
If product in eyes, wash it out immediately with water. 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 131 126.
### ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ac</td>
<td>active constituent (benzovindiflupyr)</td>
</tr>
<tr>
<td>acs</td>
<td>active constituents (benzovindiflupyr+propiconazole)</td>
</tr>
<tr>
<td>ADI</td>
<td>Acceptable Daily Intake (for humans)</td>
</tr>
<tr>
<td>ai</td>
<td>active ingredient</td>
</tr>
<tr>
<td>AR</td>
<td>applied radioactivity</td>
</tr>
<tr>
<td>ARID</td>
<td>Acute Reference Dose</td>
</tr>
<tr>
<td>bw</td>
<td>bodyweight</td>
</tr>
<tr>
<td>BBCH</td>
<td>The BBCH-scale is used to identify the phenological development stages of plants</td>
</tr>
<tr>
<td>BCF</td>
<td>bioconcentration factor</td>
</tr>
<tr>
<td>d</td>
<td>day</td>
</tr>
<tr>
<td>DAT</td>
<td>Days After Treatment</td>
</tr>
<tr>
<td>DT&lt;sub&gt;50&lt;/sub&gt;</td>
<td>period required for 50 percent dissipation</td>
</tr>
<tr>
<td>DT&lt;sub&gt;90&lt;/sub&gt;</td>
<td>period required for 90 percent dissipation</td>
</tr>
<tr>
<td>EC</td>
<td>emulsifiable concentrate</td>
</tr>
<tr>
<td>EC&lt;sub&gt;50&lt;/sub&gt;</td>
<td>effective concentration, median</td>
</tr>
<tr>
<td>E&lt;sub&gt;50&lt;/sub&gt;C&lt;sub&gt;50&lt;/sub&gt;</td>
<td>concentration at which the rate of growth of 50 per cent of the test population is impacted</td>
</tr>
<tr>
<td>EI</td>
<td>Export Interval</td>
</tr>
<tr>
<td>ER&lt;sub&gt;25&lt;/sub&gt;</td>
<td>effective rate, 25th percentile</td>
</tr>
<tr>
<td>ER&lt;sub&gt;50&lt;/sub&gt;</td>
<td>effective rate, median</td>
</tr>
<tr>
<td>F&lt;sub&gt;0&lt;/sub&gt;</td>
<td>original parent generation</td>
</tr>
<tr>
<td>g</td>
<td>gram</td>
</tr>
<tr>
<td>GAP</td>
<td>Good Agricultural Practice</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practice</td>
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<tr>
<td>h</td>
<td>hour</td>
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<tr>
<td>ha</td>
<td>hectare</td>
</tr>
<tr>
<td>IPM</td>
<td>Integrated Pest Management</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<td>--------------</td>
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</tr>
<tr>
<td>iv</td>
<td>intravenous</td>
</tr>
<tr>
<td>in vitro</td>
<td>outside the living body and in an artificial environment</td>
</tr>
<tr>
<td>in vivo</td>
<td>inside the living body of a plant or animal</td>
</tr>
<tr>
<td>kg</td>
<td>kilogram</td>
</tr>
<tr>
<td>K&lt;sub&gt;ow&lt;/sub&gt;</td>
<td>octanol-water partition coefficient</td>
</tr>
<tr>
<td>L</td>
<td>Litre</td>
</tr>
<tr>
<td>LC&lt;sub&gt;50&lt;/sub&gt;</td>
<td>concentration that kills 50 per cent of the test population of organisms</td>
</tr>
<tr>
<td>LC&lt;sub&gt;50corr&lt;/sub&gt;</td>
<td>lethal concentration, median, corrected</td>
</tr>
<tr>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>dosage of chemical that kills 50 per cent of the test population of organisms</td>
</tr>
<tr>
<td>LOD</td>
<td>Limit of Detection—level at which residues can be detected</td>
</tr>
<tr>
<td>Log K&lt;sub&gt;ow&lt;/sub&gt;</td>
<td>Log to base 10 of octanol water partitioning co-efficient, synonym P&lt;sub&gt;ow&lt;/sub&gt;</td>
</tr>
<tr>
<td>LOQ</td>
<td>Limit of Quantitation—level at which residues can be quantified</td>
</tr>
<tr>
<td>LR&lt;sub&gt;50&lt;/sub&gt;</td>
<td>lethal rate, median</td>
</tr>
<tr>
<td>mg</td>
<td>milligram</td>
</tr>
<tr>
<td>mL</td>
<td>millilitre</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum Residue Limit</td>
</tr>
<tr>
<td>MSDS</td>
<td>Material Safety Data Sheet</td>
</tr>
<tr>
<td>NEDI</td>
<td>National Estimated Daily Intake</td>
</tr>
<tr>
<td>NESTI</td>
<td>National Estimated Short Term Intake</td>
</tr>
<tr>
<td>ng</td>
<td>nanogram</td>
</tr>
<tr>
<td>NOEC/NOEL</td>
<td>No Observable Effect Concentration Level</td>
</tr>
<tr>
<td>NOAEL</td>
<td>No Observed Adverse Effect Level</td>
</tr>
<tr>
<td>ppb</td>
<td>parts per billion</td>
</tr>
<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
</tr>
<tr>
<td>ppm</td>
<td>parts per million</td>
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<tr>
<td>Q-value</td>
<td>Quotient-value</td>
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<tr>
<td>REI</td>
<td>Re-Entry Interval</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>s</td>
<td>second</td>
</tr>
<tr>
<td>SFO</td>
<td>single first order</td>
</tr>
<tr>
<td>µg</td>
<td>microgram</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
<tr>
<td>vmd</td>
<td>volume median diameter</td>
</tr>
<tr>
<td>WHP</td>
<td>Withholding Period</td>
</tr>
<tr>
<td><strong>GLOSSARY</strong></td>
<td></td>
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<tr>
<td>---------------------------------------------------------------</td>
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<tr>
<td><strong>Active constituent</strong></td>
<td>The substance that is primarily responsible for the effect produced by a chemical product</td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td>Having rapid onset and of short duration</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td>The ability to cause cancer</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td>Of long duration</td>
</tr>
<tr>
<td><strong>Codex MRL</strong></td>
<td>Internationally published standard maximum residue limit</td>
</tr>
<tr>
<td><strong>Desorption</strong></td>
<td>Removal of a material from or through a surface</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>Production of the desired effect</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>A combination of both active and inactive constituents to form the end use product</td>
</tr>
<tr>
<td><strong>Genotoxicity</strong></td>
<td>The ability to damage genetic material</td>
</tr>
<tr>
<td><strong>Hydrophobic</strong></td>
<td>Repels water</td>
</tr>
<tr>
<td><strong>Leaching</strong></td>
<td>Removal of a compound by use of a solvent</td>
</tr>
<tr>
<td><strong>Metabolism</strong></td>
<td>The chemical processes that maintain living organisms</td>
</tr>
<tr>
<td><strong>Photodegradation</strong></td>
<td>Breakdown of chemicals due to the action of light</td>
</tr>
<tr>
<td><strong>Photolysis</strong></td>
<td>Breakdown of chemicals due to the action of light</td>
</tr>
<tr>
<td><strong>Toxicokinetics</strong></td>
<td>The study of the movement of toxins through the body</td>
</tr>
<tr>
<td><strong>Toxicology</strong></td>
<td>The study of the nature and effects of poisons</td>
</tr>
</tbody>
</table>
REFERENCES

