Australian Government

Australian Pesticides and Veterinary Medicines Authority

PUBLIC RELEASE SUMMARY

on the evaluation of the new active florpyrauxifen-benzyl (Rinskor™) in the Product GF-3301 Herbicide

APVMA Product Number 82885

MARCH 2018

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This publication is available from the APVMA website: www.apvma.gov.au.

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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Ageing and State Departments of Primary Industries.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking community involvement in decision making. Part of that process is the publication of Public Release Summaries for products containing new active constituents.

The information and technical data required by the APVMA to assess the safety 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.

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 its advisory agencies. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience thereby encouraging public comment.

About this document

This is a Public Release Summary.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an agricultural or veterinary chemical. It provides a summary of the APVMA's assessment, which may include details of:

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

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

Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of GF-3301 Herbicide 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 10 March 2018 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.

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:

Case Management and Administration Unit
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Kingston ACT 2604
Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

Further information

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

Copies of technical evaluation reports covering 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: www.apvma.gov.au.

1 INTRODUCTION

1.1 Purpose of application

Dow AgroSciences Australia Limited has applied to the APVMA to register GF-3301 Herbicide, containing the 300 g/L florpyrauxifen-benzyl, suspension concentrate product for the control of certain grass and broadleaf weeds in rice. GF-3301 Herbicide is an arylpicolinate herbicide, for post-emergence or in-flood use in rice.

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of the product GF-3301 Herbicide, and approval of the new active constituent, florpyrauxifen-benzyl (Trade name Rinskor^{TM}).

1.2 Product claims and use pattern

GF-3301 Herbicide will be applied to rice crops for post-emergent or in-flood control of grass and broadleaf weeds via boom spray or SCWIIRT (Soluble Chemical Water Injection In Rice Technique) rig using a steel wheeled tractor, all-wheel drive motor bike or aircraft. It will be applied at rates of 100 mL/ha (30 g a.i./ha) for foliar application or 150 mL/ha (45 g a.i./ha) for in flood application.

1.3 Mode of Action

Florpyrauxifen-benzyl belongs to the arylpicolinate group of synthetic auxin herbicides. Florpyrauxifen-benzyl mimics the effect of a persistent high dose of the natural plant hormone auxin, causing over-stimulation of specific auxin-regulated genes which results in the disruption of several growth processes in susceptible plants. The product has the disrupters of plant cell growth mode-of-action. For weed resistance management, the product is a Group I herbicide

1.4 Overseas Registrations

Florpyrauxifen benzyl is registered in US, China, Korea and Chile. Registrations are pending in other rice producing countries such as Columbia, Brazil, Argentina, Spain, Italy, Turkey, Egypt, India, Thailand, Vietnam, Indonesia and Japan.

2 CHEMISTRY AND MANUFACTURE

2.1 Active Constituent

The chemical active constituent florpyrauxifen-benzyl is a new arylpicolinate herbicide which will be manufactured overseas. Florpyrauxifen-benzyl is a tan powder, with a melting point of 137 °C. The compound decomposes before boiling, with a decomposition temperature of 287 °C. The vapour pressure is 3.2×10^{-5} Pa at 20 °C and 4.6×10^{-5} Pa at 25 °C; therefore it is not volatile. Florpyrauxifen-benzyl is mostly insoluble in water and in pH 5, 7 and 9 buffers (< 0.015 mg/L at 20 °C). It is soluble in most organic solvents, but only slightly soluble in heptane. The octanol / water partition coefficient is high (>5) and does not vary significantly at pH 5, 7 or 9. Florpyrauxifen-benzyl does not dissociate in the pH range of 4 to 10. The compound is not highly flammable, is not explosive or oxidising.

Table 1: Key identification information for the active constituent florpyrauxifen-benzyl

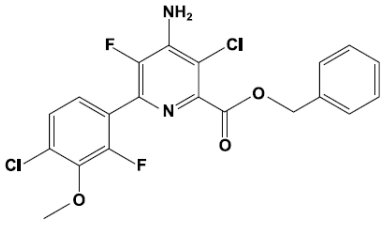
COMMON NAME (ISO):	Florpyrauxifen-benzyl
CHEMICAL NAME (IUPAC):	Benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylate
MANUFACTURER'S CODE:	XDE-848 Benzyl Ester
TRADE NAME:	Rinskor™ active
CAS REGISTRY NUMBER:	1390661-72-9
EMPIRICAL FORMULA:	$C_{20}H_{14}Cl_2F_2N_2O_3$
MOLECULAR WEIGHT:	439.248 g/mol
STRUCTURAL FORMULA:	

Table 2: Key physicochemical properties for florpyrauxifen-benzyl active constituent

PHYSICAL FORM:	Off-white powder at 21.1 °C (99. 4%) Tan powder at 21.1 ºC (96.4 %)
RELATIVE DENSITY:	1.46 g/cm^3 (20 ºC)
ODOUR:	Mild odour
MELTING POINT:	137.07 °C
PH:	pH 6.58 at 23.4 ºC (1% w/w dispersion in distilled water)
OCTANOL/WATER PARTITION COEFFICIENT (KOW):	pH 5 ($\log_{10}P_{ow}$ = 5.4 ± 0.1) pH 7 ($\log_{10}P_{ow}$ = 5.5 ± 0.04) pH 9 ($\log_{10}P_{ow}$ = 5.5 ± 0.1)
VAPOUR PRESSURE:	4.6 ×10^{-5} Pa at 25 °C and 3.2 ×10^{-5} Pa at 20 °C.
WATER SOLUBILITY AT 20 OC:	Purified water: 0.015 mg/L pH 5 buffer solution: 0.014 mg/L pH 7 buffer solution: 0.011 mg/L pH 9 buffer solution: 0.012 mg/L
SOLUBILITY IN ORGANIC SOLVENTS AT 20 OC:	Acetone 210 g/L Methanol 13 g/L 1,2-dichloroethane 95 g/L Xylene 14 g/L n- heptane 0.053 g/L n-octanol 4.9 g/L Ethyl acetate 120 g/L
BULK DENSITY **TAPPED DENSITY**	0.202 g/mL at 23.4 °C 0.320 g/mL at 23.4 °C
HYDROLYSIS RATE AT 25 OC	pH 4 DT_{50} = 913 days pH 7 DT_{50} = 111 days pH 9 DT_{50} = 1.3 days
FLAMMABILITY	Not highly flammable
AUTO-FLAMMABILITY	Not observed up to the maximum test temperature (400 ºC)
OXIDISING PROPERTIES	Not oxidising
STORAGE STABILITY	Stable to normal and elevated temperatures, and in the presence of common metals and metal ions

2.2 Formulated Product

The product, GF-3301 Herbicide will be manufactured overseas and will be available in 0.5 L, 1 L, 5 L, 10 L and 20 L HDPE containers. It is a suspension concentrate formulation containing 300 g/L florpyrauxifen-benzyl as the only active constituent.

Table 3: Key characteristics and physicochemical properties of GF-3301 Herbicide.

DISTINGUISHING NAME:	GF-3301 Herbicide
FORMULATION TYPE:	Suspension Concentrate (SC)
ACTIVE CONSTITUENT CONCENTRATION:	300 g/L
PHYSICAL FORM:	Tan liquid
ODOUR:	Solvent like
PH VALUE:	5.47 (pH ~1 % w/w dilution in distilled water at 22.9 °C)
RELATIVE DENSITY:	1.1278 g/mL @ 20 °C
VISCOSITY:	Non-Newtonian fluid: viscosity decreasing with increasing shear rate
FLASH POINT:	Not applicable
OXIDISING PROPERTIES:	No oxidising properties
EXPLOSIVE PROPERTIES:	No explosive properties
CORROSIVE HAZARD:	Not corrosive to HDPE containers

2.3 Recommendations

The APVMA Chemistry and Manufacture Section has evaluated the chemistry aspects of florpyrauxifen-benzyl and GF-3301 Herbicide (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 technical active and formulated product are expected to remain stable for up to two years when stored under normal conditions.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA active constituent standard be established for florpyrauxifen-benzyl:

Proposed APVMA active constituent standard for florpyrauxifen-benzyl

Table 4: APVMA active constituent standard proposed for the active constituent florpyrauxifen-benzyl

CONSTITUENT	SPECIFICATION	LEVEL
Florpyrauxifen-benzyl	Florpyrauxifen-benzyl content	920 g/kg minimum

Approval of the active constituent florpyrauxifen-benzyl, and registration of GF-3301 Herbicide are supported from a chemistry and manufacture perspective.

3 TOXICOLOGICAL ASSESSMENT

3.1 Evaluation of toxicology

The toxicological database for florpyrauxifen-benzyl is considered sufficient to determine its toxicology profile and to characterise the risk to humans. The data package provided 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, repeat dose neurotoxicity and immunotoxicity studies, and other information to address the human safety criteria.

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

Chemical class

Florpyrauxifen-benzyl belongs to the arylpicolinate group of synthetic auxin herbicides. Florpyrauxifen-benzyl mimics the effect of a persistent high dose of the natural plant hormone auxin, causing over-stimulation of specific auxin-regulated genes which results in the disruption of several growth processes in susceptible plants.

Toxicokinetics and metabolism

The ester linked benzyl group in florpyrauxifen-benzyl is cleaved in the gastrointestinal tract or liver to yield the florpyrauxifen acid before it enters the systemic circulation. Radiolabelled florpyrauxifen showed a peak plasma concentration 2 hours after oral gavage administration in rats. The plasma time-concentration curve demonstrated a biphasic decline with the first and second phases having apparent half-lives of 2 hours and 29-49 hours, respectively, depending on dose. Reflective of its poor absorption, florpyrauxifen-benzyl levels remained high in the gastrointestinal tract. Of the radiolabelled florpyrauxifen, levels were highest in the urinary bladder followed by plasma, kidney and liver. Florpyrauxifen and other metabolites were excreted mainly in urine followed by faeces. Owing to the poor absorption of florpyrauxifen-benzyl, its presence in faeces was related to the administered oral dose. Toxicokinetic studies consistently showed non-linear kinetics, confirming the poor absorption of florpyrauxifen-benzyl from the gastrointestinal tract. Elimination of radioactivity in bile was considered to be only a minor route, with <10% of a 100 mg/kg bw dose being present after 48 hours. Less than 0.02% of the orally administered dose remained in the tissues after 168 hours, indicating a low potential for bioaccumulation.

In rats, metabolism of florpyrauxifen was limited to glucuronidation or demethylation. A secondary minor pathway includes demethylation of florpyrauxifen-benzyl. Metabolism studies *in vitro* demonstrated that there were no appreciable differences in the range of metabolites formed in humans, rats, mice, rabbits or dogs. In plants, florpyrauxifen-benzyl is also metabolised to its acid form, florpyrauxifen. As there were no adverse effects observed following oral dosing with florpyrauxifen-benzyl, there are no crop residues of toxicological concern arising from either plant or soil metabolism.

Acute toxicity

Florpyrauxifen-benzyl has low acute oral toxicity (LD_{50} >5000 mg/kg), dermal toxicity (LD_{50} >5000 mg/kg) and inhalational toxicity (LC_{50} >5230 mg/m^3) in rats. It was not a skin irritant in rabbits but was a slight eye irritant in rabbits. Florpyrauxifen-benzyl demonstrated skin sensitisation potential in mice in a Local Lymph Node Assay (LLNA).

Repeat-dose toxicity

Repeat dose toxicity studies were conducted with florpyrauxifen-benzyl in mice, rats, rabbits and dogs. No treatment-related adverse effects were observed at the highest doses tested (300-1000 mg/kg bw/day). Florpyrauxifen-benzyl did not demonstrate neurotoxic, immunotoxic, carcinogenic, developmental or reproductive toxicity potential in the repeat dose studies. Florpyrauxifen-benzyl did not demonstrate genotoxic potential in *in vitro* and *in vivo* studies.

Product acute toxicity

The formulated product, GF-3301 Herbicide, containing 300 g/L florpyrauxifen-benzyl, has low acute oral toxicity (LD_{50} >5000 mg/kg), dermal toxicity (LD_{50} >5000 mg/kg) and inhalational toxicity in rats (LC_{50} >5660 mg/m^3). It was not a skin irritant in rabbits but was a slight eye irritant in rabbits. GF-3301 Herbicide was not a skin sensitiser in guinea pigs (Buehler method).

