Australian Government

Australian Pesticides and Veterinary Medicines Authority

# Public Release Summary

On the evaluation of the new active trifludimoxazin in the product Voraxor Herbicide

APVMA product number 86452

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**Comments and enquiries regarding copyright:**

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

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# PREFACE

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

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

## About this document

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

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

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

## Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of Voraxor 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 5 May 2020 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

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

When making a submission please include:

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

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

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

Case Management and Administration Unit

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

**Phone:** +61 2 6770 2300

**Email:** enquiries@apvma.gov.au.

## Further information

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

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

Further information on public release summaries can be found on the APVMA website.

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

# 1 INTRODUCTION

This publication includes a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of Voraxor Herbicide and approval of the new active constituent, trifludimoxazin. Trifludimoxazin is presented as a new active constituent for use in agricultural chemical products for the non-selective pre-plant knockdown and selective pre-emergence residual control of a range of broadleaf weeds and suppression of key grass weeds prior to planting of cereal crops; for non-selective pre-plant knockdown prior to establishment of forestry plantations and fallow; to aid in fallow maintenance; and for weed control around commercial, industrial and agricultural buildings, public service areas and yards and fence lines. The proposed product also contains the approved active saflufenacil; another Group G herbicide, which will inhibit the protoporphyrinogen oxidase (PPO) enzyme. There are currently no weeds resistant to Group G herbicides in Australia.

## 1.1 Applicant

BASF Australia Ltd.

## 1.2 Purpose of application

BASF Australia Ltd has applied to the APVMA for registration of the new product, Voraxor Herbicide, containing 250 g/L saflufenacil and 125 g/L trifludimoxazin as a suspension concentrate (SC).

## 1.3 Proposed claims and use pattern

Voraxor Herbicide is a herbicide intended for the non-selective pre-plant knockdown and selective pre-emergence residual control of a range of broadleaf weeds and suppression of key grass weeds prior to planting of cereal crops; for non-selective pre-plant knockdown prior to establishment of forestry plantations and fallow; to aid in fallow maintenance; and for weed control around commercial, industrial and agricultural buildings, public service areas and yards and fence lines.

## 1.4 Mode of action

Trifludimoxazin is a 1,3,5–triazinane herbicide that inhibits the protoporphyrinogen oxidase (PPO) enzyme, ultimately interfering with the chlorophyll biosynthetic pathway. The Herbicide Resistance Action Committee (HRAC) has designated both saflufenacil and trifludimoxazin as Group G herbicides.

## 1.5 Overseas registrations

Submissions have been made in other countries; however, trifludimoxazin is not currently registered anywhere else in the world.

Saflufenacil is registered for use in a number of products in many countries including Australia.

# 2 CHEMISTRY AND MANUFACTURE

## 2.1 Active constituent

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

Trifludimoxazin is an odourless off-white to beige crystalline powder. It is practically insoluble in pure water (1.78 mg/L at 20.1°C and pH 7.88). It has low solubility in n-heptane (0.027 g/L) and moderate solubility in methanol (10.8 g/L) and toluene (36 g/L). It is highly soluble in acetone (423.8 g/L), dichloromethane (238.4 g/L), and ethyl acetate (155.2 g/L). Trifludimoxazin is not volatile at ambient temperatures. Neither the purified active ingredient nor the technical grade active ingredient are surface-active. There are no safety properties (eg flammability, explosive, and/or oxidizing) of concern regarding trifludimoxazin. Trifludimoxazin is expected to be stable for at least four years when stored under normal conditions.

**Table 1: Nomenclature and structural formula of the active constituent trifludimoxazin**

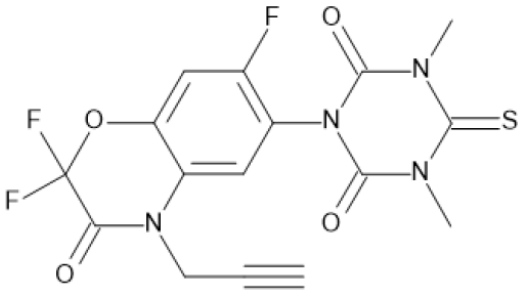
| | |
|---|---|
| **Common name (ISO):** | Trifludimoxazin |
| **IUPAC name:** | 1,5-Dimethyl-6-thioxo-3-[2,2,7-trifluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-1,3,5-triazinane-2,4-dione |
| **CAS registry number:** | 1258836-72-4 |
| **Molecular formula:** | $C_{16}H_{11}F_3N_4O_4S$ |
| **Molecular weight:** | 412.3 g/mol |
| **Structural formula:** |  |

Table 2: Key physicochemical properties of the active constituent trifludimoxazin

| | |
|---|---|
| **Physical form:** | Crystalline powder (solid) at room temperature |
| **Colour:** | Off-white to beige |
| **Odour:** | Odourless at room temperature |
| **Melting point:** | 206°C |
| **Boiling point:** | Decomposes at 225°C before reaching the intrinsic boiling point |
| **Specific gravity/density/bulk density** | 1.598 g/cm$^3$ (20°C) |
| **Stability:** | At ambient temperature, trifludimoxazin was shown to be stable for at least 4 years. At elevated temperatures, no changes in the active were observed after 2 weeks storage at 54ºC. No adverse reactions with metals or metal ions (iron and aluminium, and aluminium acetate and iron acetate) were observed following storage at 25ºC and 54ºC for 14 days. Technical trifludimoxazin is therefore expected to be stable on storage for at least 4 years under normal conditions. |
| **Safety properties:** | Not considered flammable. Not explosive. Not auto-flammable. Except photo-degradation in water, trifludimoxazin technical material does not show any chemical incompatibility with oxidising and reducing agents and is essentially non-hazardous. |
| **Solubility in water:** | 1.78 mg/L (pure water, pH 7.88, 20.1°C) |
| **Organic solvent solubility:** | Acetone 423.8 g/L<br>Ethyl acetate 155.2 g/L<br>Methanol 10.8 g/L<br>Dichloromethane 238.4 g/L<br>Toluene 36.0 g/L<br>n-Heptane 0.0265 g/L |
| **Dissociation constant ($PK_a$):** | Due to the low solubility of the test item in water, the titration method and a determination by spectrophotometry are not suitable for the determination of the dissociation constant. By HPLC, PKa = 7.59 (20°C). |
| **PH:** | 5.9 and 6.3 at a 1% dilution in pure water and CIPAC water D respectively at 23ºC |
| **Octanol/water partition coefficient (Log $K_{ow}$/$K_{OW}$):** | 3.33 at 30°C |
| **Vapour pressure:** | p = 1.1 × 10–10 Pa (20°C)<br>p = 3.2 × 10–10 Pa (25°C) |
| **Henry's law constant:** | H < 2.5 × 10–8 Pa m$^3$/mol |

| | |
|---|---|
| UV/VIS absorption spectra: | Neutral pH 6.7 (methanol) = λmax 265 nm<br>pH 6.1 (Methanol:Water solution 10:90) = λmax 196 nm<br>Acidic pH 1.4 (Methanol:HCl (1M):Water solution 10:5:85) = λmax 267 nm<br>Basic pH 12.1 (Methanol:NaOH (1M):Water solution 10:5:85)= λmax 216 nm |

## 2.2 Formulated product

The product Voraxor Herbicide will be manufactured overseas. Tables 3 and 4 outline some key aspects of the formulation and physicochemical properties of the product.

Voraxor Herbicide is a suspension concentrate containing 250 g/L saflufenacil and 125 g/L trifludimoxazin and will be available in 5 L, 10 L, 20 L, 110 L HDPE (high density polyethylene) containers.

**Table 3: Key aspects of the formulation of the product Voraxor Herbicide**

| | |
|---|---|
| Distinguishing name: | Voraxor Herbicide |
| Formulation type: | Suspension concentrate (SC) |
| Active constituent concentration/s: | 250 g/L saflufenacil and 125 g/L trifludimoxazin |

Table 4: Physicochemical properties of the product Voraxor Herbicide

| | |
|---|---|
| **Physical form:** | Off-white liquid suspension |
| **PH:** | Neat: 5.7 and 1% aqueous solution: 4.9 |
| **Specific gravity/density:** | 1.162 g/cm$^3$ at 20ºC |
| **Kinematic viscosity:** | 87 mPa s (at 100 s$^{-1}$) at 20ºC and 74 mPa s (at 100 s$^{-1}$) at 40ºC |
| **Pourability:** | Pour residue = 2.89%; rinsed residue = 0.16% |
| **Persistent foaming:** | 12 and 0 mL foam at 0.03% and 0.8% dilution respectively after 1 minute |
| **Spontaneity of dispersion:** | 99% (0.8% dilution) after 5 minutes |
| **Suspensibility:** | 100% (0.03% dilution) and 99% (0.8% dilution) |
| **Safety properties:** | No flash point below 137°C. Auto-ignition temperature is 460°C. No exothermic decomposition. Not classified as a flammable liquid or an explosive and/or as an oxidising substance. |
| **Storage stability:** | There were sufficient data to conclude that the product is expected to remain within specifications for at least 2 years when stored under normal conditions. |

## 2.3 Recommendations

The APVMA has evaluated the chemistry of the active constituent trifludimoxazin and associated product Voraxor Herbicide, including the manufacturing process, quality control procedures, stability, identification, physicochemical properties, batch analysis results, and analytical methods, and found them to be acceptable. The available storage stability data indicate that the formulated product is expected to remain stable for at least two years when stored under normal conditions.

The registration of Voraxor Herbicide, and approval of the active constituent trifludimoxazin, are supported from a chemistry perspective.

# 3 TOXICOLOGICAL ASSESSMENT

The toxicological assessment considered the proposed use of Voraxor Herbicide containing the new active ingredient trifludimoxazin 125 g/L, together with the existing approved active ingredient saflufenacil 250g/L. To support the application, toxicological data were provided for trifludimoxazin and several of its metabolites.

## 3.1 Evaluation of toxicology

The toxicological database for trifludimoxazin, which consists primarily of toxicity studies conducted in rats, mice, rabbits and dogs, is considered sufficient to determine the toxicology profile of trifludimoxazin and characterise the risk to humans.

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 does not necessarily indicate such effects might occur in humans. From a conservative risk assessment perspective however, adverse findings in animal species are assumed to represent potential effects in humans, unless robust 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 takes into account the likely human exposure levels compared with those that produce effects in animal studies.

Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No Observable Adverse Effect Level (NOAEL) are used to develop acceptable limits for dietary, or other, intakes at which no adverse health effects in humans would be expected.

### Chemical class

Trifludimoxazin belongs to the 1,3,5-triazinane class of herbicides which are inhibitors of a key enzyme required for the production of chlorophyll in plants (protoporphyrinogen oxidase EC1.3.3.4, also known as protoporphyrin IX oxidase, abbreviated as PPO).

Protoporphyrin IX oxidase is the last common enzyme in the biosynthesis of plant chlorophylls and mammalian heme. It is active in the nanomolar concentration range in plants but requires considerably higher concentrations in mammals to elicit detectable effects on heme production.

PPO inhibitors block the synthesis of chlorophylls, starving the plant of food by preventing photosynthesis and also causing a build-up of porphyrin precursors. Since porphyrin precursors are photoreactive in plants, this causes membrane damage and plant death.

## Toxicokinetics and metabolism

Following oral administration to rats, trifludimoxazin is rapidly and extensively absorbed. Trifludimoxazin is predominantly metabolised in the liver and as a result, the majority of systemic exposure is to the metabolites. On this basis, the toxicology studies have focussed on the metabolites rather than the parent compound.

The principal plant metabolites of trifludimoxazin are also metabolites, or metabolic intermediates, in rats. When radiolabelled trifludimoxazin is administered to rats, the radiolabel has a moderately long half-life of approximately 40 hours but does not accumulate in the tissues and most of an administered dose/radiolabel is excreted over seven days. A dermal absorption study in rats, using a product formulation to model exposure to the product concentrate and spray dilutions, found absorption of the concentrate was < 0.2 per cent and for the dilute preparations was < 10 per cent.

## Acute toxicity (active constituent)

Trifludimoxazin has low acute oral, dermal, and inhalational toxicity; is not an eye or skin irritant; and is not a skin sensitiser. Trifludimoxazin is not an acute neurotoxin at doses tested at up to 2000 mg/kg bw/day.

## Acute toxicity (product)

The product Voraxor Herbicide has low acute oral, dermal and inhalational toxicity; is not an eye irritant or skin sensitiser; and is at most a slight skin irritant following prolonged contact under a semi-occlusive dressing.

