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Proposed Registration Decision

PRD2020-15

Trifludimoxazin, Vulcarus and Voraxor

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

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Overview

Proposed registration decision for trifludimoxazin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Tirexor Herbicide Technical, Vulcarus and Voraxor, containing the technical grade active ingredient trifludimoxazin, to control weeds in barley, field corn, field pea, soybean, wheat, lentil, and chemfallow.

One of the end-use products, Voraxor, is co-formulated with saflufenacil. Saflufenacil is registered for use in Canada.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of trifludimoxazin, Vulcarus and Voraxor.

What does Health Canada consider when making a registration decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value² when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of Canada.ca.

Before making a final registration decision on trifludimoxazin, Vulcarus and Voraxor, Health Canada's PMRA will consider any comments received from the public in response to this

¹ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

² "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

consultation document.³ Health Canada will then publish a Registration Decision⁴ on trifludimoxazin, Vulcarus and Voraxor, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What is trifludimoxazin?

Trifludimoxazin is a herbicide that inhibits synthesis of protoporphyrinogen oxidase (PPO). The lack of PPO damages cell membranes, which leads to plant death. Under active growing conditions, susceptible emerged weeds develop injury symptoms within hours of exposure and die within 3–5 days. Susceptible emerging weed seedlings usually die as they reach the soil surface or shortly after emergence.

Health considerations

Can approved uses of trifludimoxazin affect human health?

Voraxor and Vulcarus, containing trifludimoxazin, are unlikely to affect your health when used according to label directions.

Potential exposure to trifludimoxazin may occur through the diet (food and drinking water), when handling and applying the product, or when entering an area that has been treated with the product. When assessing health risks, two key factors are considered; the levels at which no health effects occur and the levels to which people may be exposed.

The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose level at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient trifludimoxazin was of low acute toxicity via the oral, dermal and inhalation routes. It was minimally irritating to the eyes and non-irritating to the skin. It did not cause an allergic skin reaction.

³ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

⁴ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The end-use products Voraxor and Vulcarus were of low acute toxicity via the oral, dermal and inhalation routes. They were minimally irritating to the eyes and slightly irritating to the skin. They did not cause an allergic skin reaction.

Registrant-supplied short-term and long-term (lifetime) animal toxicity tests were assessed for the potential of trifludimoxazin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were effects on the nervous system of young rats. As these effects were observed concurrently with other toxicological effects in the parents, there was no evidence of increased sensitivity of the young. The risk assessment protects against the effects noted above and other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in water and food

Dietary risks from food and drinking water are not of health concern.

Aggregate acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups are expected to be less than 2.1% of the acute reference dose, and are not of health concern. Children 1–2 years old are the subpopulation expected to be subject to the highest exposure relative to body weight.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1–2 years old, the subpopulation which would ingest the most trifludimoxazin relative to body weight, are expected to be exposed to less 1.2% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from trifludimoxazin is not of health concern for all population subgroups.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using trifludimoxazin on legume vegetables, citrus fruits, pome fruits, tree nuts, peanuts, and cereal grains are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Occupational risks from handling Vulcarus and Voraxor

Occupational risks are not of concern when Vulcarus and Voraxor are used according to the label directions, which include protective measures.

Farmers and custom applicators mixing, loading or applying Vulcarus and Voraxor, and workers entering recently treated fields, can come in direct contact with trifludimoxazin or saflufenacil residues on the skin. Therefore, the label specifies that anyone mixing, loading and applying

Vulcarus and Voraxor must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. The label also requires that workers do not enter or be allowed entry into treated fields during the restricted-entry interval (REI) of 12 hours. Taking into consideration the label statements, the number of applications, and the duration of exposure for handlers and postapplication workers, the risks to these individuals are not of health concern.

Health risks to bystanders

Bystander risks are not of health concern when Vulcarus and Voraxor are used according to the label directions and spray drift restrictions are observed.

A standard label statement to protect against drift during application is on the label. Therefore, health risks to bystanders are not of concern.

Environmental considerations

What happens when trifludimoxazin is introduced into the environment?

When used according to label directions, trifludimoxazin is not expected to pose risks of concern to the environment.

Trifludimoxazin enters the environment when applied to soil to control weeds that come out before crops are planted. On land, trifludimoxazin breaks down and may move downward through the soil and reach groundwater. The breakdown-products of trifludimoxazin may also move through the soil and reach groundwater. After trifludimoxazin is sprayed, it can enter bodies of water (ponds, streams and rivers) where it will break down. Trifludimoxazin and its breakdown-products will move to sediments where they remain over time. Trifludimoxazin is not expected to be found in air or travel long distances in the atmosphere from where it was applied. Trifludimoxazin is not expected to build up in the tissues of plants or animals.

Trifludimoxazin presents negligible risks to terrestrial organisms (earthworms, bees, beneficial arthropods, wild birds and mammals) but may pose a risk to vegetation adjacent to treated fields, which can affect native plants and habitat for wildlife. In bodies of water, trifludimoxazin presents negligible risks to aquatic invertebrates and marine algae but may pose risks to freshwater and marine fish, amphibians, freshwater algae and vascular aquatic plants. Therefore, precautionary measures and spray buffer zones are required to minimize exposure to non-target terrestrial plants and aquatic organisms. When trifludimoxazin is used in accordance with the label directions and when the required risk reduction measures are applied, the reduced environmental exposure is considered acceptable and the risks are not an environmental concern.

Value considerations

What is the value of Vulcarus and Voraxor?

Vulcarus and Voraxor provide burndown control of several broadleaf weeds with soil residual activity to suppress secondary weed flushes in barley, field corn, field pea, soybean, wheat, lentil, and in chemfallow situations.

Vulcarus is formulated as a suspension concentrate with trifludimoxazin. It provides burndown control of cleavers, kochia, lamb's-quarters, volunteer canola, and wild buckwheat and suppression of secondary flushes of kochia, lamb's-quarters, redroot pigweed, volunteer canola, and wild mustard in barley, field corn, field pea, soybean, and wheat (spring, durum, and winter) and in chemfallow.

Voraxor is formulated as a suspension concentrate with trifludimoxazin and the registered active ingredient saflufenacil. It provides burndown control of Canada fleabane, cleavers, kochia, lamb's-quarters, narrow-leaved hawk's beard, redroot pigweed, round-leaved mallow, shepherd's purse, stinkweed, volunteer canola, wild buckwheat, and wild mustard and further suppression of secondary weed flushes in barley, field corn, lentil, field pea, soybean, and wheat (spring, durum, and winter) and in chemfallow.

Registrations of Vulcarus and Voraxor will provide farmers with options for pre-plant or pre-emergent burndown control of broadleaf weeds, including key weeds present in agricultural systems, in the early season with soil residual activity. Application of Vulcarus or Voraxor reduces early season weed competition to the emerging crop, allowing the crop to benefit from additional moisture, nutrients, and light that would otherwise be captured by weeds. Management of weeds at this time is critical, as the crop does not compete well with weeds until crop canopy closure. As Vulcarus and Voraxor have soil residual activity, the reduction in competition of weeds with the crop is extended.

Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Tirexor Herbicide Technical, Vulcarus and Voraxor to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

To reduce the potential of workers coming in direct contact with trifludimoxazin on the skin or through inhalation of sprays, workers mixing, loading and applying Vulcarus and Voraxor, and performing cleaning and repair activities must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. In addition, standard label statements to protect against drift

during application are on the labels. The labels also require that workers not enter or be allowed entry into treated fields during the restricted-entry interval (REI) of 12 hours.

Environment

Label statements and spray buffer zones to reduce the risk of spray drift to non-target terrestrial plants, freshwater fish, amphibians, aquatic vascular plants and freshwater algae are required. Label statements to reduce the risk of surface runoff entering aquatic habitats are required.

Next steps

Before making a final registration decision on trifludimoxazin, Vulcarus and Voraxor, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When the Health Canada makes its registration decision, it will publish a Registration Decision on trifludimoxazin, Vulcarus and Voraxor (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science evaluation

Trifludimoxazin, Vulcarus and Voraxor

1.0 The active ingredient, its properties and uses

1.1 Identity of the active ingredient

Active substance Trifludimoxazin

Function Herbicide

Chemical name

1. International Union of Pure and Applied Chemistry (IUPAC) 1,5-dimethyl-6-thioxo-3-(2,2,7-trifluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxazin-6-yl)-1,3,5-triazinane-2,4-dione

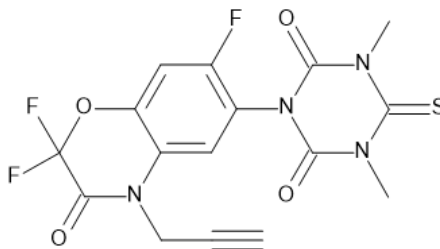
2. Chemical Abstracts Service (CAS) dihydro-1,5-dimethyl-6-thioxo-3-[2,2,7-trifluoro-3,4-dihydro-3-oxo-4-(2-propyn-1-yl)-2H-1,4-benzoxazin-6-yl]-1,3,5-triazine-2,4(1H,3H)-dione

CAS number 1258836-72-4

Molecular formula C₁₆H₁₁F₃N₄O₄S

Molecular weight 412.3 g/mol

Structural formula



Purity of the active ingredient 99.2%

1.2 Physical and chemical properties of the active ingredient and end-use products

Technical product - Tirexor Herbicide Technical

Property	Result
Colour and physical state	Off-white solid
Odour	Odourless
Melting range	206°C (onset)

Property	Result														
Boiling point or range	Decomposes before boiling														
Density	1.598 (relative) at 20°C														
Vapour pressure at 20°C	1.1×10^{-10} Pa														
Ultraviolet (UV)-visible spectrum	λ_{\max} is 265 nm in neutral media (smaller peak at 202 nm), 267 nm in acidic media (smaller peak at 198 nm), and 216 nm in basic medium (smaller peak at 290 nm).														
Solubility in water at 20°C	1.78 mg/L														
Solubility in organic solvents at 20°C	<table border="1"> <thead> <tr> <th>Solvent</th> <th>Solubility (g/L)</th> </tr> </thead> <tbody> <tr> <td>Acetone</td> <td>423.8</td> </tr> <tr> <td>Ethyl acetate</td> <td>155.2</td> </tr> <tr> <td>Methanol</td> <td>10.8</td> </tr> <tr> <td>Dichloromethane</td> <td>238.4</td> </tr> <tr> <td>Toluene</td> <td>36.0</td> </tr> <tr> <td>n-Heptane</td> <td>0.0265</td> </tr> </tbody> </table>	Solvent	Solubility (g/L)	Acetone	423.8	Ethyl acetate	155.2	Methanol	10.8	Dichloromethane	238.4	Toluene	36.0	n-Heptane	0.0265
Solvent	Solubility (g/L)														
Acetone	423.8														
Ethyl acetate	155.2														
Methanol	10.8														
Dichloromethane	238.4														
Toluene	36.0														
n-Heptane	0.0265														
<i>n</i> -Octanol-water partition coefficient (K_{ow})	$\log K_{ow} = 3.33$ (30°C)														
Dissociation constant (pK_a)	No dissociation														
Stability (temperature, metal)	Stable up to 54°C and in the presence of metals														

End-use product - Vulcarus

Property	Result
Colour	Beige
Odour	Faint sweet
Physical state	Liquid
Formulation type	Suspension
Label concentration	500 g/L
Container material and description	1-1000 L to bulk high density polyethylene jugs, totes, and drums
Density	1.20 g/cm ³
pH of 1% dispersion in water	6.7
Oxidizing or reducing action	Compatible with oxidizing agents, reducing agents, fire extinguishing agents and water.
Storage stability	Stable in HDPE containers at 54°C for 2 weeks.
Corrosion characteristics	Not corrosive to its HDPE packaging
Explosibility	Not explosive

End-use product - Voraxor

Property	Result
Colour	Off-white
Odour	Faint sweet
Physical state	Liquid
Formulation type	Suspension
Label concentration	Trifludimoxazin ... 125 g/L, Saflufenacil ... 250 g/L
Container material and description	1-1000 L to bulk high density polyethylene jugs, totes, and drums
Density	1.16 g/cm ³
pH of 1% dispersion in water	4.9
Oxidizing or reducing action	Compatible with oxidizing agents, reducing agents, fire extinguishing agents and water.
Storage stability	Stable in HDPE containers at 54°C for 2 weeks.
Corrosion characteristics	Not corrosive to its HDPE packaging
Explosibility	Not explosive

1.3 Directions for use

1.3.1 Vulcarus

The application of Vulcarus provides burndown control of cleavers, kochia (suppression only), lamb's-quarters, volunteer canola, and wild buckwheat (suppression only) and suppression of secondary flushes of kochia, lamb's-quarters, redroot pigweed, volunteer canola, and wild mustard in barley, field corn, field pea, soybean, and wheat (spring, durum, and winter) and in chemfallow situations (Appendix I, Table 24).

Vulcarus is recommended for application prior to planting or after planting but prior to crop emergence at 50–75 mL/ha. Apply Vulcarus at the higher rate for suppression of wild buckwheat or for longer residual control or when high weed populations are expected. Vulcarus may also be applied in tank mix with glyphosate herbicides for improved burndown weed control. Merge Adjuvant at 0.5% v/v is required for application with Vulcarus.

Efficacy of Vulcarus is maximized when it is applied to actively growing weeds less than 15 cm in height.

1.3.2 Voraxor

The application of Voraxor provides burndown control of Canada fleabane, cleavers, kochia, lamb's-quarters, narrow-leaved hawk's beard, redroot pigweed, round-leaved mallow, shepherd's purse, stinkweed, volunteer canola, wild buckwheat, and wild mustard and suppression of secondary flushes of some of these weeds in barley, field corn, lentil, field pea,

soybean, and wheat (spring, durum, and winter) and in chemfallow situations (Appendix I, Table 25).

Voraxor is recommended for application prior to planting or after planting but prior to crop emergence at 48–72 mL/ha for burndown weed control or 100–144 mL/ha for burndown weed control plus further suppression of late weed flushes. Apply Voraxor at the higher rates when weed populations are high and/or weed staging is late. Voraxor may be applied in tank mix with glyphosate herbicides for improved burndown weed control or with Zidua SC Herbicide for additional early season residual weed suppression, or both. Merge Adjuvant at 0.5% v/v is required for application of Voraxor.

Efficacy of Voraxor is maximized when it is applied to actively growing weeds less than 15 cm in height.

1.4 Mode of action

Trifludimoxazin is a potent inhibitor of protoporphyrinogen oxidase (PPO), which is the last common enzyme in the biosynthetic pathway leading to heme (needed for electron transfer chains) and chlorophyll (needed for photosynthesis). The inhibition of PPO not only blocks the production of chlorophyll and heme, but also results in the formation of highly reactive molecules that attack and destroy lipids and protein membranes. When the membranes are destroyed, cells become leaky and cell organelles dry and disintegrate rapidly.

Trifludimoxazin is absorbed by shoots and/or roots of the plant and usually burns plant tissues within hours or days of exposure. Symptoms appear most quickly with bright and sunny conditions at application. Under active growing conditions, susceptible emerged weeds die within 3–5 days. Susceptible emerging weed seedlings usually die as they reach the soil surface or shortly after emergence.

Trifludimoxazin is classified as a Group 14 herbicide by the Weed Science Society of America (WSSA) and as a Group E by the Herbicide Resistance Action Committee (HRAC).

2.0 Methods of analysis

2.1 Methods for analysis of the active ingredient

The methods provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable.

2.2 Method for formulation analysis

The method provided for the analysis of the active ingredients in the formulations has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for residue analysis

High performance liquid chromatography methods with tandem mass spectrometric detection (HPLC-MS/MS; Method D1407/02 in plant matrices and Method D1718/01 in animal matrices) were developed and proposed for data gathering and enforcement purposes. Method D1407/02 fulfilled the requirements with regards to specificity, accuracy and precision at the method limit of quantitation (0.01 ppm). Acceptable recoveries (70–120%) were obtained in plant matrices, and the method was successfully validated by an independent laboratory using various plant matrices. Method D1718/01 fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limits of quantitation (0.01 ppm/0.001ppm) for each trifludimoxazin and M850H001. Acceptable average recoveries (70–120%) were generally obtained in animal matrices, with some lower recoveries observed in bovine fat (66–69%). Although some of the values were outside the range of acceptable recoveries, the standard deviations and relative standard deviations had low variability, and were within laboratory repeatability criteria. The proposed enforcement method was successfully validated by an independent laboratory for bovine muscle, liver, fat and milk. Poultry matrices were not included in the method validation and independent laboratory validation (ILV). When a poultry feeding study is conducted, the enforcement method for animal matrices will be validated in relevant poultry matrices. Extraction solvents used in the methods were similar to those used in the metabolism studies; thus, demonstrating that extraction efficiency of bioincurred residues was not required for the enforcement method.

HPLC-MS/MS methods (D1401/02 for soil and D1724/01 for water) were also developed and proposed for data generation and enforcement purposes in soil, sediment and water. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in environmental media.

Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on human and animal health

3.1 Toxicology summary

Trifludimoxazin is a protoporphyrinogen IX oxidase (PPO) inhibitor herbicide. PPO inhibitors act by disrupting chlorophyll synthesis in plants. The same enzyme is also a component of a similar pathway in animals that is involved in heme biosynthesis. Deficiency of this enzyme is seen in humans as an autosomal dominantly inherited disease known as variegate porphyria.

A detailed review of the toxicology database for trifludimoxazin was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. Additional studies included mechanistic studies examining the thyroid toxicity pathway and studies assessing the toxicity of select metabolites of trifludimoxazin. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to characterize the potential health hazards associated with trifludimoxazin.

Metabolism and toxicokinetics in the rat were investigated using trifludimoxazin radiolabelled at the phenyl, triazine, or oxazinone ring. Trifludimoxazin was well absorbed at low dose levels, with peak plasma concentrations occurring between 8 and 24 hours. Absorption as a percent of the administered dose (AD), decreased with increasing dose level. The highest residues during the final sacrifices were found in the gut and gut contents, liver, thyroid, plasma, and kidneys. Elimination of orally-administered trifludimoxazin was rapid and extensive. The majority of the AD was recovered in the excreta within 48 hours. The major route of excretion was via the feces, with urinary excretion also representing a significant portion of the AD; a biliary excretion study indicated high absorption and excretion of orally-administered trifludimoxazin. Radioactivity in tissues 168 hours after single or repeat oral dose administration was low and there was no evidence of tissue accumulation. The distribution and excretion of radiolabel following pre-treatment with multiple non-radiolabelled doses were not significantly different from that following administration of a single radiolabelled dose. The metabolic and toxicokinetic parameters measured were comparable between sexes.

Twenty-three metabolites were identified in excreta. Additionally, unchanged trifludimoxazin was not identified in urine or bile, indicating extensive metabolism. The main biotransformation reactions of trifludimoxazin in rats are as follows: conversion of the thioxo group of the triazine ring into an oxo group; N-demethylation at the triazine ring; loss of the propyne moiety; and decomposition of the triple bond of the propyne moiety via conjugation with glutathione and subsequent stepwise cleavage of the conjugate. A pH-dependent reversible ring opening of the benzoxazine moiety was also observed.

In a number of repeat-dose oral toxicity studies, plasma levels of trifludimoxazin and metabolites M850H001, M850H002, M850H003, M850H005, M850H006, and M850H012 were determined. The identification of select metabolites is presented in Appendix I, Table 2. In rats, mice, and dogs, plasma levels of trifludimoxazin and its metabolites rose with increasing dose level, but in a non-proportional manner. The relative proportions of observed metabolites varied between species, but were usually consistent between sexes of the same species.

In acute toxicity testing, the technical grade active ingredient trifludimoxazin was of low acute toxicity via the oral, dermal, and inhalation routes in rats. It was minimally irritating to the eyes and non-irritating to the skin of rabbits. Trifludimoxazin was negative for skin sensitization in guinea pigs when tested using the Maximization method.

The end-use products Voraxor and Vulcarus were both of low acute toxicity via the oral, dermal, and inhalation routes in rats. They were minimally irritating to the eyes and slightly irritating to the skin of rabbits, and were negative for skin sensitization when tested in guinea pigs using the Buehler method.

The liver and thyroid were identified as targets of toxicity for trifludimoxazin following repeated dietary exposure in mice and rats. In addition to weight changes in these organs, histopathological alterations were observed in several studies. Liver effects observed among mice and rats included increased weight, hepatocyte enlargement, vacuolation, fatty change, multi-nucleation, single cell necrosis, and clinical chemistry effects, as well as elevated liver enzymes. Thyroid effects included increased weight, follicular cell hypertrophy or hyperplasia,

and altered colloid observed in rats in short-term and long-term dietary studies. Other effects observed in mice and rats included increases in fatty change and weight of the adrenal glands, porphyrin pigmentation in the kidneys, as well as foci and spermatogenic granulomas in the epididymides. There was no evidence that duration of dosing increased toxicity in mice or rats.

The nervous system was the primary target of toxicity for trifludimoxazin following repeated oral capsule exposure in dogs. The mid and high dose level groups were terminated early in the 90-day study due to ill health. In consideration of these results, the long-term study was dosed more conservatively, and showed no adverse toxicological effects.

In the rat acute gavage neurotoxicity study, there was no evidence of neurotoxicity up to the limit dose. The rat 90-day dietary toxicity study showed degeneration and loss of myelin in the spinal cord, though these same effects were not observed in the 2-year dietary toxicity study, possibly due to the lower dose levels tested. There was evidence of neurotoxicity in dogs in the 28- and 90-day repeat dose oral capsule administration studies, in the form of clinical signs such as unsteady gait, and microscopically as degeneration of cells in the spinal cord. There was evidence of a progressive effect for neurotoxicity, where dosing for longer periods of time correlated with increased neurotoxicity.

While trifludimoxazin is classified as a PPO inhibitor, effects relating to anemia were generally only observed at higher dose levels in mice and rats and not at all in dogs. All three test animal species showed increased porphyrins in the liver and feces following repeated dosing; however, this effect was not considered adverse in the absence of other signs of hematotoxicity.

No systemic toxicity occurred in rats following daily dermal application of trifludimoxazin up to the limit dose for 28 days.

There was no evidence of genotoxicity in a battery of in vitro and in vivo genotoxicity studies conducted with trifludimoxazin, nor was there evidence of treatment-related tumorigenicity in mice or rats after long-term dietary administration. An increased number of thyroid follicular cell tumours were observed in some dose groups in the rat two-year dietary toxicity study, and a mode of action (MOA) for the development of the thyroid tumours in rats was proposed by the applicant in conjunction with several mechanistic studies to support this proposed MOA. These studies were considered in the overall hazard characterization, however, as there was no dose-response relationship, the thyroid tumours were considered incidental to treatment. As such, a separate cancer risk assessment was not necessary.

The rat extended 1-generation dietary reproductive toxicity study with trifludimoxazin included mating of the first generation to produce a second generation. Test cohort sub-groups were established to assess the potential for neurotoxicity and immunotoxicity. No adverse impact on reproductive performance was observed, though the percentage of abnormal sperm was increased in the F1 males of the high-dose group. Liver and thyroid toxicity were observed in adult animals of both generations. In F1 offspring, there were alterations in brain morphometry parameters at the high-dose level that were considered treatment-related. At the same dose level, a slight decrease in auditory startle response amplitude and increased incidence of dilated renal pelvis were also observed. Although the effects observed on the brain and startle response are

considered serious in nature, concern for these findings is tempered by the fact that they occurred in the presence of toxicological effects in the parental animals. There was no evidence of immunotoxicity.

In the gavage developmental toxicity studies, there was no evidence of sensitivity of the young in either rats or rabbits. No adverse effects were noted in maternal animals or fetuses in the rat developmental toxicity study up to the limit dose of testing. In rabbits, decreased body weight, body weight gain, and food consumption were observed in maternal animals at the mid-dose level and above, the same dose levels where decreases in mean fetal weight occurred. At the high-dose level, aborted litters and increased post-implantation loss were observed.

The toxicity of select metabolites of trifludimoxazin was investigated to a limited extent. Metabolite M850H003 was negative in three out of four genotoxicity studies, but was positive in the presence of metabolic activation in the in vitro chromosome aberration study. Metabolite M850H012 was negative in a bacterial reverse gene mutation study, and of slight acute oral toxicity and of low acute inhalation toxicity in rats. Although there was limited information available, for the purposes of risk assessment the metabolites were considered to be of equivalent toxicity to trifludimoxazin.

The identification of select metabolites is presented in Appendix I, Table 2. Results of the toxicology studies conducted on laboratory animals with trifludimoxazin, the associated end-use products and select metabolites, are summarized in Appendix I, Tables 3, 4 and 5. The toxicology reference values for use in the human health risk assessment are summarized in Appendix I, Table 6.

Health incident reports

Trifludimoxazin is a new active ingredient pending registration for use in Canada, and as of 5 February 2020, no human, domestic animal or environment incident reports had been submitted to the PMRA.

3.1.1 *Pest Control Products Act* hazard characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the trifludimoxazin toxicity database as it pertains to the toxicity to infants and children, the database contains the full complement of required studies including gavage developmental toxicity studies in rats and rabbits, and a dietary extended 1-generation reproductive toxicity study in rats, which included two generations.

With respect to concerns regarding potential prenatal and postnatal toxicity, no evidence of sensitivity of the young was observed in the available studies. In the gavage rabbit developmental toxicity study, both dams and fetuses demonstrated effects on body weight at the

same dose level. At the highest dose-level tested, there were five aborted litters and an increase in post-implantation loss. In the extended 1-generation reproductive toxicity study, parental animals exhibited thyroid toxicity at a lower dose level than offspring, and liver toxicity at the same dose level that produced the serious effect of brain morphometric alterations and reduced auditory startle response in the offspring.