3.2 Public health standards

Poisons scheduling

On 31 October 2017 the Delegate of the Secretary of the Department of Health published a final Scheduling decision to exempt florpyrauxifen-benzyl from Scheduling in the Poisons Standard and create a new Appendix B entry for florpyrauxifen-benzy. The reasons for the Delegate's decision to create a new Appendix B entry for florpyrauxifen-benzyl were: low acute toxicity of florpyrauxifen-benzyl consistent with Appendix B; no systemic toxicity reported in repeat dose studies. This decision was implemented on 1 February 2018.

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 establishment of a numerical ADI for florpyrauxifen-benzyl was not considered necessary, based on its low repeat dose toxicity and the lack of evidence for neurotoxic, immunotoxic, carcinogenic, developmental and reproductive toxicity potential with repeat dietary exposure. Therefore, the ADI for florpyrauxifen-benzyl is 'not specified'.

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 establishment of an ARfD for florpyrauxifen-benzyl was not considered necessary, based on its low acute toxicity and the absence of any other toxicologically relevant effect that might be attributable to a single dose.

4 RESIDUES ASSESSMENT

4.1 Introduction

The proposed use pattern of GF-3301 as a herbicide for use in rice at rates of up to 150 ml/ha are described in Section 9. The proposed use pattern defines the developmental stage of the rice plant for application and provides plant back periods for following crops.

As part of the residue assessment for registration of florpyrauxifen-benzyl, plant and animal metabolism studies, supervised residue trials, analytical methodology, fate in storage and processing and residues in trade information were considered in light of the proposed use pattern.

4.2 Metabolism

Metabolism studies were provided for rice, rotational crops, lactating goats and laying hens.

Plants

A rice metabolism study was submitted in which three typical rice planting/ application scenarios were studied: water injected scenario (W), foliar-flooded scenario (F) and dry-seeded scenario (D). The study showed that florpyrauxifen-benzyl (XDE-benzyl ester) is metabolised through de-esterification to yield XDE-848 acid (X11438848). XDE-848 acid is then metabolised to XDE-848 hydroxyl acid (X11966341), which is conjugated with glucose to form X12431091. Florpyrauxifen-benzyl can also photodegrade through dechlorination to X12131932. Metabolism proceeds through natural incorporation into plant constituents. The majority of the extractable residue was present as florpyrauxifen-benzyl, XDE-848 hydroxyl acid and XDE-848 acid.

Rice grain contained low levels of extractable radioactive residue, with about 20% to 58% TRR (Total Radioactive Residues) isolated in starch. Rice grain for the foliar flooded scenario yielded enough extractable radioactive residues (about 40% of the TRR) for HPLC characterisation. HPLC analysis indicated the presence of parent florpyrauxifen-benzyl, XDE-848 hydroxyl acid, XDE-848 acid and dechlorinated XDE-848 (X12131932), each at levels less than 0.002 mg eq./kg.

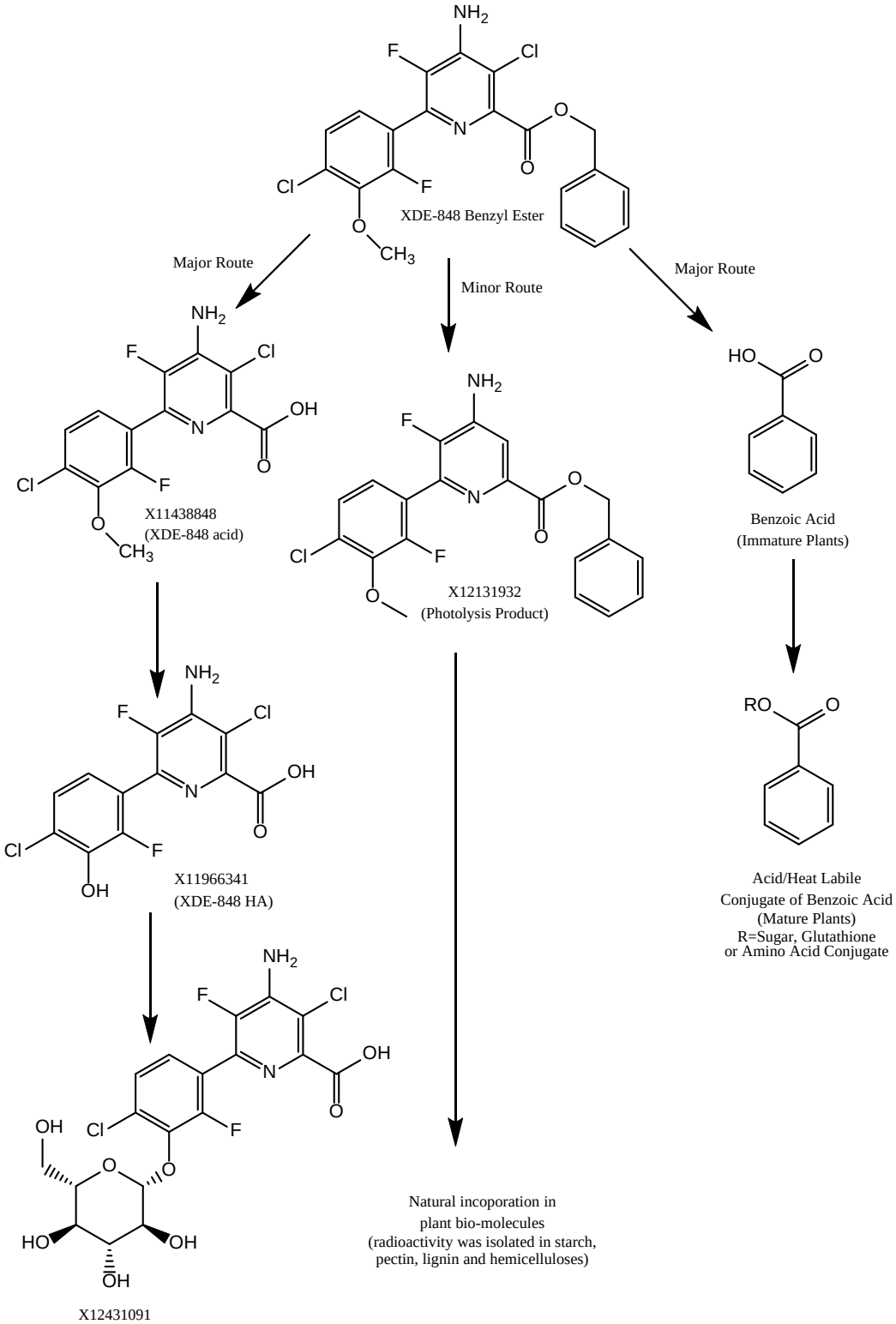
For the water-injected scenario the most dominant metabolite was XDE-848 acid principally determined in straw at levels as high as 0.054 mg eq./kg. For the foliar-flooded scenario and dry-seeded scenario, the major residues, determined in straw, were parent (max. 0.78 mg eq./kg), XDE-848 hydroxyl acid (max. 0.24 mg eq./kg) and XDE-848 acid (max. 0.10 mg eq./kg).

A confined rotational study was supplied. The metabolism of florpyrauxifen-benzyl in representative rotational crops (wheat, lettuce or mustard, and radish) from three consecutive rotations was investigated. Phenyl-, pyridine- and benzyl-labelled ^{14}C-florpyrauxifen-benzyl were each formulated as an EC formulation and soil applied to confined plots of sandy loam soil at a rate of 120 g a.i./ha which is 4× the proposed foliar application rate and 2.66× the proposed SCWIIRT in-flood application rate. The crops were each sown at 30, 90 and 271 days after soil application.

The TRR levels were determined by extraction and/or combustion. The TRRs were <0.01 mg/kg in all matrices from each label at all PBIs, except wheat hay and straw. For wheat hay and straw, residues in crops at all plant-back intervals ranged from 0.001 to 0.046 mg eq./kg (parent equivalents). These data demonstrate that neither parent nor metabolites are significantly taken up by plants grown in soil treated with florpyrauxifen-benzyl.

Given the low level of residues in rotational crops and the similarity in the residues profiles between rice and rotational crops, the residue definition should be the same as recommended for rice.

Figure 1: Biotransformation pathway of florpyrauxifen-benzyl (XDE-848 benzyl ester) in rice and rotational crops.



Animals

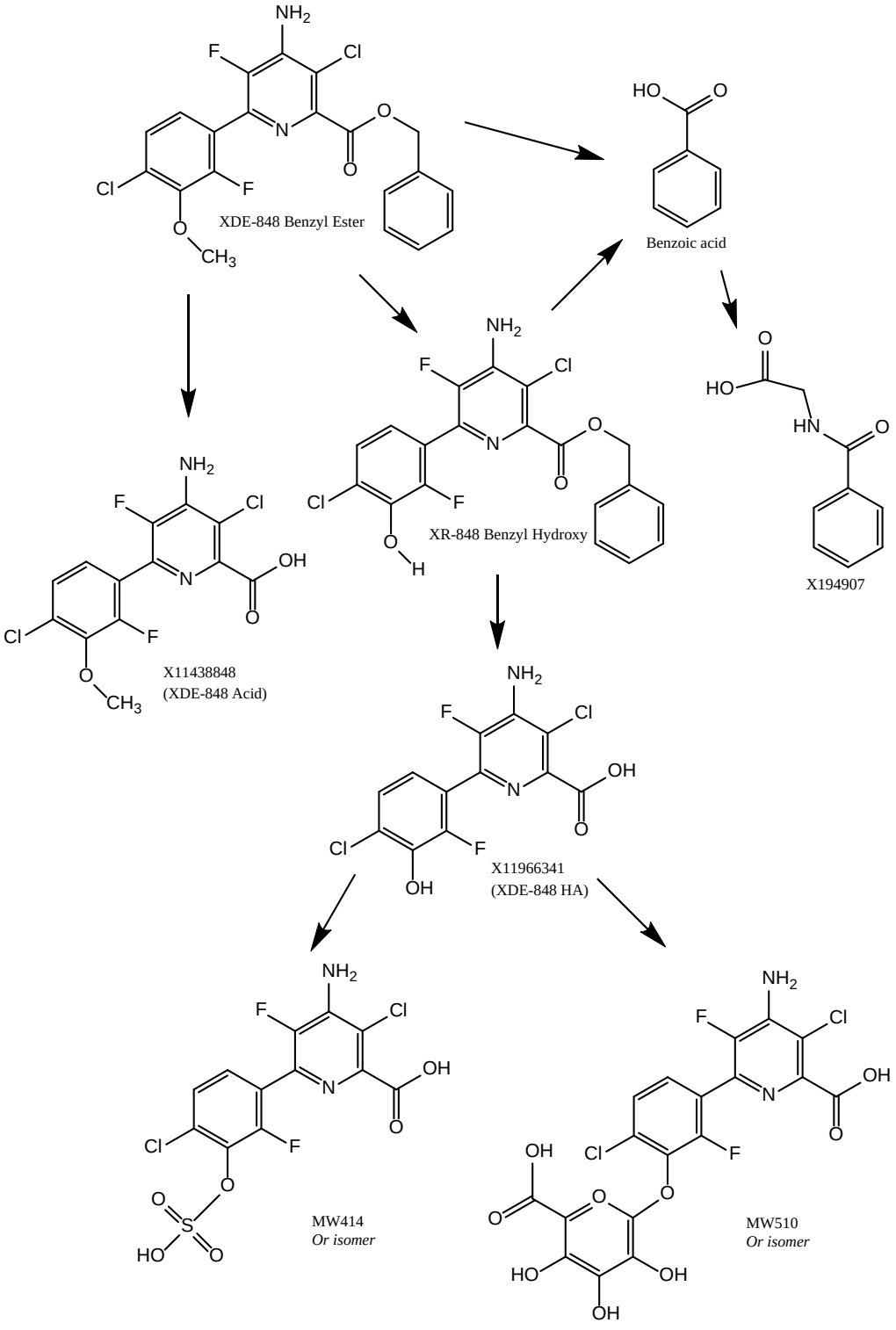
Lactating goat and laying hen metabolism studies were submitted which indicated degradation pathways similar to the plant metabolism studies.

A lactating goat metabolism study was provided where animals were dosed over seven consecutive days with ^{14}C-florpyrauxifen-benzyl labelled materials at approximately 11 ppm in the diet. Florpyrauxifen-benzyl was extensively excreted in faeces and to a lesser extent in urine and less than 1% of the administered radioactivity was recovered in edible tissues and milk.