## Systemic effects

PPO inhibition at high doses resulted in a range of observations in mammalian toxicology studies. As oxidised porphyrin is a key component of mammalian haemoglobin, a common finding at comparatively high doses in toxicology studies was a slight reduction in haemoglobin levels and related blood parameters. Inhibition of porphyrin synthesis results in precursor porphyrins accumulating in the liver where they are excreted in the bile coupled with cholesterol. This process results in deposition of pigment in the liver and other tissues, as well as alterations in cholesterol levels due to increased production to compensate for that lost with the porphyrin excretion.

At very high doses associated with systemic toxicity in longer term studies (greater than ten times those used to establish the Acceptable Daily Intake (ADI)), evidence of endocrine disruption was observed in mice and rats consisting of a mix of decreased sperm motility, sperm structural abnormalities, uterine atrophy, vaginal epithelial hypertrophy, and fatty change in the adrenals. In the 12 month dog study, no evidence of endocrine-related effects was observed at the highest dose tested, 15 mg/kg bw/day. Given the high doses required to generate the endocrine effects, they are not relevant to human health at realistically achievable exposures through either dietary or occupational exposures. In longer-term studies, effects defining the Lowest Observable Adverse Effect Level (LOAEL) were primarily related to liver toxicity and reduced body weight gains.

Due to low dermal penetration, toxicity via the dermal route is low. In a 28 day dermal toxicity study in rats, trifludimoxazin was applied five days per week at doses of 0, 40, 200, and 1000 mg/kg bw/d. Liver porphyrin levels were increased at 1000 mg/kg bw/d, consistent with the mode of action, ie, inhibition of PPO. These findings were treatment-related but not adverse as they occurred without any associated adverse clinical, haematological, or relevant histopathological findings. The NOAEL was 1000 mg/kg bw/day, the highest dose tested.

## Carcinogenicity and genotoxicity

Trifludimoxazin was not genotoxic in three bacterial reverse mutation studies: an *in vitro* Chinese hamster V79 cell chromosome aberration study, an in vivo gene mutation study in L5178Y mouse lymphoma cells, or in an *in vivo* mouse bone marrow chromosome aberration study.

Trifludimoxazin was not carcinogenic in long-term studies in rats and mice with the exception of thyroid follicular tumours in rats. Mode of action studies subsequently demonstrated that these tumours were due to a rat-specific mechanism involving increased liver metabolism of thyroid hormones and a compensatory stimulation of the thyroid, which leads to hyperstimulation of the thyroid follicular cells. Rats are hypersensitive to increased thyroid hormone turnover in comparison to humans and the finding is therefore not relevant to the human risk assessment at realistically achievable exposures.

In the mouse study, animals were administered a dose of up to 109.1/132.4 mg/kg bw/day in males and females, respectively, for 18 months. The rat was the more sensitive species.

In the rat study, animals were administered up to 68/95 mg/kg bw/d in males and females respectively for 24 months and the NOAEL in rats for carcinogenicity was 1500 ppm, equivalent to 68 mg/kg bw/day; the highest dose tested. The NOAEL for chronic toxicity in the 12 month satellite arm of the rat study was 250 ppm, equivalent to 10.7 mg/kg bw/day based on altered liver histopathology associated with enlarged livers and increased serum GGT in both sexes at 750 ppm equivalent to 39.2 mg/kg bw/day. The rat chronic toxicity study sets the overall NOAEL for trifludimoxazin.

## Reproductive and developmental toxicity

In a one generation reproduction dose-ranging study, rats were administered trifludimoxazin in the diet at levels of 0, 300, 650, 1250, and 2500 ppm from premating until the end of lactation. Systemic toxicity was seen at 1250 ppm, which was associated with infertility. Trifludimoxazin was not a reproductive toxin in rats at doses up to 600 ppm. Based on this study, doses of 0, 75, 250, and 750 ppm were selected for the definitive two generation reproduction study.

In the two generation reproduction study, parental fertility was unaffected in both sexes at all doses. In both sexes at 750 ppm, evidence of liver toxicity was observed (enlarged livers, increased serum liver enzymes, and microscopic alterations). In the first generation of pups reared to adulthood, haematology findings were limited to a slightly decreased clotting time, a decreased HCT in females at 750 ppm, and evidence of liver toxicity was again observed at 750 ppm. A non-adverse build-up of porphyrin pigment was also observed.

The NOAEL for general systemic toxicity in adult parental rats was 250 ppm, equivalent to 21 mg/kg bw/d, based on histological evidence of liver toxicity at 750 ppm. The NOAEL for reproductive performance and

fertility was 750 ppm, equivalent to 64 mg/kg bw/d, the highest dose tested. The NOAEL for developmental toxicity, developmental neurotoxicity, and developmental immunotoxicity was 750 ppm, equivalent to 64 mg/kg bw/d in parental animals, the highest dose tested.

Three developmental toxicity studies were conducted in rats in order to explore successively higher doses in an attempt to find the lowest observed adverse effect level (LOAEL) and to define the NOAEL. Consequently, the NOAEL is set by the third study with the highest dose.

Trifludimoxazin was not a teratogen in foetuses from dams administered trifludimoxazin at doses up to, and including, 1000 mg/kg bw/day from gestation day six to 19 and was not foeto-toxic. The NOAEL for maternal toxicity was 600 mg/kg bw/day based on an increase in liver weight of > 20 per cent and the absence of histological investigations at a comparable dose to confirm an absence of adverse outcomes over a comparable treatment period. The overall NOAEL for foetal toxicity and teratogenicity was 1000 mg/kg bw/day; the highest dose tested.

Pregnant rabbits were administered trifludimoxazin by gavage at 0, 50, 200, or 500 mg/kg bw/day from gestation day six to 28. Five does at 500 mg/kg bw/day aborted and were subsequently sacrificed. Based on an increased serum AST, with associated increased liver weights, and a decreased white blood cell count at 50 mg/kg bw/day, the NOAEL for maternal toxicity is below 50 mg/kg bw/day, the lowest dose tested in this study. The NOAEL for teratogenicity is 500 mg/kg bw/day, the highest dose tested. The NOAEL for foetal toxicity is 200 mg/kg bw/day based on increased foetal death at 500 mg/kg bw/day.

### Neurotoxicity

Trifludimoxazin was not acutely neurotoxic in rats at a dose of 2000 mg/kg bw/day but clear, pronounced, neurotoxicity was seen in repeat dose studies in mice, rats and dogs, which manifested in clinical signs, histopathology, and neurological examinations but with clear threshold doses identified in each species. The generation of neurotoxicity required at least 12 days of exposure at 164 mg/kg bw/day (greater than 1000-fold the proposed ADI), equivalent to 11.5 grams a day for a 70 kg adult.

### Toxicity of metabolites and/or impurities

Toxicity studies were conducted on two plant metabolites of trifludimoxazin designated M850H03 (which is also the major metabolite found in animal studies) and M850H012.

M850H03 was not genotoxic in a bacterial reverse mutation assay, a gene mutation assay in L5178Y mouse lymphoma cells, or in an *in vivo* bone marrow micronucleus assay in mice. The metabolite was negative in a Chinese hamster V79 chromosome aberration assay without metabolic activation but positive with activation. The weight of evidence indicates that the metabolite is unlikely to present a genotoxic risk.

Metabolite M850H012 was not genotoxic in a bacterial reverse mutation assay. The metabolite had moderate acute toxicity in rats with an LD50 between 500 mg/kg bw and 2000 mg/kg bw; however, it had low acute inhalation toxicity with the LC50 > 5284 mg/m$^3$, no deaths, and clinical signs of toxicity limited to non-specific symptoms related to dust inhalation related.

## 3.2 Health-based guidance values and poisons scheduling

### Poisons Standard

Trifludimoxazin is included in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons, except in preparations containing 12.5 per cent or less. Saflufenacil is included in Schedule 5 in water-dispersible granules or a water-based suspension concentrate. On this basis, Voraxor Herbicide is included in Schedule 5 of the Poisons Standard, and requires a 'CAUTION' Signal Heading on the label.

### Health-based guidance values

#### *Acceptable Daily Intake*

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

In repeat-dose toxicity studies with trifludimoxazin, the most sensitive species was the rat and the lowest observable adverse effect level (LOAEL) was 33 mg/kg bw/day, a dose that caused toxicity to the liver during a 24 month study by dietary administration. The APVMA considers it appropriate to use the NOAEL of 10.7 mg/kg bw/d in this study to establish the ADI.

Since the toxicological database for trifludimoxazin is extensive (including several long-term oral toxicity studies in mice, rats, and dogs, and carcinogenicity studies in mice and rats), a 100 fold uncertainty factor (allowing for differences in toxicokinetics, toxico-dynamics and sensitivity between and within species) is considered appropriate.

Applying an uncertainty factor of 100 to the NOAEL of 10.7 mg/kg bw/d, based on altered liver histopathology associated with enlarged livers and increased serum GGT in both sexes at the next higher dose, the APVMA proposed to establish an ADI of 0.1 mg/kg bw/d (rounded) for trifludimoxazin.

#### *Acute Reference Dose*

The Acute Reference Dose (ARfD) is the maximum quantity of an agricultural or veterinary chemical that can safely be consumed in a single meal or over a single day as an isolated event.

The APVMA concluded that an ARfD was not necessary for trifludimoxazin on the basis of its low acute toxicity; the lack of evidence for any acute neurotoxicity; and the absence of any other toxicologically relevant effect that might be attributable to a single dose, or single day exposure, at realistically achievable dietary intakes.

## 3.3 Recommendations

There are no objections on human health grounds to the approval of trifludimoxazin.

There are no objections on human health grounds to the registration of the product Voraxor Herbicide, containing 125 g/L trifludimoxazin together with the existing approved active ingredient 250 g/L saflufenacil.

# 4 RESIDUES ASSESSMENT

The residue assessment of Voraxor Herbicide considered metabolism, analytical methodology, residue trial data, and trade aspects related to the new active constituent, trifludimoxazin. No further data were considered for saflufenacil. The current maximum residue limits (MRLs) established for saflufenacil do not require further evaluation.

## 4.1 Metabolism

Metabolism studies of trifludimoxazin were provided for corn, potatoes, soybeans, and confined rotational crops (lettuce, white radish and spring wheat). Studies have also been conducted on laying hens and lactating goats.

### Plants

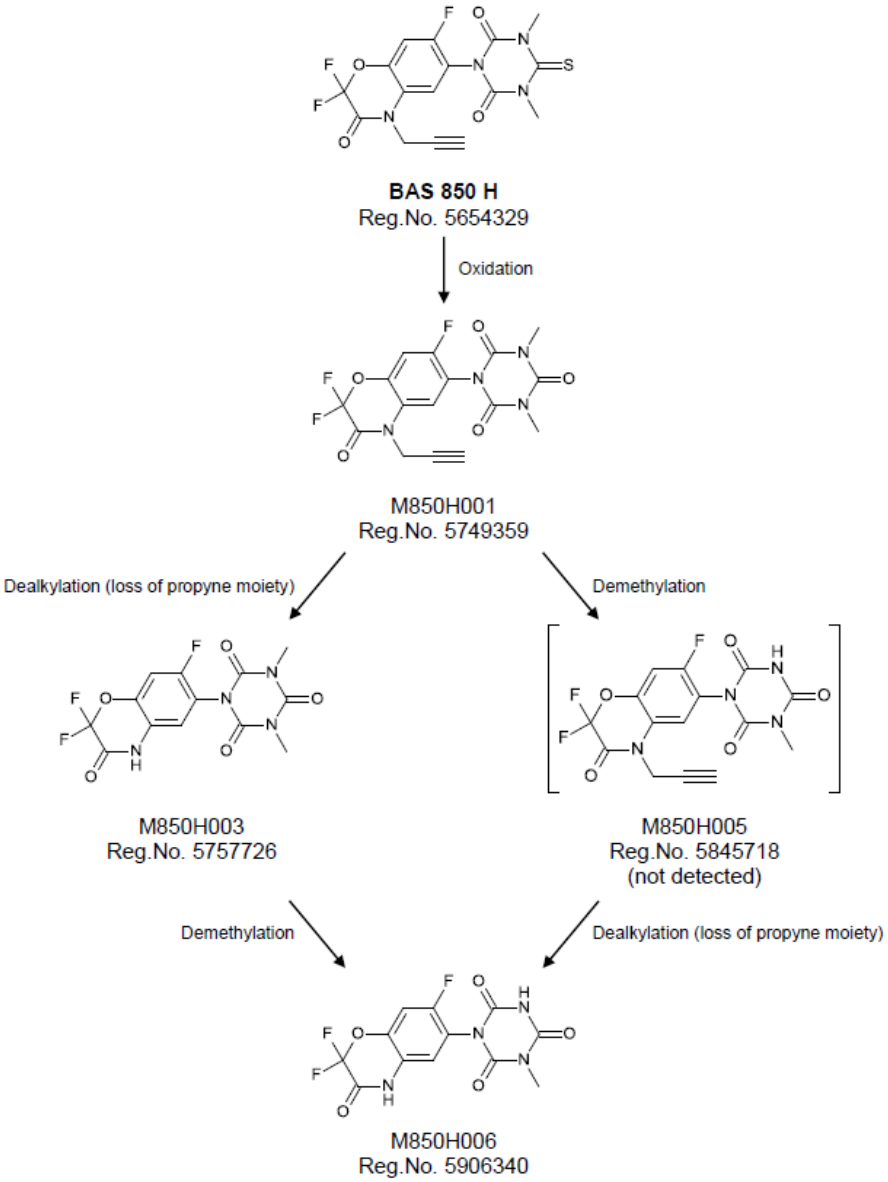
The parent compound was not observed in the available plant metabolism studies; however, for corn (forage, grain, husk and straw) and potato tubers, no radioactive residues above 0.01 mg/kg were observed, precluding further identification. In general, metabolite M850H006 was the most abundant or only identified compound in soybean matrices (up to 38 per cent total radioactive residue (TRR) in soybean leaf, but ≤8.2 per cent TRR in soybean seed). M850H003 was identified as the main component in potato haulm (21 per cent TRR). M850H006 and M850H003 were also identified in rotational crops at up to 18 per cent TRR and 8.9 per cent TRR in wheat straw respectively. A minor metabolite in potato haulm and rotational lettuce was M850H001 at 13 per cent TRR and 11 per cent TRR respectively.