Overall, the database is adequate for determining the sensitivity of the young. There is a low level of concern for sensitivity of the young as effects on the young are well-characterized and occurred in the presence of parental toxicity. The offspring effects were considered serious endpoints although the concern was tempered by the presence of parental toxicity. Therefore, the PCPA factor was reduced to threefold when using the rat extended 1-generation reproductive toxicity study to establish the point of departure for use in risk assessment.

3.2 Acute reference dose (ARfD)

To estimate acute dietary risk, the offspring no observed adverse effect level (NOAEL) of 23 mg/kg bw/day from the extended 1-generation reproductive toxicity study in rats was selected. At the lowest observed adverse effect level (LOAEL) of 68 mg/kg bw/day, decreases in brain size measurements and auditory startle responses were observed. These effects may result from a single exposure and are therefore relevant to an acute risk assessment. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to threefold. **Thus, the composite assessment factor (CAF) is 300.**

The ARfD is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{23 \text{ mg/kg bw/day}}{300} = 0.08 \text{ mg/kg bw of trifludimoxazin}$$

3.3 Acceptable daily intake

To estimate risk following repeated (chronic) dietary exposure, the offspring NOAEL of 23 mg/kg bw/day from the extended 1-generation reproductive toxicity study in rats was selected. At the LOAEL of 68 mg/kg bw/day, decreases in brain size measurements and auditory startle responses were observed. The selection of this endpoint was considered the most relevant for the risk assessment. Although NOAELs in the 90-day dietary toxicity study in rats and for parental animals in the reproductive toxicity study were lower, at 6 mg/kg bw/day, the 2-year dietary toxicity study in rats had a NOAEL of 11 mg/kg bw/day. This suggests the NOAELs in the 90-day study and for parental animals in the reproductive toxicity study would have been higher if a dose level between 6 mg/kg bw/day and the LOAELs for these respective studies had been tested. The study NOAEL selected for the ADI combined with the CAF is protective of the effects seen at the LOAELs in both the 90-day and 2-year rat studies. Similarly, adverse effects in dogs were observed starting at 50 mg/kg bw/day and the ADI is protective of these effects at that dose level. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to three-fold. **Thus, the CAF is 300.**

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{23 \text{ mg/kg bw/day}}{300} = 0.08 \text{ mg/kg bw/day of trifludimoxazin}$$

This ADI provides a margin of 2500 to the LOAEL for abortions and post-implantation loss in the rabbit developmental toxicity study (625 to the NOAEL).

Cancer assessment

There was no evidence of treatment-related tumours; therefore, a cancer risk assessment was not necessary.

3.4 Occupational risk assessment

Occupational exposures to Vulcarus and Voraxor are characterized as short-term for farmers and intermediate-term for custom applicators, and are predominantly by the dermal and inhalation routes for mixers, loaders, and applicators. Postapplication exposures are not expected based on the proposed use patterns.

3.4.1 Toxicological reference values

Short-, intermediate-term dermal and inhalation

For short- and intermediate-term dermal and inhalation risk assessment, the offspring NOAEL of 23 mg/kg bw/day from the dietary 1-generation reproductive toxicity study in rats was selected. The available short-term dermal toxicity study did not address the endpoint of concern (developmental neurotoxicity) and a short-term inhalation toxicity study was not available, thus necessitating the use of an oral study for risk assessment. At a dose level of 68 mg/kg bw/day, offspring brain measurements and auditory startle responses were decreased in the presence of maternal toxicity (liver and thyroid effects). Worker populations could include pregnant women and therefore, this endpoint was considered appropriate for occupational risk assessment. The target margin of exposure (MOE) for these scenarios is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, as well as a factor of threefold for the reasons outlined in the *Pest Control Products Act Hazard Characterization* section. The selection of this study NOAEL and target MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Aggregate risk assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation). For trifludimoxazin, the aggregate assessment consisted of combining food and drinking water exposure only, since residential exposure is not expected. The most relevant toxicology endpoints and assessment factors for

acute and chronic oral aggregate exposure are the same as those selected for the ARfD (see section 3.2) and the ADI (see section 3.3), respectively.

Cumulative assessment

The *Pest Control Products Act* requires Health Canada's PMRA to consider the cumulative effects of pest control products that have a common mechanism of toxicity. Trifludimoxazin belongs to a class of herbicides known as PPO inhibitors. Within this class, there are several herbicides registered in Canada and internationally that have the same MOA, namely the inhibition of a key enzyme in the chlorophyll synthesis pathway, protoporphyrinogen oxidase (PPOase, also referred to as Prottox). The same enzyme and pathway are involved in heme biosynthesis in mammals, resulting in changes in hematopoietic parameters. Overall, based on the similar MOA of these compounds and as per the Agency's Cumulative Health Risk Assessment Framework (SPN2018-02), a cumulative health risk assessment of all the chemicals that belong to this cumulative assessment group (CAG) will be conducted separately.

3.4.1.1 Dermal absorption

A rat in vivo dermal absorption study was reviewed. Based on the data presented in the study, a dermal absorption value of 9% was selected for the risk assessment of trifludimoxazin.

The dermal absorption of ¹⁴C-BAS 850 H (trifludimoxazin) was studied at three dose levels in male CrI:WI (Han) rats (303–377g at 10 weeks of age) following a single dermal application of ¹⁴C-BAS 850 H in BAS 850 00 H blank solution, simulating the concentrate and spray dilutions. For dilutions, an aliquot of the radiolabelled formulation concentrate was diluted with tap water at 1:67 and 1:667. The actual dose levels of BAS 850 H were 5064 µg/cm², 76 µg/cm², and 7.5 µg/cm². Four rats per treatment per monitoring time were administered 10µL/cm² over a 10cm² shaved area of the back within a fixed glass saddle covered with gauze and bandage. Mean recoveries of radioactivity from all dose groups were in the range of 93.4 % to 107.1 % of the total radioactivity applied.

For the low-dose (1:667 dilution), mean radioactivity recovered from protective covers during the exposure period did not exceed 3.12%. The largest proportions of radioactivity, recovered from the first skin washes, were in the range of 84% to 88%. The radioactivity recovered in the tape strips and application site decreased from 8 hours to 120 hours, while recoveries of the directly absorbed dose increased (2.1% to 5.6%), indicating that residue was being absorbed during this period. The mean dermal absorption value (including skinbound residue) at termination after the 8-hour exposure period was 9.11%, and at 24 and 120 hours post-dosing were 6.25% and 6.25%, respectively.

For the mid-dose (1:67 dilution), higher recoveries were detected in the protective covers of some animals (3–21% of the radioactivity applied), which reduces the confidence in the data. In addition, at 120h, one animal was removed from the group due to a high amount of radioactivity recovered in the faeces (13% within the first 24 hours). The mean radioactive recoveries of the first skin washes were in the range of 76–94%. The radioactivity recovered in the tape strips and application site decreased from 8 hours to 120 hours, while recoveries of the directly absorbed

dose increased (2.86 to 7.03%), indicating that residue was being absorbed during this period. The mean dermal absorption value (including skinbound residue) at termination after the 8-hour exposure period was 7.74%, and at 24 and 120 hours post-dosing were 7.61% and 9.04%, respectively.

For the high-dose (concentrate), mean radioactivity recovered from the protective cover over application site skin during the exposure period ranged from 3.5–10.4% of the radioactivity applied. The mean radioactive recoveries of the first skin washes were in the range of 89–95%. The radioactivity recovered in the tape strips and application site decreased from 8 hours to 120 hours, while recoveries of the directly absorbed dose increased (0.05% to 0.16%), indicating that residue was being absorbed during this period. The mean dermal absorption value (including skinbound residue) at termination after the 8-hour exposure period was 0.79%, and at 24 and 120 hours post-dosing were 0.33 and 0.32%, respectively.

Given the uncertainty regarding deposition under actual field conditions, and based on the likely worker exposure timeframe of 10-hour workdays, it is considered appropriate to derive an estimate of dermal absorption based on the results from a monitoring interval beyond the exposure duration of 8 hours. Therefore, the most appropriate dermal absorption value is 9% (including skinbound residue) from the mid-dose (75 µg/cm²) group of animals that were terminated after a monitoring period of 120 hours.

3.4.2 Occupational exposure and risk

3.4.2.1 Mixer/loader/applicator exposure and risk assessment

Individuals have potential for exposure to Vulcarus and Voraxor during mixing, loading and application. Dermal and inhalation exposure estimates for workers were generated using the Agricultural Handlers Exposure Task Force (AHETF) database.

Exposure to workers mixing, loading and applying Vulcarus and Voraxor is expected to be short-term in duration for farmers, and intermediate-term in duration for custom applicators, and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixers, loaders, and applicators applying Vulcarus and Voraxor, as pre-seed or pre-emergent applications to listed crops and chemfallow fields, to control broadleaf weeds using ground application equipment. The exposure estimates are based on mixers, loaders, and applicators wearing a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes.

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted.

Dermal exposure was estimated by coupling the unit exposure values with the area treated per day (ATPD) and maximum application rate with the dermal absorption value. Inhalation exposure was estimated by coupling the unit exposure values with the ATPD and maximum application rate with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicological reference values (no observed adverse effects levels) to obtain the MOE; the target MOE is 300 (Table 1).

Table 1 Mixer/loader/applicator risk assessment.

Product	Exposure scenario	Unit exposure (µg/kg a.i. handled) ¹		ATPD (ha/day) ²	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day) ³	Combined MOE ⁴
		Dermal	Inhalation				
PPE: Long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes							
Vulcarus	M/L Liquid, open pour and Applicator, open cab groundboom	83.9	2.31	360	0.0375	0.00166	13822
Voraxor					0.018	0.00080	28795

¹ Unit exposures based on AHETF

² PMRA Default Area Treated per Day (2017-09-20) for custom applicators (covers farmers)

³ Daily exposure = (((Dermal Unit Exposure × Dermal Absorption Value) + Inhalation Unit Exposure) × ATPD × Rate) / (80 kg bw × 1000 µg/mg)

⁴ Combined MOE= NOAEL (mg/kg bw/day) / Daily exposure (mg/kg/day); NOAEL of 23 mg/kg bw/day; and target MOE = 300

3.4.2.2 Exposure and risk assessment for workers entering treated areas

The treatment is directed towards weeds or soil in fields as a pre-seeding or pre-emergence application to crops. Worker dermal exposure is expected to be negligible, as there is minimal contact with the treated weeds and ground. Inhalation exposure is considered minimal, as trifludimoxazin is not volatile. Therefore, a quantitative post-application worker risk assessment is not required.

3.4.2.3 Bystander exposure and risk

Bystander exposure is considered negligible as application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings. Therefore, bystander exposure and risk are not of health concern since the potential for drift is expected to be minimal.

3.5 Concentrations in drinking water

Modelling estimates

Environmental concentrations of trifludimoxazin in potential drinking water sources were estimated using numerical models for human health risk assessment. Modelling was conducted using the Pesticides in Water Calculator (PWC) version 1.52, using standard PMRA scenarios which take into account regional weather and soil characteristics as well as relevant plant properties.

Environmental water monitoring data can complement modelling estimates and are considered in conjunction with each other when estimating the potential exposure to humans. Monitoring information was not available for trifludimoxazin.

Application information and model inputs

A subset of use-patterns was considered which is intended to represent all labelled uses. The use-pattern selected for the modelling of trifludimoxazin was one application of 37.5 g a.i./ha using ground application equipment, which encompasses both the highest single and yearly rate. As the intended crops are spring-planted grains, chemfallow land and winter grains, trifludimoxazin can be applied in Canada between April and October. For drinking water, trifludimoxazin was modelled as a combined residue with the transformation products M850H001, M850H002 and M850H003. The environmental fate modelling inputs for the drinking water assessment are listed below in Table 2.

Table 2 Major fate input parameters for the drinking water modelling.

Fate parameter	Drinking water
Residues modelled	Trifludimoxazin, M850H001, M850H002 and M850H003
Adsorption K_d	4.67
Hydrolysis half-life at pH 7 and 20°C (days)	277
Photolysis half-life in water at 30°N latitude (days)	32
Aerobic soil biotransformation half-life at 20°C (days)	559
Aerobic aquatic biotransformation half-life at 20°C (days)	426
Anaerobic aquatic biotransformation half-life at 20°C (days)	817 (trifludimoxazin alone) Stable (combined residues)

3.5.1 Estimated concentrations in drinking water sources

For the human health assessment, estimated concentrations in potential drinking water sources were determined for both groundwater and surface water.

For surface water, PWC calculates the amount of pesticide entering the water body by runoff and drift, and the subsequent degradation of the pesticide in the water system. Concentrations were calculated by modelling a total land area of 173 ha draining into a 5.3 ha reservoir with a depth of 2.7 m. Groundwater concentrations were calculated by simulating leaching through a layered soil profile and reporting the average concentration in the top 1 m of a water table.

Drinking water modelling follows a tiered approach consisting of progressive levels of refinement. Level 1 concentrations are conservative values intended to screen out pesticides that are not expected to pose any concern related to drinking water. These are calculated using conservative inputs with respect to application rate, application timing, and geographic scenario. Level 2 concentrations are based on a narrower range application timing, methods, and geographic scenarios, and are not considered conservative values that cover all regions of Canada.

Modelling was performed at Level 1. Concentrations for surface water were calculated based on a single standard scenario. Concentrations in groundwater were calculated for several scenarios representing different regions of Canada; only the highest concentrations from across these scenarios are reported. Modelling runs were based on 50-year simulations. Level 1 concentrations, expressed as parent equivalent, are reported in Table 3.

Table 3 Estimated environmental concentrations of combined residues of trifludimoxazin in potential drinking water sources as parent equivalent.

Use pattern	Groundwater (µg a.i./L)		Surface water (µg a.i./L)		
	Daily ¹	Yearly ²	Daily ³	Yearly ⁴	Overall ⁵
1 × 37.5 g a.i./ha	6.3	6.2	2.6	0.34	0.19

¹90th percentile of daily average concentrations

²90th percentile of 365-day moving average concentrations

³90th percentile of the peak concentrations from each year

⁴90th percentile of yearly average concentrations

⁵Average of all yearly average concentrations

3.6 Food residues exposure assessment

3.6.1 Residues in plant and animal foodstuffs

The residue definition for enforcement in plant products and animal commodities is trifludimoxazin. The data gathering/enforcement analytical methods are valid for the quantitation of trifludimoxazin residues in plant and animal matrices. Residues of trifludimoxazin are stable in high-water commodities (apples, lettuce), high-protein (field beans), high-starch (wheat grain, potatoes), high-acid (oranges), and dry feed (pea hay), when stored frozen for up to 37 months. Residues of parent are stable up to 42 months in high-oil commodity (dry soybeans). A comparison of the metabolic profiles for each of the individual animal matrices tested in the livestock metabolism studies demonstrated that these were qualitatively comparable when poultry matrices were stored for up to 27 months and ruminant matrices were stored for up to 31 months at -20°C. Quantifiable residues of trifludimoxazin are not expected to occur in livestock matrices with the current use pattern. Crop field trials conducted throughout Canada and the United States using end-use products containing trifludimoxazin applied at approved rates to legume vegetables, citrus fruits, pome fruits, tree nuts, peanuts, and cereal grains are sufficient to support the proposed maximum residue limits. Field rotational crop studies were conducted in/on radish, lettuce and wheat.

3.6.2 Dietary risk assessment

Chronic (non-cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™).

3.6.2.1 Acute dietary exposure results and characterization

The following assumptions were applied in the basic acute analysis for trifludimoxazin: 100% crop treated, default processing factors (where available), recommended MRLs for legume vegetables, citrus fruits, pome fruits, tree nuts, peanuts, and cereal grains. The recommended MRLs in eggs, milk, meat, meat byproducts of cattle, goats, hogs, horses, poultry and sheep were also included. The basic acute dietary exposure from all supported trifludimoxazin food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 1.9% of the acute reference dose (ARfD). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that acute dietary exposure to trifludimoxazin from food and drinking water is 0.9% (0.000755 mg/kg bw/day) of the ARfD for the total population (95th percentile, deterministic). The highest exposure and risk estimate is for children 1–2 years old at 2.1% (0.001698 mg/kg bw/day) of the ARfD.

3.6.2.2 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic (non-cancer) analysis for trifludimoxazin: 100% crop treated, default processing factors (where available), and recommended MRLs in/on legume vegetables, citrus fruits, pome fruits, tree nuts, peanuts, and cereal grains. The recommended MRLs in eggs, milk, meat, meat byproducts of cattle, goats, hogs, horses, poultry and sheep were also included. The basic chronic dietary exposure from all supported trifludimoxazin food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 1% of the acceptable daily intake. Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to trifludimoxazin from food and drinking water is 0.4% (0.000296 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children 1–2 years old at 1.2% (0.000964 mg/kg bw/day) of the ADI.

3.6.3 Aggregate exposure and risk

The aggregate risk for trifludimoxazin consists of exposure from food and drinking water sources only; there are no residential uses.

3.6.4 Maximum residue limits

Table 4 Recommended maximum residue limits

MRL (ppm)	Food commodity
0.01	Legume vegetables (crop group 6), citrus fruits (crop group 10 revised), pome fruits (crop group 11-09), tree nuts (crop group 14-11), cereal grains (crop group 15), peanuts, eggs, fat, meat, meat byproducts of cattle, goats, hogs, horses, poultry and sheep, milk

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the [Residue Chemistry Crop Groups](#) webpage in the Pesticides section of Canada.ca. For

additional information on Maximum Residue Limits (MRLs) in terms of the international situation and trade implications, refer to Appendix II.

The nature of the residues in animal and plant matrices, analytical methodologies, field trial data, and dietary risk estimates are summarized in Appendix I, Tables 1, 7 and 8.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

A summary of the physical and chemical properties and environmental fate characteristics of trifludimoxazin are outlined in Appendix I, Tables 9 and 10.

4.1.1 Physical and chemical properties

Trifludimoxazin (BAS 850 H) has low solubility in water (1.78 mg/L at pH 7) indicating it has a low potential for transport in surface runoff and for reaching groundwater by percolation through soil. Trifludimoxazin is non-volatile from soil and water based on its vapour pressure (1.1×10^{-10} Pa at 20°C) and Henry's law Constant ($1/H = 9.56 \times 10^{10}$ at 20°C) and thus, not expected to be present in the atmosphere. Although, the octanol-water partitioning coefficient of trifludimoxazin ($\log K_{ow} = 3.33$) indicates it has a potential to bioaccumulate, accumulation in fish was low (bioconcentration factor = 51.9–81.5) with nearly all residues (>95%) being eliminated rapidly from fish tissues after 7 days, thereby showing it has a low potential to accumulate in biota.

4.1.2 Fate in the terrestrial environment

4.1.2.1 Transformation

In the terrestrial environment, trifludimoxazin (BAS 850 H) will undergo degradation to several transformation products primarily through biotransformation in soil. A record of these transformation products is summarized in Appendix I, Table 11. Of these transformation products, seven have been identified as major transformation products (>10% of applied) and were designated as M850H001, M850H002, M850H003, M850H004, M850H012, M850H033 and M850H040.

Of the transformation processes in soil, hydrolysis of trifludimoxazin would not occur under acidic conditions (pH 4 and 5) and similarly, under neutral conditions (pH 7), hydrolysis would be a very slow process (half-life = 244 days). Under alkaline soil conditions (pH 9.0), however, trifludimoxazin can transform rapidly via hydrolysis (half-life = 0.55 days). The major transformation products of hydrolysis were M850H004, M850H040, M850H012 and M850H033. Phototransformation of trifludimoxazin on soil was slow (half-life = 36 days) and hence, not a major route of transformation; the major phototransformation products were M850H001 and M850H002.

Biotransformation of trifludimoxazin was the primary route of transformation in aerobic soil. Under laboratory conditions, trifludimoxazin was non-persistent to moderately persistent in aerobic soil ($DT_{50} = 11.8$ – 87.4 days). The major transformation products were M850H001,

M850H002 and M850H003. Once formed in aerobic soil, M850H001 showed slow transformation whereas M850H002 decreased steadily over time. M850H003 was the most persistent of the three transformation products as it did not readily transform once formed in aerobic soil.

Under anaerobic soil conditions, trifludimoxazin was moderately persistent to persistent (DT_{50} = 58.1–383 days). The major transformation products were M850H001, M850H002, M850H003 and M850H004. Once formed in anaerobic soil, M850H001 decreased steadily over time and M850H002 was moderately persistent (DT_{50} = 49.8–92 days). M850H003 and M850H004 showed slow transformation in anaerobic soil.

Under terrestrial field conditions, trifludimoxazin dissipated rapidly from soil (DT_{50} = 1.3–9.1 days) and was classified as non-persistent. The major transformation products identified were M850H001, M850H002 and M850H003. M850H001 was non-persistent to moderately persistent (DT_{50} = 1.2–65.9 days), M850H002 was moderately persistent (DT_{50} = 65.1–91.2 days) and M850H003 was persistent (DT_{50} = 332–995 days) in soil.

4.1.2.2 Mobility in soil

The parent trifludimoxazin overall had lower mobility in soil than its transformation products. In soil mobility studies, trifludimoxazin had medium to low mobility in soil based on its soil adsorption coefficient (K_{oc} = 336.3–812.7). M850H001 and M850H002 had high to medium mobility (K_{oc} = 52.1–181.5 and 139.6–500, respectively), M850H003 showed very high to medium mobility (K_{oc} = 33.1–206.6) and M850H004 had medium to low mobility (K_{oc} = 224.9–1410).

Mobility in soil was further examined using both the leaching potential criteria of Cohen et al. (1984) and the groundwater ubiquity score (Gustafson, 1989). Although trifludimoxazin met some of the criteria of Cohen et al. (1984), it did not meet the criterion for solubility in water, hydrolysis, dissociation constant and adsorption. On this basis, trifludimoxazin is not expected to leach appreciably through the soil column. Using the most conservative aerobic soil half-life (226 days) and corresponding K_{oc} (509.3) for trifludimoxazin, the groundwater ubiquity score (GUS) was determined to be 3.04 indicating it is classified as a leacher (>2.8). For major transformation products, using the most conservative aerobic soil half-life and corresponding K_{oc} values, the GUS values for M850H003 and M850H004 were 5.03 and 1.53 corresponding to the classifications of leacher and non-leacher, respectively.

Under field conditions, trifludimoxazin did leach to soil depths of 61.0 cm indicating it has the potential to reach groundwater. Similarly, M850H001 and M850H003 leached to soil depths of 45.7 cm indicating a potential to reach groundwater. M850H002 was not considered a leacher as it did not leach beyond a soil depth of 30.5 cm.

Overall, given the mobility classifications and the leaching results from field studies, the parent trifludimoxazin and its transformation products, M850H001, M850H002 and M850H003, have the potential to leach to groundwater.

4.1.3 Fate in the aquatic environment

4.1.3.1 Transformation

In the aquatic environment, trifludimoxazin can transform rapidly through hydrolysis under alkaline conditions (pH 9). Under neutral conditions (pH 7), hydrolysis will be slow (half-life = 95 days) and hydrolysis will not occur under acidic conditions (pH 4 and 5). There are four major transformation products of hydrolysis including M850H004, M850H040, M850H012 and M850H033. Phototransformation of trifludimoxazin was relatively slow in water (half-life = 10.5 days) thus, not considered as a major route of transformation.

Under laboratory conditions, trifludimoxazin was non-persistent to moderately persistent in aerobic aquatic systems (DT_{50} = 3.5–94.8 days). Three major transformation products were formed: M850H001, M850H004 and M850H035. Once formed under aerobic aquatic conditions, these transformation products decreased steadily over time.

In anaerobic aquatic systems, trifludimoxazin was non-persistent to moderately persistent (DT_{50} = 6.0–83.2 days). Four major transformation products were formed; M850H002, M850H004, M850H033 and M850H042. Once formed under anaerobic aquatic conditions, M850H004 and M850H042 were slow to transform whereas, M850H002 and M850H033 decreased steadily over time.

A record of the transformation products identified in aquatic systems is summarized in Appendix I, Table 11.

4.1.3.2 Partitioning in aquatic systems

Trifludimoxazin has the potential to partition into aquatic sediments where it is expected to transform to residues that become bound to sediments. In aerobic aquatic systems, 75–78% of the trifludimoxazin in the water phase partitioned to the sediment after 100 days with non-extractable residues increasing over time in amounts of 10.2–42.6% of applied trifludimoxazin. No major transformation products were detected in the sediment of aerobic and anaerobic aquatic systems; minor transformation products were $\leq 5\%$ of applied parent.

4.2 Environmental risk characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated EECs are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species

sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value ($RQ = \text{exposure}/\text{toxicity}$), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

The environmental risk of trifludimoxazin and its related end-use product to non-target organisms was assessed based upon the maximum annual application rate of 37.5 g a.i./ha for Vulcarus (trifludimoxazin alone) and 167 g end-use product/ha for Voraxor (trifludimoxazin in combination with saflufenacil); equivalent to 18 g a.i./ha for trifludimoxazin and 36 g a.i./ha for saflufenacil.

4.2.1 Risks to terrestrial organisms

In determining the risk to terrestrial organisms, uncertainty factors are applied to acute toxicity endpoints (for example, LC_{50} or LD_{50}) to generate endpoint values that are used in calculating risk quotients ($RQ = \text{exposure}/\text{endpoint value}$). No uncertainty factors are applied to chronic endpoints (for example, NOEC). For earthworms and beneficial arthropods, the acute endpoint is divided by the uncertainty factor of 2 and the resulting risk quotient (RQ) is compared to the LOC of 1. For birds and mammals, the acute endpoint is divided by the uncertainty factor of 10 and the resulting RQ is also compared to the LOC of 1. For bees, the acute endpoint is used directly (with no uncertainty factor) to calculate the RQ which is compared to the LOC of 0.4. With terrestrial plants, the acute endpoint (in other words, HR_5 of EC_{50} values) is used directly without an uncertainty factor to calculate the RQ which is then compared to the LOC of 1.