As the total radioactive residues in muscle, fat and milk were less than 0.010 mg eq./kg, the characterisation of the residues was only investigated in kidney and liver, where the TRRs were up to 0.0220 and 0.0215 mg/kg respectively. Parent was not observed in either liver or kidney with any label. XDE-848 acid was present in liver at 6-7% TRR (0.001 mg eq./kg) and in kidney at 28-45% TRR (0.004-0.010 mg eq./kg). XDE-848 hydroxyl acid was present in liver at 21% TRR (0.002-0.003 mg eq./kg) and in kidney at 24-25% TRR (0.003-0.005 mg eq./kg).

In a laying hen metabolism study, two groups of hens were orally dosed once daily for a total of 14 days at 11-12 ppm in the diet. Florpyrauxifen-benzyl was extensively excreted and TRR levels in egg, liver, muscle, skin and fat were low, with less than 1% of the dose recovered in the eggs and edible tissues. As the TRRs in eggs and tissues were less than 0.010 mg eq./kg, the characterisation of the residues was only investigated in selected excreta samples which showed that the major radioactive components in the excreta were florpyrauxifen-benzyl and the two metabolites XDE-848 acid and XDE-848 hydroxyl acid.

Figure 2: Biotransformation pathway of florpyrauxifen-benzyl (XDE-848 benzyl ester) in lactating goats.



4.3 Analytical methods

A number of validated analytical methods for the determination of residues in plant and animal commodities were submitted. These included the analytical method used in the Australian rice trials, measured residues of florpyrauxifen-benzyl, and metabolites XDE-848 acid and XDE-848 hydroxyl acid (LC-MS/MS, LOQ = 0.01 mg/kg). The submitted QuEChERS method was found to be applicable for determination of residues of florpyrauxifen-benzyl and its acid metabolite in plant and animal matrices.

4.4 Stability of the pesticide in stored analytical samples

A study has been submitted which shows that residues of florpyrauxifen-benzyl, its acid metabolite and its hydroxyl acid metabolite are stable in rice grain and straw, and rice processed fractions (bran, hulls and flour), for at least 12 months in frozen storage at -20°C.

Another study was submitted which shows that residues of florpyrauxifen-benzyl, its acid metabolite and its hydroxyl acid metabolite are stable in milk, muscle and eggs for at least 65 days in frozen storage at -20°C. In liver samples, residues of the acid metabolite and the hydroxyl acid are stable when stored frozen for up to 65 days. Residues of florpyrauxifen-benzyl were observed to decline in liver samples and were shown to hydrolyse to XDE 848 acid after 27 days storage. When including the observed XDE-848 acid as florpyrauxifen-benzyl equivalents in the recovery calculation of florpyrauxifen-benzyl, satisfactory recovery was obtained. The data indicate that residues of florpyrauxifen-benzyl can be accurately quantified as the sum of florpyrauxifen-benzyl and the XDE-848 acid metabolite (expressed as florpyrauxifen-benzyl equivalents) in liver when stored for up to 65 days.

4.5 Residue definition

Major metabolic pathways include cleavage of the benzyl ester to give the XDE-848 acid metabolite and benzyl alcohol (theoretical hydrolysis product). Parent florpyrauxifen-benzyl and the acid metabolite were generally the predominant residues observed in primary crops, rotational crops and livestock. The hydroxy acid metabolite which was also observed, is a hydrolysis product of XDE-848 acid and was not a major residue (<0.01 mg/kg) in the edible tissues, kidney and liver in the goat metabolism study.

Based on the major metabolites identified in the available plant and animal metabolism data, the capability of the analytical methods and toxicological advice, and noting that quantifiable residues are not expected to occur in plant and animal commodities from the proposed use, it is concluded that a residue definition of parent florpyrauxifen-benzyl and XDE-848 acid expressed as florpyrauxifen-benzyl, is considered appropriate for enforcement of florpyrauxifen-benzyl residues for commodities of plant and animal origin. It is not necessary to consider a separate definition for risk assessment, as no HBGVs were considered to be necessary.

The residue definition may be reconsidered if there is a future application to extend the label to other crops.

4.6 Residue trials

The proposed GAP (Good Agricultural Practices) of GF-3301 Herbicide for rice is for a maximum of one application of florpyrauxifen-benzyl per season at 30 g a.i./ha for post-emergence (foliar) use or 45 g a.i./ha for SCWIIRT or Bickley boom (in-flood) application, with a harvest WHP of “Not required when used as directed”. A grazing WHP of 1 week is proposed.

Field trials were conducted in Australia in 2013 and 2104 that involved the proposed formulation GF-3301 Herbicide, and GF-3206 (25 g a.i./L) and GF-3262 (300 g a.i./L) which were experimental formulations containing florpyrauxifen-benzyl. All trials involved the addition of an adjuvant and were applied by foliar or SCWIIRT application. Samples were analysed for florpyrauxifen-benzyl and the major metabolites XDE-848 acid and XDE-848 hydroxy acid.

In three Australian trials conducted in 2013, no detectable residues of either florpyrauxifen-benzyl or XDE-848 acid were observed in rice grain at harvest following two foliar applications of GF-3206 at 30 or 60 g a.i./ha or GF-3262 at 30g a.i./ha.

In two Australian trials conducted in 2014, no detectable residues of either florpyrauxifen-benzyl or XDE-848 acid were observed in rice grain at harvest following two foliar applications of GF-3206 at 30 or 60 g a.i./ha or GF-3301 Herbicide at 30g a.i./ha, or two applications of GF-3301 Herbicide at 30 or 60 g a.i./ha *via* the SCWIIRT method.

The submitted Australian trials indicate that no quantifiable residues are expected after application according to the proposed GAP. As the proposed residue definition for florpyrauxifen-benzyl is the combined residues of florpyrauxifen-benzyl and XDE-848 acid and the LOQ for each component of the definition is 0.01 mg/kg, it is considered appropriate to establish an MRL for GC 0649 Rice at *0.02 mg/kg.

A processing study was conducted with two applications at 200g a.i./ha (6.7× the maximum proposed rate for foliar application and 4.4× the maximum proposed rate for SCWIIRT application), in order to ensure quantifiable residues in the RAC. Residues of florpyrauxifen-benzyl and metabolites were non-detectable (<0.003 mg/kg) in treated grain samples from which the processed fractions are generated, and in samples of the processed fractions. No potential for concentration of the active ingredient during processing was observed, therefore residues appear to be unlikely to concentrate above levels observed in rice grain treated with the proposed use pattern.

In the three Australian trials from both 2103 and 2014, the highest residue observation in rice straw was 0.19 mg/kg. A florpyrauxifen-benzyl MRL of 0.5 mg/kg was recommended for AS 0649 Rice straw and fodder, dry.

In the three Australian trials from both 2103 and 2014, the highest residue observation in rice forage at a 7 day WHP was 2.40 mg/kg on a dry weight basis. A florpyrauxifen-benzyl MRL of 5 mg/kg was recommended for Rice forage (green).

4.7 Animal commodity MRLs

Table 5 shows the predicted residue contribution from rice forage used as feed for livestock.

Table 5: Predicted residue contribution from rice forage used as feed for livestock

BEEF AND DAIRY CATTLE 500 kg bw, 20 kg dm/day

COMMODITY	RESIDUE (mg/kg)	BASIS	DM (%)	RESIDUE DW (mg/kg)	MAXIMUM DIET CONTENT (%)	MG/ANIMAL	RESIDUE CONTRIBUTION (ppm)
Rice forage	2.40*	HR	100	2.40	20	48	2.4
Total					**100**		**2.4**

Highest observation in forage (3.28 mg/kg at a 6 day WHP after two applications at 59.7 and 61.6 g a.i./ha, Site 140904) converted to expected residues (2.40 mg/kg) at the highest proposed application rate of 45 g a.i./ha.

A dairy cattle feeding study was submitted. Four treatment groups of four dairy cows each were dosed orally for 28 consecutive days with florpyrauxifen-benzyl. The average dose levels of florpyrauxifen-benzyl based on concentration in the diet (DM feed basis) were 2.58 ppm, 13.1 ppm, 23.9 ppm and 110.8 ppm. For beef and dairy cattle the estimated maximum livestock burden for florpyrauxifen-benzyl is 2.40 ppm, based on a diet of 100% rice forage.

The predicted residues of florpyrauxifen-benzyl in the milk and tissues of cattle fed with a 2.4 ppm dietary burden are shown in Table 6

Table 6: Predicted residues of florpyrauxifen-benzyl in the milk and tissues

BEEF AND DAIRY CATTLE

FEEDING LEVEL (ppm)	MILK	MUSCLE	LIVER	KIDNEY	FAT
	FLORPYRAUXIFEN-BENZYL + XDE-848 ACID RESIDUE (mg/kg)				
2.58	<0.02	<0.02	<0.02	<0.02	<0.02
2.40 – beef and dairy, estimated burden	<0.02	<0.02	<0.02	<0.02	-
Recommended MRLs	*0.02	*0.02	*0.02		*0.02

The likelihood of quantifiable residues occurring in livestock commodities as a result of the proposed use is very low. It is appropriate to establish animal commodity MRLs at the respective combined LOQs of florpyrauxifen-benzyl and XDE-848 acid in the analytical methods (each 0.01 mg/kg), to satisfy the proposed residue definition for animal commodities. The following MRLs are recommended:

MO 0105 Edible offal (mammalian) *0.02 mg/kg

MM 0095 Meat (mammalian) [in the fat] *0.02 mg/kg

ML 0106 Milks *0.02 mg/kg

For poultry broilers and layers the estimated maximum dietary burden for florpyrauxifen-benzyl is 0.0154 ppm, based on a diet of 50% rice grain and 20% rice bran/pollard. For turkeys the estimated maximum dietary burden for florpyrauxifen-benzyl is 0.0213 ppm, based on a diet of 60% rice grain, 15% rice bran/pollard and 20% rice hulls.

Tables 7 and 8 show the predicted residue contribution from rice commodities used as feed for poultry and turkeys.

Table 7: Predicted residue contribution from rice commodities used as feed for poultry

POULTRY BROILERS AND LAYERS- 2 KG bw, 0.15 kg dm/day

COMMODITY	RESIDUE (mg/kg)	BASIS	DM (%)	RESIDUE DW (mg/kg)	MAXIMUM DIET CONTENT (%)	MG/ANIMAL	RESIDUE CONTRIBUTION (ppm)
Rice grain	0.02	STMR	88	0.0227	50	0.0017	0.011
Rice bran/ pollard	0.02	STMR-P	90	0.022	20	0.00066	0.0044
Total					**70**		**0.0154**

Table 8: Predicted residue contribution from rice commodities used as feed for turkeys

TURKEYS 10 kg bw, 0.4 kg dm/day[2]

COMMODITY	RESIDUE (mg/kg)	BASIS	DM (%)	RESIDUE DW (mg/kg)	MAXIMUM DIET CONTENT (%)	MG/ANIMAL	RESIDUE CONTRIBUTION (ppm)
Rice grain	0.02	STMR	88	0.0227	60	0.00545	0.0136
Rice bran/ pollard	0.02	STMR-P	90	0.022	15	0.00132	0.0033
Rice hulls	0.02	STMR	90	0.022	20	0.00176	0.0044
Total					**95**		**0.0213**

[2] Guidance Document on Residues in Livestock, Page 48, www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)8&doclanguage=en

In a laying hen metabolism study, two groups of hens were orally dosed with either [^{14}C]-florpyrauxifen-benzyl PH or [^{14}C]-florpyrauxifen-benzyl PY label (phenyl or pyridine label), administered in a gelatin capsule, once daily for a total of 14 days at 12 or 11 ppm in the diet (PH and PY labels respectively). Florpyrauxifen-benzyl was extensively excreted and TRR levels in egg, liver, muscle, skin and fat were low, with less than 1% of the dose recovered in the eggs and edible tissues. As the TRRs in eggs and tissues were less than 0.010 mg/kg, the characterisation of the residues was only investigated in selected excreta samples.