### Livestock

Metabolism of trifludimoxazin in livestock was more extensive. In general, unchanged parent trifludimoxazin (5.4–57 per cent TRR in goat study; 22–76 per cent TRR in poultry study) and the metabolite M850H001 (20–76 per cent TRR in goat study; 16–51 per cent TRR in poultry study) were the predominant components of the residue in edible livestock commodities.

The structures of the trifludimoxazin metabolites and the proposed pathways for their formation are shown below.

Figure 1: Metabolites of trifludimoxazin (BAS 850 H) and proposed pathways for their formation




## 4.2 Analytical methods and storage stability

### Plant commodities

Trifludimoxazin and metabolites M850H001, M850H003, M850H006 and M850H012 were extracted from blended samples by homogenising twice with methanol followed by water. An aliquot of the extract was filtered prior to analysis by Liquid Chromatography (LC) coupled with tandem mass spectrometric detection

(MS-MS). Quantitation was achieved using external matrix standards. The limit of quantitation (LOQ) was 0.01 mg/kg for each analyte in cereal forage, grain and straw, the limit of detection (LOD) was 0.002 to 0.003 mg/kg. Recoveries from fortified control samples were generally within acceptable limits.

### Animal commodities

Residues of trifludimoxazin and its metabolite M850H001 in muscle, liver, and kidney samples were extracted (twice) by homogenization with methanol, centrifuged, and diluted with water. Residues in an aliquot of the combined extracts were diluted with acidified methanol:water, filtered, and analyzed. Residues in fat samples were extracted by homogenization with dichloromethane and centrifuged. Residues in an aliquot of the extract were concentrated, partitioned against a mixture of hexane and acidified acetonitrile:water, and then residues in an aliquot of the aqueous layer were evaporated to dryness, re-dissolved in acidified methanol:water and filtered prior to determination. Residues in milk samples were extracted by vortexing with acetonitrile and residues in a portion of extract were treated with a mixture of salts (magnesium sulphate and sodium chloride) and partitioned with and into acetonitrile. Residues in the combined aliquots of the acetonitrile layer were evaporated to dryness, re-dissolved in acidified methanol:water, and filtered prior to LC-MS/MS determination.

The method LOD and LOQ for trifludimoxazin and M850H001 residues in bovine muscle, liver, kidney, and fat were 0.002 mg/kg and 0.01 mg/kg for each analyte respectively, for milk the LOD and LOQ were 0.0002 mg/kg and 0.001 mg/kg respectively. Mean overall recoveries of trifludimoxazin and M850H001 from livestock commodity samples fortified with each analyte at 0.01 mg/kg and 1 mg/kg were within acceptable limits.

### Storage stability

The results of a storage stability study show that trifludimoxazin, M850H001, M850H003 and M850H006 are stable fortified in representative crop commodities, apple fruit and lettuce leaves (high water); soybean dried seed (high oil); field bean dried seed (high protein); wheat grain and potato tuber (high starch); orange fruit (high acid); and pea hay (feed), and stored frozen for at least 24 to 42 months, the longest intervals tested. M850H012 was stable fortified in frozen soybean seed and wheat grain and was relatively stable fortified in frozen pea hay, each for at least 24 months, but was unstable after short term storage (≥0 to three months) in apple fruit, lettuce leaves, field bean dried seed, potato tubers, and orange fruit (one to 28 per cent M850H012 was recovered from these commodities after 24 months storage).

In the trifludimoxazin residue trials submitted, all cereal grain, forage, and straw samples were maintained under freezer conditions, (ie –18°C) prior to analysis and tested within 24 months of collection. This is acceptable for the purposes of the current application.

## 4.3 Residue definition

Given the low residues of metabolites observed in edible plant commodities in the available plant metabolism studies (the corn metabolism study did not identify any radioactive residues) and the results of the wheat and barley residue trials which found <LOQ residues in grain and only low levels of residues in forage of parent and metabolites M850H001, M850H003, M850H006 and M850H012, a residue definition of parent

compound is recommended for trifludimoxazin for commodities of plant origin. The definition is suitable for both enforcement and dietary risk assessment.

Given the low residues expected in animal feeds, and the fact that parent is a suitable marker for misuse (observed in each matrix except skimmed milk), an enforcement definition of parent compound only is recommended for trifludimoxazin in commodities of animal origin. Given the significant levels of M850H001 observed in the goat and hen metabolism studies, this metabolite will be included with parent in the risk assessment definition. The same analytical method is used for the determination of both trifludimoxazin and M850H001 in animal matrices. The recommended residue definition is:

Commodities of plant origin: Trifludimoxazin.

Commodities of animal origin for enforcement: Trifludimoxazin.

Commodities of animal origin for dietary exposure assessment: Sum of trifludimoxazin and 1,3-dimethyl-5-(2,2,7-trifluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-benzo[b][1,4]oxazin-6-yl)-1,3,5-triazinane-2,4,6-trione (M850H001), expressed as trifludimoxazin.

## 4.4 Residues in food and animal feeds

The maximum proposed application rate of trifludimoxazin to wheat and barley is up to 30 g ai/ha at seven to 21 days prior to sowing. The proposed harvest withholding period is ‘not required when used as directed’, the grazing withholding period (WHP) is six weeks. For the other uses on the label, including fallow, a restraint has been proposed to prevent livestock from grazing treated weeds.

Details of trifludimoxazin residue trials conducted on cereals grown in Australia and North America have been provided.

### Grain

Residues of parent trifludimoxazin in the wheat, barley, and oat grain from Australian trials at harvest 164 to 205 days after a post-sowing pre-emergent (PSPE) or incorporated by sowing (IBS) application at approximately 50 g ai/ha (1.7× proposed) were all <0.003 mg/kg (n = 8).

Residues of parent trifludiomoxazin in sorghum grain from Australian trials at harvest 104 to 111 days after a PSPE application at approximately 50 g ai/ha (1.7× proposed) were <0.003 mg/kg (n = 2).

In North American trials on wheat (25) and barley (10), residues of parent trifludiomoxazin in grain at harvest 84–267 days after a pre-emergent application at approximately 38 g ai/ha (1.3× proposed) were <0.002 mg/kg (n = 35).

MRLs of *0.01 mg/kg are recommended for trifludimoxazin on GC 0640 Barley and GC 0654 Wheat (which will also cover durum), in conjunction with a harvest withholding period of ‘Not required when used as directed’.

### Straw

Residues of parent trifludimoxazin in the wheat, barley, and oat straw from Australian trials at harvest 164–205 days after a PSPE or IBS application at approximately 50 g ai/ha (1.7× proposed) were all <0.003 mg/kg (n = 8).

Residues of parent trifludimoxazin in sorghum fodder from Australian trials at harvest 104–111 days after a PSPE application at approximately 50 g ai/ha (1.7× proposed) were <0.003 mg/kg (n = 2).

In North American trials on wheat (25) and barley (10), residues of parent trifludiomoxazin in straw at harvest 84–267 days after a pre-emergent application at approximately 38 g ai/ha (1.3× proposed) were <0.002 mg/kg (n = 35).

MRLs of *0.01 mg/kg are recommended for trifludimoxazin on AS 0640 Barley straw and fodder, dry and AS 0654 Wheat straw and fodder, dry.

### Forage

Residues of parent trifludimoxazin in the wheat, barley, and oat forage from Australian trials at 39–46 days after a PSPE or IBS application at approximately 50 g ai/ha (1.7× proposed) were <0.003 (6), 0.060 and 0.076 mg/kg (DW). The two highest residues were at 42 days after treatment.

Residues of parent trifludiomoxazin in sorghum forage from Australian trials at 29–30 days after a PSPE application at approximately 50 g ai/ha (1.7× proposed) were <0.003 mg/kg (n = 2).

In North American trials on wheat, residues of parent trifludimoxazin in forage at 21–41 days after a pre-emergent application at approximately 38 g ai/ha (1.3× proposed) were <0.002 mg/kg (n = 15).

MRLs of 0.1 mg/kg are recommended for trifludimoxazin on barley forage and wheat forage in conjunction with a six week grazing withholding period.

## 4.5 Crop rotation

The label recommends plant-back intervals for certain crops that show sensitivity to soil residues (six months for sorghum and selected pulses, nine months for canola, cotton, and other selected oilseeds). The residues aspects of crop rotation for trifludimoxazin are considered below.

At one location each in North America (Georgia and Texas) during the 2014–15 season, a bare ground plot was planted with a primary wheat crop that was treated within three days (pre-emergence) with a broadcast soil-directed spray application of an SC formulation of trifludimoxazin. The nominal application rate was 50 g ai/ha (1.7× proposed) made in a spray volume of 197 to 221 L/ha.

The primary wheat crop grew for a period of four months, six months, or nine months and was then removed from the plot area. Following removal of the primary wheat crop, the plot was planted immediately with the follow-on rotational crop of lettuce, radish, or wheat. For the wheat trials, samples of wheat forage, wheat hay, wheat grain, and wheat straw were harvested at the appropriate growth stage. Samples of lettuce leaf

and radish tops and roots were harvested at normal maturity (BBCH 49). Samples were analysed for parent trifludimoxazin and metabolites M850H001, M850H003, M850H006, and M850H012.

Residues of parent trifludimoxazin were below the LOD (0.002 mg/kg) in all samples. While residues of metabolites were detected in some samples, none exceeded the LOQ (0.01 mg/kg).

The proposed use is unlikely to result in residues of trifludimoxazin in following or rotational crops. Neither plant-back intervals from a residues perspective, nor MRLs in respect of rotational crops, are required for trifludimoxazin.

## 4.6 Residues in animal commodities

Detectable residues of trifludimoxazin are not expected to occur in cereal grain or straw at harvest from the proposed uses. The highest trifludimoxazin residue in forage was 0.076 mg/kg (DW) after application at 1.7× the proposed rate. The scaled HR is 0.045 mg/kg (DW). Cereal forage can form up to 100 per cent of the diet for grazing livestock in Australia. The estimated maximum livestock dietary burden is therefore 0.045 ppm.