A summary of the effects on terrestrial organisms considered in the selection of toxicity endpoints is provided in Appendix I, Table 12. The most sensitive terrestrial endpoints used in the risk assessment are provided in Appendix I, Table 14.

The screening level risk assessment for terrestrial organisms other than birds and mammals is summarized in Appendix I, Table 15. The screening level risk for birds and mammals is summarized in Appendix I, Tables 16 and 17, respectively.

When used according to approved label directions, the LOC was not exceeded and the risks associated with trifludimoxazin are acceptable for the following terrestrial organisms:

- Earthworms
- Pollinators
- Beneficial arthropods
- Wild birds and mammals

The LOC for trifludimoxazin is exceeded for terrestrial vascular plants, however, with the observance of preventative measures and use-restrictions to reduce exposure, the risks are acceptable.

4.2.1.1 Screening level risk assessment for terrestrial organisms

The screening level risk assessment was based on the maximum ground application rate of 37.5 g a.i./ha for Vulcarus (BAS 850 00H) and 167 g end-use product/ha for Voraxor (BAS 851 00H) and the most sensitive endpoints within each group of terrestrial organism. When the LOC was exceeded further characterization of the risk was completed and presented in section 4.2.1.2.

Terrestrial Invertebrates: The LOC was not exceeded in all terrestrial invertebrate species tested representing earthworms, pollinators and beneficial arthropods for the application of Vulcarus and Voraxor.

Non-Target Terrestrial Plants: For non-target vascular plants, an HR₅ (hazard rate affecting 5% of the population) value was determined based on a species sensitivity distribution of the ER₅₀ values for plant dry weight in vegetative vigour tests. The HR₅ of 1.3 g a.i./ha, resulted in an RQ (EEC/HR₅) of 288.5 indicating that the LOC was exceeded.

Terrestrial Vertebrates: For birds and small mammals, the LOC was not exceeded for all feeding guilds.

4.2.1.2 Further characterization of risk assessment for terrestrial organisms

For those organisms where the LOC was exceeded, further characterization of exposure was conducted which considered off-target spray drift when trifludimoxazin is applied as a broadcast spray using field sprayers. The off-target spray drift considered is 6% of the application rate at one metre downwind from the point of application for field sprayers if the spray quality (droplet size distribution) used is classified as ASAE Medium.⁵ The 6% value is derived from the PMRA spray drift model for field sprayers based on data generated by Wolf and Caldwell (2001). Here, the EEC of 2.25 g a.i./ha resulting from spray drift (6% of maximum applied rate for a medium spray quality) was used to assess the risk to terrestrial non-target plants.

⁵ Droplet size classification system of the American Society of Agricultural Engineers (ASAE) based on the volume median diameter (VMD) of spray droplets.

Non-target terrestrial plants: For non-target plants that are exposed to spray drift at one metre downwind from the point of application, the LOC is exceeded (RQ = 17.3) (Appendix I, Table 18). Therefore, spray drift buffer zones will be required to mitigate the risk.

4.2.2 Risks to aquatic organism

A summary of the effects on aquatic organisms considered in the selection of toxicity endpoints is provided in Appendix I, Table 13. The most sensitive aquatic endpoints used in the risk assessment are provided in Appendix I, Table 14.

When used according to approved label directions, the risks are acceptable to the following aquatic organisms from the use of trifludimoxazin:

- Freshwater and marine invertebrates
- Marine algae

The level of concern for trifludimoxazin was exceeded for the following organisms. With the addition of preventative measures to reduce drift and precautionary measures to inform users of the potential for surface runoff, the risks are acceptable for:

- Freshwater algae
- Aquatic vascular plants
- Freshwater and marine fish
- Amphibians

4.2.2.1 Screening level risk assessment for aquatic organisms

The screening level risk assessment (Appendix I, Table 19) was based on the maximum ground application rate of 37.5 g a.i./ha for Vulcarus (BAS 850 00H), 167 g end-use product/ha for Voraxor (BAS 851 00H) and the most sensitive endpoints within each group of aquatic organisms. The screening level EECs considered for the application of Vulcarus were 25 µg a.i./L (amphibian habitat) and 4.7 µg a.i./L (shallow pond). For Voraxor, the screening level EECs considered was 21.0 µg end-use product/L (shallow pond). When the level of concern was exceeded, further characterization of the risk was completed and presented in section 4.2.2.2.

Aquatic invertebrates: The screening level RQs for freshwater and marine invertebrates (RQ = 0.00049-0.59) did not exceed the LOC for these organisms for the application of Vulcarus and Voraxor, hence, the risks are acceptable.

Aquatic vertebrates (fish and amphibians): The acute risks for freshwater fish (RQ = 0.03), for marine fish (RQ = 0.016) and amphibians (RQ = 0.15) did not exceed the LOC for these organisms, hence, the acute risks are acceptable. Similarly, the chronic risk in freshwater fish (RQ = 0.39) did not exceed the LOC. If, however, the USEPA's molar threshold approach is considered that takes into account enhanced toxicity due to UV-light exposure that is characteristic of protoporphyrinogen oxidase (PPO) inhibitors, the chronic risk in freshwater fish (RQ = 5.7) exceeded the LOC. The chronic risks in marine fish (RQ = 1.7) and amphibians (RQ

= 2.1) did exceed the LOC. In addition, in considering the USEPA's molar threshold approach, the chronic risk in marine fish ($RQ = 5.7$) and amphibians ($RQ = 30.5$) also exceeded the LOC. Thus, further refinement to the risk assessment was considered for chronic exposure in freshwater and marine fish and amphibians.

Aquatic plants: The risks to freshwater algae ($RQ = 11.7\text{--}47$) and vascular aquatic plants ($RQ = 23.3\text{--}81.0$) exceeded the LOC with the application of Vulcarus and Voraxor, hence, further refinement to the risk assessment was conducted for these organisms.

4.2.2.2 Further characterization of risk assessment for aquatic organisms

For those organisms where the LOC was exceeded, further characterization of exposure was conducted which considered off-target spray drift and surface runoff when trifludimoxazin is applied as a broadcast spray using field sprayers. The refined risk to aquatic organisms is provided in Appendix I, Table 20.

The off-target spray drift considered is 6% of the application rate at one metre downwind from the point of application for field sprayers if the spray quality (droplet size distribution) used is classified as ASAE Medium.⁶ The 6% value is derived from the PMRA spray drift model for field sprayers. The EECs of trifludimoxazin resulting from spray drift for Vulcarus are $1.5\ \mu\text{g a.i./L}$ (amphibian habitat) and $0.28\ \mu\text{g a.i./L}$ (shallow pond). For Voraxor, the EECs of trifludimoxazin resulting from spray drift are: $0.14\ \mu\text{g a.i./L}$ (shallow pond) and $0.74\ \mu\text{g a.i./L}$ (amphibian habitat).

Surface runoff was considered in which the EECs were modelled based on a 10-ha watershed adjacent to a 1-ha water body of 15-cm deep (amphibian habitat) or 80-cm deep (shallow pond). The model calculates the amount of pesticide entering the water body by runoff and the subsequent degradation of the pesticide in the water and sediment. Deposition of pesticide on the water body due to spray drift is not included. The model estimates are based on 50-year simulations. The parameters used for the modelling are presented in Table 2.

Aquatic vertebrates: For spray drift entering aquatic systems, the chronic risk in freshwater and marine fish ($RQ_{\text{drift}} = 0.34$) did not exceed the LOC. For amphibians, the chronic risk ($RQ_{\text{drift}} = 1.8$) exceeded the LOC, hence, spray drift mitigation is required for these organisms.

For exposure through surface runoff entering aquatic systems, the chronic risk in freshwater and marine fish ($RQ_{\text{runoff}} = 2.8$) and amphibians ($RQ_{\text{runoff}} = 10.7$) exceeded the LOC. Hence, precautionary measures for surface runoff entering aquatic systems are required for these organisms.

Aquatic plants: For spray drift entering aquatic systems, the risks to freshwater algae ($RQ = 2.8$) and aquatic vascular plants ($RQ = 4.8$) exceeded the LOC for Vulcarus. For Voraxor, the risk to freshwater algae ($RQ = 0.7$) did not exceed the LOC however, the risk to aquatic vascular

⁶ Droplet size classification system of the American Society of Agricultural Engineers (ASAE) based on the volume median diameter (VMD) of spray droplets.

plants (RQ = 1.4) exceeded the LOC. Hence, spray drift mitigation is required for these organisms.

Exposure through surface runoff is based on the highest 96-h EEC which resulted from modelling the use-pattern scenario for Prince Edward Island (PEI) as typically, the PEI scenario generates the highest EECs given the unusual occurrence of severe rainstorm events. The LOC was exceeded in freshwater vascular plants and freshwater algae for both Vulcarus (RQ = 43.1 and RQ = 25, respectively) and Voraxor (RQ = 12 and RQ = 6, respectively). Moreover, the 96-h EECs determined for the other regions of Canada were also considered to further characterize exposure through surface runoff. In considering other regions of Canada, the RQs for freshwater algae and aquatic vascular plants also exceeded the LOC (RQ = 3–18 and RQ = 5.2–31, respectively, for Vulcarus and RQ = 1.4–4.3 and RQ = 1.4–8.6, respectively, for Voraxor) (Appendix I, Tables 21 and 22). It should be noted that, the modelling estimates of surface runoff are based on historical meteorological data which includes the frequency, intensity and duration of rainfall events. The modelling however, does not consider infiltration of runoff into soil and the filtering effects of riparian zones that border aquatic habitats. As a result, the refined modelling of surface runoff remains fairly conservative indicating that there may be an overestimation of the risk. In addition, the effects on aquatic vascular plants and algae are expected to be transitory given their rapid recovery as trifludimoxazin is non-persistent to moderately persistent in aquatic systems. Nonetheless, precautionary measures for surface runoff entering aquatic systems are required for these organisms.

Overall, the risks to freshwater algae and aquatic vascular plants can be effectively mitigated through precautionary measures and the requirement of spray buffer zones for the application of Vulcarus and Voraxor.

4.3 Risk mitigation

4.3.1 Spray drift

Trifludimoxazin can enter aquatic and terrestrial habitats through spray drift. The observance of buffer zones, however, can effectively mitigate the risk of spray drift to aquatic and terrestrial organisms. Pesticide spray drift from field sprayers (ground boom) is predicted using a model that is based on the data of Wolf and Caldwell (2001). Buffer zones are, therefore, required for broadcast applications of trifludimoxazin to mitigate spray drift.

4.3.2 Surface runoff

Trifludimoxazin can enter aquatic habitats through surface runoff. There are precautionary measures that are required on product labels to minimize the risk of aquatic contamination from surface runoff.

5.0 Value

Vulcarus and Voraxor provide pre-plant or pre-emergent burndown control of several broadleaf weeds, including key weeds present in agricultural systems, in the early season with soil residual activity. Applications of these herbicides reduces early season weed competition to the emerging

crop, allowing the crop to benefit from additional moisture, nutrients, and light that would otherwise be captured by weeds. Management of weeds at this time is critical, as crops do not compete well with weeds until crop canopy closure. As trifludimoxazin and saflufenacil have some soil residual activity, the reduction in competition of weeds with the crop is extended.

Vulcarus and Voraxor are both Group 14 herbicides that may help growers to manage serious weeds which are resistant to other modes of action, including Group 2 resistant kochia and wild mustard, Group 5 resistant redroot pigweed and lamb's-quarters, and Group 4 and Group 5 resistant wild mustard.

5.1 Vulcarus

Value information submitted for review included data from 40 efficacy trials, 37 dedicated crop tolerance trials, and 16 rotational crop tolerance trials. The trials were conducted in the Canadian Prairies and Ontario between 2014 and 2018, and Nebraska and Washington State in 2012, at sites representing a range of soil types and climate conditions.

In the efficacy trials, it was demonstrated that a pre-plant or pre-emergent application of Vulcarus at 50-75 mL/ha with Merge Adjuvant at 0.5% v/v provided acceptable burndown control of kochia (suppression only), lamb's-quarters, volunteer canola (all types including Roundup Ready), cleavers, and wild buckwheat (suppression only at 75 mL/ha).

The trial data also demonstrated that the application of Vulcarus plus Merge Adjuvant in tank mix with glyphosate herbicides provided improved burndown weed control.

In residual efficacy trials, it was shown that a pre-plant or pre-emergent application of Vulcarus at 50–75 mL/ha provided acceptable suppression of un-emerged weeds, including volunteer canola, kochia, lamb's-quarters, redroot pigweed, and wild mustard.

Efficacy data also indicated that Vulcarus should be applied at the higher rate for longer residual weed control or when high weed populations were expected. Efficacy of Vulcarus was maximized when it was applied to actively growing weeds less than 15 cm in height.

In the host crop tolerance trials, it was demonstrated that visual crop injury was either minor or not observed for field corn, soybean, wheat (spring, durum, and winter), and spring barley and yield of these crops was unaffected. Injury to field pea was observed in the early season in some trials, but outgrown in the late season and yield of field pea was unaffected.

Data from the rotational crop tolerance trials in conjunction with data from the host crop tolerance trials demonstrated that:

- Field corn, field pea, soybean, wheat (spring, durum, and winter), and spring barley can be planted as rescue crops if the initial planting of the host crop fails.
- Winter wheat as a rotational crop can be safely planted three months after the application of Vulcarus.

- Field corn, canola, field pea, soybean, wheat (spring and durum), spring barley, dry common bean, flax, lentil, and mustard as rotational crops can be safely planted any time in the year following the application of Vulcarus.

5.2 Voraxor

Value information submitted for review included scientific rationales and data from 40 efficacy trials, 48 dedicated crop tolerance trials, and 14 rotational crop tolerance trials. The trials were conducted in the Canadian Prairies and Ontario between 2014 and 2018, and Nebraska and Washington State in 2012, at sites representing a range of soil types and climate conditions.

Efficacy data in conjunction with scientific rationales demonstrated that a pre-plant or pre-emergent application of Voraxor at 48–72 mL/ha with Merge Adjuvant at 0.5% v/v can be expected to provide acceptable burndown control of Canada fleabane, cleavers, kochia, lamb's-quarters, narrow-leaved hawk's beard, redroot pigweed, round-leaved mallow, shepherd's purse, stinkweed, volunteer canola (all types including Roundup Ready), wild buckwheat, and wild mustard.

The efficacy data also demonstrated that Voraxor plus Merge Adjuvant can be applied in tank mix with glyphosate herbicides for improved burndown weed control.

Data from the residual efficacy field trials in conjunction with scientific rationales demonstrated that that a pre-plant or a pre-emergent application of Voraxor at 100–144 mL/ha can be expected to provide further suppression of the secondary weed flushes of cleavers, kochia, lamb's-quarters, redroot pigweed, stinkweed, volunteer canola, wild buckwheat, and wild mustard.

A pre-plant or pre-emergent application of Voraxor in tank mix with Zidua SC Herbicide for additional early season residual weed suppression is supported based on the registration of Zidua SC Herbicide and the supported use pattern for Voraxor.

Data from the efficacy trials also indicated that Voraxor should be applied at the higher rates for longer residual control or when high weed populations were expected. Efficacy of Voraxor was maximized when it was applied to actively growing weeds less than 15 cm in height.

In the host crop tolerance trials, it was demonstrated that visual crop injury was either minor or not observed for barley, field corn, lentil, soybean, wheat (spring, durum, and winter) and yield of these crops was unaffected. Injury to field pea was observed in the early season in some trials, but outgrown in the late season and yield of field pea was unaffected.

Data from the rotational crop tolerance trials in conjunction with data from host crop tolerance trials demonstrated that:

- Barley, field corn, lentil, field pea, soybean, and wheat (spring, durum, and winter) can be planted as rescue crops if initial planting of the host crop fails.
- Winter wheat as a rotational crop can be safely planted three months after the application of Voraxor.

- Barley, canola, field corn, lentil, field pea, soybean, wheat (spring and durum), dry common bean, flax, and mustard as rotational crops can be safely planted anytime in the year following the application of Voraxor.

6.0 Pest control product policy considerations

6.1 Toxic substances management policy considerations

The Toxic Substances Management Policy (TSMP)⁷ is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, trifludimoxazin and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria. The PMRA has reached the following conclusion that trifludimoxazin and its transformation products do not meet all of the Track 1 criteria. Please refer to Appendix I, Table 23 for further information on the TSMP assessment.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern⁸. The list is used as described in the PMRA Notice of Intent NOI2005-01⁹ and is based on existing policies and regulations including the Toxic Substances Management Policy and the Formulants Policy,¹⁰ and taking into consideration the Ozone-depleting Substance and Halocarbon Alternatives Regulations, under the *Canadian Environmental Protection Act, 1999* (substances designated under the Montreal Protocol).

The PMRA has reached the conclusion that trifludimoxazin and the end-use products Vulcarus and Voraxor do not contain any formulants or contaminants in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

⁷ DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

⁸ SI/2005-114, last amended on June 25, 2008. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

⁹ PMRA's Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*

¹⁰ DIR2006-02, *Formulants Policy and Implementation Guidance Document*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human health and safety

The toxicology database is adequate to characterize the potential hazards associated with trifludimoxazin. There was no evidence of tumourigenicity in rats or mice after long-term dosing. No evidence of genotoxicity was demonstrated. There was no evidence of increased sensitivity of the young in reproductive or developmental toxicity studies. In short-term and chronic studies on laboratory animals, the primary targets were the liver and thyroid. Additionally, signs of neurotoxicity were observed in adult animals in the short-term dog studies and in young animals in the rat reproductive toxicity study. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Mixers, loaders, and applicators handling Vulcarus and Voraxor, and workers entering treated fields are not expected to be exposed to levels of trifludimoxazin that will result in an unacceptable risk when the products are used according to label directions. The personal protective equipment on the product labels is adequate to protect workers.

The nature of the residues in plants and animals is adequately understood. The residue definition for enforcement is trifludimoxazin in plant products and in animal matrices. The proposed domestic use of trifludimoxazin on dry lentils (including Clearfield lentils), dry field peas, dry soybeans, field corn, wheat, barley and imported commodities (citrus fruits, pome fruits, tree nuts, peanuts, edible beans, edible peas and cereal grains) does not constitute a health risk of concern for acute or chronic dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. The PMRA recommends that the following MRLs be specified for residues of trifludimoxazin.

MRL (ppm)	Food commodity
0.01	Legume vegetables (crop group 6), citrus fruits (crop group 10 revised), pome fruits (crop group 11-09), tree nuts (crop group 14-11), cereal grains (crop group 15), peanuts, eggs, fat, meat, meat byproducts of cattle, goats, hogs, horses, poultry and sheep, milk

7.2 Environmental risk

The risks associated with the use of trifludimoxazin through the application of Vulcarus and Voraxor at the proposed application rates are acceptable provided that precautionary measures and spray buffer zones on the product labels are followed. The risks posed by trifludimoxazin were acceptable for all terrestrial organisms (earthworms, beneficial arthropods, pollinators (bees), birds and small mammals) except for non-target terrestrial plants. Moreover, the risks posed by trifludimoxazin were acceptable for freshwater and marine invertebrates and marine algae but did pose risks to amphibians, freshwater and marine fish, freshwater algae and aquatic

vascular plants. To mitigate the risk of spray drift to non-target terrestrial plants, aquatic vascular plants and freshwater algae, spray buffer zones and standard precautionary label statements alerting users of the potential for runoff are required on the product labels of Vulcarus and Voraxor.

7.3 Value

The registrations of Vulcarus and Voraxor will provide Canadian growers with options for pre-plant and pre-emergent burndown control of several broadleaf weeds in the early field season with some soil residual activity. They control key weeds which are present in agricultural systems, including volunteer canola and Group 2 resistant kochia.

Value information consisting of data from replicated field trials and scientific rationales demonstrated that the pre-plant and pre-emergent applications of Vulcarus and Voraxor can be expected to provide burndown control of a number of broadleaf weeds and suppression of secondary weed flushes in barley, field corn, field pea, soybean, wheat, lentil, and in chemfallow situations.

7.4 Toxic substance management policy considerations

Trifludimoxazin does not meet any TSMP criteria for a Track 1 (virtual elimination) substance.

8.0 Proposed regulatory decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Tirexor Herbicide Technical, Vulcarus and Voraxor, containing the technical grade active ingredient trifludimoxazin, to control weeds in barley, field corn, field pea, soybean, wheat, lentil, and chemfallow.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

Additional information being requested

Since this technical product is manufactured only at pilot scale before registration, five-batch data representing commercial-scale production will be required as post-market information after registration.

List of abbreviations

↑	increased
↓	decreased
♂	male
♀	female
µg	microgram(s)
a.e.	acid equivalent
a.i.	active ingredient
AD	administered dose
ADI	acceptable daily intake
AHETF	Agricultural Handlers Exposure Task Force
ALT	alanine aminotransferase
AR	applied radioactivity
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
atm	atmosphere
ATPD	area treated per day
AUC	area under curve
BCF	bioconcentration factor
BROD	7-benzyloxyresorufin-O-debenzylase
bw	body weight
bwg	bodyweight gain
CAF	composite assessment factor
CAG	cumulative assessment group
CAS	Chemical Abstracts Service
cm	centimetre(s)
cm ³	cubic centimetre(s)
d	day(s)
DALA	days after last application
DCM	dichloromethane
DEEM-FCID	Dietary Exposure Evaluation Model – Food Commodity Intake Database
DT ₅₀	dissipation time 50% (time required to observe a 50% decline in concentration)
dw	dry weight
EC ₅₀	effective concentration 50%
EDE	estimated daily exposure
EEC	estimated environmental concentration
ER ₂₅	effective rate for 25% of the population
ER ₅₀	effective rate on 50% of the population
EROD	7-ethoxyresorufin O-dealkylase
F1	first generation
fc	food consumption
FIR	food ingestion rate
FOB	functional observational battery
g	gram(s)
h	hour(s)
ha	hectare(s)

HAFT	highest average field trial
Hb	hemoglobin
Hct	hematocrit
HC ₅	hazard concentration affecting 5% of the population
HDPE	high-density polyethylene
HPLC	high performance liquid chromatography
HR ₅	hazard rate affecting 5% of the population
HRAC	Herbicide Resistance Action Committee
1/H	Henry's Law Constant
¹²⁵ I	radiolabelled iodine
IC ₅₀	inhibition concentration 50%
ILV	independent laboratory validation
IUPAC	International Union of Pure and Applied Chemistry
K _d	adsorption coefficient
kg	kilogram(s)
K _{oc}	adsorption quotient normalized to organic carbon
K _{ow}	octanol water partition coefficient
L	litre(s)
LAFT	lowest average field trial
LC50	concentration estimated to be lethal to 50% of the test population
LD50	dose estimated to be lethal to 50% of the test population
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOQ	limit of quantitation
LR ₅₀	lethal rate 50%
LSC	liquid scintillation counting
m	metre(s)
MAS	maximum average score for 24, 48 and 72 hours
MCH	mean corpuscular hemoglobin
MCV	mean corpuscular volume
mg	milligram(s)
mg eq/kg	milligram equivalent per kilogram
MIS	maximum irritation score
mL	millilitre(s)
MS/MS	tandem mass spectrometry
MOA	mode of action
MOE	margin of exposure
MRL	maximum residue limit
MUF-GT	4-methylumbeliferone-glucuronyltransferase
m/z	mass-to-charge ratio of an ion
NA	not applicable
NMR	nuclear magnetic resonance
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NR	not reported
OC	organic carbon

P	parental generation
Pa	pascal(s)
PBI	plantback interval
PCPA	<i>Pest Control Products Act</i>
PES	postextraction solids
PHI	preharvest interval
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PPO	protoporphyrinogen oxidase
PROD	pentoxyresorufin o-dealkylase
PTU	propylthiouracil
RAC	raw agricultural commodity
RBC	red blood cells
RD	residue definition
rel	relative
S9	mammalian metabolic activation system
SC	soluble concentrate
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TGAI	technical grade active ingredient
TP	transformation product
TRR	total radioactive residue
TSH	thyroid stimulating hormone
TSMP	<i>Toxic Substances Management Policy</i>
UDP-GT	uridine diphosphate glucuronyltransferase
UF	uncertainty factor
US	United States
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
wk	week
WSSA	Weed Science Society of America
wt	weight

Appendix I Tables and figures

Table 1 Residue analysis

Analytical methods	Matrices	Analyte	Method ID/ type	Limit of quantitation	Reference (PMRA#)
Livestock Commodities					
Enforcement Method	Bovine muscle, kidney, liver, fat and milk	Trifludimoxazin	D1718/01/ LC-MS/MS	0.01 ppm for tissues; 0.001 ppm for milk	2923883
ILV of Enforcement Method	Bovine muscle, liver, fat and milk	Trifludimoxazin	D1718/01/ LC-MS/MS	0.01 ppm for tissues; 0.001 ppm for milk	2923886
Plant Commodities					
Enforcement Method	Apples, soybeans, wheat grain, oranges, dry field bean	Trifludimoxazin	D1407/02/ LC-MS/MS	0.01 ppm	2923880
ILV of Enforcement Method	Apples, kidney bean, dry soybean, oranges and potatoes	Trifludimoxazin	D1407/02/ LC-MS/MS	0.01 ppm	2923881
Environmental matrices					
Data-gathering and enforcement Method	Soil and sediment	Parent, M850H001, M850H002, M850H003, M850H004	D1401/02; HPLC-MS/MS	0.001 mg/kg	2923888, 2923775
	Water	Parent, M850H001, M850H002, M850H003, M850H004, M850H012, M850H035	D1724/01; HPLC-MS/MS	0.03 µg/L	2923891, 2923893
ILV of Soil Method	Soil and sediment	Parent, M850H001, M850H002, M850H003, M850H004	D1401/02; LC-MS/MS	0.001 ppm	2923887
ILV of Water Method	Water	Parent, M850H001, M850H002, M850H003, M850H004, M850H012, M850H035	D1724/01; LC-MS/MS	0.03 µg/L	2923890

Table 2 Chemical identities of select trifludimoxazin metabolites

Metabolite	Chemical name
M850H001	1,3-dimethyl-5-(2,2,7-trifluoro-3-oxo-4-prop-2-ynyl-1,4-benzoxazin-6-yl)-1,3,5-triazinane-2,4,6-trione
M850H003	1,3-dimethyl-5-(2,2,7-trifluoro-3-oxo-4H-1,4-benzoxazin-6-yl)-1,3,5-triazinane-2,4,6-trione
M850H005	1-methyl-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-2,4,6-trione
M850H006	1-methyl-3-(2,2,7-trifluoro-3-oxo-3,4-dihydro-2H-1,4-benzoxazin-6-yl)-1,3,5-triazinane-2,4,6-trione
M850H012	6-amino-2,2,7-trifluoro-4-prop-2-ynyl-1,4-benzoxazin-3-one

Table 3 Toxicity profile of Voraxor containing trifludimoxazin

Effects are known or assumed to occur in both sexes unless otherwise noted.