TRRs found in the laying hen metabolism study after dosing at 12 or 11 ppm in the diet (PH and PY labels respectively) are summarised below:

Table 9: TRRs observed in the laying hen metabolism study

COMPOUND	EGG TRR (mg eq./kg)	LEG MUSCLE TRR (mg eq./kg)	BREAST MUSCLE TRR (mg eq./kg)	FAT TRR (mg eq./kg)	LIVER % TRR (mg eq./kg)
12 ppm (PH label)					
XDE-848 BE	<0.0017	<0.0017	<0.0017	0.004	0.005
11 ppm (PY label)					
XDE-848 BE	<0.0017	<0.0017	<0.0017	<0.0017	<0.0017

LOQ = <0.0017 mg eq./kg

Predicted residues of florpyrauxifen-benzyl in tissues and eggs of poultry as a result of feeding at 0.0213 ppm are calculated below:

Table 10: TRRs observed in the turkey metabolism study

FEEDING LEVEL (ppm)	EGGS	LEG MUSCLE	BREAST MUSCLE	FAT	LIVER
	FLORPYRAUXIFEN-BENZYL RESIDUE (mg/kg)				
12 (PH label)	<0.0017	<0.0017	<0.0017	0.004	0.005
0.0213 – turkeys, estimated burden	<0.000003	<0.000003	<0.000003	0.000007	0.000009
Recommended MRLs	*0.02	-	-	*0.02	*0.02

The likelihood of quantifiable residues occurring in animal commodities as a result of the proposed use is low. It is appropriate to establish animal commodity MRLs at the respective combined LOQs of florpyrauxifen-benzyl and XDE-848 acid in the analytical methods (each 0.01 mg/kg), to satisfy the proposed residue definition for animal commodities. The following MRLs are recommended:

PE 0112 Eggs	*0.02 mg/kg
PO 0111 Poultry, Edible offal of	*0.02 mg/kg
PM 0110 Poultry meat [in the fat]	*0.02 mg/kg.

4.8 Estimated dietary intake

Health Based Guidance Values (ADI and ARfD) were not established due to the low toxicity of the product. It is therefore not necessary to undertake a dietary risk assessment for florpyrauxifen-benzyl.

4.9 Bioaccumulation potential

The log P_{ow} value for florpyrauxifen-benzyl is 5.5 at 20°C and pH 7 indicating that there is a likelihood for bioaccumulation in fat.

The lactating goat metabolism study found that florpyrauxifen-benzyl TRRs were less than 0.01 mg eq./kg in both fat and muscle, and that both were lower than that in offal (liver and kidney).

Although no residues of either parent or the XDE-benzyl ester acid were detected in muscle or fat at the lowest feeding level (2.58 ppm) in the lactating cow feeding study, residues at the 13.11, 23.87 and 110.77 ppm levels were always higher in fat compared to muscle, for both parent and the XDE-benzyl ester acid and were higher than in liver or kidney. Similarly, residues of parent in cream were higher than milk at those three feeding levels. No residues of XDE-benzyl ester acid were observed in milk or cream at the three lowest feeding levels. Residues in cream were not detectable and residues in milk were 0.004 mg/kg after feeding at 110.77 ppm.

The florpyrauxifen-benzyl hen metabolism study submitted by the Applicant showed slightly higher TRRs in fat compared to both leg and breast muscle but all levels were very low (<0.01 mg eq./kg).

MRLs for mammalian and poultry meat were recommended as ‘in the fat’.

4.10 Spray drift

The draft label includes a restraint that the product should not be applied with spray droplets smaller than a COARSE spray droplet size category.

Calculations using ground (high and low ground boom with coarse droplets) and aerial (aerial fixed wing, average and large applications, coarse droplet and 20 km/h wind speed) scenarios at a maximum application rate of 30 g a.i/ha show that a no-spray zone is not required for application to rice for the protection of international trade.

4.11 Residues in rotational crops

No detectable residues of florpyrauxifen-benzyl, XDE-848 acid or XDE-848 hydroxyl acid were observed in the representative following crops leafy brassica (kale, mustard greens and collards), root vegetables (radishes, turnips and beets), cereal grains (spring wheat, winter wheat, and sorghum) and oil seed (soybean) in the field rotational study conducted in the USA at two locations (Texas and California), after one application at 75 or 60 g a.i./ha to bare soil. Each trials site had multiple test plots: plot 1 was an untreated control plot; plots 2, 3, 4, 5, 6, 7 and 8 received one soil application with florpyrauxifen-benzyl at 75 g a.i,./ha or 60 g a.i./ha, representing 30, 90, 120 or 270 day plant-back intervals (PBIs). Data in the submitted interim report covered crop samples harvested at 30 and 90 PBI plots.

The results of the field rotational study suggest that it is unlikely that residues of florpyrauxifen-benzyl and XDE-848 acid (the two proposed components of the residue definition) or XDE-848 hydroxyl acid would be present in succeeding crops. It is therefore considered unlikely that any following crops could take up residues at a quantifiable level and no plant-back interval is therefore considered to be necessary from a residues and trade perspective.

4.12 Recommendations

Tables 11-13 lists the amendments that are proposed to the APVMA MRL Standard (www.apvma.gov.au/node/10806) for food commodities (Standard Table 1), residue definition (Standard Table 3) and animal feed commodities (Standard Table 4).

Table 11: Amendments that are proposed to the APVMA MRL Standard Table 1

COMPOUND		FOOD	MRL (mg/kg)
Florpyrauxifen-benzyl			
DELETE:			
MO	0105	Edible offal (Mammalian)	T*0.02
PE	0112	Eggs	T*0.02
MM	0095	Meat (mammalian) [in the fat]	T*0.02
ML	0106	Milks	T*0.02
PO	0111	Poultry, Edible offal of	T*0.02
PM	0110	Poultry meat [in the fat]	T*0.02
GC	0649	Rice	T*0.02
ADD:			
MO	0105	Edible offal (Mammalian)	*0.02
PE	0112	Eggs	*0.02
MM	0095	Meat (mammalian) [in the fat]	*0.02
ML	0106	Milks	*0.02
PO	0111	Poultry, Edible offal of	*0.02
PM	0110	Poultry meat [in the fat]	*0.02
GC	0649	Rice	*0.02

Table 12: Amendments that are proposed to the APVMA MRL Standard Table 3

COMPOUND	RESIDUE
Florpyrauxifen-benzyl	
DELETE:	{T} Sum of florpyrauxifen-benzyl and the XDE-848 acid metabolite [4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylic acid] expressed as florpyrauxifen-benzyl
ADD:	Sum of florpyrauxifen-benzyl and the XDE-848 acid metabolite [4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylic acid] expressed as florpyrauxifen-benzyl

Table 13: Amendments that are proposed to the APVMA MRL Standard Table 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
ADD:			
Florpyrauxifen-benzyl			
		Rice forage (green)	5
AS	0649	Rice straw and fodder, dry	0.5

5 ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

5.1 Commodities exported

Rice grain is considered to be a major export commodity[3], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed treated rice grain, forage and straw. Residues of florpyrauxifen-benzyl are not expected to arise in major trades commodities as a result of the proposed use.

5.2 Destination of exports

Australian exports of rice totalled 422 kt (value $538 m) in 2015/16[4]. The major export markets for rice grain include countries in the Middle East, North America, Asia and nations in the Pacific[5,6].

5.3 Comparison of Australian MRLs with Codex and International MRLs

Florpyrauxifen-benzyl has not been considered by Codex. The following MRLs are proposed globally:

Table 14: Proposed residue definitions and MRLs for florpyrauxfen-benzyl

COUNTRY/REGION	COMMODITY	MRL (mg/kg)	RESIDUE DEFINITION
EU	Rice without hulls (Brown rice)	0.02 (proposed)	Parent florpyrauxfen-benzyl and XDE-848 acid (expressed as florpyrauxfen-benzyl) for crop, animal commodities and water
	Rice with hulls (Paddy rice)	0.2 (proposed)	
USA	Rice without hulls	0.01 (proposed)	
China	Rice with hulls	0.2 (proposed)	
Vietnam			

[3] APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B)

[4] Agricultural commodity statistics, 2016, ABARES, December 2016

http://data.daff.gov.au/data/warehouse/agcstd9abcc002/agcstd9abcc0022016_Sn9Dg/ACS_2016_v1.1.0.pdf

[5] www.rga.org.au/the-rice-industry.aspx

[6] www.planthealthaustralia.com.au/industries/rice/

5.4 Potential risk to trade

Rice

There is no significant risk to trade in rice associated with the proposed use as finite residues are not expected.

Rotational crops

Residues are not expected to occur in major export commodities from the use of GF-3301 Herbicide on rotational crops.

Animal commodities

As quantifiable residues of florpyrauxifen-benzyl are not expected to occur in animal commodities the overall risk to trade is considered to be low.

6 OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

6.1 Use pattern

GF-3301 Herbicide will be applied to rice crops for post-emergent or in-flood control of grass and broadleaf weeds via boom spray or SCWIIRT (Soluble Chemical Water Injection In Rice Technique) rig using a steel wheeled tractor, all-wheel drive motor bike or aircraft. It will be applied at rates of 100 mL/ha (30 g a.i./ha) for foliar application or 150 mL/ha (45 g a.i./ha) for in flood application.

6.2 Exposure during use

GF-3301 Herbicide is for professional use only (farmers and commercial spray operators). Workers may be exposed to the product when opening containers, using the product, cleaning up spills, maintaining equipment and entering treated areas. The main routes of exposure to the product will be dermal and inhalation.

Based on the consistently low short- and long-term toxicity of florpyrauxifen-benzyl (NOAELs of 1000 mg/kg bw/day and 300–1000 mg/kg bw/day, respectively) and the expected low dermal absorption of florpyrauxifen-benzyl, a quantitative occupational exposure assessment was not considered necessary. The risk to workers from repeat exposure is expected to be low. However, the formulated product GF-3301 Herbicide is a slight eye irritant and appropriate safety directions have been set based on this hazard.

6.3 Exposure during re-entry

The risk associated with re-entering treated areas is expected to be limited to exposure via the dermal route; exposure to dried spray may occur with activities such as inspections of weed control levels.

Given the low repeat dose toxicity of florpyrauxifen-benzyl, and the low acute dermal toxicity and lack of skin irritation and sensitisation potential for GF-3301 Herbicide, a quantitative risk assessment of post-application exposure was not considered necessary. The risk to workers re-entering treated crops is considered to be low and therefore no re-entry interval is considered necessary.

6.4 Recommendations for safe use

The following first aid instructions and safety directions are recommended for inclusion on the product label:

First aid instructions

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766.

Safety directions

May irritate the eyes. Avoid contact with eyes. Wash hands after use.

6.5 Conclusion

The registration of GF-3301 Herbicide, containing 300 g/L of florpyrauxifen-benzyl in a suspension concentrate formulation for post-emergent or in-flood control of grass and broadleaf weeds in rice, is supported from a human health perspective.

7 ENVIRONMENTAL ASSESSMENT

7.1 Introduction

To support the application a full suite of environmental fate and toxicity data were provided for the formulated product, the technical active constituent, and several of its metabolites. A full environmental risk assessment was undertaken. The risk assessment has been performed with the PERAMA (Pesticide Environmental Risk Assessment Model for Australia) model.

Foraging birds and mammals can be exposed through their diet by feeding on insects, seeds or vegetation in treated fields or directly through drinking water. Aquatic organisms may be exposed as the result of spray drift, run-off and through leaching of the chemical into the groundwater. For rice use in the southern states, florpyrauxifen-benzyl could potentially be contained in a paddy during the growing season, allowing time for transformation/degradation to occur. In contrast, the dry wet cycle in Queensland may allow for florpyrauxifen-benzyl to move downstream shortly after application.

Non-target terrestrial invertebrates including bees and other arthropods, soil dwelling organisms such as earthworms and soil microbes, can also be exposed through the proposed application. Similarly, terrestrial plants may be exposed to a fraction of the application rate of florpyrauxifen-benzyl through spray drift.

7.2 Fate and behaviour in the environment

Fate and behaviour in soil

The photolytic half-life of florpyrauxifen-benzyl ester (XDE-848 BE) in soil was calculated to be about 49 days of natural summer sunlight at 30 to 50° N. As photolytic breakdown was faster than abiotic degradation on the air-dried soil, soil photolysis will contribute to overall degradation.

Under aerobic soil conditions in four soils, florpyrauxifen-benzyl half-lives ranged from 8.9 to 348 days. Florpyrauxifen-benzyl primarily degraded into XDE-848 acid, with the maximum concentration ranging from 30 to 62% of applied radioactivity (AR). The other primary degradate was XDE-848 hydroxy BE which formed at <3% AR.