An animal transfer study for trifludimoxazin has not been provided. In a goat metabolism study, radiolabelled trifludimoxazin was administered for seven consecutive days at a nominal dose of 11 mg/kg feed. TRRs in milk and tissues are summarised below:

**Table 5: Goat metabolism study of trifludimoxazin**

| Matrix | Sampling time | TRR calculated (mg/kg) | Parent (mg/kg) | M850H001 (mg eq/kg) | TRR calculated (mg/kg) | Parent (mg/kg) | M850H001 (mg eq/kg) |
|---|---|---|---|---|---|---|---|
| | | Phenyl label | | | Triazine label | | |
| Skimmed milk | 96–144 h | 0.062 | Nd | 0.030 | 0.056 | 0.003 | 0.011 |
| Cream | 96–144 h | 0.993 | 0.349 | 0.590 | 1.012 | 0.580 | 0.388 |
| Liver | Terminal | 0.537 | 0.055 | 0.120 | 0.818 | 0.170 | 0.199 |
| Kidney | Terminal | 0.330 | 0.030 | 0.099 | 0.346 | 0.032 | 0.088 |
| Muscle | Terminal | 0.104 | 0.026 | 0.047 | 0.138 | 0.031 | 0.055 |
| Fat | Terminal | 0.643 | 0.136 | 0.488 | 0.600 | 0.288 | 0.343 |

*Calculated TRR = sum of extractable radioactive residues and the residual radioactive residue after solvent extraction; nd = not detected*

The highest TRR after dosing at 11 ppm was 1.01 mg/kg in cream. The estimated total residue in cream from feeding at 0.045 ppm is 0.004 mg/kg. Given also that this is a total residue consisting of several components, it is appropriate to establish mammalian commodity MRLs for trifludimoxazin at the LOQ for the analytical

method, noting estimated total residue in whole milk is 0.0005 mg/kg. The following MRLs are recommended:

| | |
|---|---|
| MO 0105 Edible offal (mammalian) | *0.01 mg/kg |
| MM 0095 Meat (mammalian) | *0.01 mg/kg |
| ML 0106 Milks | *0.001 mg/kg |

Cereal grains, including wheat and barley, can form 100 per cent of the diet for poultry in Australia. However, detectable residues of trifludimoxazin are not expected to occur in wheat or barley grain as a result of the proposed use. Poultry commodity MRLs for trifludimoxazin will be recommended at the LOQ for the analytical method for other livestock commodities. The following MRLs are recommended:

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

## 4.7 Spray drift

In the lactating goat metabolism study dosing with trifludimoxazin at 11 ppm gave a maximum total radioactive residue in liver of 0.818 mg/kg. For total residues to be at the LOQ (0.01 mg/kg), the trifludimoxazin regulatory acceptable level (RAL) for the protection of international trade of livestock commodities is 0.13 mg/kg.

Saflufenacil residues in cattle liver fed 0.1 ppm saflufenacil daily for 28 days in feed reached up to 0.26 mg/kg which is approximately equivalent to the Codex edible offal MRL of 0.3 mg/kg. The saflufenacil RAL for the protection of international trade of livestock commodities is 0.1 mg/kg.

The APVMA Spray Drift Risk Assessment Tool indicates that the no-spray zones ranging from not required to 15 meters are required for livestock areas for the protection of international trade of animal commodities.

## 4.8 Dietary risk assessment

The chronic dietary exposure to trifludimoxazin is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the chemical and the mean daily dietary consumption data derived primarily from the 2011–12 National Nutritional and Physical Activity Survey. The NEDI calculation is made in accordance with WHO Guidelines and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for trifludimoxazin is equivalent to <1 per cent of the ADI. It is concluded that the chronic dietary exposure to trifludimoxazin is acceptable.

An acute reference dose was not required for trifludimoxazin. A National Estimated Short Term Intake (NESTI) calculation for acute exposure was not necessary for trifludimoxazin.

## 4.9 Recommendations

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

### Table 6: Amendments to the APVMA MRL Standard

| Amendments to Table 1 | | | |
|---|---|---|---|
| **Compound** | | **Food** | **MRL (mg/kg)** |
| ADD: | | | |
| Trifludimoxazin | | | |
| GC | 0640 | Barley | *0.01 |
| MO | 0105 | Edible offal (mammalian) | *0.01 |
| PE | 0112 | Eggs | *0.01 |
| MM | 0095 | Meat [mammalian] | *0.01 |
| ML | 0106 | Milks | *0.001 |
| PO | 0111 | Poultry, edible offal of | *0.01 |
| PM | 0110 | Poultry meat | *0.01 |
| GC | 0654 | Wheat | *0.01 |

| Amendments to Table 3 | |
|---|---|
| **Compound** | **Residue** |
| ADD: | |
| **Trifludimoxazin** | Commodities of plant origin: trifludimoxazin<br>Commodities of animal origin for enforcement: trifludimoxazin<br>Commodities of animal origin for dietary exposure assessment: sum of trifludimoxazin and 1,3-dimethyl-5-(2,2,7-trifluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-benzo[b][1,4]oxazin-6-yl)-1,3,5-triazinane-2,4,6-trione (M850H001), expressed as trifludimoxazin |

| Amendments to Table 4 | | | |
|---|---|---|---|
| **Compound** | | **Animal feed commodity** | **MRL (mg/kg)** |
| ADD: | | | |
| **Trifludimoxazin** | | | |
| | | Barley forage | 0.1 |
| AS | 0640 | Barley straw and fodder, dry | *0.01 |
| | | Wheat forage | 0.1 |
| AS | 0654 | Wheat straw and fodder, dry | *0.01 |

MRL amendments recommended for Tables 1 and 3 above will be considered for inclusion in Schedule 20 of the Australia New Zealand Food Standards Code.

# 5 ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

## 5.1 Commodities exported and main destinations

Wheat and barley are considered to be major export commodities[2], as are commodities of animal origin such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated wheat and barley. Residues in these commodities resulting from the use of Voraxor Herbicide may have the potential to unduly prejudice trade.

Total exports of barley were 7997 kilotonnes in 2017–18, valued at $2.3 billion. Total exports of wheat (including flour) were 15 492 kilotonnes in 2017–18, valued at $4.7 billion (ABARES). Major export destinations are summarised below:

**Table 7: Commodities exported and main destinations**

| Commodity | Major destinations |
|---|---|
| Barley | China, Japan, Korea, Vietnam, the Philippines, Taiwan, Saudi Arabia, Kuwait, United Arab Emirates |
| Wheat | Indonesia, India, Korea, China, Japan, Thailand, Malaysia, Philippines, Vietnam, Egypt, Nigeria, Yemen, Kuwait, New Zealand |

The significant export markets for Australian beef, sheep, pig meat and offals are listed in the APVMA Regulatory Guidelines—Data Guidelines: Agricultural, Overseas trade (Part 5B).

## 5.2 Overseas registrations and approved label instructions

The applicant indicated that trifludimoxazin products are not currently registered in any overseas countries, although an application to register trifludimoxazin was to be submitted in North America.

## 5.3 Comparison of Australian MRLs with Codex and international MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Trifludimoxazin has not been considered by Codex and no relevant MRLs for trifludimoxazin are established overseas.

[2] APVMA Regulatory Guidelines—Data Guidelines: Agricultural, Overseas trade (Part 5B)

## 5.4 Potential risk to trade

Export of treated produce containing finite (measurable) residues of trifludimoxazin may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Quantifiable levels of residues of trifludimoxazin are not expected to occur in wheat (including durum) or barley grain or in animal commodities as a result of the proposed use. The risk to trade is considered to be low.

# 6 WORK HEALTH AND SAFETY ASSESSMENT

## 6.1 Health hazards

The product Voraxor Herbicide has low acute oral, dermal, and inhalational toxicity; is not an eye irritant or skin sensitiser; and is at most a slight skin irritant following prolonged contact under a semi occlusive dressing.

## 6.2 Occupational exposure

### Exposure during use

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

The main routes of exposure to the product will be dermal and inhalational.

In the absence of exposure data for the proposed mode of application, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide (1998) was used to estimate exposure. Because the two active constituents have the same mechanism of action (inhibition of protoporphyrin IX oxidase), the OH&S assessment used a worst-case approximation. Specifically, the risks of the combined exposure were based on the lower of the NOAELs from the two compounds, the higher dermal absorption factor, and an assumption of additive toxicity. The toxic endpoint of concern and identified NOAEL is derived from a repeat dose study in animals, and in this instance, a Margin of Exposure (MOE) of 100 or above is considered acceptable. The MOE takes into account potential interspecies and intraspecies variation. Using this highly conservative approach, the MOE was found to be substantially higher than 100 and therefore, acceptable without further modelling. Had this not been the case further refinement of the model would have been necessary.

The MOEs for workers associated with short-term use of the product, conducting mixing and loading activities, and application by ground boom are acceptable (ie, MOE > 100) without the use of specific personal protective equipment.

### Exposure during re-entry or rehandling

As acceptable MOEs were determined on the day of treatment, and the product is at most a slight skin irritant, no re-entry statement is required.

## 6.3 Public exposure

The product is intended for professional use only and is not intended for application to areas accessible to the general public. An assessment using the APVMA spray drift model determined that no buffer zone is required for protection of bystanders from spray drift.

## 6.4 Recommendations

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

### First aid instructions

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

### Safety directions

Wash hands after use. After each days use wash contaminated clothing.

### Precautionary (warning) statements

Do not use if pregnant.

# 7 ENVIRONMENTAL ASSESSMENT

## 7.1 Fate and behaviour in the environment

### Soil

Trifludimoxazin was moderately persistent in four aerobic laboratory soils (geomean $DT_{50}$ 52 days); persistent in four anaerobic laboratory soils (geomean $DT_{50}$ 116 days); and non-persistent under field conditions at six sites in the United States ($DT_{50}$ 6.6–42 days, geomean 14 days). Major soil metabolites were M850H001 (up to 45 per cent under both laboratory and field conditions); M850H002 (up to 21 per cent under laboratory conditions); M850H003 (up to 38 per cent under both laboratory and field conditions); and M850H004 (7.3 per cent under anaerobic conditions in the laboratory only). Photolytic degradation of trifludimoxazin in soil did not result in additional unique metabolites (photodegradates).

Trifludimoxazin is considered to be moderately mobile in soil (mean $K_{Foc}$ 436 mL/g) and remains in the upper 15 cm of soil, which was demonstrated in the field dissipation studies. Both M850H001 and M850H003 are more mobile in soil (mean $K_{Foc}$ values of 75 and 73 mL/g, respectively); M850H002 is moderately mobile (mean $K_{Foc}$ 226 mL/g); and M850H004 is only slightly mobile (mean $K_{Foc}$ 806 mL/g).

### Water and sediment

Trifludimoxazin was relatively stable at pH 4 and 5. At pH 7, trifludimoxazin degraded slowly with a $DT_{50}$ of 77 days over a study period of 30 days at 25°C. Rapid degradation was observed at pH 9 at all temperatures tested.

Under aqueous conditions, trifludimoxazin was susceptible to photolysis. To exclude hydrolytic effects, the study was performed at low pH. In sterile pH 5 buffer, a $DT_{50}$ value of 7.2 days was observed while in the dark control only little degradation occurred. M850H002 (26 per cent) was determined to be a photodegradate.

In aquatic (water/sediment) systems, trifludimoxazin redistributed from the water to the sediment phase (water phase $DT_{50}$ of 2.0 to 27 days) and accounted for up to 40 per cent of applied radioactivity in the sediment. Degradation of trifludimoxazin in the total system followed bi-phasic kinetics with $DT_{50}$ values of 2.8 to 97 days. Major metabolites in the aquatic systems were M850H001 (16 per cent) and M850H004 (58 per cent).

### Air

No risk of air contamination following applications of trifludimoxazin is expected. Trifludimoxazin has little potential for volatilization as indicated by its low vapour pressure (3.2 x 10–$^{10}$ Pa at 25°C) and Henry's Law constant (<2.5 x $10^{-11}$ kPa·$m^3$/mol). Furthermore, the half-life of trifludimoxazin in air (Atkinson method) was calculated to be rapid, 0.30 hours (12 h day), due to reaction with hydroxyl radicals.

## 7.2 Effects and associated risks to non-target species

### Terrestrial vertebrates

Following gavage administration, trifludimoxazin had low toxicity to mammals ($LD_{50}$ >2000 mg ac/kg bw, *Rattus norvegicus*) and birds ($LD_{50}$ >2000 mg ac/kg bw, three species tested). Trifludimoxazin was more toxic to birds when administered in the diet ($LC_{50}$ 561 mg ac/kg bw/d, *Anas platyrhynchos*). In one-generation reproductive toxicity studies on birds, substance-related effects on egg-laying and on survival rates during the egg development were observed at doses as low as 46 mg ac/kg bw/d (NOAEL 16 mg ac/kg bw/day, *Anas platyrhynchos*). No ecologically relevant effects were observed in mammals at the highest dose in a modified extended one-generational study (NOEL 76 mg ac/kg bw/d, *Rattus norvegicus*).