Study type/animal/PMRA#	Study results
Acute Oral Toxicity (Gavage) Wistar rats PMRA# 2924191	LD50 > 2000 mg/kg bw (♀) No clinical signs of toxicity Low toxicity
Acute Dermal Toxicity Wistar rats PMRA# 2924192	LD50 > 5000 mg/kg bw (♂/♀) No clinical signs of toxicity Low toxicity
Acute Inhalation Toxicity Wistar rats PMRA# 2924193	LC50 > 3.2 mg/L (♂/♀) Clinical signs of toxicity included intermittent respiration, abdominal respiration, colorless or red discharge of the nose, red encrusted nose, hunched posture, poor general condition, unsteady gait, no feces, piloerection and substance-contaminated fur; two females died during treatment Low toxicity
Eye Irritation New Zealand White rabbits PMRA# 2924195	MAS = 0.2/110 MIS = 4.7/110 at 1 h Minimally irritating
Dermal Irritation New Zealand White rabbits PMRA# 2924194	MAS = 0.9/8 MIS = 1.8 at 1 h Slightly irritating
Skin Sensitization, Buehler Method Hartley guinea pigs PMRA# 2924196	Negative

Table 4 Toxicity profile of Vulcarus containing trifludimoxazin

Effects are known or assumed to occur in both sexes unless otherwise noted.

Study type/animal/PMRA#	Study results
Acute Oral Toxicity (Gavage) Wistar rats PMRA# 2924259	LD50 > 2000 mg/kg bw (♀) Clinical signs of toxicity included impaired general state, piloerection, and reduced defecation Low toxicity
Acute Dermal Toxicity Wistar rats	LD50 > 5000 mg/kg bw (♂/♀) No clinical signs of toxicity

Study type/animal/ PMRA#	Study results
PMRA# 2924260	Low toxicity
Acute Inhalation Toxicity	LC50 > 3.4 mg/L (♂/♀)
Wistar rats	Clinical signs of toxicity included intermittent respiration, hunched posture, poor general state, piloerection, injury on the left side of the head, and substance-contaminated fur; one female died during treatment
PMRA# 2924261	Low toxicity
Eye Irritation	MAS = 0.6/110 MIS = 2.7/110 at 24 h Minimally irritating
New Zealand White rabbits	
PMRA# 2924263	
Dermal Irritation	MAS = 1.3/8 MIS = 2/8 at 0 h Slightly irritating
New Zealand White rabbits	
PMRA# 2924262	
Skin Sensitization, Buehler Method	Negative
Hartley guinea pigs	
PMRA# 2924264	

Table 5 Toxicity profile of technical trifludimoxazin

Effects observed in both sexes are presented first followed by sex-specific effects in males, then females, each separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted. Effects seen above the LOAEL(s) have not been reported in this table for most studies for reasons of brevity.

Study type/ animal/PMRA#	Study results
Toxicokinetic Studies	
Absorption, distribution, metabolism, excretion	Trifludimoxazin was orally administered to ♂ and ♀ rats by single gavage doses of 5 or 100 mg/kg bw (triazine or phenyl radiolabel), doses of 1/1, 6/7, 30/35, 75/75, 100/110, 150/150 mg/kg bw (♂/♀; phenyl radiolabel), or multiple gavage doses for 14 days of unlabelled trifludimoxazin followed by a single radiolabelled dose at 100 mg/kg bw (triazine or phenyl label). Additionally, an intravenous administration was also performed at 1.0 mg/kg bw (phenyl radiolabel). An oxazinone 15N radiolabel was included in some of the phenyl radiolabel treatment groups for further metabolite identification.
Wistar rat	
PMRA# 2923894, 2923895	
	Kinetics: Trifludimoxazin was readily absorbed from the gastrointestinal tract after oral administration and reached maximum plasma concentrations (depending on the sex and the dose level) between 8 and 24 h post-dosing. Bile excretion experiments showed that for both sexes and radiolabel positions, 46–60% of the AD was absorbed at a target dose level of 100 mg/kg bw, whereas 81–91% of the AD was absorbed at a target dose level of 5 mg/kg bw. Excretion of radioactive residues occurred mainly within three days after dosing with a high urinary excretion, especially at the lower dose level. After 14 oral administrations with unlabelled trifludimoxazin at 100 mg/kg bw and one oral

Study type/ animal/PMRA#	Study results
	<p>administration with labelled trifludimoxazin at 100 mg/kg bw, urinary excretion was similar to single dosing.</p> <p>Plasma kinetics demonstrated fast excretion and a sublinear correlation of the internal exposure to the oral dose. The highest residues during the final sacrifices were found in the gut and gut contents, liver, thyroid, plasma, and kidneys. There was no evidence of tissue accumulation.</p> <p>Tissue distribution experiments confirmed a lack of accumulation and showed generally a sublinear correlation between the radioactive residues in organs and tissues and the external dose. The qualitative distributions in tissues were assessed to be generally comparable between doses and radiolabel positions. The radioactive residue concentrations generally declined in organs and tissues parallel to the radioactive residues in plasma for the low and high dose levels.</p> <p>Metabolism: The high number of identified metabolites and the absence of unchanged trifludimoxazin, particularly in urine and bile, indicate extensive metabolism. The main biotransformation reactions of trifludimoxazin in rats are conversion of the thioxo group of the triazine ring into an oxo group, N-demethylation at the triazine ring, loss of the propyne moiety, decomposition of the triple bond of the propyne moiety via conjugation with glutathione and subsequent stepwise cleavage of the conjugate, and/or a reversible ring opening of the benzoxazine moiety</p>
Acute Toxicity Studies	
Acute Oral Toxicity (Gavage) Wistar rats PMRA# 2923901	LD ₅₀ > 2000 mg/kg bw No clinical signs of toxicity Low toxicity
Acute Dermal Toxicity Wistar rats PMRA# 2923902	LD ₅₀ > 5000 mg/kg bw No clinical signs of toxicity Low toxicity
Acute Inhalation Toxicity Wistar rats PMRA# 2923903	LC ₅₀ > 2.665 mg/L Clinical signs of toxicity included labored and abdominal respiration, noisy respiration, closed eyelid and red encrusted eye, and substance-contaminated fur Low toxicity
Eye Irritation New Zealand White rabbits PMRA# 2923905	MAS = 0.2/110 MIS = 0.7/110 at 1 h Minimally irritating
Dermal Irritation New Zealand White rabbits PMRA# 2923904	MAS = 0/8 MIS = 1/8 at 1 h Non-irritating
Skin Sensitization, Maximization Method	Negative

Study type/ animal/PMRA#	Study results
Hartley guinea pigs PMRA# 2923906	
Short-Term Toxicity Studies	
28-Day Dermal Toxicity Wistar rats PMRA# 2923916	NOAEL = 1000 mg/kg bw/day LOAEL = Not determined No treatment-related adverse effects.
28-Day Oral Toxicity (Diet) C57BL mice PMRA# 2923907	NOAEL = 149/194 mg/kg bw/day (♂/♀) LOAEL = 224/261 mg/kg bw/day (♂/♀) Effects at the LOAEL: ↓ bw, ↓ bwg, ↓ fc, ↓ water consumption, ↓ albumin, ↑ triglycerides, ↑ centrilobular and diffuse hepatocellular hypertrophy, ↑ cytoplasmic vacuolation of proximal tubular epithelial cells (♂/♀); ↑ ALT, ↓ total protein, ↓ seminal vesicle wt, ↑ coagulative necrosis of hepatocytes and ↑ multinucleated hepatocytes, hepatocellular cytoplasmic macrovesicular vacuolar change, ↓ RBC, ↓ Hb, ↓ Hct (♂); ↑ apathy, hunched posture, poor general condition, semi-closed eyelid, high stepping gait, hyperplasia/hypertrophy of interstitial stromal cells in ovaries, diffuse atrophy of the uterus and epithelial hypertrophy with mucification in the vagina (♀)
90-Day Oral Toxicity (Diet) C57BL mice PMRA# 2923910	NOAEL = 80/106 mg/kg bw/day (♂/♀) LOAEL = 170/217 mg/kg bw/day (♂/♀) Effects at the LOAEL: ↑ liver wt, ↑ multifocal hepatocellular necrosis, ↑ hepatocellular pigmentation (♂/♀); ↑ hepatocellular hypertrophy, ↑ Kupffer cell pigmentation, ↑ epithelial hypertrophy of adrenal cortex (♂); ↑ thymus wt, ↑ multifocal hepatocellular necrosis, ↑ hepatocellular fatty change (midzonal), ↑ epithelial hypertrophy of the vagina (♀)
28-Day Oral Toxicity (Diet) Wistar rats PMRA# 2923908	NOAEL = Not established LOAEL = 90/79 mg/kg bw/day (♂/♀) Effects at the LOAEL: ↑ liver wt, ↑ pigment storage in kidney, ↑ follicular hypertrophy/hyperplasia and altered colloid in the thyroid (♂/♀); ↑ rel thyroid wt, ↑ discolouration of the liver, fatty change in the adrenal gland, ↑ immature epididymal ducts and interstitial edema, ↑ pigmentation in liver (♂)
90-Day Oral Toxicity (Diet) Wistar rats PMRA# 2923911	NOAEL = 6/7 mg/kg bw/day (♂/♀) LOAEL = 33/36 mg/kg bw/day (♂/♀) Effects at the LOAEL: ↑ epithelial degeneration/regeneration of Harderian gland (♂/♀)
90-Day Oral Toxicity (Diet) Wistar rats, ♀ only PMRA# 2923912	NOAEL was not established as study was considered supplemental 286 mg/kg bw/day (♀): ↓ bw and fc, ↓ activity, ↑ stiff or unsteady gait during FOB, ↑ microcytic hypochromic anemia, ↑ urinary bilirubin and urobilinogen (breakdown products of porphyrins), ↓ Hb, ↓ HCT, ↓ MCV, ↓ MCH, ↓ albumin, ↑ RBC, ↑ liver wt, ↑ axonal degeneration and loss of myelin in the fasciculus gracilis of the cervical cord 430 mg/kg bw/day (♀): All animals sacrificed moribund days 8-9, ↓ general condition, ↑ piloerection, ataxia, high-stepping gait, ↓ bw and fc, clinical pathology and pathology not assessed No treatment- related effects in motor activity testing.

Study type/ animal/PMRA#	Study results
28-Day Oral Toxicity (Capsule) Beagle dogs PMRA# 2923909	NOAEL = 750/500 mg/kg bw/day (♂/♀) LOAEL = Not determined/750 mg/kg bw/day (♂/♀) Effects at the LOAEL: ↑ minimal degeneration of the fasciculus gracilis in the dorsal part of the cervical cord, ↑ degeneration of the fasciculus gracilis in the thoracic spinal cord, unsteady gait/vomiting (♀)
90-Day Oral Toxicity (Capsule) Beagle dogs PMRA# 2923913	NOAEL = Not established LOAEL = 50 mg/kg bw/day (♂/♀) Effects at the LOAEL: ↑ soft feces, ↑ unsteady gait (gradual and progressive), ↑ paralysis of limbs, ↑ wide stance at this dose level and typically ↑ in severity with ↑ dose, ↑ degeneration of nervous system tissues (cervical cord, thoracic cord, lumbar cord, medulla oblongata), ↑ lesions of fasciculus gracilis (electron microscopic examination revealed degeneration of myelin sheath, occasional myelin figures, cellular debris within myelin sheaths, and axons with reduced myelin sheaths), ↑ fecal and liver porphyrin levels (♂/♀); ↓ sperm in epididymis (♂); ↓ vagina/cervix/uterus size (♀)
Chronic Toxicity/Oncogenicity Studies	
12-Month Oral Toxicity (Capsule) Beagle dogs PMRA# 2923915	NOAEL = 15 mg/kg bw/day (♂/♀) LOAEL = Not determined No treatment-related adverse effects.
18-Month Oral Toxicity (Diet) C57BL/6 J Rj mice PMRA# 2923926	NOAEL = 55/67 mg/kg bw/day (♂/♀) LOAEL = 109/132 mg/kg bw/day (♂/♀) Effects at the LOAEL: ↑ liver wt, ↑ thyroid follicular cell hyperplasia (♂/♀); ↑ hepatocellular hypertrophy, ↑ centrilobular pigment storage, slight ↑ fatty change in liver (♂); ↓ bw, ↓ bwg, ↓ fc, ↑ hepatic oval cell hyperplasia, ↑ hepatocellular necrosis, ↑ concretion of gallbladder (likely porphyrin) (♀) No evidence of treatment-related tumourigenicity
24-Month Oral Toxicity with 12-Month Satellite Group (Diet) Wistar rats PMRA# 2923923	NOAEL = 11/16 mg/kg bw/day (♂/♀) LOAEL = 33/47 mg/kg bw/day (♂/♀) The NOAEL and LOAEL above represent the full study values; the corresponding satellite group NOAEL and LOAEL are at equivalent dietary levels, but are marginally higher when calculated as mg/kg bw/day Satellite group Effects at the LOAEL: ↑ liver wt (♂/♀); ↓ triglycerides, ↑ thyroid wt, ↑ discoloured liver (♂); ↑ cholesterol, ↑ total protein, ↑ albumin, ↑ globulin (♀) Full study Effects at the LOAEL: ↑ liver wt, ↑ pigment in kidneys, ↑ multinucleated hepatocytes, ↑ altered colloid and follicular cell hyperplasia in thyroid (♂/♀); ↑ epididymal foci and spermatogenic granulomas (♂); ↑ bile duct hyperplasia (♀) No evidence of treatment-related tumourigenicity
Developmental/Reproductive Toxicity Studies	
Extended 1-Generation Reproductive Toxicity (Diet) First generation was mated to produce a	Parental NOAEL = 6.4/6.7 mg/kg bw/day (♂/♀) Parental LOAEL = 21/23 mg/kg bw/day (♂/♀) Effects at the LOAEL: ↑ thyroid follicular cell hypertrophy/hyperplasia P/F1 (♂/♀), ↑ altered colloid in thyroid P/F1, ↑ TSH F1 (♂)

Study type/ animal/PMRA#	Study results
second generation Immunotoxicity (F1) and neurotoxicity (F2) cohorts were included Wistar rats PMRA# 2923933	Reproductive NOAEL = 21/68 mg/kg bw/day (♂/♀) Reproductive LOAEL = 64 mg/kg bw/day Not determined (♂/♀) Effects at the LOAEL: ↑ abnormal sperm F1 (♂) Offspring NOAEL = 23 mg/kg bw/day Offspring LOAEL = 68 mg/kg bw/day Effects at the LOAEL: ↑ dilated renal pelvis F2, ↓ auditory startle response F2 (♂/♀); ↓ size in the frontal cortex, nucleus caudatus, and corpus callosum F2 (♂) No evidence of sensitivity of the young or developmental immunotoxicity in the F1 generation when tested via immunization to sheep RBCs
Developmental Toxicity (Gavage) Wistar rats PMRA# 2923934, 2923935, 2923936	Maternal NOAEL = 1000 mg/kg bw/day Maternal LOAEL = Not determined No treatment-related adverse effects Developmental NOAEL = 1000 mg/kg bw/day Developmental LOAEL = Not determined No treatment-related adverse effects No evidence of sensitivity of the young No evidence of treatment-related malformations
Developmental Toxicity (Gavage) New Zealand White rabbits PMRA# 2923937	Maternal NOAEL = 50 mg/kg bw/day Maternal LOAEL = 200 mg/kg bw/day Effects at the LOAEL: ↓ bw, ↓ bwg, ↓ fc Developmental NOAEL = 50 mg/kg bw/day Developmental LOAEL = 200 mg/kg bw/day Effects at the LOAEL: ↓ mean fetal wt No evidence of sensitivity of the young No evidence of treatment-related malformations
Genotoxicity Studies	
Bacterial reverse mutation <i>S. typhimurium</i> strains TA1535, TA1537, TA98 and TA100, and E coli strain WP2uvrA PMRA# 2923917	Negative ± metabolic activation Tested up to limit concentration
Bacterial reverse mutation <i>S. typhimurium</i> strains TA1535, TA1537, TA98 and TA100, and E coli strain WP2uvrA PMRA# 2923918	Negative ± metabolic activation Tested up to limit concentration

Study type/ animal/PMRA#	Study results
Bacterial reverse mutation <i>S. typhimurium</i> strains TA1535, TA1537, TA98 and TA100, and E coli strain WP2uvrA PMRA# 2923919	Negative ± metabolic activation Tested up to limit concentration
Chromosome aberration Chinese hamster (V79) in vitro PMRA# 2923921	Negative ± metabolic activation Tested up to cytotoxic concentration
Mammalian cell forward gene mutation Mouse lymphoma L5178Y cells in vitro PMRA# 2923920	Negative ± metabolic activation Tested up to cytotoxic concentration
Micronucleus (Gavage) NMRI mouse bone marrow in vivo PMRA# 2923922	Negative 2000 mg/kg bw: piloerection, hunched posture, reduced general condition
Neurotoxicity Studies	
Acute Neurotoxicity (Gavage) Wistar rats PMRA# 2923938	NOAEL = 2000 mg/kg bw (♂/♀) LOAEL = Not determined (♂/♀) No treatment-related adverse effects. No evidence of neurotoxicity
Mechanistic Studies	
Liver Enzyme Induction Dietary, 14 days Wistar rats PMRA# 2923929	NOAEL was not established as study was considered supplemental ≥ 3.5/3.7 mg/kg bw/day: ↑ thyroid follicular cell hypertrophy/hyperplasia (♂) ≥ 17/21 mg/kg bw/day: ↑ liver, thyroid wt (♂/♀); ↑ T4-UDP-GT, ↑ EROD, ↑ MUF-GT (♀) ≥ 50/52 mg/kg bw/day: ↑ TSH, ↑ T4-UDP-GT, ↑ PROD, BROD (♂); ↑ thyroid follicular cell hypertrophy/hyperplasia (♀)
Thyroid Perchlorate Discharge Assay Dietary, 14 days Wistar rats PMRA# 2923930	NOAEL was not established as study was considered supplemental 140/131 mg/kg bw/day: ↑ thyroid wt, ↑ 125I uptake by thyroid Results consistent with phenobarbital control (non-TPO inhibitor) and not PTU positive control (TPO inhibitor)

Study type/ animal/PMRA#	Study results
Metabolite Studies	
M850H003	
Bacterial reverse mutation <i>S. typhimurium</i> strains TA1535, TA1537, TA98 and TA100, and E coli strain WP2uvrA PMRA# 2923940	Negative ± metabolic activation Tested up to limit concentration
Mammalian cell forward gene mutation Mouse lymphoma L5178Y cells in vitro PMRA# 2923939	Negative ± metabolic activation Tested up to limit of solubility under culture conditions
Chromosome aberration Chinese hamster (V79) in vitro PMRA# 2923941	Positive in the presence of S9 at dose levels that were not cytotoxic Negative in the absence of S9 Tested up to limit of solubility under culture conditions
Micronucleus (Gavage) NMRI mouse bone marrow in vivo PMRA# 2923942	Negative 800 mg/kg bw: one mortality, piloerection, hunched posture, irregular respiration, reduced general condition
M850H012	
Acute Oral Toxicity (Gavage) Wistar rats PMRA# 2923944	LD50 between 500 and 2000 mg/kg bw (♀) Clinical signs of toxicity included impaired or poor general state, dyspnea, and piloerection; there was one death at 300, one death at 500 and three deaths at 2000 mg/kg bw Slight acute toxicity
Acute Inhalation Toxicity Wistar rats PMRA# 2923945	LC50 > 5.3 mg/L (♂/♀) No clinical signs of toxicity Low acute toxicity
Bacterial reverse mutation <i>S. typhimurium</i> strains TA1535, TA1537, TA98 and TA100, and E coli strain WP2uvrA PMRA# 2923943	Negative Tested up to a cytotoxic concentration

Table 6 Toxicology reference values for use in health risk assessment for trifludimoxazin

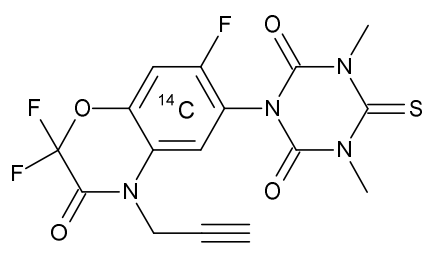
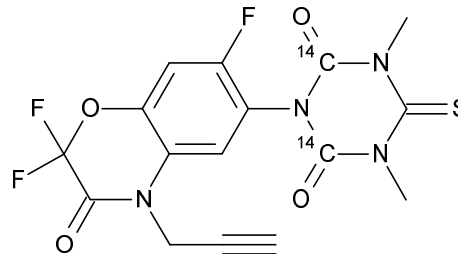
Exposure scenario	Study	Point of departure and endpoint	CAF ¹ or target MOE
Acute dietary	Extended 1-generation reproductive toxicity study in rat (dietary)	Offspring NOAEL = 23 mg/kg bw/day Decreased size in brain measurements and reduced auditory startle response ARfD = 0.08 mg/kg bw	300
Repeated dietary (Chronic)	Extended 1-generation reproductive toxicity study in rat (dietary)	Offspring NOAEL = 23 mg/kg bw/day Decreased size in brain measurements and reduced auditory startle response ADI = 0.08 mg/kg bw/day	300
Short-term, intermediate-term dermal ² and inhalation ³	Extended 1-generation reproductive toxicity study in rat (dietary)	Offspring NOAEL = 23 mg/kg bw/day Decreased size in brain measurements and reduced auditory startle response	300
Cancer	A cancer risk assessment was not required		

¹ CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational assessments.

² Since an oral NOAEL was selected, a dermal absorption factor of 9% was used in a route-to-route extrapolation.

³ Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 7 Integrated food residue chemistry summary

POSITIONS OF RADIOLABELS FOR PLANT AND ANIMAL METABOLISM STUDIES	
Phenyl-U-¹⁴C 	Triazine-2,4-¹⁴C 
NATURE OF THE RESIDUE IN LAYING HEN	
PMRA # 2923955	
For both radiolabels, total identified residues in egg yolk were 91–97% of the TRRs (5.25–5.358 ppm), and total characterized residues were 1–3% of the TRRs (0.071–0.139 ppm). In liver, muscle, and fat, total identified residues were 74–100% of the TRRs (0.351–15.277 ppm), and total characterized residues were 0.4–13% of the TRRs (0.009–0.377 ppm). Post-extraction solids from liver and egg yolk were subjected to enzyme hydrolyses which released an additional 11–13% of the TRRs (0.254–0.299 ppm), and 1–2% of the TRRs (0.016–0.104 ppm), respectively.	
Species and Numbers	Laying hen (<i>Gallus gallus</i> ; Isa Warren, Warren Brown); 10 hens (phenyl) and 9 hens (triazine)
Radiolabel position	[Phenyl-U- ¹⁴ C]-Trifludimoxazin (specific activity: 2.1 MBq/mg) [Triazine-2,4- ¹⁴ C]-Trifludimoxazin (specific activity: 1.7 MBq/mg)
Average dose	12.37 ppm (phenyl); 11.88 ppm (triazine)
Treatment Regimen	Gelatin capsule administered once daily using oral dosing gun.
Study period	14 consecutive days
Collection time	Twice daily for eggs when available.
Tissues collected	Liver, fat (peritoneal, subcutaneous), muscle (thigh, breast)
Other collected specimens	Blood, GI tract and contents, partially formed eggs, carcass and bile (where available); cage wash.