An aerobic soil study, under flooded condition was provided. The half-lives for florpyrauxifen benzyl, were 12 and 39 days in two soils from Italy. Entire system DT_{50} values were 10 and 33 days. Major degradates in this study included XDE- 848 hydroxy acid, XDE-848 acid and XDE-848 benzyl hydroxy. Two metabolites were observed at concentrations of greater than 10% of the applied radioactivity in the flooded soil system. XDE-848 acid and XDE- 848 hydroxy acid reached average maximum concentrations of 33% and 62% AR. The major transformation products detected in the soil were XDE-848 acid and XDE- 848 hydroxy acid, with maximum concentrations of 21% and 42% AR. The major transformation products detected in the water were XDE-848 acid and XDE- 848 hydroxy acid, with maximum concentrations of 16% and 25% AR.

Under anaerobic conditions in four soils, florpyrauxifen-benzyl primarily degraded into XDE-848 acid, with the maximum concentration ranging from 25 to 74% AR. The other primary degradate was XDE-848 hydroxy BE, formed at <3% AR. The XDE-848 acid and hydroxy BE degraded to XDE-848 hydroxy acid. The maximum concentration of XDE-848 hydroxy acid ranged from 58 to 69% AR. The terminal products were CO_2 and non-extractable residues (NER). Soil DT_{50} values ranged from 7.8 to 15 days.

Degradation under field conditions was studied in two paddy rice sites in Texas and California as well as in a further study in six commercial rice paddies in Italy and Spain. In general, florpyrauxifen-benzyl degrades at a very rapid rate when applied to rice paddies under water seeded and dry seeded conditions. In the paddy water, florpyrauxifen-benzyl degraded to XDE-848 acid, which also dissipated rapidly. In the paddy soil, florpyrauxifen-benzyl degraded to XDE-848 hydroxy acid, which dissipated more slowly. Rapidly dissipating XDE-848 acid and XDE-848 hydroxy BE degradates were also detected. Leaching beyond the surface 0-15 cm depth was detected only sporadically and at low concentrations.

Soil adsorption coefficients were determined for florpyrauxifen-benzyl in six global soils. Florpyrauxifen-benzyl is immobile (average KFOC 22657). No correlation between soil pH and sorption of XDE-838 BE was observed.

Soil adsorption coefficients for the major metabolites were determined in 13 global soils. One metabolite, XDE-848 hydroxy BE, is also considered immobile (average KFOC 5121). XDE-848 acid and XDE-848 hydroxy acid would be classified as mobile (average KFOC 94 and 102, respectively). XDE-848 acid, X11966341 and XDE-848 hydroxy BE all showed a clear dependence of sorption with pH, with increased sorption in acidic soils.

Fate and behaviour in water

At 10 °C and pH 4, florpyrauxifen-benzyl did not undergo hydrolytic degradation. At 10 °C, the DT_{50} of florpyrauxifen-benzyl was 952 and 9 days at pH 7 and 9, respectively. At 25 °C, the DT_{50} of florpyrauxifen-benzyl was 913, 111, and 1.3 days at pH 4, 7 and 9, respectively. At 35 °C, the DT_{50} of florpyrauxifen-benzyl was 397, 35 and 0.4 days at pH 4, 7 and 9, respectively. XDE-848 acid and X195023 were the major degradates which did not undergo hydrolytic degradation at pH 4, 7 or 9 in sterile buffer.

Photodegradation of florpyrauxifen-benzyl in sterile pH 4 buffer and natural water was extremely rapid with DT_{50} values of 0.07 and 0.16 days (corrected for summer sunlight at 40° N latitude), respectively. The quantum yield in pH 4 buffer was 0.145. Florpyrauxifen-benzyl photolyzed rapidly to dechlorinated XDE-848 BE, which hydrolyzed rapidly to dechlorinated XDE-848 acid.

When applied to the water layer in aerobic water-sediment systems, florpyrauxifen-benzyl either hydrolyzed to the XDE-848 acid in the water layer or partitioned to the sediment where it degraded to the XDE-848 hydroxy BE. The maximum total system concentrations of XDE-848 acid and XDE-848 hydroxy BE were 45% and 23% AR, respectively. Both metabolites further degraded to XDE-848 hydroxy acid. The maximum total system concentration of XDE-848 hydroxy acid was 78% AR. The average total water/sediment system DT_{50} values over the two aquatic systems were approximately 5, 6, 10, and 87 days for florpyrauxifen-benzyl, XDE-848 acid, XDE-848 hydroxy BE, and XDE-848 hydroxy acid, respectively. Final termination products were CO_2 and NER.

When applied to the water layer in anaerobic water-sediment systems, florpyrauxifen-benzyl displayed the same degradation pathway as was observed under aerobic conditions, except the XDE-848 hydroxy BE was observed primarily in the water layer instead of the sediment. The maximum total system concentrations of XDE-848 acid and XDE-848 hydroxy BE were 43% and 28% AR, respectively. Both metabolites completely degraded to the XDE-848 hydroxy acid metabolite so that the maximum total system concentration of XDE-848 hydroxy acid was 100% AR. The average total water/sediment system DT_{50} values were approximately 2, 4, and 7 days for florpyrauxifen-benzyl, XDE-848 acid, and XDE-848 hydroxy BE, respectively. The concentration of XDE-848 hydroxy acid was increasing or did not exhibit a distinct decline at study termination so a DT_{50} value could not be calculated. Final termination products were CO_2 and NER.

Fate and behaviour in air

The low vapour pressure of florpyrauxifen-benzyl (3.2 x 10-5 Pa at 20 °C) together with the low Henry's law constant (1.28 Pa m3/mol at pH 7) and the estimated photochemical oxidation half-life in air of 1.124 days indicate that levels of florpyrauxifen-benzyl in air following normal usage will be very low.

7.3 Effects and associated risks to non-target species

Terrestrial vertebrates

Florpyrauxifen-benzyl is of low acute and long-term toxicity to avian species. The proposed use of florpyrauxifen-benzyl is not expected to see any significant exposure to birds; birds and mammals can be exposed through their diet by feeding on insects, seeds or vegetation in treated fields or directly through drinking water. The risk to mammals and birds was determined by considering relevant Australian species. This was done on a dose basis by taking into account the species' energy requirements and hence food intake, and the amount of florpyrauxifen-benzyl predicted to be present on that food. This dose was then compared with the studied acute and chronic effects of florpyrauxifen-benzyl on birds and mammals. Water consumption was also calculated. In all cases the risk was found to be acceptable.

Aquatic species

Florpyrauxifen-benzyl is of low acute and long-term toxicity to fish. LC_{50} values greater than the limit of functional solubility of florpyrauxifen-benzyl in freshwater (>0.041 mg/L) have been established for *Oncorhynchus mykiss*, *Pimephales promelas* and *Cyprinus carpio*. In an early-life stage study, a NOEC of 0.037 mg/L was determined for *Pimephales promelas*. The acute LC_{50} of GF-3301 Herbicide for carp (*Cyprinus carpio*) was >1.9 mg/L. The metabolites relevant to surface water(XDE-848 acid, dechlorinated XDE-848 BE, dechlorinated XDE-848 acid, X11966341 and X12483137) are also of low toxicity to fish in acute studies, with LC_{50} values all above the top concentration in the corresponding studies (>1.0 mg/L). An early-life stage study for XDE-848 acid also indicates a low toxicity to fish with a NOEC of 30 mg/L.

Florpyrauxifen-benzyl is of low acute and long-term toxicity to freshwater invertebrates. In acute studies EC_{50} for daphnids, LC_{50} for the others greater than the limit of functional solubility of florpyrauxifen-benzyl in freshwater (>0.042 mg/L) have been established for *Daphnia magna*, *Gammarus pseudolimnaeus* and *Lymnaea stagnali*. For marine species, LC_{50} >0.026 mg/L and EC_{50} 0.025 mg/L for *Americamysis bahia* and *Crassostrea virginica*, respectively has been established. In a chronic study, a NOEC of 0.038 mg/L was determined for *Daphnia magna*. A chronic study has been performed also with the mysid shrimp (*Americamysis bahia*) exposed to florpyrauxifen-benzyl. The NOEC for this study was determined to be 0.0078 mg/L. No mortality or sublethal effects were observed in daphnids (*Daphnia magna*) exposed to concentrations of GF-3301 Herbicide up to 80 mg/L and the corresponding EC_{50} was >80 mg/L. Similarly, in an acute mysid (*Americamysis bahia*) study, exposure to GF- 3301 resulted in an EC_{50} greater than the highest test concentration of 1.4 mg/L. In a study with oyster (*Crassostrea virginica*) exposed to GF-3301 Herbicide , the EC_{50} was > 1.1 mg/L. The metabolites relevant to surface water (XDE-848 acid, dechlorinated XDE-848 BE, dechlorinated XDE-848 acid, X11966341 and X12483137) are also of low toxicity to daphnids in acute studies, with EC_{50} values all above the top concentration in the corresponding studies (>0.98 mg/L). A chronic *Daphnia magna* study for XDE-848 acid also indicates a low toxicity to daphnids with a NOEC of 25 mg/L.

Florpyrauxifen-benzyl is not toxic to algae. 72-h and 96-h ErC_{50} values higher than the limit of functional solubility of florpyrauxifen-benzyl in freshwater (>0.034 mg/L) have been established for *Pseudokirchneriella subcapitata*, *Navicula pelliculosa*, *Skeletonema costatum* and *Anabaena flos-aquae*. Dechlorinated XDE-848 BE, dechlorinated XDE-848 acid and X11966341 are also of low toxicity to algae, with 72-h and 96-h ErC_{50} values all above the top concentration in the corresponding studies (>0.36 mg/L). In the case of XDE-848 acid, the 72-h and 96-h ErC_{50} values were lower than the highest test concentration, but they are nonetheless indicative of only a minor toxicity to algae with values of 57 and 61 mg/L. Finally, for X12483137 a 96-h ErC_{50} to *Navicula pelliculosa* of >1.4 mg/L was determined.

EC_{50} values for florpyrauxifen-benzyl were higher than the limit of functional solubility for *Lemna gibba* (i.e. >0.046 mg/L). A number of studies were performed on other aquatic macrophytes (*Myriophyllum spicatum*, *Ceratophyllum demersum* and *Cabomba caroliniana*). The most sensitive species was found to be the water milfoil (*Myriophyllum spicatum*) with a 28-d ErC_{50} 0.13 µg/L. The toxicity of GF-3301 Herbicide to aquatic plants *Lemna gibba* and *Myriophyllum spicatum* showed similar results to those for the active constituent. EC_{50} values for *Lemna gibba* were higher than 2.1 mg formulation/L. The Er_{50} was 0.52 µg formulation/L (0.138 µg ac/L) for *Myriophyllum spicatum*. Further studies were also performed for the metabolite XDE-848 acid on the same macrophyte species used in the tests with the active substance. As for the active substance, the water milfoil (*Myriophyllum spicatum*) was found to be the most sensitive species. Two studies were available for XDE-848 acid on *Myriophyllum spicatum*, resulting in ErC_{50} 1.7 µg/L and 14-d ErC_{50} shoot length 0.35 µg/L.

The other metabolites (dechlorinated XDE-848 BE, dechlorinated XDE-848 acid, XDE-848 hydroxy BE, X11966341 and X12483137) were tested on the most sensitive species, the water milfoil. The most sensitive endpoint for the metabolites were as follows; dechlorinated XDE-848 BE ErC_{50} 0.65 mg/L, dechlorinated XDE-848 acid ErC_{50} 2.47 mg/L, XDE-848 hydroxy BE ErC_{50} 0.041 mg/L, X11966341 ErC_{50} 0.37 mg/L, and X12483137 ErC_{50} 9.8 mg/L.

Florpyrauxifen-benzyl is of low acute and long-term toxicity to sediment dwellers. An acute 10-day spiked sediment NOEC was 11 mg ac/kg dry sediment. A chronic study with spiked water was also conducted which resulted in a NOEC of 0.079 mg/L. The metabolite XDE-848 hydroxy BE was also found to be of low toxicity to *Chironomus riparius* in a long-term study where the test item was spiked into the sediment (NOEC 1000 mg/kg dry sediment). Finally, the metabolite X11966341 was also evaluated in a midge study with spiked sediment and the resulting NOEC was 160 mg/kg dry sediment, based on effects on average emergence time for males observed at higher concentrations.

The risk to aquatic species from spray drift was determined using the standard APVMA scenario for high boom and COARSE spray quality. The downwind no spray zone was determined by calculating the fraction of the proposed spray rate required to achieve a concentration in a 3 m wide 15 cm deep water body, below the regulatory acceptable level. The risk assessment has identified the need for downwind no-spray zones for the protection of aquatic organisms.