Although the log $K_{ow}$ of 3.3 indicates potential for bioaccumulation of trifludimoxazin, a food chain assessment indicated that any accumulated residues in earthworms or fish are not expected to reach levels harmful to predators under the proposed conditions of use. In addition, based on toxicokinetic studies, biomagnification is not expected along the food chain.

Dietary risks of trifludimoxazin to terrestrial vertebrates were determined to be acceptable under a realistic worst-case scenario, which assumed non-target species fed exclusively on over-sprayed food items within the treatment area. As a result, no specific protection statements are required on the label for terrestrial vertebrates.

### Aquatic species

Trifludimoxazin was not toxic to fish at the limit of water solubility ($LC_{50}$ >1.7 mg ac/L, four species tested), which is confirmed when tested in an SC formulation ($LC_{50}$ >41 mg ac/L, *Oncorhynchus mykiss*). Low toxicity was similarly observed in *Daphnia magna* ($EC_{50}$ >1.9 mg ac/L for technical active; $EC_{50}$ >41 mg ac/L for an SC formulation), eastern oyster ($EC_{50}$ >2.9 mg ac/L, *Crassostrea virginica*), and sediment dwellers ($LC_{50}$ >71 mg ac/kg dry sediment, three species tested).

In contrast, trifludimoxazin was toxic to mysid shrimp ($LC_{50}$ 0.37 mg ac/L, *Americamysis bahia*) and very toxic to algae (lowest $E_rC_{10}$ 0.00022 mg ac/L, $E_rC_{50}$ 0.00046 mg ac/L, *Navicula pelliculosa*) and aquatic plants ($E_rC_{10}$ 0.000042 mg ac/L, $E_rC_{50}$ >0.38 mg ac/L, $E_rC_{50}$ 0.00017 mg ac/L, *Lemna gibba*).

Following long-term exposure to trifludimoxazin, reduced growth was observed in fish at concentrations at low as 0.0047 mg ac/L (NOEC 0.0027 mg ac/L, *Cyprinodon variegatus*), and complete parental mortality of aquatic invertebrates was observed at 0.020 mg ac/L (NOEC 0.011 mg ac/L, *Daphnia magna*). No adverse effects were observed in sediment dwellers following long-term exposure to the highest test concentrations (NOEC 0.41 mg ac/kg dry sediment).

Available data indicate that the major metabolites M850H001, M850H002, and M850H004 are significantly less toxic than the parent compound trifludimoxazin. Metabolites have been demonstrated to be as much as 15 times less toxic to fish and algae than parent compound and as much as 234 times less toxic to aquatic plants.

Risks of trifludimoxazin due to spray drift were acceptable using ground application equipment at a low boom setting (0.5 metres above the target canopy) provided a mandatory no-spray of 60 metres is observed. Runoff risks were only acceptable under zero-till or no-till farming practices.

## Bees and other non-target arthropods

Trifludimoxazin is not considered to be acutely toxic to adult bees by contact exposure ($LD_{50}$ >100 µg ac/bee, *Apis mellifera*) or oral exposure ($LD_{50}$ >100 µg ac/bee, *Apis mellifera*). Low toxicity was also observed in bee larvae ($LD_{50}$ 46 µg ac/bee, *Apis mellifera*). Following long-term dietary exposure to trifludimoxazin, no adverse effects were observed in adult bees at the highest test concentration (NOEL 10 µg ac/bee/d, *Apis mellifera*), while increased larval mortality was observed after 22 days at 13 µg ac/bee (NOEL 6.3 µg ac/bee, *Apis mellifera*). Formulation toxicity data did not show any enhanced toxicity.

Risks of trifludimoxazin to bees were determined to be acceptable under a realistic worst-case scenario, which assumed plants within the treatment area transported the pesticide to pollen and nectar following soil application. As a result, no specific protection statements are required on the label for bees.

An SC formulation of trifludimoxazin was not toxic to the standard indicator species *Typhlodromus pyri* and *Aphidius rhopalopiphi* in Tier 1 laboratory (glass plate) tests at exaggerated rates (both $LR_{50}$ >450 g ac/ha). Therefore, risks of trifludimoxazin to other beneficial arthropods were considered to be acceptable without further assessment and no specific protection statements are required on the label.

## Soil organisms

Trifludimoxazin was not toxic to soil macro-organisms such as earthworms ($LC_{50corr}$ >500 mg ac/kg dry soil, *Eisenia fetida*). Following long-term exposure in soil, trifludimoxazin inhibited reproduction at corrected concentrations as low as 278 mg ac/kg dry soil ($NOEC_{corr}$ 154 mg ac/kg dry soil, *Eisenia andrei*). No adverse effects were observed on soil processes such as nitrogen and carbon mineralisation at exaggerated soil concentrations (NOEC 1.3 to 2.4 mg ac/kg dry soil). Formulation data did not show any enhanced toxicity.

Risks of trifludimoxazin to soil organisms were determined to be acceptable under a realistic worst-case scenario, which assumed a direct overspray of soil without interception at the maximum rate. As a result, no specific protection statements are required on the label for soil organisms.

## Non-target terrestrial plants

Data were provided addressing the toxicity of an SC formulation of trifludimoxazin to non-target terrestrial plants following pre- and post-emergent exposure. These studies examined the effects on seedling emergence and vegetative vigour in ten crop species, with growth inhibition (dry weight) being the most significant response. The most sensitive species from the seedling emergence exposure was tomato ($ER_{50}$ 2.2 g ac/ha, *Lycopersicon esculentum*). The most sensitive species following post-emergent exposure was soybean ($ER_{50}$ 0.27 g ac/ha, *Glycine max*). An analysis of the species sensitivity distributions was undertaken and the $HR_5$ values of 2.2 g ac/ha (for pre-emergent exposure) and 0.24 g ac/ha (for post-emergence exposure) were determined.

Risks of the proposed use of Voraxor Herbicide to non-target terrestrial plants are driven by the active constituent saflufenacil. An analysis of the species sensitivity distributions for saflufenacil was undertaken and the $HR_5$ value of 0.046 g/ha saflufenacil for post-emergence exposure was determined. Risks of spray drift were acceptable using ground application equipment at a low boom setting (0.5 metres above the target canopy) provided a mandatory no-spray of 220 metres is observed. When the product is applied at 100 mL/ha in combination with glyphosate, a buffer zone of 325 metres is required.

## 7.3 Recommendations

Based on an assessment of the environmental data, it was considered that there should be no unacceptable adverse effects on non-target organisms from the use of Voraxor Herbicide when used in accordance with label directions.

The following restraints and protection statements are recommended to mitigate risks of spray drift and runoff.

RESTRAINTS

DO NOT apply by aircraft.
DO NOT apply if heavy rains or storms are forecast within 3 days.
DO NOT irrigate to the point of runoff for at least 3 days after application.
DO NOT apply unless zero-till or no-till farming is practiced.
DO NOT apply more than 240 mL/ha in a single season.

**Table 8: Buffer zones for boom sprayers**

| Application rate | Boom height above the target canopy | Mandatory downwind buffer zones | |
|---|---|---|---|
| | | Natural aquatic areas | Vegetation areas |
| Up to maximum label rate | 0.5 metres or lower | 60 metres | 220 metres |
| 100 mL/ha or lower | 0.5 metres or lower | 30 metres | 70 metres |
| | 1.0 metres or lower | 85 metres | 220 metres |
| 100 mL/ha in combination with glyphosate | 0.5 metres or lower | 30 metres | 325 metres |

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

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

# 8 EFFICACY AND SAFETY ASSESSMENT

## 8.1 Proposed product use pattern

Voraxor Herbicide containing 250 g/L saflufenacil and 125 g/L trifludimoxazin is intended for the non-selective pre-plant knockdown and selective pre-emergence residual control of a range of broadleaf weeds and suppression of key grass weeds prior to planting of cereal crops; for non-selective pre-plant knockdown prior to establishment of forestry plantations and fallow; to aid in fallow maintenance; and for weed control around commercial, industrial and agricultural buildings, public service areas and yards and fence lines.

Voraxor Herbicide is a non-selective burn down and selective pre-emergence herbicide. Crop selectivity is accomplished by a combination of metabolic and application method selectivity. Cereals are more tolerant to saflufenacil than trifludimoxazin on a gram-for-gram basis and Voraxor Herbicide contains half the amount of trifludimoxazin than saflufenacil. Although both herbicides are members of the same MoA group, their different physical chemical properties mean they provide complimentary activity in the formulated product. For example, the two active constituents have different water solubilities, which increases the herbicidal coverage of the product in the soil. Trifludimoxazin is quite insoluble so has lower soil mobility and provides control of small-seeded broadleaf weeds while saflufenacil controls larger-seeded weeds that emerge from deeper in the soil profile.

## 8.2 Efficacy and target crop/animal safety

Voraxor Herbicide containing 250 g/L saflufenacil and 125 g/L trifludimoxazin was compared to several industry standards in a total of 139 trials.

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

### Efficacy

Efficacy was investigated for burn down weed control, pre-plant residual control, pre-plant burn down and residual control for selected weeds including: annual ryegrass, Lolium rigidum, sowthistle, Sonchus oleraceus, wild radish, Raphanus raphanistrum, wild turnip, Rapistrum rugosum, shepherd purse, Capsella bursa-pastoris, black bindweed, Polygonum convolvulus, Indian hedge mustard, Sisymbrium orientale, crassula, Crassula spp., bedstraw, Gallium spp., field bindweed, Convolvulous arvensis, deadnettle, Lamium amplexicaule, wireweed, Polygonum aviculare, volunteer canola, Brassica napus/napus, prickly lettuce, Lactuca serriola, capeweed, Arctotheca calendula, fumitory, Fumaria spp., fleabane, Conyza spp. vetch, Vicia spp., spear thistle, Cirsium vulgare and barrel medic, Medicago truncatula.

Trial data indicated that Voraxor Herbicide provided rapid burn down with prolonged residual control when used alone and in combination with industry standard knockdown herbicides.

Applied to wheat cv. Sunlin at the proposed label rate, Voraxor Herbicide resulted in rapid burn down of two-leaf to first tiller annual ryegrass. Applied at 100 ml/ha, Voraxor Herbicide resulted in 80 per cent control of

annual ryegrass at seven days after treatment compared to 71.7 per cent control for the industry standard. Mean ryegrass control in multiple trials at seven to eight days after treatment was 52 per cent, compared to 21 per cent for the glyphosate industry standard; 67 per cent for an industry standard; and 72 per cent for Voraxor Herbicide tank-mixed with glyphosate. Residual control measured in the same trial, indicated that Voraxor Herbicide applied at 100 ml/ha resulted in 100 per cent control of ryegrass at 41 days after the initial burn down treatment (20 days after the IBS treatment) compared to 100 per cent control for the glyphosate standard and the Voraxor Herbicide glyphosate tank-mix. The tank-mix of Voraxor Herbicide with glyphosate or paraquat consistently provided better burn down and reportedly increased the spectrum of weeds controlled. Mean ryegrass control in multiple trials was 48 per cent at 17 to 28 days after treatment for Voraxor Herbicide applied at the proposed label rate compared to 86 per cent for the Voraxor Herbicide glyphosate tank-mix; 85 per cent for glyphosate applied alone; and 95 per cent for an industry standard. Voraxor Herbicide in the tank-mix improved rapid burn down but was still effective as a residual control. Trial data also confirmed that Voraxor Herbicide controlled glyphosate-resistant ryegrass.

Voraxor Herbicide applied to wheat cv. Trojan resulted in 62 per cent control of wild radish at seven days after treatment compared to 55 per cent for the Voraxor Herbicide glyphosate tank-mix and 30 per cent for the glyphosate standard applied alone. At 91 days after treatment, Voraxor Herbicide resulted in 33 per cent between-row control compared to 23 per cent for the Voraxor Herbicide glyphosate tank-mix and 0 per cent for glyphosate applied alone.

Mean control of wild radish applied at the proposed label rate in multiple trials was 59 per cent, compared to 39 per cent for the Voraxor Herbicide glyphosate tank-mix; 23 per cent for glyphosate; and 64 per cent for an industry standard.

Mean control of nine common broadleaf weeds at 17 to 28 days after treatment in multiple trials was 100 per cent at 28 days after treatment, compared to 98 per cent for the Voraxor Herbicide glyphosate tank-mix; 95 per cent for glyphosate alone; and 92 per cent for and industry standard. Voraxor Herbicide consistently controlled common weeds and was bioequivalent to industry standards with more rapid burn down than industry standards.