Interval from last dose to sacrifice	6 hours										
Plateau of residues in eggs	Day 10–13 at approximately 2 ppm										
Extraction solvents	Egg white, liver, muscle: Sequentially with MeOH; MeOH:H ₂ O (4:1, v/v); MeOH:H ₂ O (3:7; v/v) Fat and egg yolk: Sequentially with dichloromethane; MeOH; MeOH:H ₂ O (4:1; v/v)										
Distribution of Radioactivity in Laying Hens Following Administration of [Phenyl-U-¹⁴C]/ [Triazine-2,4-¹⁴C]-Trifludimoxazin.											
Matrices	% Administered Dose					Measured TRRs by Combustion (ppm)					
Excreta	65.6–71.3					4.7–8.6					
Cage Wash and Rinse	6.0–6.3					0.6					
GI Tract	0.7–1.2					3.1–4.0					
GI contents	0.5–2.1					1.5–2.8					
Residual carcass	8.3					2.2					
Pooled Egg Yolk (day 9–13)	2.9–3.2					5.2–5.7					
Pooled Egg White (day 9–13)	1.2					0.7					
Partly Formed Eggs	1.3–2.0					-					
Liver	0.4–0.6					2.0–2.8					
Peritoneal fat	3.6					16.2–17.4					
Subcutaneous fat	4.7					7.5					
Breast muscle	0.9					0.3–0.5					
Leg/thigh muscle	1.4					0.9–1.5					
TOTAL	92.2–93.2					-					
Extractability of Radioactive Residues in Tissues and Eggs and Overall Calculated TRRs.											
Matrices	TRR¹	Extract 1²		Extract 2²		Extract 3²		Total Extractables³		PES⁴	
	ppm	%TRRs	ppm	%TRRs	ppm	%TRRs	ppm	%TRRs	ppm	%TRRs	ppm
[Phenyl-U-¹⁴C]- and [Triazine-2,4-¹⁴C]-Trifludimoxazin											
Egg yolk	5.446	65.7	3.703	29.7	1.612	2.5	0.147	97.7	5.315	1.8	0.106
	5.892	68.0	3.867	30.1	1.772			98.3	5.786	2.4	0.131
Egg white	0.698	88.4	0.618	5.1	0.035	0.2	0.001	95.3	0.670	0.3	0.002
	0.699	94.4	0.661	6.1	0.042	0.8	0.010	99.7	0.697	4.7	0.028
Liver	1.967	77.2	1.590	4.9	0.097	1.2	0.026	87.1	1.713	11.9	0.254
	2.817	80.9	2.175	9.7	0.273	1.3	0.034	88.1	2.482	12.9	0.335
Breast muscle	0.354	87.3	0.317	7.4	0.026	0.4	0.001	97.3	0.344	2.7	0.010
	0.552	89.6	0.481	9.6	0.053		0.003	97.4	0.537		0.015
Leg/thigh muscle	1.016	92.4	0.939	4.6	0.058	0.1	0.001	98.2	0.998	0.7	0.010
	1.462	94.5	1.383	5.7	0.067	0.2	0.002	99.3	1.452	1.8	0.018
Peritoneal fat	15.537	96.3	14.959	2.6	0.433	0.2	0.002	100.1	15.521	0.1	0.016
	16.662	97.3	16.210	3.6	0.560			100.1	16.645		0.017
Subcutaneous fat	7.731	91.2	7.058	6.9	0.551	0.3	0.018	99.6	7.708	0.2	0.016
	7.985	92.6	7.400	8.1	0.627	0.4	0.023	99.9	7.969	0.3	0.023
¹ Overall Calculated TRR = Sum of extractable residues from combined solvent extracts and unextractable (PES) residues											
² For calculations, values <0.001 ppm or <0.1% of the TRRs were set as 0.001 ppm or 0.1% of the TRRs											
³ Total Extractables = sum of solvent extracts											
⁴ Postextraction solids											
Note: Depending on the matrices: Extract 1: 1× dichloromethane; 2× MeOH; Extract 2: 2× MeOH/H ₂ O (4:1); 3× MeOH Extract 3: 2× MeOH/H ₂ O (3:7); 2× MeOH/H ₂ O (4:1)											
Summary of Major Metabolites Identified in Hen Matrices											
Radiolabel Position	[Phenyl-U-¹⁴C]- and [Triazine-2,4-¹⁴C]-Trifludimoxazin										
Egg yolk	Trifludimoxazin; M850H001										
Egg white	Trifludimoxazin; M850H001; M850H040										
Liver	Trifludimoxazin; M850H001; M850H003										

Muscle	Trifludimoxazin; M850H001
Fat	Trifludimoxazin; M850H001

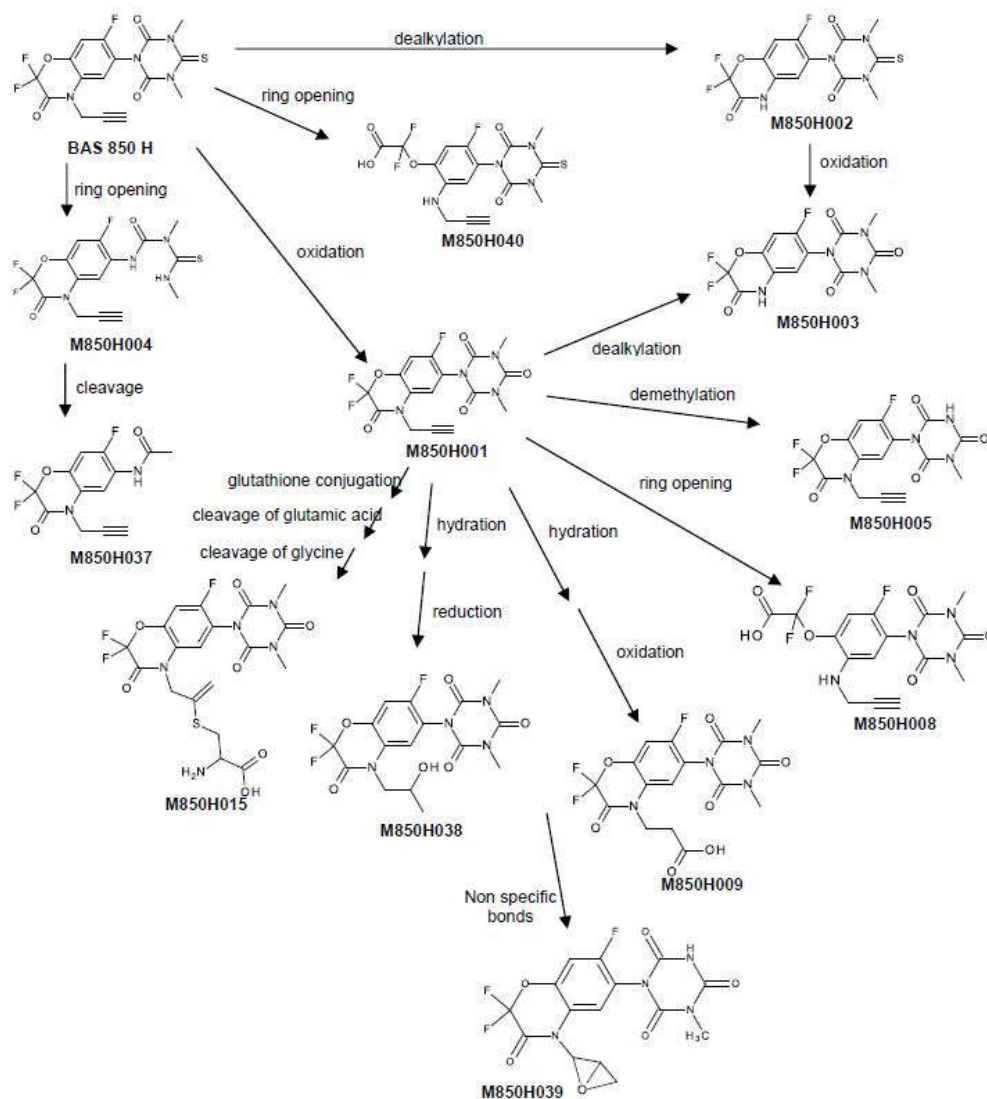
NATURE OF THE RESIDUE IN LACTATING GOAT		PMRA # 2923956; 2923957	
For both radiolabels in milk (skim and cream), total identified residues were 41–96% of the TRRs (0.022–0.968 ppm), and total characterized residues were 5–45% of the TRRs (0.026–0.044 ppm), leaving 0.1–3% of the TRRs (0.001–0.019 ppm) as post-extraction solids (PES). In liver, kidney, muscle, and fat, total identified residues were 74–105% of the TRRs (0.094–0.662 ppm), and total characterized residues were 4–26% of the TRRs (0.012–0.169 ppm) with remaining PES of 0.1–5.0% of the TRRs (0.001–0.017 ppm). Liver PES were subjected to protease treatment, which released an additional 7–8% of the TRRs (0.042–0.057 ppm).			
Species and Numbers	Lactating goat (<i>Capra hircus</i>); 2 goats per radiolabel		
Radiolabel position	[Phenyl-U- ¹⁴ C]-Trifludimoxazin (specific activity: 2.07 MBq/mg) [Triazine-2,4- ¹⁴ C]-Trifludimoxazin (specific activity: 1.96 MBq/mg)		
Average dose	11 ppm for each radiolabel		
Treatment Regimen	Gelatin capsule administered once daily using oral dosing gun.		
Study period	7 consecutive days		
Collection time	Twice daily for milk		
Tissues collected	Liver, kidneys, fat (omental, renal, subcutaneous), muscle (flank, loin)		
Other collected specimens	Blood, GI tract and contents, skin and carcass, brain, spinal cord, bone marrow, bile, and cage wash.		
Interval from last dose to sacrifice	4–6 hours		
Plateau of residues in milk	Day 3-6 at approximately 0.1 ppm		
Extraction solvents	Liver, kidney, muscle: 2× MeOH; 2× MeOH: H ₂ O (4:1; v/v); 2× MeOH: H ₂ O (3:7; v/v) Skim milk: 3× MeOH Cream: 1× DCM; 3x MeOH Fat: 1× DCM; 2× MeOH; 2× MeOH: H ₂ O (4:1; v/v)		
Distribution of Radioactivity in Lactating Goats.			
Matrices	[Phenyl-U- ¹⁴ C]-Trifludimoxazin/[Triazine-2,4- ¹⁴ C]-Trifludimoxazin		
	% Administered Dose	Measured ¹ TRRs (ppm)	Calculated ² TRRs (ppm)
Feces (day 4–6)	21.6–28.9	3.1–3.4	-
Urine (day 4–6)	26.2–40.2	5.0–9.5	-
Bile	-	3.4–6.3	-
Cage wash and rinse	1.3–3.5	-	-
Pooled Skim milk (day 4-6)	0.6–0.8	0.05–0.06	0.056–0.062
Liver	0.6–0.8	0.5–0.7	0.537–0.818
Kidney	0.1	0.3–0.4	0.330–0.346
Composite Fat	4.2–5.9	0.3–0.6	0.600–0.643
Composite Muscle	1.5–2.0	0.1	0.104–0.138
GI tract and contents	7.6–14.6	-	-
Brain and spinal cord	<0.1	-	-
Skin	<0.1–0.3	-	-
Bone marrow	<0.1–0.1	-	-
Carcass	8.4–9.9	0.3	-
Total % of Administered Dose	85.6–93.2	-	-
¹ Measured TRRs by combustion; ² Calculated TRRs = Sum of solvent extractable TRRs + PES			
Summary of Major Metabolites Identified in Goat Matrices			
Radiolabel Position	[Phenyl-U- ¹⁴ C], [Triazine-2,4- ¹⁴ C]		
Skim milk	M850H001; M850H003; M850H037; M850H038		
Cream	Trifludimoxazin; M850H001		
Liver	Trifludimoxazin; M850H001; M850H015; M850H038		

Kidney	M850H001; M850H003; M850H005; M850H015; M850H038
Composite muscle	Trifludimoxazin; M850H001; M850H038
Composite fat	Trifludimoxazin; M850H001

Trifludimoxazin was metabolized via the following reactions:

- conversion of the thio group of the triazine ring into an oxo group
- loss of the propyne moiety alone or in combination with other reactions
- *N*-demethylation at the triazine ring in combination with other reactions
- hydration of the propyne moiety followed by reduction or oxidation
- decomposition of the triple bond of the propyne moiety via conjugation with glutathione and subsequent stepwise cleavage of the conjugate or via oxidation
- ring opening and ring cleavage of the triazine moiety
- hydrolysis and ring opening of the oxazinone moiety

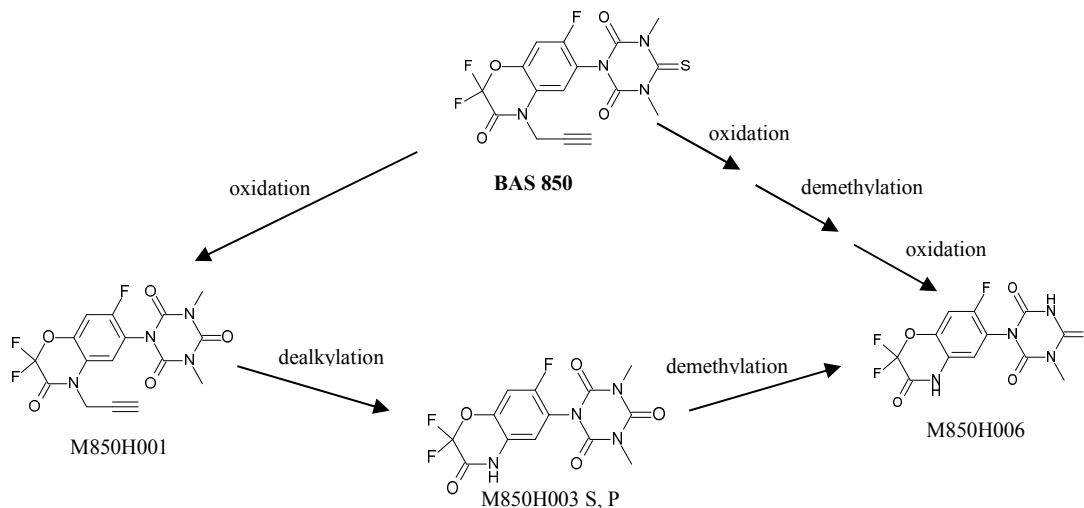
Proposed Metabolic Pathway in Livestock Matrices



NATURE OF THE RESIDUE IN FIELD CORN		PMRA# 2923951, 2923953	
Since the TRRs were <0.01 ppm in field corn grain, husks, cobs, forage from both radiolabels, and straw from the [Phenyl-U- ¹⁴ C] label, no further analysis was conducted. Quantifiable residues were only observed in field corn straw (0.015 ppm) from the [Triazine-2,4- ¹⁴ C]-trifludimoxazin label. The majority of the residues in field corn straw was extracted in methanol (54% of the TRRs; 0.0095 ppm), and 11% of the TRRs (0.0020 ppm) in water. Following sequential enzyme hydrolyses of the post-extraction solids, an additional 10% of the TRRs (0.0017 ppm) were released from field corn straw. The final PES was 10% of the TRRs (0.0018 ppm). Attempts to identify/characterize the residues in the concentrated methanol extracts of field corn straw by HPLC-UV resulted in one large peak which did not correspond to the parent or any of the reference standards. Therefore, a metabolic pathway was not proposed.			
Radiolabel Position	[Phenyl-U- ¹⁴ C]-Trifludimoxazin (specific activity: 5.87 MBq/mg) [Triazine-2,4- ¹⁴ C]-Trifludimoxazin (specific activity: 5.57 MBq/mg)		
Test Site	In individual pots in climatic chambers.		
Treatment	Bare soil		
Total Rate	100 g a.i./ha for both radiolabels		
Formulation	Suspension concentrate (SC) formulation of trifludimoxazin (guarantee: 500 g/L)		
Harvest	Corn forage harvested at 35–38 days; grain, husks, cobs, and straw harvested at 126–127 days.		
Extraction solvent	3× MeOH		
Matrices	PHI (days)	[Phenyl-U- ¹⁴ C]- and [Triazine-2,4- ¹⁴ C]-Trifludimoxazin	
		Measured ¹ TRRs	Calculated ² TRRs (ppm)
Field corn forage	35–38	0.004–0.005	-
Field corn grain	126–127	0.001	-
Field corn husks	126–127	0.003	-
Field corn cobs	126–127	0.001	-
Field corn straw	126–127	0.007–0.018	0.015
¹ Measured TRRs by combustion; ² Calculated TRRs = Sum of solvent extractable TRRs + PES			
NATURE OF THE RESIDUE IN SOYBEANS		PMRA # 2923952	
In soybean matrices, the majority of the residues were extracted with methanol (19–60% of the TRRs; 0.005–0.128 ppm) with smaller amounts in water extracts (5–35% of the TRRs; <0.001–0.048 ppm). For both radiolabels, in all of the soybean matrices, the total identified residues were 8–53% of the TRRs (0.003–0.093 ppm) with total characterized residues of 23–55% of the TRRs (0.003–0.073 ppm). Following sequential enzyme hydrolyses, an additional 6–33% of the TRRs (0.002–0.018 ppm) were released from the soybean matrices. The final PES was 1.5–31% of the TRRs (0.001–0.027 ppm).			
Radiolabel Position	[Phenyl-U- ¹⁴ C]-Trifludimoxazin (specific activity: 5.87 MBq/mg) [Triazine-2,4- ¹⁴ C]-Trifludimoxazin (specific activity: 5.57 MBq/mg)		
Test Site	In individual pots in glass-roofed vegetation hall.		
Treatment	Bare soil		
Total Rate	50 g a.i./ha for each radiolabel		
Formulation	Suspension concentrate (SC) formulation of trifludimoxazin (guarantee: 500 g/L)		
Harvest	Forage harvested at 58 days; leaves, rest of plant, hulls and seeds harvested at 118–119 days.		
Extraction solvents	3× MeOH and 2× H ₂ O		
Distribution of Radioactivity in Soybeans.			
Matrices	PHI (days)	[Phenyl-U- ¹⁴ C]-and [Triazine-2,4- ¹⁴ C]-Trifludimoxazin	
		Measured TRRs ¹ (ppm)	Calculated TRRs ² (ppm)
Soybean forage	58	0.014–0.015	0.008–0.011
Soybean leaves	118–119	0.170–0.210	0.177–0.216
Soybean rest of plants	118–119	0.039–0.045	0.034–0.039

Soybean hulls	118–119	0.045–0.064	0.039–0.060
Soybean seeds	118–119	0.034–0.052	0.031–0.049
¹ Measured TRRs by combustion; ² Calculated TRRs = Sum of solvent extractable TRRs + PES			
Summary of Major Identified Metabolites in Plant Matrices			
Radiolabel Position	[Phenyl-U-¹⁴C]- and [Triazine-2,4-¹⁴C]-Trifludimoxazin		
Soybean forage	M850H003; M850H006		
Soybean leaves	M850H003; M850H006		
Soybean rest of plants	M850H003; M850H006		
Soybean hulls	None		
Soybeans seeds	None		
NATURE OF THE RESIDUE IN POTATOES			PMRA# 2923954
Due to low amounts of radioactive residues measured in potato tubers, no further investigations were carried out. The majority of the residues in potato haulms were extracted with methanol (80–82% of the TRRs; 0.008–0.013 ppm) and minor amounts were extracted with water (7% of the TRRs; 0.001 ppm). In potato haulm, the total identified residues were 27–33% of the TRRs (0.0030-0.0044 ppm) with 32–48% of the TRRs (0.003–0.0076 ppm) as total characterized residues. Following sequential buffer and enzymatic hydrolyses, an additional 1–9% of the TRRs (0.000–0.0015 ppm) were released. The final PES was 10% of the TRRs (0.001–0.002 ppm).			
Radiolabel Position	[Phenyl-U- ¹⁴ C]-Trifludimoxazin (specific activity: 9.74 MBq/mg) [Triazine-2,4- ¹⁴ C]-Trifludimoxazin (specific activity: 5.57 MBq/mg)		
Test Site	In individual pots under natural climatic conditions in outdoor lysimeter area of the testing facility.		
Treatment	Bare soil		
Total Rate	[Phenyl-U- ¹⁴ C]-Trifludimoxazin: 74 g a.i./ha [Triazine-2,4- ¹⁴ C]-Trifludimoxazin: 75 g a.i./ha		
Formulation	Suspension concentrate (SC) formulation of trifludimoxazin (guarantee: 500 g/L)		
Harvest	Potato tubers and haulms harvested at 103-109 days.		
Extraction solvents	3× MeOH and 2× H ₂ O		
Distribution of Radioactivity in Potato Matrices.			
Matrices	PHI (days)	[Phenyl-U-¹⁴C]- and [Triazine-2,4-¹⁴C]- Trifludimoxazin	
		Measured TRRs^{1*} (ppm)	Calculated TRRs² (ppm)
Potato tubers	103–109	0.002–0.003	-
Potato haulms	103–109	0.011–0.015	0.010–0.016
¹ Measured TRRs by combustion; ² Calculated TRRs = Sum of solvent extractable TRRs + PES			
Summary of Major Identified Metabolites in Potato Haulm			
Radiolabel Position	[Phenyl-U-¹⁴C]; [Triazine-2,4-¹⁴C]		
Potato haulms	M850H001; M850H003		
The metabolism of trifludimoxazin includes replacement of the sulfur of the triazine ring by oxygen (M850H001), loss of propargyl group (dealkylation) (M850H003) and <i>N</i> -demethylation at position 1 of the triazine ring (M850H006). Metabolite M850H006 is formed either directly from the parent or results from demethylation of metabolite M850H003.			

Proposed Metabolic Pathway of Trifludimoxazin in Plant Matrices (S= soybean, P= potato)



FREEZER STORAGE STABILITY IN PLANT MATRICES

PMRA # 2923948

Samples of apple and lettuce (high-water), soybean seed (high-oil), field bean (high-protein), wheat grain and potato (high-starch), orange (high-acid) and pea hay (feed) were each fortified with trifludimoxazin at a fortification level of 0.1 ppm and put into freezer storage at -25°C. At intervals of approximately 0, 1–2, 3–4, 6–8, 12–13, 18–19, 24–26 and 37 months, stored samples and freshly fortified samples were analyzed for residues of trifludimoxazin. Soybean seeds were also stored for an additional interval of 42 months.

Category	Tested Matrices	Analyte	Demonstrated freezer storage intervals (months)
High-water	Apples	Trifludimoxazin	37
	Lettuce		37
High-acid	Oranges		37
High-protein	Field beans		37
High-oil	Dry soybeans		42
High-starch	Wheat grain		37
	Potatoes		37
Dry feed	Pea hay		37

CROP FIELD TRIALS & RESIDUE DECLINE ON LEGUME VEGETABLES, CITRUS FRUITS, POME FRUITS, TREE NUTS, PEANUTS, AND CEREAL GRAINS

PMRA # 2923958–2023960, 2923963–2923965

Crop field trials were conducted in North American growing regions during the 2014-2015 growing seasons with a variety of crops using BAS 850H (500 g /L SC). A single ground application with adjuvants was used in/on all crops at all field trial sites. The number and geographic distribution of trials were generally in accordance with Health Canada's DIR2010-05 and USEPA OPPTS 860.1500. Independence of trials was assessed for each representative crop from the various crop groups. Residue decline could not be assessed as residues were less than LOQ. Adequate storage stability data are available on diverse crop types to support the storage intervals of the crop field trials. Samples were analyzed using a validated analytical method.