The risk to aquatic species from run-off water containing from treated fields entering the aquatic environment was also considered. The predicted concentration was calculated using MED-rice (for flooded systems) and an OECD proposed model (non-flooded systems), which takes into account florpyrauxifen-benzyl degradation and mobility from soil characteristics. Run-off risks were determined to be acceptable.

Bees and other non-target arthropods

Florpyrauxifen-benzyl is of low acute oral and contact toxicity to honeybees. In acute oral and contact studies LC_{50} values of >105 and >100 µg/bee and NOEL was 105 µg ac/bee and for oral toxicity test have been established for *Apis mellifera*. The product is not expected to be applied during flowering and thus direct exposure to bees is not considered likely.

Tier 1 LR50 values for the standard test species exceeded 500 mL formulation/ha, which is ~3.3 times higher than the maximum application rate for florpyrauxifen-benzyl. The lack of toxicity up to the maximum application rates indicates the risk to non-target terrestrial arthropods both in- and off-field is acceptable.

Soil organisms

Florpyrauxifen-benzyl is of low acute (14-day LC_{50} was estimated to be greater than 2000 mg/kg soil) (LC_{50} corr 1000 mg ac/kg) and long-term toxicity to earthworms. In a long-term reproductive study a NOEC of 135 mg/kg dry soil (NOECcorr 68 mg ac/kg dry soil) based on reduced number of juveniles at 270 mg ac/kg dry soil was established for *Eisenia foetida*. Risk to earthworms and other soil macro-organisms was found to be acceptable.

Florpyrauxifen-benzyl is of low toxicity to soil micro-organisms, with no deviation >25% to the control observed both in the nitrogen mineralization and the carbon transformation studies at the highest test concentration of 17 mg/kg dry soil. The metabolites relevant to soil (XDE-848 acid, X11966341 and X12483137) are also of low toxicity to soil micro-organisms, with no deviation >25% to the control observed both in the nitrogen mineralization and the carbon transformation studies at the top concentration in the corresponding studies (0.43 to 0.47 mg/kg dry soil).

Non-target terrestrial plants

A total of ten terrestrial plant species were tested in the seedling emergence and the vegetative vigour studies with florpyrauxifen-benzyl, formulated as an SC typical end-use product (GF-3301 Herbicide, containing 300 g ac/L). A range of sensitivities has been found across these species in each study and in pre-emergence studies a lower susceptibility has been observed. In the seedling emergence study emergence, survival, shoot length and shoot weight ER50 values have been determined. ER_{50} values ranged between 10 and >30 g ac/ha for emergence, between 23 and >30 g ac./ha for shoot length and between 3 and >30 g ac./ha for shoot weight. Survival LR_{50} values were >30 g ac/ha for all species. In the vegetative vigour study survival, shoot length and shoot weight ER_{50} values have been determined and ranged between 1.9 and >30 g ac/ha for survival, between 0.062 and >30 g ac/ha for shoot length and between 0.067 and >30 g ac/ha for shoot weight. The risk assessment has identified the need for downwind no-spray zones for the protection terrestrial plants.

7.4 Conclusion

The registration of GF-3301 Herbicide, containing 300 g/L of florpyrauxifen-benzyl in a suspension concentrate formulation, for post-emergent or in-flood control of grass and broadleaf weeds in rice, is supported from an environmental safety perspective provided specified downwind no-spray zones on the product label are observed for the protection of aquatic environments and non-target vegetation.

8 EFFICACY AND SAFETY ASSESSMENT

8.1 Proposed use pattern

GF -3301 Herbicide is to be applied for the post-emergent foliar and in-flood control or suppression of specified weeds in rice. For post-emergent foliar use, one application of 100 mL/ha before rice panicle initiation provides control of Arrowhead, Barnyard grass and suppression of Dirty dora, Starfruit and Water Plantain. For in-flood application, one application of 150 mL/ha before rice panicle initiation provides control of Arrowhead and suppression of Dirty dora, Jerry Jerry, Starfruit and Water plantain. Both use patterns require the addition of adjuvants; Uptake Spraying Oil, Hasten Spray Adjuvant or Loveland Products MSO with Leci-Tech Spray Adjuvant.

8.2 Summary of efficacy and crop safety

The applicant submitted 41 efficacy/plant safety trials conducted in rice growing areas in Australia over 2012–2015 to justify the label claims.

Post-emergent foliar application: 17 small plot trials were conducted at sites near Cobram, Victoria. GF-3301 Herbicide (or earlier similar formulations) was applied post-emergent at 20-40 g ac/ha with adjuvant at 1-2 L/ha to rice and weeds. A high to very high level of efficacy was found at the proposed rate of 30 g ac/ha (+ adjuvant) against Arrowhead (*Sagittaria calycina*), Barnyard grass (*Echinochloa crus-galli*), Starfruit (*Damasonium minus*) and Water plantain (*Alisma plantagoaquatica*), and suppression was found against Dirty dora (*Cyperus difformis.* Crop Safety was shown to be acceptable. These data support the inclusion on the product label of Arrowhead, Barnyard grass, Starfruit and Water plantain as target weeds for control and Dirty dora for suppression with the proposed rate and instructions for post emergence foliar application. Three additional trials were conducted to determine the efficacy on Barnyard grass and crop safety of GF-3301 Herbicide with various crop oils. A slightly lower rate than proposed (25 g ac/ha) was used to look for differences between the adjuvants. A high to very high level of control of Barnyard grass was obtained with Uptake, MSO and Hasten at 1% or 2% v/v. Control appeared to be slightly lower at 0.5% v/v. No rice injury was apparent in any of the three trials. These data provide further support for efficacy against barnyard grass with foliar application, and support the use of any of these three adjuvants at 1–2 L/ha for post-emergence foliar sprays.

In-flood application: 10 small plot trials were conducted at sites near Cobram, Victoria. GF-3301 Herbicide was applied at 15–180 g ac/ha with adjuvant at 2–8 L/ha to rice by the SCWIIRT method. A high to very high level of efficacy was found at the proposed SCWIIRT application rate of 45 g ac/ha (+ adjuvant) against Arrowhead, Jerry jerry (*Ammania multiflora*), Starfruit and Water plantain, and suppression was found against Dirty dora. Crop Safety was shown to be acceptable. These data support the inclusion on the product label of Arrowhead, Jerry jerry, Starfruit and Water plantain as target weeds for control and Dirty dora for suppression with the proposed rate and instructions for in-flood SCWIIRT application.

Aerial application: Four large scale trials were conducted on rice farms in NSW. A high to very high level of control of Barnyard grass was obtained by the proposed label rate of 100 mL/ha GF-3301 Herbicide (30 g ac/ha) when applied by air, similar to that obtained with the current standard control treatment. No crop safety effects were observed in the trials. The data support the inclusion of aerial application as an option on the product label for post emergence foliar application.

Post-emergent foliar crop safety: Seven small plot trials conducted at Cobram, Victoria, Jerilderie and Leeton New South Wales to determine the crop safety of GF-3310 Herbicide when applied to various rice varieties by foliar spray. . The trials indicate that in the majority of cases, treatments with GF-3301 Herbicide resulted in an acceptable level of crop injury (mean values < ~10% injury score). However, in some cases a higher level of damage occurred, in the range 15–40%. The label carries a crop safety warning discussing the minor, transient crop effects that may be observed, and means to reduce the risk of more severe effects occurring. An appropriate restraint against application to crops which may be stressed is also included on the label.

8.3 Resistance Management

GF-3301 Herbicide contains a member of the arylpicolinate group of herbicides. The product has the disrupters of plant cell growth mode-of-action. For weed resistance management, the product is a Group I herbicide. Strategies to minimize the risk of herbicide resistance are included on the label.

8.4 Conclusions

Trial data support that GF-3301 Herbicide will provide acceptable control or suppression of specified weeds in rice when used according to label instructions. The product is also expected to provide acceptable levels of crop safety in rice when used as directed.

For post-emergent foliar use, one application of 100 mL/ha before rice panicle initiation provides control of Arrowhead, Barnyard grass and suppression of Dirty dora, Starfruit and Water Plantain. For in-flood application use one application of 150 mL/ha before rice panicle initiation provides control of Arrowhead and suppression of Dirty dora, Jerry Jerry, Starfruit and Water plantain. Both applications require the addition of adjuvants.

9 LABELLING REQUIREMENTS

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Dow AgroSciences

GF-3301

Herbicide

ACTIVE CONSTITUENT: 300 g/L FLORPYRAUXIFEN-BENZYL

GROUP I HERBICIDE

A suspension concentrate formulation for post-emergent and in-flood control of grass, sedge and broadleaf weeds in rice as specified in the DIRECTIONS FOR USE.

Dow AgroSciences Australia Limited
A.B.N. 24 003 771 659
20 Rodborough Road
FRENCHS FOREST NSW 2086
www.dowagrosciences.com.au
CUSTOMER SERVICE TOLL FREE: 1-800 700 096

SHAKE WELL BEFORE USE

Net Contents: 500 mL, 1 L, 5L, 10L and 20 L

DIRECTIONS FOR USE

RESTRAINTS

DO NOT apply to crops or weeds which may be stressed due to a range of factors including, but not limited to drought, prolonged cold, sustained high temperatures, poor nutrition (including deficiency and trace element toxicity), root diseases or previous herbicide treatment as reduced weed control and / or increased crop injury may result.
DO NOT treat weeds if mud, cracks or firm soil have appeared through fields prior to treatment, as poor control will result due to moisture stress.
DO NOT treat weeds of high density or growth stage larger than specified in the DIRECTIONS FOR USE as poor control will result.
DO NOT apply if rain is likely within one (1) hour as weed control may be reduced.
DO NOT apply any later than panicle initiation (BBCH 30).
DO NOT apply prior to three leaf stage (BBCH 13).
DO NOT apply more than one (1) application per season, and follow Integrated Weed Management techniques, which include use of a foundation treatment at planting.

SPRAY DRIFT RESTRAINTS

DO NOT apply GF-3301 HERBICIDE with spray droplets smaller than a coarse spray droplet size category according to the "APVMA Compliance Instructions for Mandatory COARSE or VERY COARSE Droplet Size Categories" located under this title in the **GENERAL INSTRUCTIONS** section of this label.

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 KEEP this record for a minimum of two (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/situation and weed/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).

DOWNWIND MANDATORY NO SPRAY ZONES

Aquatic areas

DO NOT apply if there are aquatic or wetland areas including aquacultural ponds, surface streams and rivers downwind from the application area and within the **MANDATORY NO-SPRAY ZONES** shown in Table 1 below.

Broadacre application

Table 1 – No-Spray Zones for Protection of the Aquatic Environment		
FOR AERIAL APPLICATION		
Wind speed range at time of application	**Downwind Mandatory No-Spray Zone**	
	Fixed wing	**Helicopter**
From 3 to 7 kilometres per hour	30 metres	30 metres
From 7 to 14 kilometres per hour	40 metres	40 metres
From 14 to 20 kilometres per hour	50 metres	50 metres
FOR GROUND APPLICATION		
From 3 to 20 kilometres per hour	5 metres	

Aerial SCWIIRT or Bickley boom (in-flood) application

Table 1 – No-Spray Zones for Protection of the Aquatic Environment		
FOR AERIAL APPLICATION		
Wind speed range at time of application	**Downwind Mandatory No-Spray Zone**	
	Fixed wing	**Helicopter***
From 3 to 7 kilometres per hour	5 metres	5 metres
From 7 to 14 kilometres per hour	10 metres	5 metres
From 14 to 20 kilometres per hour	20 metres	5 metres

*DO NOT fly helicopter at speeds faster than 50 knots. For higher speeds observe fixed wing no-spray zones.

Terrestrial areas

DO NOT apply if there are sensitive crops, gardens, landscaping vegetation, protected native vegetation or protected animal habitat downwind from the application area and within the **MANDATORY NO-SPRAY ZONES** shown in Table 2 below.