When applied IBS (0 to seven days before sowing) at 200 ml/ha, Voraxor Herbicide resulted in 76 per cent control of wild radish compared to 40 per cent to 52 per cent for pre-emergence industry standards. When applied at seven to 21 days before sowing, Voraxor Herbicide resulted in 84 per cent control when applied at 200 ml/ha.

## Crop safety

Crop safety was assessed on multiple cultivars of wheat, durum, and barley by evaluating crop emergence, crop biomass, yield, and crop phytotoxicity from three to 101 days after treatment. Plant-back safety and re-cropping times on mungbean, chick pea, faba bean, field pea, lentil, canola, safflower, cotton, sunflower, and sorghum were also assessed.

Voraxor Herbicide applied to wheat at the maximum label rate of 240 ml/ha as a pre-plant burn down treatment, resulted in 123 per cent emergence as a percentage of the untreated control at seven days after treatment. When applied to wheat IBS at the maximum label rate of 200 ml/ha, Voraxor Herbicide resulted in

100 per cent emergence compared to the untreated control. No statistically significant differences were reported in emergence of barley and durum when Voraxor Herbicide was applied IBS at 200 ml/ha.

Mean (53 trials) crop phytotoxicity of Voraxor Herbicide applied pre-plant burn down to wheat at 200 ml/ha and 240 ml/ha was 0 per cent. When applied IBS at 200 ml/ha, Voraxor Herbicide resulted in 0.6 per cent mean phytotoxicity. Data confirmed crop safety of Voraxor Herbicide at 240 ml/ha applied from seven to 21 days before sowing and 200 ml/ha when applied IBS up to seven days before sowing at 200 ml/ha.

Mean crop phytotoxicity of Voraxor Herbicide applied IBS at 200 ml/ha was 1.0 per cent and 2.0 per cent for durum and barley respectively.

Mean biomass in wheat was 100.5 per cent of untreated when Voraxor Herbicide was applied as a pre-plant burn down treatment at the 240 ml/ha label rate. Minimal biomass reduction was recorded for barley (98 per cent of untreated) and durum (96 per cent).

Multiple trials assessed possible soil carry over after the application of Voraxor Herbicide on wheat, barley, and durum and conservative re-cropping intervals were established for the crops listed on the proposed label. In these trials, plant establishment, crop biomass, phytotoxicity, and yield were assessed from one week to six months after treatment with proposed label rates. Mung bean planted at a one week re-crop interval showed significant impact on mean establishment (67 per cent of untreated at 21 days after planting) and biomass (54 per cent of untreated at 21 days after planting). No reduction in crop establishment or biomass was recorded at one and three-month assessments. Re-planting interval for mung beans was conservatively set at three months. Establishment and biomass affects were recorded on sunflower when planted six months after treatment and so the re-planting interval was set at nine months.

### Resistance management

Trifludimoxazin is a 1,3,5-triazinane herbicide with a protoporphyrinogen oxidase (PPO) enzyme inhibitor mode of action herbicide. The Herbicide Resistance Action Committee (HRAC), has designated saflufenacil and trifludimoxazin as Group G herbicides.

There are currently no known populations of weeds resistant to Group G herbicides in Australia according to CropLife Australia.

## 8.3 Recommendations

Voraxor Herbicide provided effective control of the weeds evaluated in field trials and confirmed the proposed label rates and timings; providing similar or superior control to other registered herbicides for pre-plant knockdown and knockdown use in fallow.

Trial data confirmed crop safety of Voraxor Herbicide when applied to wheat, durum and barley pre-crop and IBS at the proposed label rates. Trial data also confirmed plant-back safety at the proposed label intervals.

# 9 LABELLING REQUIREMENTS

## CAUTION

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

# VORAXOR® HERBICIDE

**ACTIVE CONSTITUENTS: 250 g/L SAFLUFENACIL**
**125 g/L TRIFLUDIMOXAZIN**

| GROUP | G | HERBICIDE |
|---|---|---|

For the non-selective pre-plant knockdown and selective pre-emergence residual control of a range of broadleaf weeds and suppression of key grass weeds prior to planting of cereal crops; for non-selective pre-plant knockdown prior to establishment of forestry plantations and fallow; to aid in fallow maintenance; and for weed control around commercial, industrial and agricultural buildings, public service areas and yards and fence lines; as per the DIRECTIONS FOR USE table.

**IMPORTANT: READ THE LEAFLET BEFORE USING THIS PRODUCT**

NET CONTENTS: 5L, 10L, 20L, 110L

BASF Australia Ltd ABN 62 008 437 867
Level 12, 28 Freshwater Place Southbank VICTORIA 3006
Website: www.crop-solutions.basf.com.au

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**RESTRAINTS**
DO NOT apply by aircraft.
DO NOT apply by vertical sprayer.
DO NOT apply if heavy rains or storms are forecast within 3 days.
DO NOT irrigate to the point of runoff for at least 3 days after application.
DO NOT apply unless zero-till or no-till farming is practiced.
DO NOT apply more than 240 mL/ha in a single season.
DO NOT apply prior to sowing crops with under-sown legumes

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

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

**DO NOT** apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The buffer zones in the buffer zone table below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.

**DO NOT** apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

**DO NOT** apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature inversion conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.

**DO NOT** apply by a boom sprayer unless the following requirements are met:

- Spray droplets are not smaller than a COARSE spray droplet size category
- Minimum distances between the application site and downwind sensitive areas are observed (see the table titled 'Buffer zones for boom sprayers in the 'Mandatory downwind buffer zones' section below).

**Buffer zones for boom sprayers**

| Mandatory downwind buffer zones | | | | | | |
|---|---|---|---|---|---|---|
| **Application rate** | **Boom height above the target canopy** | **Bystander areas** | **Natural aquatic areas** | **Pollinator areas** | **Vegetation areas** | **Livestock areas** |
| Up to maximum label rate | 0.5 metres or lower | Not required | 60 metres | Not required | 220 metres | 5 metres |
| 100 mL/ha or lower | 0.5 metres or lower | Not required | 30 metres | Not required | 70 metres | Not required |
| | 1.0 metres or lower | Not required | 85 metres | Not required | 220 metres | 15 metres |
| 100 mL/ha in combination with glyphosate | 0.5 metres or lower | Not required | 30 metres | Not required | 325 metres | Not required |

For the non-selective pre-plant knockdown and selective pre-emergence residual control of a range of broadleaf weeds and suppression of key grass weeds prior to planting of cereal crops; for non-selective pre-plant knockdown prior to establishment of forestry plantations and fallow; to aid in fallow maintenance; and for weed control around commercial, industrial and agricultural buildings, public service areas and yards and fence lines.

| SITUATION | WEEDS CONTROLLED | WEED STAGE | RATE | CRITICAL COMMENTS |
|---|---|---|---|---|
| Prior to starting a fallow, fallow maintenance and prior to establishment of Forestry Plantations<br><br>Pre-plant burndown prior to sowing wheat, durum and barley<br><br>To assist in weed control in Commercial, Industrial and Public Service areas, around Agricultural buildings, yards, fence lines | See Weed Table A | Up to 6 leaf stage | 100 ml/ha + 1% Hasten or high quality MSO | DO NOT apply post-sowing pre-emergent (PSPE).<br>ALWAYS apply VORAXOR HERBICIDE with 1% v/v Hasten Spray adjuvant or high quality methylated seed oil (MSO) for knockdown uses<br>Apply to weeds up to six leaf growth stage and actively growing under good conditions.<br>The 100 ml/ha rate will provide rapid burndown of label weeds but should not be relied upon for residual control of broadleaf weeds. Use higher rates as per label directions for residual control.<br>Refer to the plant-back interval table on this label and also refer to the appropriate companion product label, in case a longer re-cropping interval is required.<br>It is important to establish size and age of weeds (check root system as an indication) prior to application to ensure control. Some weeds that appear small may in fact be older and have an established root system and may not be completely controlled and regrowth may occur.<br>Weeds that have been grazed or previously treated with herbicide can be difficult to manage and may not be fully controlled. |
| | Annual ryegrass (*Lolium rigidum*) | At least 1 true leaf to early tillering (Z13) | 100 ml/ha + recommended label rate of glyphosate herbicide or paraquat herbicide + 1% Hasten or high quality MSO | Some glyphosate resistant annual ryegrass biotypes have shown to be controlled prior to tillering (1 true leaf to 2 leaf) growth stage. The addition of glyphosate in the mixture has shown a positive impact on controlling glyphosate resistant annual ryegrass and will broaden spectrum to control other weeds present.<br>Any weed that has germinated but not achieved at least 1 true leaf may not be controlled. A follow up application of a knockdown herbicide with another mode of action may be required. Refer also to the product label for the knockdown herbicide used. |
| | Glyphosate resistant annual ryegrass (*Lolium rigidum*) | At least 1 true leaf to 2 leaf | | |
| | For the control of broadleaf and grass weeds listed in | Up to 10 leaf (broadleaf weeds)<br>At least 1 true leaf to | 100 ml/ha + recommended label rate of glyphosate herbicide + 1% | Refer to Critical Comments above and in addition:<br>**Summer Grass Weeds**<br>Reduction of glyphosate activity on summer grasses may occur from the tank mix, which may result in reduced control of certain grass weeds. If summer grass weeds are present |

| SITUATION | WEEDS CONTROLLED | WEED STAGE | RATE | CRITICAL COMMENTS |
|---|---|---|---|---|
| | Table A **and** Table B | early tillering (Z13) (grass weeds) | Hasten or high quality MSO | and their control is important, it is recommended that the highest labelled rate of glyphosate be used for the use situation encountered. Good coverage is essential for control of Silver Grass.<br><br>If summer grass weeds recover, a follow up application of a knockdown herbicide with another mode of action may be required. Refer also to the product label for the knockdown herbicide used.<br>Refer to the plant-back interval table on this label and also refer to the appropriate companion product label, in case a longer re-cropping period is required. |
| | For the control of broadleaf and grass weeds listed in Weed Table A as well as:<br><br>Annual ryegrass (*Lolium spp.)*<br>Brome grass (*Bromus spp.)*<br>Chickweed (*Stellaria spp.)*<br>Silver grass (*Vulpia spp.)* | | 100 mL/ha + recommended label rate of paraquat herbicide plus 1 % Hasten or high quality MSO | Refer to Critical Comments above and in addition:<br><br>Use of VORAXOR HERBICIDE with paraquat herbicide may increase the speed at which broadleaf and grass weeds develop visible symptoms and improve control of a range of grass and broadleaf weeds (compared to results achieved with paraquat applied alone).<br><br>Apply only as a tank mix with recommended rates of herbicide containing paraquat, ensuring the correct mixing order is followed. See MIXING section below. Ensure to observe and understand all restraints, rates, safety directions, first aid instructions and general instructions on the paraquat product label. Good coverage is essential for control of Silver Grass.<br><br>Hasten at 1% v/v must be added when applying VORAXOR HERBICIDE with paraquat herbicide. |