Crops	Total Application Rate (g a.i./ha)	PHI (days)	Trifludimoxazin Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SDEV
DOMESTIC								
Soybean forage	37–40	33–63	16	<0.01	<0.01	<0.01	<0.01	na
Soybean hay	37–40	48–78	16	<0.01	<0.01	<0.01	<0.01	na
Dry soybean seeds	37–40	114–146	16	<0.01	<0.01	<0.01	<0.01	na
Field pea hay	37–40	41–84	13	<0.01	<0.01	<0.01	<0.01	na

Field pea vines	37-40	61-113	13	<0.01	<0.01	<0.01	<0.01	na
Dry field pea seeds	37-40	70-127	13	<0.01	<0.01	<0.01	<0.01	na
Garbanzo beans	37-40	97-160	11	<0.01	<0.01	<0.01	<0.01	na
Barley hay	37-39	59-178	10	<0.01	<0.01	<0.01	<0.01	na
Barley grain	37-39	84-227	10	<0.01	<0.01	<0.01	<0.01	na
Barley straw	37-39	84-227	10	<0.01	<0.01	<0.01	<0.01	na
Field corn forage	37-40	70-125	16	<0.01	<0.01	<0.01	<0.01	na
Field corn grain	37-40	62-174	16	<0.01	<0.01	<0.01	<0.01	na
Field corn stover	37-40	62-174	16	<0.01	<0.01	<0.01	<0.01	na
Wheat forage	37-42	21-183	25	<0.01	<0.01	<0.01	<0.01	na
Wheat hay	37-42	52-203	25	<0.01	<0.01	<0.01	<0.01	na
Wheat grain	37-42	84-267	25	<0.01	<0.01	<0.01	<0.01	na
Wheat straw	37-42	84-267	25	<0.01	<0.01	<0.01	<0.01	na
IMPORTS								
Apples	96-103	0	15	<0.01	<0.01	<0.01	<0.01	na
Pears	99-102	0	9	<0.01	<0.01	<0.01	<0.01	na
Oranges	150	0	12	<0.01	<0.01	<0.01	<0.01	na
Grapefruits	150	0	6	<0.01	<0.01	<0.01	<0.01	na
Lemons	150	0	5	<0.01	<0.01	<0.01	<0.01	na
Mandarins	150	0	4	<0.01	<0.01	<0.01	<0.01	na
Pecan nutmeat	100-102	7	5	<0.01	<0.01	<0.01	<0.01	na
Pistachio nutmeat	101-103	7	3	<0.01	<0.01	<0.01	<0.01	na
Almond nutmeat	99-101	6-7	5	<0.01	<0.01	<0.01	<0.01	na
Almond hulls	99-101	6-7	5	<0.01	0.061	0.014	0.023	0.021
Peanut nutmeat	34-40	97-157	12	<0.01	<0.01	<0.01	<0.01	na
Peanut hay	34-40	97-157	12	<0.01	<0.01	<0.01	<0.01	na
Sweet corn K+CWHR	37-39	70-111	5	<0.01	<0.01	<0.01	<0.01	na
Sweet corn forage	37-39	70-111	5	<0.01	<0.01	<0.01	<0.01	na
Sweet corn stover	37-39	90-147	5	<0.01	<0.01	<0.01	<0.01	na
Rice grain	37-39	118-156	12	<0.01	<0.01	<0.01	<0.01	na
Rice straw	38-39	118-156	12	<0.01	<0.01	<0.01	<0.01	na
Sorghum forage	38-39	74-127	9	<0.01	<0.01	<0.01	<0.01	na
Sorghum grain	38-39	110-178	9	<0.01	<0.01	<0.01	<0.01	na
Sorghum stover	38-39	110-178	9	<0.01	<0.01	<0.01	<0.01	na
Podded soybean seeds	37-40	74-118	16	<0.01	<0.01	<0.01	<0.01	na
Shelled soybean seeds	37-40	74-118	16	<0.01	<0.01	<0.01	<0.01	na
Shelled field peas	37-40	61-113	13	<0.01	<0.01	<0.01	<0.01	na
Podded field peas	37-40	61-113	13	<0.01	<0.01	<0.01	<0.01	na
HIGH-TEMPERATURE HYDROLYSIS STUDY						PMRA# 2923966		
The radiolabeled test compounds [Phenyl-U- ¹⁴ C] and [Triazine-2,4- ¹⁴ C]-Trifludimoxazin were used for hydrolysis investigations with a concentration of approximately 1 ppm. As the pH and hydrolysis temperature increases, the % radioactivity of trifludimoxazin decreases, while that of the metabolites increases. Trifludimoxazin is hydrolytically stable in pH 4 and pH 5 buffer when incubated at 90°C or 100°C for 20 or 60 minutes. M850H004 and M850H012 are formed at pH 6 buffer when incubated at 120°C for 20 minutes.								
Processing	Pasteurization		Baking/Brewing/Boiling		Sterilization			
Conditions	pH 4/90°C/20 min		pH 5/100°C/60 min		pH 6/120°C/20 min			

Major Identified Metabolites	Trifludimoxazin	Trifludimoxazin	Trifludimoxazin; M850H004; M850H012
PROCESSED FOOD AND FEED – CROP		PMRA# 2923967, 2923968, 2923971-2923976	
Processing studies were conducted in distinctive North American growing regions using trifludimoxazin (500 g/L SC) at three to fivefold of the maximum single seasonal use rate in/on dry soybeans, oranges, field corn, sweet sorghum, rice, barley, and wheat. Adequate storage stability data are available on diverse crop types to support the storage intervals of the processed food and feed. Samples were analyzed using a validated analytical method. Residues of trifludimoxazin were all <LOQ (<0.01 ppm) in dry soybeans, oranges, field corn, rice, barley, wheat and all processed commodities. Therefore, processing factors could not be calculated for trifludimoxazin in processed fractions.			
CONFINED ACCUMULATION IN ROTATIONAL CROPS –Lettuce, radish and wheat		PMRA # 2923977	
Low to moderate translocation of TRRs from soil into plants was observed. The overall measured TRRs (from combustion) were highest in the wheat matrices (straw, hay, grain, and forage) at all plantback intervals for both radiolabels. The overall TRRs generally decreased with increasing plantback intervals (30, 120 and 373 days) in lettuce, white radish and spring wheat for both radiolabels. Trifludimoxazin, was not identified in any of the rotational crops at a 30-d, 120-d, and 373-d plantback intervals. In the 1 st rotation, the predominant residues were M850H001 (11% of the TRRs; 0.001 ppm) and M850H003 (14–40% of the TRRs; 0.002–0.003 ppm) in immature lettuce; M850H003 (11–36% of the TRRs; 0.002–0.005 ppm) in white radish tops; and M850H006 in spring wheat matrices (11–28% of the TRRs (0.003–0.027 ppm). In the 2 nd rotation, the only major identified residue was M850H006 (11–21% of the TRRs; 0.002–0.012 ppm) in spring wheat (forage, hay and straw). In the 3 rd rotation, M850H006 comprised the major part of spring wheat hay and straw (14–18% of the TRRs; 0.003–0.007 ppm).			
Radiolabel Position	[Phenyl-U- ¹⁴ C]-Trifludimoxazin (specific activity: 5.87 MBq/mg) [Triazine-2,4- ¹⁴ C]-Trifludimoxazin (specific activity: 5.57 MBq/mg)		
Test Site	Plastic containers kept under natural climatic conditions in a glass-roofed vegetation hall		
Soil Type	Sandy loam		
Treatment	Bare soil was treated at 200 g a.i./ha, and aged for 30, 120 and 373 days.		
Formulation	Suspension concentrate (SC) formulation of trifludimoxazin (guarantee: 500 g/L)		
Harvest	Immature and mature lettuce leaves; radish tops and roots; Spring wheat forage, hay, straw and grain		
Extraction solvents	3× MeOH and 2× H ₂ O		
Distribution of Radioactivity in Rotated Crops			
Matrices	PBI (days)	[Phenyl-U- ¹⁴ C]- and [Triazine-2,4- ¹⁴ C]-Trifludimoxazin	
		Measured TRRs ¹ (ppm)	
Immature lettuce	30	0.010–0.012	0.009–0.013
	120	0.005*	-
	373	0.001–0.002*	-
Mature lettuce	30	0.007–0.009*	-
	120	0.004*	-
	373	0.001*	-
Radish roots	30	0.005–0.006*	-
	120	0.002*	-
	373	0.001–0.003*	-
Radish tops	30	0.017–0.018	0.014–0.015
	120	0.007–0.009*	-
	373	0.003–0.006*	-
Wheat forage	30	0.022–0.026	0.019–0.022
	120	0.008–0.011	0.008
	373	0.005–0.007*	-
Wheat hay	30	0.071–0.116	0.067–0.106
	120	0.044–0.070	0.035–0.064
	373	0.026–0.051	0.019–0.051
Wheat straw	30	0.130–0.158	0.133–0.152
	120	0.041–0.078	0.038–0.071

	373	0.038–0.071	0.039–0.075
Wheat grain	30	0.049–0.071	0.048–0.071
	120	0.016–0.020	0.015–0.020
	373	0.018–0.020	0.018–0.021

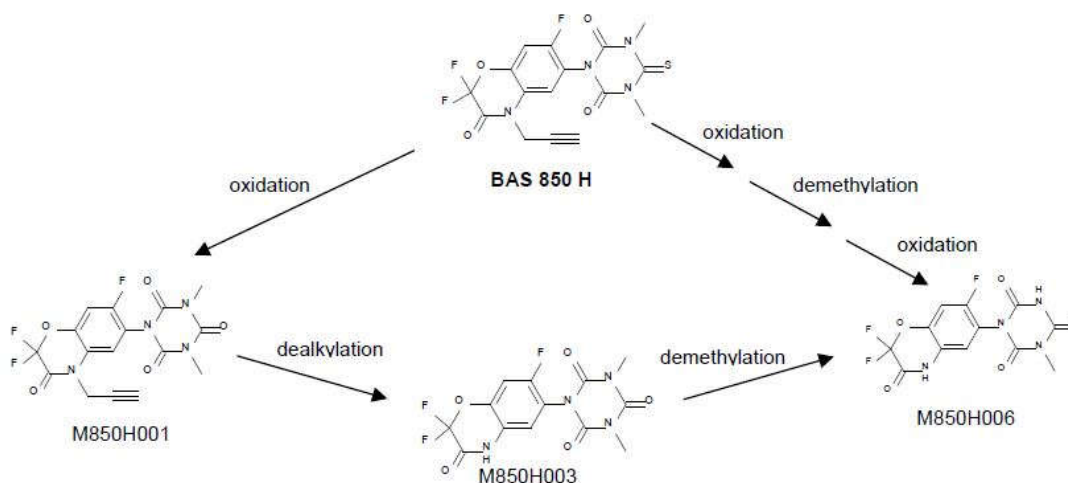
¹Measured TRRs by combustion; ²Calculated TRRs = Sum of solvent extractable TRRs + PES

* not further analyzed due to low TRRs

Summary of Major Identified Metabolites in Rotated Crops

Radiolabels	[Phenyl-U- ¹⁴ C]- and [Triazine-2,4- ¹⁴ C]-Trifludimoxazin		
Plant-back Intervals (PBI)	1 st Rotation (30-day PBI)	2 nd Rotation (120-day PBI)	3 rd Rotation (373-day PBI)
Immature lettuce	M850H001; M850H003	None	None
Mature lettuce	Not analyzed further	Not analyzed further	Not analyzed further
White radish tops	M850H003	None	None
White radish roots	Not analyzed further	Not analyzed further	Not analyzed further
Spring wheat forage	M850H006	M850H006	None
Spring wheat hay	M850H006	M850H006	M850H006
Spring wheat straw	M850H006	M850H006	M850H006
Spring wheat grain	M850H006	None	None

Proposed Metabolic Pathway in Rotational Crops



RESIDUE DATA IN ROTATIONAL CROPS

PMRA # 2972720

Six trials (two each for radish, lettuce and winter wheat) were conducted in two North American growing regions during the 2014–2015 growing seasons. One broadcast application was made to bare soil with BAS 850H SC at a rate of 46–53 g a.i./ha with the use of adjuvants at all trial sites. Adequate storage stability data are available on diverse commodity categories to support the storage intervals of the rotational crop field trials. Samples were analyzed using a validated analytical method.

Commodity	Total Application Rate (g a.i./ha)	PBI (months)	Trifludimoxazin Residue Levels (ppm)				
			n	LAFT	HAFT	Mean	SDEV
Wheat forage	48–53	4, 6, 9	2	<0.01	<0.01	<0.01	na
Wheat hay			2	<0.01	<0.01	<0.01	na
Wheat grain			2	<0.01	<0.01	<0.01	na
Wheat straw			2	<0.01	<0.01	<0.01	na

Lettuce leaves	46–48	4, 6, 9	2	<0.01	<0.01	<0.01	na
Radish tops	46–53	4, 6, 9	2	<0.01	<0.01	<0.01	na
Radish roots			2	<0.01	<0.01	<0.01	na
Values based on per-trial averages. For computation, values <LOQ are assumed to be at the LOQ. n = number of independent field trials.							
LIVESTOCK FEEDING STUDIES							
A waiver for livestock feeding studies was provided based on the low expected dietary burden. Therefore, the lactating goat and laying hen metabolism studies were used to estimate the anticipated residues in the relevant livestock matrices.							
Dairy Cattle							
Matrices	RD	Highest residue (ppm)	Feeding level of Metabolism Study (ppm)	DB	Anticipated Residues (ppm)		
Whole milk*	Trifludimoxazin	0.580	11	0.02	0.00105		
Composite Muscle	Trifludimoxazin	0.031		0.02	0.00006		
Composite Fat	Trifludimoxazin	0.288		0.02	0.00052		
Liver	Trifludimoxazin	0.170		0.02	0.00031		
Kidney	Trifludimoxazin	0.032		0.02	0.00006		
Swine							
Composite Muscle	Trifludimoxazin	0.031	11	0.01	0.00003		
Composite Fat	Trifludimoxazin	0.288		0.01	0.00026		
Liver	Trifludimoxazin	0.170		0.01	0.00015		
Kidney	Trifludimoxazin	0.032		0.01	0.00003		
Poultry							
Egg**	Trifludimoxazin	3.573		0.01	0.00298		
Composite Muscle	Trifludimoxazin	0.909		0.01	0.00076		
Composite Fat	Trifludimoxazin	12.653		0.01	0.01054		
Liver	Trifludimoxazin	0.990		0.01	0.00083		
*based on highest residues observed in cream; **based on highest residues observed in egg yolk							

Table 8 Food residue chemistry overview of metabolism studies and risk assessment

PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT Primary crops (field corn, potatoes, soybeans) Rotational crops (lettuce, radish , wheat)	Trifludimoxazin
RESIDUE DEFINITION FOR RISK ASSESSMENT Primary crops (field corn, potatoes, soybeans) Rotational crops (lettuce, radish, wheat)	Trifludimoxazin
METABOLIC PROFILE IN DIVERSE CROPS	Similar in diverse crops
ANIMAL STUDIES	
ANIMALS	Ruminant and Poultry
RESIDUE DEFINITION FOR ENFORCEMENT	Trifludimoxazin
RESIDUE DEFINITION FOR RISK ASSESSMENT	Trifludimoxazin, M850H001
METABOLIC PROFILE IN ANIMALS (goat, hen, rat)	Similar in rat, hen and goat
FAT SOLUBLE RESIDUE	Yes

DIETARY RISK FROM FOOD AND DRINKING WATER			
Basic chronic (non-cancer) dietary exposure analysis ADI = 0.08 mg/kg bw/day Estimated chronic drinking water concentration = 0.0062 ppm	POPULATION	ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)	
		Food Alone	Food and Drinking Water
	All infants <1 year	0.4	1.0
	Children 1–2 years	1.0	1.2
	Children 3–5 years	0.7	0.8
	Children 6–12 years	0.4	0.5
	Youth 13–19 years	0.2	0.3
	Adults 20–49 years	0.1	0.3
	Adults 50–99 years	0.1	0.3
Total population	0.2	0.4	
Basic acute dietary exposure analysis ARfD = 0.08 mg/kg bw/day Estimated acute drinking water concentration = 0.0063 ppm	POPULATION	ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)	
		Food Alone	Food and Drinking Water
	All infants <1 year	1.2	2.0
	Children 1–2 years	1.9	2.1
	Children 3–5 years	1.3	1.5
	Children 6–12 years	0.7	1.0
	Youth 13–19 years	0.4	0.6
	Adults 20–49 years	0.3	0.6
	Adults 50–99 years	0.3	0.6
Total population	0.7	0.9	

Table 9 Physical and chemical properties of trifludimoxazin

Property	Result	Interpretation
Vapour pressure at 20°C	1.1×10^{-10} Pa	Non-volatile.
Henry's law Constant	$1/H = 9.56E+10$ $K = 2.5E-8$ atm.m ³ /mole	Not expected to be volatile from soil and water.
Ultraviolet (UV)-visible spectrum	λ_{max} is 265 nm in neutral media (smaller peak at 202 nm), 267 nm in acidic media (smaller peak at 198 nm), and 216 nm in basic medium (smaller peak at 290 nm).	Not expected to phototransform under environmental conditions.
Solubility in water at 20°C	1.78 mg/L	Low solubility in water
<i>n</i> -Octanol-water partition coefficient (K_{ow})	$\log K_{ow} = 3.33$ (30°C)	Potential for bioaccumulation
Dissociation constant (pK_a)	No dissociation	Not expected to dissociate under environmental conditions.

Table 10 Fate and behaviour in the environment

Study (with parent or TP)	Test conditions	Value	Interpretation	Major TPs (>10% AR)	Study #
Abiotic transformation					
Hydrolysis (parent)	pH 4, pH 5, 25°C	Stable	Not a route of transformation under acidic conditions	None detected	2923861 2923862
	pH 7, 25°C	$t_{1/2} = 244$ d $DT_{50} = 75$ d	Not a major route of transformation under neutral pH conditions	M850H004 M850H040	
	pH 9, 25°C	$t_{1/2} = 0.55$ d	A major route of	M850H004	

Study (with parent or TP)	Test conditions	Value	Interpretation	Major TPs (>10% AR)	Study #
		DT ₅₀ = 0.31 d	transformation under alkaline conditions	M850H012 M850H033	
Phototransformation on soil (parent)	Moist soil under continuous irradiation, pH 6.8, 22°C	t _{1/2} = 36 d	Not a major route of transformation	M850H001 M850H002	2923985 2923986
Phototransformation in water (parent)	pH 5.0, 25°C, continuous irradiation	t _{1/2} = 10.5 d	Not a major route of transformation	M850H001 t _{1/2} = 10.2 d	2923863 2923864
Biotransformation					
Aerobic soil (parent)	IN loam pH 5.7, 20°C	t _{1/2} = 226 d DT ₅₀ = 87.4 d	Moderately persistent in aerobic soil	M850H001 M850H002 M850H003	2923981 2923982
	NJ loam pH 6.8, 20°C	t _{1/2} = 22.2 d DT ₅₀ = 11.8 d	Non-persistent in aerobic soil	M850H001 M850H002 M850H003	
	LUFA 2.2 sandy loam pH 6.1, 20°C	t _{1/2} = 150 d DT ₅₀ = 39.6 d	Slightly persistent in aerobic soil	M850H001 M850H002 M850H003	
	LUFA 2.3 sandy loam pH 7.6, 20°C	t _{1/2} = 13.1 d DT ₅₀ = 13.1 d	Non-persistent in aerobic soil	M850H001 M850H002 M850H003	
Aerobic soil (TP - M850H004)	LA silt loam pH 4.8, 20°C	t _{1/2} = 2.6 d DT ₅₀ = 0.98 d	Non-persistent in aerobic soil		2923990
	NC sandy loam pH 5.0, 20°C	t _{1/2} = 20.9 d DT ₅₀ = 11.4 d	Non-persistent in aerobic soil		
	WI loamy sand pH 5.2, 20°C	t _{1/2} = 26.3 d DT ₅₀ = 16.7 d	Slightly persistent in aerobic soil		
	Speyer 5M pH 7.0, 20°C	t _{1/2} = 4.3 d DT ₅₀ = 4.3 d	Non-persistent in aerobic soil		
Aerobic soil (TP - M850H003)	LUFA 5M sandy loam pH 7.3, 20°C	t _{1/2} = 75.1 d DT ₅₀ = 24.4 d	Slightly persistent in aerobic soil		2923989
	LUFA 2.2 sandy loam pH 5.4, 20°C	t _{1/2} = 488 d DT ₅₀ = 421 d	Persistent in aerobic soil		
	LUFA 2.3 sandy loam pH 6.9, 20°C	t _{1/2} = 92.1 d DT ₅₀ = 20.8 d	Slightly persistent in aerobic soil		
	NJ loam pH 6.5, 20°C	t _{1/2} = 145 d DT ₅₀ = 37.4 d	Slightly persistent in aerobic soil		
Anaerobic soil (parent)	CA sandy clay loam pH 7.7, 20°C	t _{1/2} = 55.3 d DT ₅₀ = 58.1 d (total system)	Moderately persistent in anaerobic soil M850H002: t _{1/2} = 63.2 d (SFO) DT ₅₀ = 49.8 d (SFO) moderately persistent in anaerobic soil	M850H002 M850H003 M850H004	2923983 2923984
	LA silt loam pH 5.5, 20°C	t _{1/2} not reliable DT ₅₀ = 383 d (total system)	Persistent in anaerobic soil	M850H001 M850H002 M850H002: moderately persistent in anaerobic soil DT ₅₀ = 92 d	
	LUFA 2.2 sandy loam pH 5.6, 20°C	t _{1/2} = 84.9 d DT ₅₀ = 101 d (total system)	Moderately persistent in anaerobic soil	M850H001 M850H002 M850H003	

Study (with parent or TP)	Test conditions	Value	Interpretation	Major TPs (>10% AR)	Study #
				M850H004	
	LUFA 2.3 sandy loam pH 7.5, 20°C	$t_{1/2} = 89.9$ d $DT_{50} = 81.3$ d (total system)	Moderately persistent in anaerobic soil	M850H001 M850H002 M850H003 M850H002: moderately persistent in anaerobic soil $t_{1/2}$ = 42.2 d $DT_{50} = 63$ d	
Aerobic water systems (parent)	NC pond sandy loam, pH 5.4–5.9, 20°C	$t_{1/2} = 224$ d $DT_{50} = 94.8$ d (total system)	Moderately persistent in aerobic aquatic systems	M850H001	2924009 2924010
	ND pond clay loam, pH 7.4–8.3, 20°C	$t_{1/2} = 18.9$ d $DT_{50} = 3.5$ d (total system)	Non-persistent in aerobic aquatic systems	M850H004 M850H035	
Anaerobic water systems (parent)	NC pond sandy loam, pH 7.0, 20°C	$t_{1/2} = 817$ d $DT_{50} = 83.2$ d (total system)	Moderately persistent in anaerobic aquatic systems	M850H004	2924011 2924012
	ND pond 1 clay loam, pH 8.4, 20°C	$t_{1/2} = 15.6$ d $DT_{50} = 10.6$ d (total system)	Non-persistent in anaerobic aquatic systems	M850H004 M850H002 M850H033 M850H042	
	ND pond 2 clay loam, pH 8.4, 20°C	$t_{1/2} = 8.8$ d $DT_{50} = 6.0$ d (total system)	Non-persistent in anaerobic aquatic systems	M850H004	
Mobility					
Adsorption / desorption in soil (parent)	IN loam pH 6.5, 1.33% OC	$K_{oc} = 509.3$	Low mobility in soil		2923999 2924000
	LA silt loam pH 5.5, 0.81% OC	$K_{oc} = 812.7$	Low mobility in soil		
	NJ loam pH 6.9, 1.33% OC	$K_{oc} = 394.5$	Medium mobility in soil		
	NC sandy loam pH 6.1, 0.90% OC	$K_{oc} = 461.4$	Medium mobility in soil		
	WI loamy sand pH 6.3, 1.57% OC	$K_{oc} = 336.3$	Medium mobility in soil		
	Obihiro, Japan loam pH 6.9, 3.4% OC	$K_{oc} = 362.4$	Medium mobility in soil		
	Li10, Europe loamy sand pH 6.8, 0.93% OC	$K_{oc} = 507.1$	Low mobility in soil		
	LUFA 5M sandy loam pH 8.2, 1.07% OC	$K_{oc} = 432.7$	Medium mobility in soil		
Adsorption / desorption in soil	IN loam pH 6.5,	$K_{oc} = 60.6$	High mobility in soil		2924005 2924006

Study (with parent or TP)	Test conditions	Value	Interpretation	Major TPs (>10% AR)	Study #
(TP – M850H003)	1.33% OC				
	LA silt loam pH 5.5, 0.81% OC	$K_{oc} = 206.6$	Medium mobility in soil		
	NJ loam pH 6.9, 1.33% OC	$K_{oc} = 46.7$	Very high mobility in soil		
	NC sandy loam pH 6.1, 0.90% OC	$K_{oc} = 76.1$	High mobility in soil		
	WI loamy sand pH 6.3, 1.57% OC	$K_{oc} = 62.7$	High mobility in soil		
	Obihiro, Japan loam pH 6.9, 3.4% OC	$K_{oc} = 65.8$	High mobility in soil		
	Li10, Europe loamy sand pH 6.8, 0.93% OC	$K_{oc} = 49.2$	Very high mobility in soil		
	LUF 5M sandy loam pH 8.2, 1.07% OC	$K_{oc} = 33.1$	Very high mobility in soil		
Adsorption / desorption in soil (TP – M850H004)	LA silt loam pH 4.6, 0.8% OC	$K_{oc} = 1410$	Low mobility in soil		2924007 2924008
	NJ loam pH 6.3 1.1% OC	$K_{oc} = 742.6$	Low mobility in soil		
	NC sandy loam pH 4.7 0.9% OC	$K_{oc} = 771.4$	Low mobility in soil		
	WI sand pH 5.5 1.9% OC	$K_{oc} = 842.1$	Low mobility in soil		
	Speyer 5M sandy loam pH 7.3 1.0% OC	$K_{oc} = 224.9$	Medium mobility in soil		
Adsorption / desorption in soil (TP – M850H001)	IN loam pH 6.5, 1.33% OC	$K_{oc} = 71.5$	High mobility in soil		2924001 2924002
	LA silt loam pH 5.5, 0.81% OC	$K_{oc} = 181.5$	Medium mobility in soil		
	NJ loam pH 6.9, 1.33% OC	$K_{oc} = 54.1$	High mobility in soil		
	NC sandy loam pH 6.1, 0.90% OC	$K_{oc} = 75.4$	High mobility in soil		
	WI loamy sand pH 6.3, 1.57% OC	$K_{oc} = 52.1$	High mobility in soil		
	Obihiro, Japan loam pH 6.9, 3.4% OC	$K_{oc} = 75.0$	High mobility in soil		
	Li10, Europe	$K_{oc} = 66.8$	High mobility in soil		

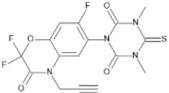
Study (with parent or TP)	Test conditions	Value	Interpretation	Major TPs (>10% AR)	Study #
	loamy sand pH 6.8, 0.93% OC				
	LUFA 5M sandy loam pH 8.2, 1.07% OC	$K_{oc} = 60.9$	High mobility in soil		
Adsorption / desorption in soil (TP – M850H002)	IN loam pH 6.5, 1.33% OC	$K_{oc} = 264.0$	Medium mobility in soil		2924003 2924004
	LA silt loam pH 5.5, 0.81% OC	$K_{oc} = 500.0$	Medium mobility in soil		
	NJ loam pH 6.9, 1.33% OC	$K_{oc} = 188.2$	Medium mobility in soil		
	NC sandy loam pH 6.1, 0.90% OC	$K_{oc} = 364.1$	Medium mobility in soil		
	WI loamy sand pH 6.3, 1.57% OC	$K_{oc} = 196.5$	Medium mobility in soil		
	Obihiro, Japan loam pH 6.9, 3.4% OC	$K_{oc} = 337.8$	Medium mobility in soil		
	Li10, Europe loamy sand pH 6.8, 0.93% OC	$K_{oc} = 273.0$	Medium mobility in soil		
	LUFA 5M sandy loam pH 8.2, 1.07% OC	$K_{oc} = 139.6$	High mobility in soil		
Adsorption / desorption in sediment	Aerobic aquatic NC pond sandy loam, pH 5.4–5.9, 20°C	75–78% of parent in water phase partitioned to sediment at day- 100			2924009 2924010
	Aerobic aquatic ND pond clay loam, pH 7.4–8.3, 20°C	54.3–69.6% of parent in water phase partitioned to sediment at day- 100			
Bioconcentration in fish (parent)	pH 6.4–6.6, 15°C 16-h light: 8-h dark	Whole fish BCF (lipid corrected) = 51.9–81.5	Not expected to bioconcentration After 7 days of depuration in clean water, whole-body residues in fish declined to <5% mean steady-state concentration		2924075 2924076