Broadacre application

Table 2 – No-Spray Zones for Protection of the Terrestrial Environment		
FOR AERIAL APPLICATION		
Wind speed range at time of application	**Downwind Mandatory No-Spray Zone**	
	Fixed wing	**Helicopter**
From 3 to 7 kilometres per hour	350 metres	200 metres
From 7 to 14 kilometres per hour	350 metres	250 metres
From 14 to 20 kilometres per hour	350 metres	250metres
FOR GROUND APPLICATION		
From 3 to 20 kilometres per hour	35 metres	

Aerial SCWIIRT or Bickley boom (in-flood) application

Table 2 – No-Spray Zones for Protection of the Terrestrial Environment		
FOR AERIAL APPLICATION		
Wind speed range at time of application	**Downwind Mandatory No-Spray Zone**	
	Fixed wing	**Helicopter***
From 3 to 7 kilometres per hour	250 metres	40 metres
From 7 to 14 kilometres per hour	300 metres	60 metres
From 14 to 20 kilometres per hour	300 metres	60 metres

*DO NOT fly helicopter at speeds faster than 50 knots. For higher speeds observe fixed wing no-spray zones.

Table 1: WEEDS CONTROLLED OR SUPPRESSED IN RICE – POST EMERGENCE (foliar) application. DO NOT apply any later than panicle initiation (BBCH 30). Always use GF-3301 in sequence with foundation herbicide treatments having a different mode of action.

Always apply with Uptake™ Spraying Oil, Hasten® Spray Adjuvant or Loveland ™ Products MSO* with Leci-Tech ™ Spray Adjuvant at 1–2 L/ha. See **ADJUVANTS SECTION** in **GENERAL INSTRUCTIONS**. Use the higher rate where weeds are large or dense at spray time. Ensure floodwater is lowered sufficiently to expose 75% of weed foliage. See **WATER MANAGEMENT** in **GENERAL INSTRUCTIONS**.			
WEEDS CONTROLLED	**WEED GROWTH STAGE**	**RATE (mL /ha)**	**CRITICAL COMMENTS**
Arrowhead (*Sagittaria calycina*)	Up to 4 leaf and not more than 5 cm across	100	See **WATER MANAGEMENT** in **GENERAL INSTRUCTIONS**. Only treat small seedling weeds that are actively growing. Weeds larger than 5 leaf will not be controlled.
Barnyard grass (*Echinochloa crus-galli*)	Up to the 5 leaf stage and not more than 7 cm high		
Suppression: Dirty dora (*Cyperus difformis*)	Up to 4 leaf stage and not more than 3 cm high		Dirty dora submerged by floodwater will not be controlled by post-emergence treatment.
Starfruit (*Damasonium minus*)	Up to 4 leaf and not more than 5 cm across		
Water plantain (*Alisma plantago-aquatica*)			

Table 2: WEEDS CONTROLLED OR SUPPRESSED IN RICE – SCWIIRT or Bickley boom (in-flood) application. DO NOT apply any later than panicle initiation (BBCH 30). Always use GF-3301 in sequence with foundation herbicide treatments having a different mode of action.

Always apply with Uptake™ Spraying Oil, Hasten Spray Adjuvant or Loveland Products MSO with Leci-Tech Spray Adjuvant at 2–8 L/ha in total spray volume of 5–20 L/ha. Premix GF-3301 thoroughly in oil, then once fully dispersed, add remaining water to make up total spray mix volume.			
WEEDS CONTROLLED	**WEED GROWTH STAGE**	**RATE (mL /ha)**	**CRITICAL COMMENTS**
Arrowhead (*Sagittaria calycina)*	Up to 4 leaf and not more than 5 cm across or high	150	See **WATER MANAGEMENT** in **GENERAL INSTRUCTIONS**. A follow up treatment with a herbicide having a different mode of action may be required for complete control of weeds larger than label size or growth stage.
Suppression: Dirty dora (*Cyperus difformis*)	Up to 3 leaf stage and not more than 3 cm across or high		
Jerry Jerry (*Ammania multiflora*)	Up to 4 leaf and not more than 5 cm across or high		
Starfruit (*Damasonium minus*)			
Water plantain (*Alisma plantago-aquatica*)			

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 AS DIRECTED**.
Grazing: **DO NOT GRAZE OR CUT TREATED CROPS FOR STOCK FEED FOR 7 DAYS AFTER APPLICATION.**

LIVESTOCK DESTINED FOR EXPORT MARKETS

When GF-3301 is used as directed and the above withholding period is observed, livestock commodities are considered acceptable for export.

When using GF-3301 in a tank mix with another product, observe whichever Harvest or Grazing/Stockfood Withholding Period that is the longer of the products used.

CROP SAFETY

Minor, transient crop effects may be observed following an application of GF-3301. Grain yield is unaffected. Crop effects may be slight leaf crinkling, height or minor growth retardation. Crops that are stressed due to one or more factors may be more likely to show crop effects and will be slower to recover. **DO NOT** apply to crops or weeds which may be stressed due to a range of factors including, but not limited to drought, prolonged cold, sustained high temperatures, poor nutrition (including deficiency and trace element toxicity),

root diseases or previous herbicide treatment as reduced weed control and / or increased crop injury may result. **DO NOT** apply prior to three leaf stage (BBCH 13).

GENERAL INSTRUCTIONS

GF-3301 is an arylpicolinate herbicide, for post-emergence or in-flood use in rice. It will not reliably control weeds that emerge after treatment. Best results are achieved under good growing conditions. Treatment of crop or weeds that are stressed must be avoided.

WATER MANAGEMENT

Post-emergence (foliar application)

At least 1-2 cm or more of water must be in bays at application time, to ensure active growth and avoid moisture stress of weeds on high sides of bays treated, whilst allowing adequate exposure of the weeds to the foliar spray. Use steel wheeled tractor, all wheel drive motorbike (or similar) ground boom sprayers or aircraft to ensure GF-3301 is applied when water is present in the bays. Ensure that 75% of weed foliage is exposed above floodwater. **DO NOT** treat weeds if mud, cracks or firm soil have appeared in the bay prior to treatment, as poor control will result due to moisture stress.

SCWIIRT (in-flood application)

GF-3301 may be directly applied to floodwater by SCWIIRT rig, using a minimum of 5–20 L spray mix/ha by steel wheeled tractor, all wheel drive motorbike or aircraft (helicopter or plane). Apply to seedling weeds, more than 12 hours after water movement has stopped and is clear of sediment, with flood depth sufficient to allow even distribution throughout the bay and enable full water coverage of soil for a lock-up period of five (5) days. Ensure flood gates are secured to avoid water movement. Treated bays may be topped up for normal water management after the five (5) day lock-up period. Reduced weed control will result where there is muddy water, too shallow to allow effective mixing or where soil is exposed.

RESISTANT WEEDS WARNING

GROUP I HERBICIDE

GF-3301 contains a member of the arylpicolinate group of herbicides. The product has the disrupters of plant cell growth mode-of-action. For weed resistance management, the product is a Group I herbicide. Some naturally-occurring weed biotypes resistant to GF-3301 and other Group I herbicides may exist through normal genetic variability in any weed population. The resistant individuals can eventually dominate the weed population if these herbicides are used repeatedly. These resistant weeds may not be controlled by GF-3301 or other Group I herbicides.

Since the occurrence of resistant weeds is difficult to detect prior to use, Dow AgroSciences Australia Limited accepts no liability for any losses that may result from the failure of this product to control resistant weeds.

Strategies to minimize the risk of herbicide resistance are available. Consult your farm chemical supplier, consultant, Rice Crop Protection Guide (NSW DPI) or the CropLife website. (www.croplifeaustralia.org.au).

A follow-up treatment of Basagran/MCPA for broadleaf weeds or Barnstorm Herbicide for grass weeds is recommended where needed to give a second mode of action, to limit the likelihood of weed survival and onset of resistance. To reduce the risk of weed resistance, it is recommended to use two or more mode of action treatments for rice weed management in any season and follow Integrated Weed Management techniques, which include use of a foundation treatment at planting, as outlined in the Rice Crop Protection Guide. Foundation treatment at planting is essential for effective rice weed management in either water or drill seeded rice.

CROP ROTATION RECOMMENDATIONS

Safe recropping periods apply for all crops following GF-3301 application. Susceptible crops include, but are not limited to, those listed in the table below. Also see **PROTECTION OF CROPS, NATIVE AND OTHER NON-TARGET PLANTS**.

Crop to be sown	Application rate (mL/Ha)	Minimum time from application to planting	Rain (mm) from treatment to planting
Barley, oats, triticale, wheat, ryegrass	100-150	4 weeks	none
Legumes (grain or pasture)	100-150	6 months	150

GF-3301 is broken down in soil by microbial activity. Quickest breakdown occurs in warm, moist soil that favours highest microbial activity. Breakdown may be slow in very dry seasons, or in cold, waterlogged soils, extending the safe plant back interval for susceptible crops.

- Rotational crops may only be planted after both the time and rainfall requirement have been met.
- Plantback periods for other crops have not yet been established. Contact your Dow AgroSciences representative.

WEED DENSITY:
Control may be reduced where weed density is very high and limits spray coverage or movement in floodwater.

WEED GROWTH STAGE:
Best results are achieved when applied to small, seedling weeds up to 2-5 leaf stage.

APPLICATION
Foliar application – aircraft
DO NOT apply under extremely hot, dry conditions, which could reduce spray deposition or stress weeds. Apply by accurately calibrated aircraft using more than 40 L/ha for early season application, when rice canopy is open and light. Use 80 L/ha or more late in the season when rice canopy has begun to close in and is heavy.

Foliar application - ground
Apply in 80–100 L/ha water by ground boom and in more than 40 L/ha by aerial application.

SCWIIRT application – in-flood
GF-3301 may be directly applied to floodwater by SCWIIRT rig, using 5–20 L spray mix/ha by steel wheeled tractor, all wheel drive motorbike or aircraft.

APVMA compliance instructions for mandatory COARSE or larger droplet size categories

Important information
These instructions inform those using this chemical product how to lawfully comply with the requirement of a COARSE or larger spray droplet size category for spray application.

Spray droplet size categories are defined in the ASAE S572 Standard (newer name may also be shown as ASABE) or the BCPC guideline. Nozzle manufacturers may refer to one or both of these documents, to identify droplet size categories; however, for a nozzle to comply with this requirement, the manufacturer must refer to at least one.

Complying with the label requirement to use a specific droplet size category means using the correct nozzle that will deliver that droplet size category under the spray operation conditions being used. The APVMA has approved only the following specific methods for choosing the correct nozzle. Use one of the methods specified in these instructions to select a correct nozzle to deliver a COARSE or larger droplet size category.

Instructions for Ground Application—for COARSE droplet size or larger categories

Mandatory Instructions for Ground Applications
USE ONLY nozzles that the nozzles' manufacturer has rated to deliver a COARSE, a VERY COARSE or an EXTREMELY COARSE droplet size category, as referenced in ASAE S572 or BCPC. Choose a nozzle that is specified to provide the droplet size category required in the label SPRAY DRIFT RESTRAINTS.
DO NOT use a higher spray system pressure than the maximum the manufacturer specifies for the selected nozzle to deliver the droplet size category required in the label SPRAY DRIFT RESTRAINT.

Instructions for Fixed-wing Aerial Application—for COARSE droplet size or larger categories
Instructions in this section apply to fixed-wing aerial application of products for which the label SPRAY DRIFT RESTRAINT requires a COARSE or a VERY COARSE spray droplet category.
Nozzle choices must be made using Option 1, 2 or 3 below. Option 1 nozzles are limited to a maximum aircraft speed of 110 knots and are for COARSE droplets only. Option 2 nozzles are limited to a maximum aircraft speed of 120 knots and are also for COARSE droplets only. Option 3 nozzles have their use conditions (maximum airspeed, nozzle spray angle, product used, orifice size and spray system pressure) specified in the APVMA Approved Aerial Agricultural Association of Australia (AAAA) Nozzle Calculator (described in Option 3). Depending on those use conditions, the calculator can identify a correct nozzle for either a COARSE or a VERY COARSE spray droplet category. (To use Option 3, aerial applicators must contact the AAAA for access to their approved nozzle calculator.)

Mandatory Instructions for Fixed-wing Aerial Applications
Option 1
For up to a maximum aircraft speed of 110 knots and a COARSE droplet size category, USE ONLY solid stream 0º nozzles with orifice diameter greater than or equal to 1.5 mm and oriented straight back to the flight direction. USE ONLY a spray system pressure greater than or equal to 3 bar.

Mandatory Instructions for Fixed-wing Aerial Applications (continued)
Option 2
For up to a maximum aircraft speed of 120 knots and a COARSE droplet size category, USE ONLY narrow angle flat fan nozzles with spray angle less than or equal to 40˚ and oriented straight back to the flight direction. USE ONLY a spray system pressure greater than or equal to 4 bar.