**PRE-EMERGENCE RESIDUAL CONTROL PRIOR TO SOWING WHEAT, DURUM AND BARLEY**

| SITUATION | WEEDS CONTROLLED | WEED STAGE | RATE | CRITICAL COMMENTS |
|---|---|---|---|---|
| **Immediately - 7 days** Prior to sowing wheat, Barley, or Durum<br><br>**For residual control** | Capeweed (*Arctotheca calendula*)<br>Cleavers/bedstraw (*Gallium spp.*)<br>Climbing buckwheat/bindweed (*Polygonum convolvulous*)<br>Field bindweed (*Convolvulous arvensis*)<br>Crassula/stonecrop *(Crassula sieberiana)*<br>Deadnettle (*Lamium amplexicale*)<br>Fleabane (*Conyza* spp.)<br>Fumitory (*Fumaria* spp.)<br>Indian hedge mustard (*Sisymbrium orientale)*<br>Prickly lettuce (*Lactuca seriola*),<br>Shepherd's purse (*Capsella bursa-pastoris*)<br>Spear thistle (Cirsium vulgare)<br>Sow thistle/milkthistle (*Sonchus oleracheus*)<br>Wild radish (*Raphanus raphanistrum*)<br>Wild turnip/turnip weed (*Rapistrum rugosum)*<br>Wireweed (*Polygonum avicluare*) | Pre-emergence | 200 mL/ha | For residual weed control, apply pre-sowing and incorporate by sowing (IBS) using knife points and press wheels only. Cultivation must not occur prior to the use of VORAXOR from the previous crop until the sowing of the current crop. Wide points and harrows of any type must not be used at or after the seeding operation that incorporates VORAXOR.<br><br>For best results apply just before sowing (refer to **Interval between Application and Sowing** in **GENERAL INSTRUCTIONS**).<br><br>**Using VORAXOR HERBICIDE in conjunction with a grass weed pre-emergence herbicide** - If planning to use a specific grass weed pre-emergent herbicide such as Luximax, Sakura, Boxer Gold or trifluralin as a tank mix with Voraxor Herbicide, additional caution is required as increased crop damage may occur. Tank mixes of multiple herbicides requiring physical separation results in higher loading of total herbicide and therefore imposes a greater potential impact on crops. **Refer to guidelines on both product labels for guidance on factors that contribute to performance and crop tolerance ensuring all parameters of all product labels are met**. Increasing sowing depth to >30mm, reducing speed of travel at sowing and avoiding use when heavy rainfall is forecast soon after planting will be most effective measures for increasing physical separation of seed and herbicides to gain increased crop selectivity, particularly on sandy soils and where furrow wall collapse occurs.<br><br>A decision to mix pre-emergent herbicides should be made based on weed burden and resistance management issues where some potential impact on crop selectivity is outweighed by weed control needs. Avoid throwing treated soil into adjacent crop rows when sowing with knife points and press wheels.<br><br>If emerged weeds are present at time of application, follow directions and critical comments for pre-plant knockdown application above – particularly the need for an MSO adjuvant. If grass weeds are present also consider a partner non-selective herbicide such as glyphosate or paraquat. For knockdown, observe weed growth stage as outlined in the pre-plant burn down section of the label. The increased rate of VORAXOR HERBICIDE will generally not result in increased control of larger weeds. Heavy weed burdens will reduce amount of herbicide able to reach soil and may compromise residual activity of VORAXOR HERBICIDE<br><br>To reduce the risk of crop effects, refer to **Crop Safety** in **GENERAL INSTRUCTIONS.** |

| | | | | |
|---|---|---|---|---|
| | | | | To optimise weed control apply directly to uncultivated soil. Weed control may be greatly reduced where weed seeds have been buried by cultivation prior to sowing.<br><br>Weed control may be adversely affected by one of or a combination of factors below;<br>uneven application, application to ridged or cloddy soil, stubble, plant residue or other ground cover (particularly where this exceeds 50%) resulting in a barrier and there is insufficient following rainfall to transfer VORAXOR HERBICIDE to the soil surface and the germinating weed seeds.<br>Planting equipment or techniques that result in stubble drag, germinated and emerged weeds that are not controlled by a knockdown herbicide, insufficient rainfall within 7 to 10 days after application, in soils prone to leaching, rainfall which is sufficiently heavy to cause movement of the herbicide out of the weed seed zone.<br><br>Weeds germinating in planted furrow may not be effectively controlled due to herbicide movement via sowing process. |
| | Suppression of annual ryegrass | | | For residual suppression of annual ryegrass, apply to light texture soils (>50% sand content in top 10cm). Residual control will likely be compromised unless at least 15 mm rainfall occurs within 7-10 days following application, including at least a single day of over 5 mm, to maximise activity. |
| **CROP** | **WEEDS** | **WEED STAGE** | **RATE** | **CRITICAL COMMENTS** |
| **7-21 days** Prior to sowing wheat, Barley, or Durum<br><br>**For residual control** | Capeweed (*Arctotheca calendula*)<br>Cleavers/bedstraw (*Gallium spp.*)<br>Climbing buckwheat/bindweed (*Polygonum convolvulous*)<br>Field bindweed (*Convolvulous arvensis*)<br>Crassula/stonecrop *(Crassula sieberiana)*<br>Deadnettle (*Lamium amplexicale*)<br>Fleabane (*Conyza* spp.)<br>Fumitory (*Fumaria* spp.) | Pre-emergence | 240 mL/ha | Use of 240 ml/ha rate allows earlier application between 7 to 21 days prior to sowing however any weed escapes after application and before sowing must be controlled by suitable knockdown herbicide.<br><br>**Using VORAXOR HERBICIDE followed by a pre-emergence herbicide** – Use this rate and timing if splitting the application of VORAXOR HERBICIDE and a specific grass pre-emergent herbicide. Apply VORAXOR HERBICIDE 7 to 21 days pre-sowing and apply the pre-emergent herbicide per its label requirements. VORAXOR HERBICIDE should be incorporated by sowing (IBS) using knife points and press wheels. Avoid throwing treated soil into adjacent crop rows when sowing with knife points and press wheels. VORAXOR will remain viable on the soil surface until incorporated by sowing (IBS). Some incorporation and activity may occur due to rainfall during this period, however any weed escapes after application and before sowing must be controlled by suitable knockdown herbicide. Always follow specific label instructions.<br><br>If emerged weeds are present at time of application, follow directions and critical comments for pre-plant knockdown application above – particularly the need for an MSO adjuvant. If grass weeds are present |

| | | | | |
|---|---|---|---|---|
| | Indian hedge mustard (*Sisymbrium orientale)*<br>Shepherd's purse (*Capsella bursa-pastoris*)<br>Spear thistle (*Cirsium vulgare*)<br>Spiny emex (*emex australis*)<br>Sow thistle/milkthistle (*Sonchus oleracheus*)<br>Wild radish (*Raphanus raphanistrum*)<br>Wild turnip/turnip weed (*Rapistrum rugosum)*<br>Wireweed (*Polygonum avicluare*) | | | also consider a partner non-selective herbicide such as glyphosate or paraquat. For knockdown, observe weed growth stage as outlined in the pre-plant burn down section of the label. The increased rate of VORAXOR HERBICIDE will generally not result in increased control of larger weeds. Heavy weed burdens will reduce amount of herbicide able to reach soil and may compromise residual activity of VORAXOR HERBICIDE<br><br>To reduce the risk of crop effects, refer to **Crop Safety** in **GENERAL INSTRUCTIONS.**<br><br>To optimise weed control apply directly to uncultivated soil. Weed control may be greatly reduced where weed seeds have been buried by cultivation prior to sowing.<br><br>Weed control may be adversely affected by one of or a combination of factors below;<br>uneven application, application to ridged or cloddy soil, stubble, plant residue or other ground cover (particularly where this exceeds 50%) resulting in a barrier and there is insufficient following rainfall to transfer VORAXOR HERBICIDE to the soil surface and the germinating weed seeds.<br>Planting equipment or techniques that result in stubble drag, germinated and emerged weeds that are not controlled by a knockdown herbicide, insufficient rainfall within 7 to 10 days after application, in soils prone to leaching, rainfall which is sufficiently heavy to cause movement of the herbicide out of the weed seed zone.<br><br>Weeds germinating in planted furrow may not be effectively controlled due to herbicide movement via sowing process. |
| | Suppression of annual ryegrass | | | For residual suppression of annual ryegrass, apply to light texture soils (>50% sand content in top 10cm). Residual control will likely be compromised unless at least 15 mm rainfall occurs within 7-10 days following application, including at least a single day of over 5 mm, to maximise activity. |

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

**WITHHOLDING PERIOD**

**HARVEST:** WHEAT, BARLEY, DURUM: NOT REQUIRED WHEN USED AS DIRECTED

**GRAZING:** WHEAT, BARLEY, DURUM: DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 6 WEEKS AFTER APPLICATION. DO NOT ALLOW LIVESTOCK TO GRAZE TREATED WEEDS.

| **Weed Table A** | |
|---|---|
| Amaranth | *Amaranthus spp* |
| Australian crassula | *Crassula sieberiana* |
| Bindweed/climbing buckwheat | *Fallopia convolvulus* |
| Blackberry nightshade | *Solonum nigrum* |
| Caltrop | *Tribulus terrestris* |
| Capeweed | *Arctotheca calendula* |
| Common Catsear | *Hypochaeris radicata* |
| Crassula/stonecrop | *Crassula colorata* |
| Fat Hen | *Chenopodium album* |
| Heliotrop | *Heliotropium europaeum* |
| Khaki Weed | *Alternathera repens* |
| Marshmallow/Small flowered mallow | *Malva parviflora* |
| Medics | *Medicago spp.* |
| Muskweed | Myagrum *perfoliatum* |
| Patersons curse | *Echium plantagineum* |
| Prickly lettuce | *Lactuca serriola* |
| Scarlet Pimpernel | *Anagallis arvensis* |
| Slender thistle | *Carduus pycnocephalus* |
| Shepherd's purse | *Capsella bursa pastoris* |
| Sowthistle | *Sonchus oleraceus* |
| Spiny emex | *Emex australis* |
| Stinging nettle | *Urtica dioica* |
| Storksbill | *Erodium spp.* |
| Wild radish | *Raphanus raphanistrum* |
| Volunteer canola max 4 leaf includingRoundup Ready® varieties | *Brassica napus* |
| Volunteer cotton seedlings including Roundup Ready Flex® varieties | *Gossypium spp.* |
| Volunteer pulse crops including lupin and chickpea | *Lupinus angustifolius Cicer arietinum* |
| Wild turnip/turnip weed | *Rapistrum rugosum* |
| Wireweed | *Polygonium aviculare* |

| **Weed Table B** | |
|---|---|
| Amsinckia | *Amsinckia spp.* |
| Annual ryegrass | *Lolium spp.* |
| Barley grass | *Hordium spp.* |
| Brome grass | *Bromus spp.* |
| Charlock | *Sinapis arvensis* |
| Cowvine/peachvine | *Ipomoea lonchophylla* |
| Indian hedge mustard | *Sisymbrium orientale* |
| Kochia | *Kochia scoparia* |
| Penny cress | *Thlaspi arvense* |
| Prickly lettuce | *Lactuca serriola* |
| Silver grass | *Vulpia spp.* |
| Snoutbean | *Rhynchosia minima* |
| Volunteer/wild oat | *Avena spp.* |

**GENERAL INSTRUCTIONS**
VORAXOR HERBICIDE is a non-selective burn down and selective pre-emergence herbicide.

**For knockdown uses:**
VORAXOR HERBICIDE is a fast acting contact herbicide and aids in control of weeds through a process of membrane disruption. The foliar uptake of VORAXOR HERBICIDE is rapid and plant desiccation can occur within 4 days of application. Application of VORAXOR HERBICIDE to emerged weeds should target small actively growing weeds.

VORAXOR HERBICIDE may also be used alone with a suitable adjuvant for control of a range of broadleaf weeds as per the directions for use table. When used in situations where emerged weeds are present the addition of glyphosate or paraquat based herbicides will broaden weed spectrum and may improve final control.

**For residual control:**
At label rates of 200 ml/ha to 240 ml/ha VORAXOR HERBICIDE ha provides residual control of a wide range of broadleaf weeds as well as the suppression of key grass weeds. Crop selectivity of VORAXOR HERBICIDE when applied for residual control of weeds is achieved through a combination of metabolic as well as placement selectivity.

Use rates for residual control are 200 ml/ha within 7 days prior to sowing (0–7 days before sowing) or 240 ml/ha if greater than 7 days before sowing (7–21 days before sowing). The 240 ml/ha rate should not be used within 7 days of sowing as there is increased chance of crop damage occurring.

In situations of dry sowing, or where conditions are less than ideal for even pre-emergence herbicide incorporation (rough seed bed, presence of excess soil clods, increased surface residues, etc) the ability to increase rate slightly and delay sowing for at least 7 days can improve weed control performance and provide more utility to end users. Refer to APPLICATION section for factors that may adversely affect weed control.

**SYMPTOMS**
VORAXOR HERBICIDE when applied post emergence to weeds is rapidly absorbed through the foliage of plants. Within a few hours following application, the foliage of susceptible weeds will show signs of desiccation, and in subsequent days necrosis and death of the plant. In a pre-emergent situation VORAXOR HERBICIDE is taken up by roots and hypocotyl resulting in lack of germination of weed seeds. Any affected plants that germinate may show signs of necrosis particularly in tissue that has been in contact with treated soil such as stems and first emerging leaves.

If crop damage occurs from pre-emergence use pattern, symptoms are necrosis of 1$^{st}$ emerged leaf at axis of leaf and stem resulting in leaf 1 senescing and dropping from the plant. In trials this symptom has not been associated with negative impact on crop yield.