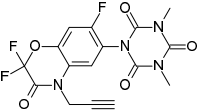
Study (with parent or TP)	Test conditions	Value	Interpretation	Major TPs (>10% AR)	Study #
Field studies					
Terrestrial field dissipation (parent)	NY silt loam - loam pH 5.2–6.3, 2.4% OC	$t_{1/2} = 6.0$ d DT ₅₀ = 1.3 d	Non-persistent in soil	M850H001 M850H003 M850H001: non- persistent $t_{1/2} = 12.3$ d DT ₅₀ = 1.2 d M850H003: persistent DT ₅₀ = 995 d	2923995 2923996
	TX clay loam – loam pH 6.4, 1.1% OC	DT ₅₀ = 2.3 d	Non-persistent in soil	M850H001 M850H003 M850H001: non- persistent DT ₅₀ = 11.2 d M850H003: persistent DT ₅₀ = 332 d	
	ND silty clay pH 7.6, 2.1% OC	$t_{1/2} = 6.0$ d DT ₅₀ = 6.0 d	Non-persistent in soil	M850H001 M850H003 M850H001: slightly persistent $t_{1/2} = 18.9$ d DT ₅₀ = 18.9 d M850H003: persistent $t_{1/2} = 666$ d DT ₅₀ = 666 d	2923991 2923992
	WA loamy sand pH 8.3, 0.2% OC	$t_{1/2} = 23.6$ d DT ₅₀ = 9.1 d	Non-persistent in soil	M850H001 M850H002 M850H001: moderately persistent $t_{1/2} = 65.9$ d DT ₅₀ = 65.9 d M850H002: moderately persistent $t_{1/2} = 91.2$ d DT ₅₀ = 91.2 d	2923993 2923994
Field leaching (parent)	NY silt loam - loam pH 5.2–6.3, 2.4% OC	Max. leaching depth 30.5–45.7 cm	Parent and TPs considered as leachers	Max. leaching depth M850H001: 30.5–45.7 cm M850H003: 30.5–45.7 cm	2923995 2923996
	TX clay loam – loam pH 6.4, 1.1% OC	Max. leaching depth 0–7.5 cm	Parent and TPs not considered as leachers	Max. leaching depth M850H001: 7.5–	

Study (with parent or TP)	Test conditions	Value	Interpretation	Major TPs (>10% AR)	Study #
				15.0 cm M850H003: 15.2–30.5 cm	
	ND silty clay pH 7.6, 2.1% OC	Max. leaching depth 0–7.6 cm	Parent not considered as a leacher M850H001 and M850H003 not considered as leachers	Max. leaching depth M850H001: 0–7.6 cm M850H003: 0–7.6 cm	2923991 2923992
	WA loamy sand pH 8.3, 0.2% OC	Max. leaching depth 45.7–61.0 cm	Parent and M850H001 considered as leachers M850H002 not considered as a leacher	Max. leaching depth M850H001: 45.7–61.0 cm M850H002: 15.2–30.5 cm	2923993 2923994

TP –transformation product; $t_{1/2}$ – representative half-life; DT_{50} – time for 50% transformation;
 IN – Indiana; NJ – New Jersey; NY - New York; NC – North Carolina; ND – North Dakota; CA – California; TX - Texas; WA – Washington;
 WI – Wisconsin; LA – Louisiana;
 LUFA 2.2 – German soil; LUFA 2.3 – German soil; Speyer 5M – German soil; LUFA 5M – German soil
 M850H001: 1,3-dimethyl-5-[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-2,4,6-trione
 M850H002: 1,5-dimethyl-6-thioxo-3-(2,2,7-trifluoro-3-oxo-3,4-dihydro-2H-1,4-benzoxazin-6-yl)-1,3,5-triazinane-2,4-dione
 M850H003: 1,3-dimethyl-5-(2,2,7-trifluoro-3-oxo-3,4-dihydro-2H-1,4-benzoxazin-6-yl)-1,3,5-triazinane-2,4,6-trione
 M850H004: N,N-dimethyl-N'-[2,2,7-trifluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl] dicarbonimidothioic-diamide
 M850H012: 6-amino-2,2,7-trifluoro-4-(prop-2-yn-1-yl)-2H-1,4-benzoxazin-3(4H)-one
 M850H033: 6-(2,4-dimethyl-5-oxo-3-thioxo-1,2,4-triazolidin-1-yl)-2,2,7-trifluoro-4-prop-2-ynyl-1,4-benzoxazin-3-one
 M850H040: 2-[4-(3,5-dimethyl-2,6-dioxo-4-thioxo-1,3,5-triazinan-1-yl)-5-fluoro-2-(prop-2-ynylamino) phenoxy]-2,2-difluoro-acetic acid

Table 11 Record of transformation products

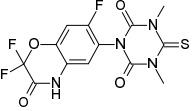
Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
PARENT				
Trifludimoxazin BAS 850 H BASF Reg.No. 1258836-72-4 1,5-dimethyl-6-thioxo-3-[2,2,7-trifluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-1,3,5-triazinane-2,4-dione CAS#: 1258836-72-4 Formula: C ₁₆ H ₁₁ F ₃ N ₄ O ₄ S MW: 412.3 g/mol		Hydrolysis (2923861)		pH 7;15°C: Phenyl = 88.6 (30) pH 7;15°C: Triazine = 88.8 (30)
				pH 7;25°C: Phenyl = 71.4 (30) pH 7;25°C: Triazine = 73.6 (30)
				pH 7;35°C: Phenyl label = 42.9 (30) pH 7;35°C: Triazine = 46.1 (30)
				pH 9;15°C: Phenyl = 3.3 (3) pH 9;15°C: Triazine = 1.5 (30)
				pH 9, 25°C: Phenyl = ND (29) pH 9, 25°C: Triazine = ND (29)
				pH 9;35°C: Phenyl = ND (30) pH 9;35°C: Triazine = ND (29)
		Soil Photolysis (2923985)		Phenyl = 36.7 (19) Triazine = 37.0 (19)
		Aqueous Photolysis (2923863)		pH 5, Phenyl = 28.3 (15) pH 5, Triazine = 22.6 (15)
		Aerobic soil (2923981)		IA (loam): Triazine = 42.1 (120) NJ (loam): Triazine = 8.5 (120) LUFA 2.2(sandy loam): Triazine = 27.0 (120) LUFA 2.2(sandy loam): Phenyl = 29.2 (120) LUFA 2.3(sandy loam): Triazine = 7.8 (120)

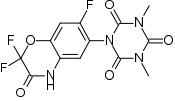
Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
		Anaerobic soil (2923983)		CA soil (rep1): (total system) Triazine = 9.6 (119) (rep2) = 9.9 (119)
				LA soil (rep1): (total system) Triazine = 52.8 (119) (rep2) = 53.3 (119)
				LUFA 2.2 (rep1): (total system) Triazine = 30.4 (119) (rep2): 24.7 (119) LUFA 2.2 (rep1): (total system) Phenyl = 23.9 (119) (rep2) = 25.5 (119)
				LUFA 2.3 (rep1): (total system) Triazine = 11.1 (119) (rep2) = 7.5 (119)
		Aerobic aquatic (2924009)		NC Pond Phenyl (total system) = 48.3 (100) NC Pond Triazine (total system) = 48.2 (100)
				Goose River Phenyl (total system) = 3.3 (100) Goose River Triazine (total system) = 3.2 (100)
		Anaerobic aquatic (2924011 ¹¹)		NC Pond Phenyl (total system) = 47.8 (100) NC Pond Triazine (total system) = 53.6 (100)
				Goose River Phenyl (total system) = 1.6 (100) Goose River Triazine (total system) = 1.6 (100)
				REPEAT Goose River Triazine (total system) = 1.7 (99)
		Field studies (2923991, 2923993, 2923995)		ND: nd (720)
				WA: nd (710)
				NY: 0.3 (631)
				TX: nd (628)
MAJOR (>10%) TRANSFORMATION PRODUCTS				
M850H001 BASF Reg. No. 5749359 1,3-dimethyl-5-[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-2,4,6-trione CAS#: N/A Formula: C ₁₆ H ₁₁ F ₃ N ₄ O ₅ MW: 396.2819 g/mol (unlabeled)		Hydrolysis at 25°C (2923861)	2.9 (22)	pH 7;15°C: Phenyl = 2.6 (30) pH 7;15°C: Triazine = 2.6 (30)
			2.8 (7)	
			3.3 (30)	pH 7;25°C: Phenyl = 3.3 (30)
			3.1 (30)	pH 7;25°C: Triazine = 3.1 (30)
			4.6 (30)	pH 7;35°C: Phenyl label = 4.6 (30) pH 7;35°C: Triazine = 4.0 (30)
			4.0 (30)	
			4.5 (30)	pH 9;15°C: Phenyl = 4.5 (30)
			4.3 (15)	pH 9;15°C: Triazine = 3.1 (30)
			4.6 (3)	pH 9, 25°C: Phenyl = 3.1 (29)
			4.8 (3)	pH 9, 25°C: Triazine = 2.1 (29)
			3.0 (3)	pH 9;35°C: Phenyl = 1.8 (30)
			3.3 (0.21)	pH 9;35°C: Triazine = 1.5 (30)
			Soil Photolysis (2923985)	24.8 (7)
17.5 (19)	Irradiated: Triazine = 17.5 (19)			
7.1 (10) 9.4 (10)	Dark: Phenyl = 6.7 (19) Dark: Triazine = 5.4 (19)			

¹¹ PMRA# 2924011/50406314: Due to poor mass balance for the Triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
		Aqueous Photolysis (2923863)	7.5 (5)	pH 5; irradiated: Phenyl = 3.5 (15) pH 5; irradiated: Triazine = 3.8 (15)
			10.4 (2)	
			9.9 (15) 11.8 (7)	pH 5; dark: Phenyl = 9.9 (15) pH 5; dark: Triazine = 11.7 (15)
		Aerobic soil (2923981)	10.2 (92)	IA (loam): Triazine = 9.8 (120)
			10.9 (7)	NJ (loam): Triazine = 1.4 (120)
			11.5 (16)	LUFA 2.2(sandy loam): Triazine = 2.7 (120)
			8.7 (28)	LUFA 2.2(sandy loam): Phenyl = 3.6 (120)
			9.7 (120)	LUFA 2.2 STERILE: Phenyl = 9.7 (120)
			6.9 (16)	LUFA 2.3(sandy loam): Triazine = 0.7 (120)
		Anaerobic soil (2923983)	5.2 (90)	CA soil (rep1): (total system) Triazine = 4.0 (119)
			6.0 (29)	(rep2) = 5.1 (119)
			12.6 (90)	LA soil (rep1): (total system) Triazine = 10.3 (119)
			9.9 (29, 90)	(rep2) = 8.8 (119)
			6.2 (6, 29)	LUFA 2.2 (rep1): (total system) Triazine = 5.8 (119)
			5.9 (2)	(rep2): 5.5 (119)
			6.2 (6, 14)	LUFA 2.2 (rep1): (total system) Phenyl = 5.6 (119)
			10.1 (90)	(rep2) = 5.0 (119)
		Aerobic aquatic (2924009)	13.0 (30)	NC Pond: Phenyl (total system) = 8.7 (100)
			16.1 (30)	NC Pond: Triazine (total system) = 8.9 (100)
			3.7 (55, 75)	Goose River: Phenyl (total system) = 4.2 (100)
			3.5 (29)	Goose River: Triazine (total system) = 2.1 (100)
		Anaerobic aquatic (2924011 ¹²)	5.8 (100)	NC Pond: Phenyl (total system) = 5.8 (100)
			4.2 (100)	NC Pond: Triazine (total system) = 4.2 (100)
			3.1 (76)	Goose River: Phenyl (total system) = 2.2 (100)
			2.8 (100)	Goose River: Triazine (total system) = 2.8 (100)
			4.2 (55)	REPEAT Goose River: Triazine (total system) = 1.7 (99)
		Field studies (2923991, 2923993, 2923995)	ND: 10.4 (10)	ND: nd (720)
WA: 16.1 (20)	WA: nd (710)			
NY: 52.5 (3)	NY: nd (631)			
TX: 26.5 (3)	TX: nd (628)			

¹² PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
M850H002 BASF Reg. No. 5757725 1,5-dimethyl-6-thioxo-3-(2,2,7-trifluoro-3-oxo-3,4-dihydro-2H-1,4-benzoxazin-6-yl)-1,3,5-triazinane-2,4-dione CAS#: N/A Formula: C ₁₃ H ₉ F ₃ N ₄ O ₄ S MW: 374.2997 g/mol (unlabeled)		Hydrolysis (2923861)	0.8 (16)	pH 7;15°C: Phenyl = ND (30) pH 7;15°C: Triazine = 4.2 (30)
			4.2 (30)	
			0.9 (7)	pH 7;25°C: Phenyl = 0.8 (30)
			2.4 (22)	pH 7;25°C: Triazine = 2.1 (30)
			0.7 (7)	pH 7;35°C: Phenyl = ND (30)
			1.2 (22)	pH 7;35°C: Triazine = ND (30)
			nd (30)	pH 9;15°C: Phenyl = ND (30)
		nd (30)	pH 9;15°C: Triazine = ND (30)	
		nd (29)	pH 9, 25°C: Phenyl = ND (29)	
		nd (29)	pH 9, 25°C: Triazine = ND (29)	
		nd(30)	pH 9;35°C: Phenyl = ND (30)	
		nd (30)	pH 9;35°C: Triazine = ND (30)	
		Soil Photolysis (2923985)	6.8 (19)	Irradiated: Phenyl = 6.8 (19)
			9.3 (19)	Irradiated: Triazine = 9.3 (19)
			18.2 (10, 19)	Dark: Phenyl = 23.5 (19) Dark: Triazine = 18.2 (19)
		Aqueous Photolysis (2923863)	23.1 (10)	pH 5;irradiated: Phenyl = 20.8 (15)
			26.5 (10)	pH 5; irradiated: Triazine = 24.8 (15)
			nd (15)	pH 5; dark: Phenyl = ND (15)
		Aerobic soil (2923981)	nd (15)	pH 5;dark: Triazine = ND (15)
			10.9 (120)	IA (loam): Triazine = 10.9 (120)
			16.5 (16)	NJ (loam): Triazine =7.5 (120)
			8.9 (59)	LUFA 2.2(sandy loam): Triazine = 7.2 (120)
			8.6 (28)	LUFA 2.2(sandy loam): Phenyl = 7.3 (120)
			10.0 (120)	LUFA 2.2 sterile: Phenyl = 10.0 (120)
			21.4 (16)	LUFA 2.3(sandy loam): Triazine = 3.3 (120)
		Anaerobic soil (2923983)	22.7 (6)	CA soil (rep1) (total system): Triazine = 5.3 (119)
			21.6 (6)	(rep2) = 5.5 (119)
			11.7 (6)	LA soil (rep1) (total system): Triazine = 9.2 (119)
12.8 (2)	(rep2) = 8.4 (119)			
9.1 (14)	LUFA 2.2 (rep1) (total system): Triazine = 5.8 (119)			
7.2 (6, 61)	(rep2): 1.7 (119)			
11.6 (61)	LUFA 2.2 (rep1) (total system): Phenyl = 11.0 (119)			
9.2 (61)	(rep2) = 5.9 (119)			
15.1 (14)	LUFA 2.3 (rep1) (total system): Triazine = 3.4 (119)			
5.6 (30)	(rep2) = 2.0 (119)			
Aerobic aquatic (2924009)	8.4 (7)	NC Pond: Phenyl (total system) = 4.5 (100)		
	8.0 (7)	NC Pond: Triazine (total system) = 5.5 (100)		
	8.3 (1)	Goose River: Phenyl (total system) = 0 (100)		
6.8 (8)	Goose River: Triazine (total system) = 0.8 (100)			


Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
		Anaerobic aquatic (2924011 ¹³)	5.4 (56) 6.0 (100) 10.1 (100) 13.6 (7) 0.3 (0)	NC Pond: Phenyl (total system) = 5.2 (100) NC Pond: Triazine (total system) = 6.0 (100) Goose River: Phenyl (total system) = 10.1 (100) Goose River: Triazine (total system) = 2.0 (100) REPEAT Goose River: Triazine (total system) = 0 (99)
		Field studies (2923991, 2923993, 2923995)	ND: 3.4 (10) WA: 1.7 (20) NY: 2.1 (60) TX: 1.3 (3)	ND: nd (720) WA: nd (710) NY: nd (631) TX: nd (628)
M850H003 BASF Reg. No. 5757726 1,3-dimethyl-5-(2,2,7-trifluoro-3-oxo-3,4-dihydro-2H-1,4-benzoxazin-6-yl)-1,3,5-triazinane-2,4,6-trione CAS#: N/A Formula: C ₁₃ H ₉ F ₃ N ₄ O ₅ MW: 358.23 g/mol (unlabelled)		Hydrolysis (2923861)	nd (30) nd (30) nd (30) nd (30) nd (30) nd (30) 3.6 (15) nd (29) nd (30) nd (30)	pH 7;15°C: Phenyl = nd (30) pH 7;15°C: Triazine = nd (30) pH 7;25°C: Phenyl = nd (30) pH 7;25°C: Triazine = nd (30) pH 7;35°C: Phenyl label = nd (30) pH 7;35°C: Triazine = nd (30) pH 9;15°C: Phenyl = nd (30) pH 9;15°C: Triazine = nd (30) pH 9, 25°C: Phenyl = nd (29) pH 9, 25°C: Triazine = nd (29) pH 9;35°C: Phenyl = nd (30) pH 9;35°C: Triazine = nd (30)
		Soil Photolysis (2923985)	7.9 (19) 8.3 (19) 5.0 (19) 2.9 (19)	Irradiated: Phenyl = 7.9 (19) Irradiated: Triazine = 8.3 (19) Dark: Phenyl = 5.0 (19) Dark: Triazine = 2.9 (19)
		Aerobic soil (2923981)	9.8 (120) 29.4 (59) 26.8 (92) 24.8 (120) 3.1 (120) 38.2 (59)	IA (loam): Triazine = 9.8 (120) NJ (loam): Triazine = 27.1 (120) LUFA 2.2(sandy loam): Triazine = 27.5 (120) LUFA 2.2(sandy loam): Phenyl = 24.8 (120) LUFA 2.2 sterile: Phenyl = 3.1 (120) LUFA 2.3(sandy loam): Triazine = 14.2 (120)
		Aerobic soil with TP M850H003(2923989 ¹⁴)	TP applied to soil TP applied to soil TP applied to soil TP applied to soil	LUFA 5M 20°C: 18.2 (123) LUFA 2.2 20°C: 75.0 (123) LUFA 2.3 20°C: 21.2 (123) NJ 20°C: 34.0 (123)
		Anaerobic soil (2923983)	11.0 (2) 10.9 (14) 6.9 (14) 5.0 (2)	CA soil (rep1): (total system) Triazine = 9.8 (119) (rep2) = 10.4 (119) LA soil (rep1): (total system) Triazine = 5.1 (119) (rep2) = 4.8 (119)

¹³ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

¹⁴ PMRA# 2923989/50406304 Except for the LUFA 2.2 soil type, the 7-, 60- and 123-DAT samples from the other 3 soils were further characterized by triple extraction with 0.5M NaOH. The radioactive residues in the NaOH extracts were further separated into fulvic and humic acid fractions through acidic precipitation. This difference in methods may account for the ~25% difference in the LUFA 2.2 recovery compared to the other soil types.

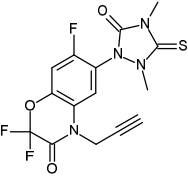
Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
			10.0 (29)	LUFA 2.2 (rep1): (total system) Triazine = 7.7 (119)
			9.2 (2)	(rep2): 8.2 (119)
			10.3 (14)	LUFA 2.2 (rep1): (total system) Phenyl = 10.1 (119)
			12.1 (14)	(rep2) = 10.5 (119)
			17.9 (14)	LUFA 2.3 (rep1): (total system) Triazine = 14.1 (119)
		Aerobic aquatic (2924009)	2.3 (100)	NC Pond: Phenyl (total system) = 2.3 (100)
			1.3 (76)	NC Pond: Triazine (total system) = 1.0 (100)
			1.8 (8)	Goose River: Phenyl (total system) = 0.5 (100)
		Anaerobic aquatic (2924011 ¹⁵)	1.1 (8)	Goose River: Triazine (total system) = 1.0 (100)
			ND	NC Pond: Phenyl (total system) = nd
			ND	NC Pond: Triazine (total system) = nd
			4.0 (15)	Goose River: Phenyl (total system) = 0.6 (100)
		Field studies (2923991, 2923993, 2923995)	nd	Goose River: Triazine (total system) = nd
			nd	REPEAT Goose River: Triazine (total system) = 0 (99)
			ND: 10.7 (40)	ND: 4.3 (720)
WA: 6.2 (48)	WA: nd (710)			
M850H004 BASF Reg. No. 5833884 N,N-dimethyl-N'-[2,2,7-trifluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]dicarbonimidothioic-diamide CAS#: N/A Formula: C ₁₅ H ₁₃ F ₃ N ₄ O ₃ S MW: 386.4 g/mol		Hydrolysis (2923861)	4.7 (30)	pH 7;15°C: Phenyl = 4.7 (30) pH 7;15°C: Triazine = 1.7 (30)
			1.7 (30)	
			18.4 (30)	pH 7;25°C: Phenyl = 18.4 (30) pH 7;25°C: Triazine = 8.5 (30)
			8.5 (30)	
			31.0 (30)	pH 7;35°C: Phenyl label = 31.0 (30) pH 7;35°C: Triazine = 14.7 (30)
			14.7 (30)	
			71.4 (15)	pH 9;15°C: Phenyl = 68.0 (30) pH 9;15°C: Triazine = 32.6 (30)
			45.3 (15)	
			75.3 (7)	pH 9, 25°C: Phenyl = 34.8 (29) pH 9, 25°C: Triazine = 23.3 (29)
			38.0 (15)	
			71.0 (1)	pH 9;35°C: Phenyl = 13.6 (30) pH 9;35°C: Triazine = ND (30)
Aerobic soil with transformation	38.9 (1)			
	TP applied to soil	LA soil = 0.6 (91)		
	TP applied to soil	NC soil = 4.3 (91)		

¹⁵ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
		product (TP) M850H004(2923990 ¹⁶)	TP applied to soil	WN soil = 5.5 (91)
			TP applied to soil	Speyer 5M = 0.4 (91)
		Anaerobic soil (2923983)	9.6 (29)	CA soil (rep1): (total system) Triazine = 6.6 (119)
			12.4 (29)	(rep2) = 8.2 (119)
			5.0 (29)	LA soil (rep1): (total system) Triazine = 1.1 (119)
			4.4 (14)	(rep2) = 3.1 (119)
			8.2 (90)	LUFA 2.2 (rep1): (total system) Triazine = 7.0 (119)
			10.3 (119)	(rep2) = 10.3 (119)
			11.3 (29)	LUFA 2.2 (rep1): (total system) Phenyl = 9.4 (119)
			18.5 (119)	(rep2) = 18.5 (119)
		Aerobic aquatic (2924009)	4.0 (30, 119)	LUFA 2.3 (rep1): (total system) Triazine = 4.0 (119)
			1.9 (119)	(rep2) = 1.9 (119)
			3.4 (56)	NC Pond: Phenyl (total system) = 2.0 (100)
			2.0 (30)	NC Pond: Triazine (total system) = 1.0 (100)
		Anaerobic aquatic (2924011 ¹⁷)	57.5 (15)	Goose River: Phenyl (total system) = 23.7 (100)
			27.1 (15)	Goose River: Triazine (total system) = 14.1 (100)
			29.3 (56)	NC Pond: Phenyl (total system) = 18.4 (100)
			16.5 (74)	NC Pond: Triazine (total system) = 11.4 (100)
			50.6 (31)	Goose River Phenyl (total system) = 17.5 (100)
		Field studies (2923991, 2923993, 2923995)	27.7 (31)	Goose River: Triazine (total system) = 10.6 (100)
29.0 (29)	REPEAT Goose River Triazine (total system) = 11.7 (99)			
ND: 0.7 (3)	ND: nd (720)			
WA: 0.48 (10)	WA: nd (710)			
M850H012		2923993, 2923995	NY: 0.5 (60)	NY: nd (631)
		Hydrolysis (2923861)	TX: 1.1 (91)	TX: nd (628)
			nd	pH 7;15°C: Phenyl = nd (30)
			nd	pH 7;25°C: Phenyl = ND (30)

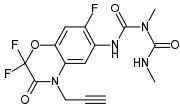
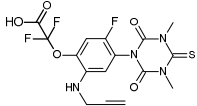
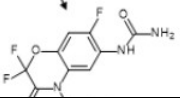
¹⁶ PMRA# 2923990/50406319: M850H004 is a soil metabolite of BAS850H and may be formed in soil. It was observed as a transformation product of BAS 850 H under anaerobic conditions (PMRA# 2923983/50406302) and could possibly co-elute with a major transition product M850H002 (PMRA# 2923981/50406301). Therefore, in order to fully assess the potential environmental impact, information on the degradation characteristics of M850H004 in aerobic soil was required. Since the study was conducted with non-labeled test compound, the extracted and unextracted residues cannot be determined. No transformation products were observed and no CO₂ formation was trapped. Since the study was conducted with non-labeled compound, no mass balance could be obtained. Therefore, the observed apparent decline in M850H004 concentrations may not be fully attributed to degradation and the calculated half-lives maybe overestimated. A few of the fortified test results were below the validity criterion of 70–110%. The results should be used with caution.