Mandatory Instructions for Fixed-wing Aerial Applications (continued)
Option 3
USE ONLY nozzles rated by the APVMA Approved AAAA Nozzle Calculator as COARSE or VERY COARSE to comply with a product label's requirement for a COARSE or a VERY COARSE spray droplet size category. Use the AAAA Nozzle Calculator, and follow the additional instructions below in **a**), b) and **c**).

a) To identify a nozzle to comply with the required spray droplet category, aerial applicators must use only the droplet size category given in the nozzle calculator at the DV(0.1) position. The categories shown at the DV(0.5) and the DV(0.9) positions in the calculator must not be used for making a nozzle selection.

b) Aerial applicators must not apply the product at airspeeds greater than the speed used to select the nozzle. If an application airspeed that is slower than 100 knots (the minimum speed specified in the nozzle calculator) is planned, a nozzle identified as COARSE or VERY COARSE at 100 knots can also be used at these slower airspeeds, provided that the nozzle angle and system pressure are kept the same.

c) When a particular pesticide product is chosen within the nozzle calculator as one of the conditions set to select a nozzle, then aerial applicators must use that specific pesticide product with that nozzle. When a pesticide product is planned for use and is not available as a choice within the nozzle calculator, aerial applicators must use the category 'Other product' in the calculator to set the condition for selecting a nozzle.

Instructions for Helicopter Aerial Application—for COARSE droplet size or larger categories
Instructions in this section apply to helicopter application of products where the label SPRAY DRIFT RESTRAINT requires a **COARSE**, a **VERY COARSE** or an **EXTREMELY COARSE** spray droplet category.
Nozzle choices must be made using Option 1, 2 or 3 below.

Mandatory Instructions for Helicoptor Aerial Applications
Option 1
For helicopter applications requiring a COARSE or a VERY COARSE spray droplet size category, USE ONLY nozzles selected with the methods previously specified for fixed-wing aircraft in Section 2.

Mandatory Instructions for Helicoptor Aerial Applications (continued)
Option 2
When using Micronair™ controlled droplet applicators (Micron Sprayers Ltd), USE ONLY nozzles selected with the Micronair Droplet Size Prediction Models designed for Micronair products (and located on the company website) to choose a nozzle to satisfy the label requirement for a COARSE droplet size category. Important: to qualify for the COARSE category, the DV(0.1) value must be greater than 156 microns. Adjust parameters as necessary (eg lower the atomizer rotation rate) in order to achieve a DV(0.1) value greater than 156 microns.

Mandatory Instructions for Helicoptor Aerial Applications (continued)
Option 3
When using Accu-Flo™ nozzles (Bishop Equipment Mfg Inc), USE ONLY nozzles rated according to the manufacturer's instructions to select the correct nozzle to apply a COARSE, a VERY COARSE or an EXTREMELY COARSE droplet size category to satisfy the label requirement for one of those specific droplet size categories.

MIXING – POST-EMERGENCE spraying
Measure the required quantity of liquid and premix with water. GF-3301 readily suspends once added to fast moving water. Maintain agitation at all times, including during mixing as well as spraying.

Spray rigs with premix hoppers
For spray rigs that have a drop down chemical induction hopper, three-quarter fill this hopper with water and have the rinsing sprinkler operating. Add GF-3301 and when suspended, transfer this batch into the quarter filled main tank. Continue to rinse the hopper until the entire product has washed through.

Spray rigs with limited bypass agitation
For spray rigs that have limited bypass agitation, premix GF-3301 in a bucket (or similar) before adding them to the main tank. Add GF-3301 while stirring until it has suspended.

Tank-mixes: The following order should be followed (wait until each formulation is mixed before adding the next one):

1. **Quarter** fill the spray tank while maintaining agitation.
2. Add GF-3301, using the mixing procedure above.
3. Fill the spray tank to **half** full.
4. Add crop oil concentrate e.g. Uptake Spraying Oil.
5. Completely fill the spray tank.

MIXING – SCWIIRT spraying
Measure the required quanity of liquid and premix with 2-8 L crop oil e.g. Uptake Spraying Oil. Ensure that GF-3301 is thoroughly dispersed in crop oil, then add to water to make up the remaining spray volume. Apply in total spray mix volume of 5-20 L/ha. Apply immediately after mixing GF-3301 plus crop oil with water. DO NOT leave to stand in premix vat or plane. Maintain continuous agitation until mix applied.

COMPATIBILITY
Herbicides: GF-3301 is compatible with Barnstorm Herbicide. Where silvertop grass or coolah grass are present tank-mix GF-3301 with Barnstorm at 1 L/ha.

Adjuvants:
Post-emergence - Uptake Spraying Oil at 1–2 L/100 L is the recommended adjuvant. Hasten Spray Oil or Loveland Products MSO with Leci-Tech Spray Adjuvant may be used as alternatives at 1–2 L/100 L.

SCWIIRT – Uptake Spraying Oil at 2–8 L/ha is the recommended adjuvant. Hasten Spray Oil or Loveland Products MSO with Leci-Tech Spray Adjuvant may be used as an alternative at 4-8 L/ha. Use the higher rate where weeds are large or dense at spray time.

CLEANING SPRAY EQUIPMENT
After using GF-3301, empty the tank completely and drain the whole system. Thoroughly wash inside the tank using a pressure hose, drain the tank and clean tank, pump, line and nozzle filters.

Partial Cleaning **- Rinse only -** before using sprayer to treat wheat, barley, oats or triticale:
After cleaning the tank as above, quarter fill the tank with clean water and circulate through the pump, line, hoses and nozzles. Drain and repeat procedure twice.

- ***Complete Cleaning*** - **Decontamination** - before using sprayer to treat crops that are sensitive to GF-3301:

Wash the tank and rinse as above. Then quarter fill the tank and add a standard alkali based laundry detergent at 500 g (or mL)/100 L water and circulate throughout the system for at least 15 minutes. If using a concentrated laundry detergent use 250 g (or mL)/100 L water. Do not use chlorine-based cleaners.

Rinse water should be discharged onto a designated disposal area or, if this is unavailable, onto unused land away from desirable plants and their roots and watercourses.

RE-ENTRY PERIOD
Not required.

PROTECTION OF CROPS, NATIVE AND OTHER NON-TARGET PLANTS

DO NOT apply under weather conditions or from spraying equipment that may cause spray to drift onto non-target vegetation.

Refer to **CROP ROTATION RECOMMENDATIONS** for crop rotation information. Crops susceptible to GF-3301 include, but are not limited to, grain legumes (summer or winter), millets (*Echinochloa* spp), lucerne, pasture legumes, cotton, fruit, hops, ornamentals, potatoes, safflower, beets, sunflower, tobacco, tomatoes, poppies, all vegetables and vines.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

GF-3301 is very toxic to aquatic life. **DO NOT** contaminate streams, rivers or watercourses with this product or used containers.

PROTECTION OF LIVESTOCK
- **DO NOT** graze or cut treated crops or plants for stock food except as specified under withholding periods.
- Poisonous plants may become more palatable after spraying and stock should be kept away from these plants until they have died down.

STORAGE AND DISPOSAL

- KEEP OUT OF REACH OF CHILDREN.
- Store in the closed, original container in a securely locked, dry, cool, well-ventilated place, out of direct sunlight.
- DO NOT store near food, feedstuffs, fertilisers or seed.

500 mL and 1 L label
Triple-rinse containers before disposal. Add rinsings to the spray tank. Do not dispose of undiluted chemicals on site. Break, crush, or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500 mm below the surface 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.

5 L, 10 L, 20 L label
This container can be recycled if it is clean, dry, free of visible residues and has the ***drum****MUSTER* logo visible. Triple or pressure rinse container for disposal. Dispose of rinsate by adding to the spray tank. Do not dispose of undiluted chemicals on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any ***drum****MUSTER* collection or similar container management site. The cap should not be replaced but may be taken separately. If not recycling, break, crush or puncture and deliver empty packaging for appropriate disposal to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500 mm below the surface 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.

SPILL AND LEAK MANAGEMENT

Do not touch or walk through spilled material. Wear a face shield or goggles, overalls buttoned to neck and wrist, chemical resistant gloves and footwear. Stop leak when safe to do so. Dam area and prevent entry into waterways, and drains.
Small spills/leaks: Absorb with material such as sand, soil or sawdust. Collect spilled product and place in sealable container for disposal. Spill residues may be cleaned using water and detergent. Contain and absorb wash water for disposal. Absorb and collect washings and place in the same sealable container for disposal. Dam the area of large spills and report them to Dow AgroSciences Emergency Services at 1-800 033 882.

SAFETY DIRECTIONS

- May irritate the eyes. Avoid contact with eyes.
- Wash hands after use.

FIRST AID

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

ABBREVIATIONS

ac	active constituent
ADI	Acceptable Daily Intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
ARfD	Acute Reference Dose
BBA	Biologische Bundesanalstalt fur Land – und forstwirschaft
bw	bodyweight
d	day
DAT	Days After Treatment
DT_{50}	Time taken for 50% of the concentration to dissipate
EA	Environment Australia
E_bC_{50}	concentration at which the biomass of 50% of the test population is impacted
EC_{50}	concentration at which 50% of the test population are immobilised
EEC	Estimated Environmental Concentration
E_rC_{50}	concentration at which the rate of growth of 50% of the test population is impacted
ER_{50}	Rate at which 50% of the test population is impacted
EI	Export Interval
EGI	Export Grazing Interval
ESI	Export Slaughter Interval
EUP	End Use Product
Fo	original parent generation
g	gram
GAP	Good Agricultural Practice
GCP	Good Clinical Practice
GLP	Good Laboratory Practice

GVP	Good Veterinary Practice
h	hour
ha	hectare
Hct	Heamatocrit
Hg	Haemoglobin
HPLC	High Pressure Liquid Chromatography *or* High Performance Liquid Chromatography
id	intradermal
im	intramuscular
ip	intraperitoneal
IPM	Integrated Pest Management
iv	intravenous
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
Kd	soil adsorption coefficient
Kf	soil Freundlich sorption coefficient
kg	kilogram
K_{oc}	Organic carbon partitioning coefficient
L	Litre
LC_{50}	concentration that kills 50% of the test population of organisms
LD_{50}	dosage of chemical that kills 50% of the test population of organisms
LOD	Limit of Detection – level at which residues can be detected
LOQ	Limit of Quantitation – level at which residues can be quantified
mg	milligram
mL	millilitre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NDPSC	National Drugs and Poisons Schedule Committee

NEDI	National Estimated Daily Intake
NER	non-extractable residues
NESTI	National Estimated Short Term Intake
ng	nanogram
NHMRC	National Health and Medical Research Council
NOEC/NOEL	No Observable Effect Concentration Level
OC	Organic Carbon
OM	Organic Matter
po	oral
ppb	parts per billion
PPE	Personal Protective Equipment
ppm	parts per million
Q-value	Quotient-value
RBC	Red Blood Cell Count
s	second
sc	subcutaneous
SC	Suspension Concentrate
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
TGAC	Technical grade active constituent
TTR	Total Radioactive Residues
T-Value	A value used to determine the First Aid Instructions for chemical products that contain two or more poisons
µg	microgram
vmd	volume median diameter
WG	Water Dispersible Granule
WHP	Withholding Period

GLOSSARY

Active constituent	The substance that is primarily responsible for the effect produced by a chemical product
Acute	Having rapid onset and of short duration.
Carcinogenicity	The ability to cause cancer
Chronic	Of long duration
Codex MRL	Internationally published standard maximum residue limit
Desorption	Removal of a material from or through a surface
Efficacy	Production of the desired effect
Formulation	A combination of both active and inactive constituents to form the end use product
Genotoxicity	The ability to damage genetic material
Hydrophobic	repels water
Leaching	Removal of a compound by use of a solvent
Log Pow	Log to base 10 of octanol water partitioning co-efficient, synonym KOW
Metabolism	The chemical processes that maintain living organisms
Photodegradation	Breakdown of chemicals due to the action of light
Photolysis	Breakdown of chemicals due to the action of light
Subcutaneous	Under the skin
Toxicokinetics	The study of the movement of toxins through the body
Toxicology	The study of the nature and effects of poisons

REFERENCES

APVMA, 2008. APVMA Operating Principals in Relation to Spray Drift. Australian Pesticides and Veterinary Medicines Authority (APVMA), 15 July 2008.