**COMPATIBILITY**
When Applying VORAXOR HERBICIDE to emerged weeds Hasten Spray Adjuvant or an alternate high quality methylated seed oil (MSO) should always be used. Crop oil concentrates or non-ionic surfactants are not recommended when using VORAXOR HERBICIDE for control of emerged weeds.

For most uses as per the Directions for Use VORAXOR HERBICIDE may be tank mixed with a good quality glyphosate or paraquat based herbicide. If mixing with paraquat it is essential that the correct mixing sequence is followed requiring VORAXOR HERBICIDE to be added to the tank prior to the selected paraquat product. Refer to MIXING section below.

VORAXOR HERBICIDE is also compatible with Arcade*, Ally*, Avadex* Xtra, Amicide* Advance 700, Amicide* 625, Boxer Gold*, Garlon*, Longran*, Lontrel*, Luximax, prosulfocarb, Nufarm Surpass* 475, Rifle*, Sakura*, triallate, trifluralin and Verdict* 520 EC.

**TIMING**
**For burn down uses:** application should be made to small, actively growing weeds as per the directions for use table. When applying VORAXOR HERBICIDE to emerged weeds, best control is achieved when weeds are exposed and are not shielded by other weeds and/or stubble.

**For residual control:** for residual weed control, apply pre-sowing and incorporate by sowing (IBS) using knife points and press wheels as per the directions for use table. Use rates for residual control are 200ml/ha within 7 days prior to sowing (0–7 days before sowing) or 240 ml/ha if greater than 7 days before sowing (7–21 days before sowing). **The 240 ml/ha rate should not be used within 7 days of sowing**.

**MIXING**
Half fill the spray tank with clean water. Commence agitation and add the required amount of product to the tank. Maintain agitation whilst filling the tank and throughout the spraying operation.

VORAXOR HERBICIDE is a suspension concentrate formulation. When using in a tank mix with other herbicides the following mix order should be observed;

1. half fill the spray tank;
2. add any granule (WG) formulated products first and allow dispersion, followed by VORAXOR HERBICIDE and any other suspension concentrates (SC/flowable);
3. add any EC formulations;
4. add paraquat and any other soluble liquids (SL) (including water soluble salts such as glyphosate);
5. add any adjuvants as recommended.

**Adjuvants**
VORAXOR HERBICIDE requires the use of an MSO type adjuvant such as Hasten to allow better uptake into the target weed for full efficacy in burn down uses. Use of non-ionic surfactants and mineral oil based adjuvants will likely result in reduced efficacy.

**APPLICATION**
The best application conditions are when soil is moist, weather fine and rain unlikely within one hour or as specified for any partner herbicide. VORAXOR HERBICIDE is rain fast one hour after application. Burn down activity may be reduced if rain or irrigation occurs within one hour of application. Extremes in environmental conditions eg temperature and moisture, soil conditions and/or cultural practices may affect the activity of VORAXOR HERBICIDE.

**For knockdown uses** against emerged weeds, VORAXOR HERBICIDE is a light activated herbicide and under intense light, warm and moist conditions, herbicide symptoms may be accelerated. Under very dry conditions, the expression of herbicidal symptoms is delayed and weeds hardened off by drought are less susceptible to VORAXOR HERBICIDE.

Stubble loads will interfere with coverage and could affect the performance of VORAXOR HERBICIDE. Reduced performance may also occur where weeds are covered with dust or silt.

**For residual control** of weeds apply 200 ml/ha within 7 days prior to sowing (0–7 days before sowing) or 240 ml/ha if greater than 7 days before sowing (7–21 days before sowing). **The 240 ml/ha rate should not be used within 7 days of sowing**. If emerged weeds are present at the time of application the addition of a suitable knockdown partner such as glyphosate or paraquat as well as MSO type adjuvant such as Hasten should be added. For residual weed control, apply pre-sowing and incorporate by sowing (IBS) using knife points and press wheels

Pre-emergent weed control may be adversely affected by one of or a combination of factors below;

- uneven application,
- application to ridged or cloddy soil,
- stubble, plant residue or other ground cover particularly where this exceeds 50%,
- planting equipment or techniques that result in stubble drag,
- germinated and emerged weeds that are not controlled by a knockdown herbicide,
- insufficient rainfall within 7 to 10 days after application,
- in soils prone to leaching,
- rainfall which is sufficiently heavy to cause movement of the herbicide out of the weed seed zone.

Weeds germinating in planted furrow may not be controlled due to herbicide movement via sowing process.

**Ground sprayers**
Apply VORAXOR HERBICIDE by ground spraying equipment only.

**Nozzles**
Spray equipment should be properly calibrated. Voraxor should be applied at the recommended rate in sufficient water to give thorough coverage of weeds. Application volumes of 80 to 250 litres per hectare are recommended. Use higher water volumes if weed infestation is dense and/or tall. To minimise off-target drift use the lowest pressure and boom height which provides uniform coverage.

**RESISTANT WEEDS WARNING**

**GROUP G HERBICIDE**

VORAXOR HERBICIDE is a member of the pyrimidindiones group of herbicides. Its mode of action is through a process of membrane disruption, which is initiated by the inhibition of the enzyme protoporphyrinogen oxidase. This inhibition interferes with the chlorophyll biosynthetic pathway. For weed resistance management VORAXOR HERBICIDE is a Group G herbicide. Some naturally occurring weed biotypes resistant to VORAXOR and other Group G herbicides may exist through normal genetic variability in any weed population and increase if these herbicides are used repeatedly. These resistant weeds will not be controlled by VORAXOR HERBICIDE or other Group G herbicides. Since the occurrence of resistant weeds is difficult to detect prior to use, BASF Australia Limited accepts no liability for any losses that may result from the failure of VORAXOR HERBICIDE or other Group G herbicides.

**CROP PLANT BACK & ROTATION RECOMMENDATIONS**
VORAXOR HERBICIDE will provide long-term residual activity and certain crops show sensitivity to soil residues. Refer to the following table for application-to-sow intervals applicable to the maximum label rate. For advice on crops not listed below or for plant backs relevant to application not at the maximum label rate, contact your local BASF Australia Ltd representative.

| **Crop to follow** pre-emergent application of VORAXOR HERBICIDE to: wheat, barley or durum at maximum label rate | **Plant Back Interval** | |
|---|---|---|
| | **6 months**<br>- after VORAXOR HERBICIDE application | **9 months**<br>-after VORAXOR HERBICIDE application |
| | Sorghum<br>Chickpeas<br>Faba beans<br>Field peas<br>Lentils<br>Mungbeans | Canola<br>Cotton<br>Safflower<br>Sunflower |

Check the label of any product mixed with VORAXOR HERBICIDE, to determine any plant back periods or restrictions on use.

**PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT**
Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.

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

**DISPOSAL**
Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500mm 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.

**SAFETY DIRECTIONS**
Wash hands after use. After each days use wash contaminated clothing.

**FIRST AID**
If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26; New Zealand 0800 764 766.

**ADDITIONAL USER SAFETY INFORMATION**
**WARNING: DO NOT use if pregnant.**

**SAFETY DATA SHEET**
Additional information is listed in the Safety Data Sheet available from your supplier.

**CONDITIONS OF USE**
All conditions and warranties rights and remedies implied by law or arising in contract or tort whether due to the negligence of BASF Australia Ltd or otherwise are hereby expressly excluded so far as the same may legally be done provided however that any rights of the Buyer pursuant to non- excludable conditions or warranties of the Competition and Consumer Act 2010 or any relevant legislation of any State are expressly preserved but the liability of BASF Australia Ltd or any intermediate Seller pursuant thereto shall be limited if so permitted by the said legislation to the replacement of the goods sold or the supply of equivalent goods and all liability for indirect or consequential loss or damage of whatsoever nature is expressly excluded. This product must be used or applied strictly in accordance with the instructions appearing hereon. This product is solely sold for use in Australia and must not be exported without the prior written consent of BASF Australia Ltd.

* = Registered trademark of other company

BASF Australia Ltd

ABN 62 008 437 867
Level 12, 28 Freshwater Place
Southbank VICTORIA 3006

**FOR SPECIALIST ADVICE IN AN EMERGENCY ONLY PHONE 1800 803 440 TOLL FREE-ALL HOURS-AUSTRALIA WIDE**

# ABBREVIATIONS

| | |
|---|---|
| ACCS/ACMS | Advisory Committee for Chemicals Scheduling/Advisory Committee for Medicines Scheduling |
| ac | active constituent |
| ADI | Acceptable Daily Intake (for humans) |
| AHMAC | Australian Health Ministers Advisory Council |
| ai | active ingredient |
| AR | applied radioactivity |
| ARfD | Acute Reference Dose |
| BBA | Biologische Bundesanalstalt fur Land—und forstwirschaft |
| BBCH | A scale used to identify the phenological development stages of plants. The abbreviation is derived from the names of the original stakeholders: Biologische Bundesanstalt, Bundessortenamt und Chemische Industrie. |
| 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 |
| EI | Export Interval |
| EGI | Export Grazing Interval |
| $ER_{50}$ | Effect rate at which the tested species shows an effect at the 50% level |
| ESI | Export Slaughter Interval |
| EUP | End Use Product |
| $F_0$ | original parent generation |
| FOB | Functional Observational Battery |

| | |
|---|---|
| g | gram |
| GAP | Good Agricultural Practice |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practice |
| GVP | Good Veterinary Practice |
| h | hour |
| ha | hectare |
| Hct | Heamatocrit |
| Hb | Haemoglobin |
| $HR_5$ | Hazard rate below which 5% of the population will be adversely affected |
| HPLC | High Pressure Liquid Chromatography *or* High Performance Liquid Chromatography |
| IBS | Incorporated by Sowing |
| id | intradermal |
| im | intramuscular |
| ip | intraperitoneal |
| IPM | Integrated Pest Management |
| iv | intravenous |
| in vitro | outside the living body and in an artificial environment |
| in vivo | inside the living body of a plant or animal |
| kg | kilogram |
| $K_{OC}$ | Organic carbon partitioning coefficient |
| L | Litre |
| $LC_{50}$ | concentration that kills 50% of the test population of organisms |
| $LD_{50}$ | dosage of chemical that kills 50% of the test population of organisms |
| LOAEL | Lowest Observable Adverse Effect Level |
| LOD | Limit of Detection—level at which residues can be detected |
| Log $K_{OW}$ | Log to base 10 of octanol water partitioning co-efficient, synonym $P_{OW}$ |

| | |
|---|---|
| LOQ | Limit of Quantitation—level at which residues can be quantified |
| mg | milligram |
| mL | millilitre |
| MRL | Maximum Residue Limit |
| MSDS | Material Safety Data Sheet |
| NEDI | National Estimated Daily Intake |
| NESTI | National Estimated Short Term Intake |
| ng | nanogram |
| NHMRC | National Health and Medical Research Council |
| NOEC/NOEL | No Observable Effect Concentration Level |
| NOAEL | No Observed Adverse Effect Level |
| OC | Organic Carbon |
| OM | Organic Matter |
| po | oral |
| ppb | parts per billion |
| PPE | Personal Protective Equipment |
| ppm | parts per million |
| PSPE | Post-sowing Pre-Emergent |
| Q-value | Quotient-value |
| RBC | Red Blood Cell Count |
| REI | Re-Entry Interval |
| s | second |
| sc | subcutaneous |
| SC | Suspension Concentrate |
| SSD | Species Sensitivity Distribution |
| SUSMP | Standard for the Uniform Scheduling of Medicines and Poisons |
| TGA | Therapeutic Goods Administration |

| | |
|---|---|
| TGAC | Technical grade active constituent |
| TRR | Total Radioactive Residue |
| 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 |
| Developmental Toxicity | The ability to cause adverse effects in the developing foetus or embryo |
| Efficacy | Production of the desired effect |
| Endocrine effects | The ability to elicit an effect on the hormonal system |
| 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 |
| Margin of Exposure | The ratio of the NOAEL (or LOEAL) to the estimated human exposure level |
| Metabolism | The chemical processes that maintain living organisms |
| Neurotoxicity | The ability to cause an adverse effect on the structure or function of the central and/or peripheral nervous system |
| Photodegradation | Breakdown of chemicals due to the action of light |
| Photolysis | Breakdown of chemicals due to the action of light |
| Plant-back Interval | The duration between application of the herbicide on a labelled crop and planting of a subsequent rotational crop |
| Subcutaneous | Under the skin |
| Systemic Toxicity | The ability to induce toxic effects at multiple sites in the body |
| Toxicokinetics | The study of the movement of toxins through the body |
| Toxicology | The study of the nature and effects of poisons |

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