¹⁷ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)	
BASF Reg. No. 5797901 6-amino-2,2,7-trifluoro-4-(prop-2-yn-1-yl)-2H-1,4-benzoxazin-3(4H)-one CAS#: N/A Formula: C ₁₁ H ₇ F ₃ N ₄ O ₅ MW: 256.2 g/mol			8.2 (30)	pH 7;35°C: Phenyl = 8.2 (30)	
			13.2 (30)	pH 9;15°C: Phenyl = 13.2 (30)	
			39.4 (29)	pH 9, 25°C: Phenyl = 39.4 (29)	
			80.9 (30)	pH 9;35°C: Phenyl = 80.9 (30)	
		Soil Photolysis (2923985)	1.9 (10)	Irradiated: Phenyl = 1.5 (19)	
		Aerobic aquatic (2924009)	2.9 (76)	NC Pond: Phenyl (total system) = 1.0 (100)	
			6.4 (100)	Goose River: Phenyl (total system) = 6.4 (100)	
		Anaerobic aquatic (2924011 ¹⁸)	2.4 (100)	NC Pond: Phenyl (total system) = 2.4 (100)	
			4.0 (76)	Goose River: Phenyl (total system) = 2.6 (100)	
		M850H033 BASF Reg. No. N/A 6-(2,4-dimethyl-5-oxo-3-thioxo-1,2,4-triazolidin-1-yl)-2,2,7-trifluoro-4-prop-2-ynyl-1,4-benzoxazin-3-one CAS#: N/A Formula: C ₁₃ H ₁₁ F ₃ N ₄ O ₃ S MW: 384.05 g/mol		Hydrolysis (2923861)	nd
nd	pH 7;15°C: Triazine = nd				
nd	pH 7;25°C: Phenyl = nd				
nd	pH 7;25°C: Triazine = nd				
nd	pH 7;35°C: Phenyl label = nd				
nd	pH 7;35°C: Triazine = nd				
28.6 (1)	pH 9;15°C: Phenyl = 9.8 (30)				
10.8 (15)	pH 9;15°C: Triazine = 8.3 (30)				
12.7 (29)	pH 9, 25°C: Phenyl = 12.7 (29)				
	pH 9, 25°C: Triazine = 1.5 (29)				
5.6 (3)					
30.1 (15)	pH 9;35°C: Phenyl = 5.4 (30)				
10.4 (22)	pH 9;35°C: Triazine = 8.6 (30)				
Aerobic aquatic (2924009)	4.0 (30)				NC Pond: Phenyl (total system) = 1.9 (100)
	1.8 (56)				NC Pond: Triazine (total system) = 1.3 (100)
	3.5 (100)	Goose River: Phenyl (total system) = 3.5 (100)			
Anaerobic aquatic (2924011 ¹⁹)	3.0 (36)	Goose River Triazine (total system) = 1.1 (100)			
	4.8 (100)	NC Pond: Phenyl (total system) = 4.8 (100)			
7.5 (74)	NC Pond: Triazine (total system) = 4.5 (100)				

¹⁸ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

¹⁹ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
			24.2 (56)	Goose River: Phenyl (total system) = 11.8 (100)
			9.9 (56)	Goose River: Triazine (total system) = 4.5 (100)
			8.1 (100)	REPEAT Goose River: Triazine (total system) = 8.1 (99)
M850H035 BASF Reg. No. 6070203 1,3-dimethyl-1-[(2,2,7-trifluoro-3-oxo-4-prop-2-ynyl-1,4-benzoxazin-6-yl)carbamoyl]urea CAS#: N/A Formula: C ₁₅ H ₁₃ F ₃ N ₄ O ₄ MW: 370.3 g/mol		Hydrolysis (2923861)	nd	pH 7;15°C: Phenyl = nd
			nd	pH 7;15°C: Triazine = nd
			nd	pH 7;25°C: Phenyl = nd
			nd	pH 7;25°C: Triazine = nd
			nd	pH 7;35°C: Phenyl label = nd
			nd	pH 7;35°C: Triazine = nd
			nd	pH 9;15°C: Phenyl = nd
		nd	pH 9;15°C: Triazine = nd	
		2.9 (21)	pH 9, 25°C: Phenyl = 1.7 (29)	
		1.3 (15)	pH 9, 25°C: Triazine = 1.0 (29)	
		2.4 (30)	pH 9;35°C: Phenyl = 2.4 (30)	
		1.6 (30)	pH 9;35°C: Triazine = 1.6 (30)	
		Aerobic aquatic 2924009 50406313	11.3 (15)	NC Pond: Phenyl (total system) = 1.7 (100)
			10.0 (15)	NC Pond: Triazine (total system) = 0.7 (100)
			nd	Goose River: Phenyl (total system) = nd
		Anaerobic aquatic 2924011 ²⁰ 50406314	nd	Goose River: Triazine (total system) = nd
			4.4 (74)	NC Pond: Phenyl (total system) = 1.8 (100)
7.9 (74)	NC Pond: Triazine (total system) = 3.0 (100)			
nd	Goose River: Phenyl (total system) = nd			
2.4 (100)	Goose River: Triazine (total system) = 2.4 (100)			
0.3 (55)	REPEAT Goose River: Triazine (total system) = 0 (99)			
M850H040 BASF Reg. No. 6095223 2-[4-(3,5-dimethyl-2,6-dioxo-4-thioxo-1,3,5-triazinan-1-yl)-5-fluoro-2-(prop-2-ynylamino)phenoxy]-2,2-difluoro-acetic acid CAS#: N/A Formula: C ₁₆ H ₁₃ F ₃ N ₄ O ₅ S MW: 430.36 g/mol		Hydrolysis (2923861)	15.2 (22)	pH 7;15°C: Phenyl = 13.7 (30)
			14.9 (22)	pH 7;15°C: Triazine = 12.3 (30)
			15.1 (22)	pH 7;25°C: Phenyl = 12.0 (30)
			16.3 (7)	pH 7;25°C: Triazine = 11.2 (30)
			13.8 (3)	pH 7;35°C: Phenyl = 8.3 (30)
			14.2 (7)	pH 7;35°C: Triazine = 7.1 (30)
			nd	pH 9;15°C: Phenyl = nd
nd	pH 9;15°C: Triazine = nd			
nd	pH 9, 25°C: Phenyl = nd			
nd	pH 9, 25°C: Triazine = nd			
M850H042 BASF Reg. No. 6112929		Aerobic aquatic (2924009)	nd	NC Pond Phenyl (total system) = nd
			nd	NC Pond Triazine (total system) = nd

²⁰ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)	
(2,2,7-trifluoro-3-oxo-4-prop-2-ynyl-1,4-benzoxazin-6-yl)urea CAS#: N/A Formula: C ₁₂ H ₈ F ₃ N ₃ O ₃ MW: 299.21 g/mol			7.1 (75)	Goose River: Phenyl (total system) = 6.1 (100)	
			3.6 (75)	Goose River: Triazine (total system) = 3.5 (100)	
		Anaerobic aquatic (2924011 ²¹)	nd	NC Pond: Phenyl (total system) = nd	
			nd	NC Pond: Triazine (total system) = nd	
			15.6 (100)	Goose River: Phenyl (total system) = 15.6 (100)	
			5.8 (76)	Goose River: Triazine (total system) = 5.2 (100)	
6.0 (99)	REPEAT Goose River: Triazine (total system) = 6.0 (99)				
Carbon dioxide CAS#: 124-38-9 Formula: CO ₂ MW: 44.0 g/mol	O=C=O	Hydrolysis (2923861 ²²)	nd	pH 7;15°C: Phenyl = na	
			nd	pH 7;15°C: Triazine = nd	
			nd	pH 7;25°C: Phenyl = na	
			2.7 (30)	pH 7;25°C: Triazine = 2.7 (30)	
			nd	pH 7;35°C: Phenyl label = na	
			17.1 (30)	pH 7;35°C: Triazine = 17.1 (30)	
			na	pH 9;15°C: Phenyl = na	
			9.1 (30)	pH 9;15°C: Triazine = 9.1 (30)	
			nd	pH 9, 25°C: Phenyl = na	
			14.4 (29)	pH 9, 25°C: Triazine = 14.4 (29)	
			nd	pH 9;35°C: Phenyl = na	
			22.1 (10)	pH 9;35°C: Triazine = 11.5 (30)	
			Soil Photolysis (2923985)	14.2 (19)	Irradiated: Phenyl = 14.2 (19)
				0.01 (19)	Irradiated: Triazine = 0.1 (19)
			Aqueous Photolysis (2923863)	28.8 (15)	pH 5;irradiated: Phenyl = 28.8 (15)
				13.9 (15)	pH 5; irradiated: Triazine = 13.9 (15)
			Aerobic soil (2923981)	0.1 (59, 92, 120)	IA (loam): Triazine = 0.1 (120)
				1.2 (120)	NJ (loam): Triazine = 1.2 (120)
				0.4 (120)	LUFA 2.2(sandy loam): Triazine = 0.4 (120)
				0.1 (120)	LUFA 2.2(sandy loam): Phenyl = 0.1 (120)
0 (120)	LUFA 2.3(sandy loam): Triazine = 0 (120)				
Anaerobic soil (2923983)	20.9 (119)	CA soil (rep1) (total system): Triazine = 20.9 (119)			
	20.9 (119)	(rep2) = 20.9 (119)			
	0.6 (119)	LA soil (rep1): (total system) Triazine = 0.6 (119)			
	0.6 (119)	(rep2) = 0.6 (119)			

²¹ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

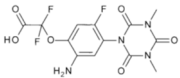
²² PMRA# 2923861/50406014: The method used to measure CO₂ may not be valid. The author assumes the volatiles are CO₂ but by adding NaOH, it enhances hydrolysis as the reaction is base catalyzed. The methods used to confirm presence of CO₂ are based on the addition of BaCl₂ in measurable quantities however, the amount was not quantified. Therefore with no verification that the BaCl₂ was applied properly, this method may not be valid (method was used for pH 7, 25°C and 35°C Triazine label only).

Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
			14.4 (119)	LUFA 2.2 (rep1) (total system): Triazine = 14.4 (119)
			14.4 (119)	(rep2) = 14.4 (119)
			0.2 (119)	LUFA 2.2 (rep1) (total system): Phenyl = 0.2 (119)
			0.2 (119)	(rep2) = 0.2 (119)
		Aerobic aquatic (2924009 ²³)	<1.3 (100)	NC Pond: Phenyl (total system) = <1.3 (100)
			14.5 (100)	NC Pond: Triazine (total system) = 14.5 (100)
			<0.9 (100)	Goose River: Phenyl (total system) = <0.9 (100)
		Anaerobic aquatic (2924011 ^{24,25})	26.9 (100)	Goose River: Triazine (total system) = 26.9 (100)
			<1.0 (100)	NC Pond: Phenyl (total system) = <1.0 (100)
			20.4 (100)	NC Pond: Triazine (total system) = 3.0 (100)
			<1.0 (100)	Goose River: Phenyl (total system) = <1.0 (100)
29.3	REPEAT Goose River Triazine (total system) = 29.3 (99)			
Non-extracted Residues (NER)	N/A	Soil Photolysis (2923985)	16.5 (19)	Irradiated: Phenyl = 16.5 (19)
			14.2 (19)	Irradiated: Triazine = 14.2 (19)
		Aerobic soil (2923981)	19.3 (120)	IA (loam): Triazine = 19.3 (120)
			49.2 (120)	NJ (loam): Triazine = 49.2 (120)
			32.4 (92)	LUFA 2.2(sandy loam): Triazine = 29.0 (120)
			26.5 (120)	LUFA 2.2(sandy loam): Phenyl = 26.5 (120)
		64.9 (92)	LUFA 2.3(sandy loam): Triazine = 64.7 (120)	
		Anaerobic soil (2923983)	24.4 (119)	CA soil (rep1): (total system) Triazine = 24.4 (119)
			25.2 (119)	(rep2) = 25.2 (119)
			22.3 (119)	LA soil (rep1): (total system) Triazine = 22.3 (119)
21.5 (119)	(rep2) = 21.5 (119)			

²³ PMRA# 2924009/50406313: In this study report there was uncharacterized radioactivity seen in the volatile trap that was partially attributed to CO₂. The values presented in the table are from the Material Balance Tables 4-7 in the associated DER. There is a difference in how the volatiles were released based on which radio-labels (phenyl vs triazine) were applied.

²⁴ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

²⁵ PMRA# 2924011/50406314: In this study report there was uncharacterized radioactivity seen in the volatile trap that was partially attributed to CO₂. The values presented in the table are from the Material Balance Tables 5-9 in the associated DER. There is a difference in how the volatiles were released based on which radio-labels (phenyl vs triazine) were applied.

Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
			16.0 (90, 119)	LUFA 2.2 (rep1) (total system): Triazine = 16.0 (119)
			16.5 (119)	(rep2) = 16.5 (119)
			23.8 (119)	LUFA 2.2 (rep1) (total system): Phenyl = 23.8 (119)
			24.4 (119)	(rep2) = 24.4 (119)
			34.3 (2)	LUFA 2.3 (rep1) (total system): Triazine = 33.0 (119)
			27.5 (2)	(rep2) = 24.4 (119)
		Aerobic aquatic (2924009)	21.2 (100)	NC Pond: Phenyl (total system) = 21.2 (100)
			10.2 (100)	NC Pond: Triazine (total system) = 10.2 (100)
			42.6 (100)	Goose River: Phenyl (total system) = 42.6 (100)
			22.4 (100)	Goose River: Triazine (total system) = 22.4 (100)
		Anaerobic aquatic (2924011 ²⁶)	11.8 (100)	NC Pond: Phenyl (total system) = 11.8 (100)
			6.2 (100)	NC Pond: Triazine (total system) = 6.2 (100)
25.2 (100)	Goose River: Phenyl (total system) = 25.2 (100)			
13.4 (100)	Goose River: Triazine (total system) = 13.4 (100)			
			21.5 (99)	REPEAT Goose River: Triazine (total system) = 21.5 (99)
MINOR (<10%) TRANSFORMATION PRODUCTS				
M850H011 BASF Reg. No. 5757726 CAS#: N/A Formula: C ₁₃ H ₁₁ F ₃ N ₄ O ₅ MW: 376 µg		Aerobic soil with TP M850H003(2923989)	4.8 (123)	LUFA 5M 20°C: 4.8 (123)
			1.1 (27)	LUFA 2.2 20°C: 0.8 (123)
			2.7 (123)	LUFA 2.3 20°C: 2.7 (123)
			3.5 (123)	NJ 20°C: 3.5 (123)
M850H041 BASF Reg. No. N/A 1-methyl-3-(2,2,7-trifluoro-3-oxo-4-prop-2-ynyl-1,4-benzoxazin-6-yl)urea CAS#: N/A Formula: C ₁₃ H ₁₀ F ₃ N ₃ O ₃ MW: 313.0674 g/mol		Hydrolysis (2923861)	nd (30)	pH 7;15°C: Phenyl = nd (30)
			nd (30)	pH 7;15°C: Triazine = nd (30)
			nd (30)	pH 7;25°C: Phenyl = nd (30)
			nd (30)	pH 7;25°C: Triazine = nd (30)
			nd (30)	pH 7;35°C: Phenyl label = nd (30)
			nd (30)	pH 7;35°C: Triazine = nd (30)
			nd (30)	pH 9;15°C: Phenyl = nd (30)
			nd (30)	pH 9;15°C: Triazine = nd (30)
1.9 (29)	pH 9, 25°C: Phenyl = 1.9 (29)			
3.7 (29)	pH 9, 25°C: Triazine = 3.7 (29)			
3.6 (30)	pH 9;35°C: Phenyl = 3.6 (30)			
2.1 (22)	pH 9;35°C: Triazine = 1.7 (30)			

²⁶ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

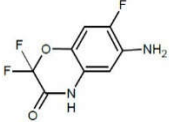
Code and chemical name	Chemical structure	Study (PMRA#)	Max %AR (d)	%AR at study end (study length, d)
		Anaerobic aquatic (2924011 ²⁷)	nd 2.3 (15) 3.9 (100) 1.8 (31) 1.2 (55)	NC Pond: Phenyl (total system) = nd NC Pond: Triazine (total system) = 1.3 (100) Goose River: Phenyl (total system) = 3.9 (100) Goose River: Triazine (total system) = 1.2 (100) REPEAT Goose River: Triazine (total system) = 0.5 (99)
ABO BASF Reg. No. 5878200 6-amino-2,2,7-trifluoro-2H-1,4-benzoxazin-3(4H)-one CAS#: N/A Formula: C ₈ H ₅ F ₃ N ₂ O ₂ MW: 218.1 g/mol		Soil Photolysis (2923985)	5.2 (7)	Irradiated: Phenyl = 3.6 (19)

Table 12 Effects on terrestrial species

Organism	Study (exposure)	Test substance	Endpoint value	Degree of toxicity	PMRA Study#
Earthworm (<i>Eisenia foetida</i>)	Acute (14-day)	TFX	LC ₅₀ >985 mg a.i./kg soil NOEC ≥ 985 mg a.i./kg soil	na	2924127 2924128
	Acute (14-day)	BAS 850 00H formulation (40.9% TFX)	LC ₅₀ >414.6 mg a.i./kg soil	na	2924168 2924169
	Acute (14-day)	BAS 851 00H formulation (11.2% TFX 21.5% SFF)	LC ₅₀ >1000 mg formulation/kg soil (LC ₅₀ >112.0 mg TFX/kg soil) (LC ₅₀ >215.0 mg SFF/kg soil)	na	2924237 2924238
	Chronic (56-day)	TFX	EC ₅₀ >1000 mg a.i./kg soil NOEC (reprod.) = 308.6 mg a.i./kg soil	na	2924129 2924130
Honey bee (<i>Apis mellifera</i>)	Acute oral (48-h)	TFX	LD ₅₀ >10.0 µg a.i./bee	Moderately toxic	2924116 2924117
	Acute contact (48-h)	TFX	LD ₅₀ >100.0 µg a.i./bee	Practically non-toxic	2924116 2924117
	Acute oral (48-h)	BAS 850 00H formulation (40.9% TFX)	LD ₅₀ >107.2 µg a.i./bee	Practically non-toxic	2924118 2924119
	Acute contact (48-h)	BAS 850 00H formulation (40.9% TFX)	LD ₅₀ >100.0 µg a.i./bee	Practically non-toxic	2924118 2924119
	Acute oral (48-h)	BAS 851 00H formulation (11.2% TFX 21.5% SFF)	LD ₅₀ >318.1 µg formulation/bee (LD ₅₀ >35.6 µg TFX/bee) (LD ₅₀ >68.4 µg SFF/bee)	Practically non-toxic	2924231 2924232
	Acute contact (48-h)	BAS 851 00H formulation (11.2% TFX 21.5% SFF)	LD ₅₀ >309.9 µg formulation/bee (LD ₅₀ >34.7 µg TFX/bee) (LD ₅₀ >66.6 µg SFF/bee)	Practically non-toxic	2924231 2924232
	Acute larval (8-day)	BAS 850 00H formulation (40.9% TFX)	LD ₅₀ >105 µg a.i./larva (LC ₅₀ >3.08 g a.i./kg diet)	Practically non-toxic	2924120 2924121

²⁷ PMRA# 2924011/50406314: Due to poor mass balance for the triazine label in the Goose River system, this set of the test was repeated with freshly collected water/sediment samples with somewhat different characteristics (water: pH 8.4; sediment: clay loam, pH 7.7, organic matter 5.9%) than the original samples collected.

Organism	Study (exposure)	Test substance	Endpoint value	Degree of toxicity	PMRA Study#
	Chronic larval (22-day repeated dose)	TFX	LD ₅₀ = 9.0 µg a.i./larva/day (larvae) LD ₅₀ = 11.0 µg a.i./larva/day (pupae) ED ₅₀ = 7.9 µg a.i./larva/day (adult emerg)	na	2924124 2924126
	Chronic adult (10-day)	TFX	LD ₅₀ >9.6 µg a.i./bee/day NOAEL = 9.6 µg a.i./bee/day	na	2924122 2924123
Parasitic wasp (<i>Aphidius rhopalosiphi</i>)	Acute (48-h)	BAS 850 00H formulation (40.9% TFX)	LR ₅₀ >444.1 g a.i./ha		2924166 2924167
	Acute (48-h)	BAS 851 00H formulation (11.2% TFX 21.5% SFF)	LR ₅₀ >600 g formulation/ha (LR ₅₀ >67.2 g TFX/ha) (LR ₅₀ >129.0 g SFF/ha)		2924233 2924234
Predatory mite (<i>Typhlodromus pyri</i>)	Acute (7-day)	BAS 850 00H formulation (40.9% TFX)	LR ₅₀ >444.1 g a.i./ha		2924164 2924165
	Acute (7-day)	BAS 851 00H formulation (11.2% TFX 21.5% SFF)	LR ₅₀ >600 g formulation/ha (LR ₅₀ >67.2 g TFX/ha) (LR ₅₀ >129.0 g SFF/ha)		2924235 2924236
Bobwhite quail	Acute oral (14-day)	TFX	LD ₅₀ >2000 mg a.i./kg bw	Practically non-toxic	2924013 2924014
	Acute dietary (5-day)	TFX	LD ₅₀ >441 mg a.i./kg bw/day (LC ₅₀ >2222 mg a.i./kg diet)	Slightly toxic	2924021 2924022
	Reproduction (20-wk.)	TFX	NOAEC = 12.0 mg a.i./kg bw /day LOAEC = 23.0 mg a.i./kg bw /day	na	2924024 2924025
Mallard duck	Acute oral (14-day)	TFX	LD ₅₀ >3000 mg a.i./kg bw	Practically non-toxic	2924015 2924016
	Acute dietary (5-day)	TFX	LD ₅₀ 554.4 mg a.i./kg bw/day (LC ₅₀ =2841 mg a.i./kg diet)	Slightly toxic	2924019 2924020
	Reproduction (21-wk.)	TFX	NOAEC <18.5 mg a.i./kg bw /day LOAEC not determinable	na	2924025 2924026
	Reproduction (5-month)	TFX	NOAEC ≥15.8 mg a.i./kg bw /day LOAEC not reported	na	2924027 2924028
Canary	Acute oral (14-day)	TFX	LD ₅₀ >2000 mg a.i./kg bw	Practically non-toxic	2924017 2924018
Rat	Acute oral	TFX	LD ₅₀ >2000 mg a.i./kg bw	Practically non-toxic	2923901
	Acute oral	BAS 850 01 H (41.86% TFX)	LD ₅₀ >2000 mg end-use product/kg bw	Practically non-toxic	2924191
	Acute oral	BAS 851 01 H (10.85% TFX, 22.08% SFF)	LD ₅₀ >2000 mg end-use product/kg bw	Practically non-toxic	2924259
	Reproductive toxicity	TFX	Parental NOAEL = 6.4/6.7 mg/kg bw/day ♂/♀ Reproductive NOAEL = 21.5/68.1 mg/kg bw/day ♂/♀ Offspring NOAEL = 22.8 mg/kg bw/day		2923933
Crop species	Seedling Emergence (21-day)	BAS 850 A0 H (514 g TFX/L)	HC ₅ of IC ₅₀ (dry wt.) = 1.24 g a.i./ha ER ₂₅ (survival) = 0.68 g a.i./ha (carrot)	na	2924047 2924048
	Vegetative vigor (21-day)	BAS 850 A0 H (514 g TFX/L)	HC ₅ of IC ₅₀ (dry wt.) = 0.13 g a.i./ha ER ₂₅ (dry wt.) = 0.049 g a.i./ha (soybean)	na	2924049 2924050
	Seedling Emergence (21-day)	TP: M850H001	Most sensitive crop: Lettuce ER ₂₅ = 0.60 g a.i./ha (emergence)	na	2924051 2924052
	Seedling Emergence (21-day)	TP: M850H002	Most sensitive crop: Lettuce ER ₂₅ = 9.37 g a.i./ha (survival)	na	2924053 2924054

Table 13 Effects on aquatic species

Organism	Study (exposure)	Test substance	Endpoint value	Degree of toxicity	PMRA Study #
<i>Daphnia magna</i>	Acute (48-h flow through)	TFX	EC ₅₀ >1.95 mg a.i./L	Moderately toxic	2924077 2924078
	Acute (48-h static)	BAS 850 00H formulation (40.9% TFX)	EC ₅₀ >44.05 mg a.i./L	Slightly toxic	2924160 2924161
	Acute (48-h static)	BAS 851 00H formulation (11.2% TFX 21.5% SFF)	EC ₅₀ >86 mg formulation/L (EC ₅₀ >9.6 mg TFX/L) (EC ₅₀ >18.5 mg SFF/L)	Moderately toxic	2924227 2924228
	Chronic (21-day)	TFX	NOEC = 0.0107 mg a.i./L		2924085 2924086
	Acute (48-h)	TP: M850H001	EC ₅₀ >9.55 mg/L	Moderately toxic	2924079 2924080
	Acute (48-h)	TP: M850H002	EC ₅₀ = 5.88 mg/L	Moderately toxic	2924081 2924082
	Acute (48-h)	TP: M850H004	EC ₅₀ >2.19 mg/L	Moderately toxic	2924083 2924084
<i>Hyalella Azteca</i>	Acute (10-day)	TFX	LC ₅₀ >0.072 mg a.i./L (overlying water) LC ₅₀ >2.19 mg a.i./L (pore water) LC ₅₀ >411 mg a.i./kg (dry sediment)	Very highly toxic	2924100 2924101
<i>Chironomus dilutus</i>	Acute (10-day spiked sediment flow-through)	TFX	LC ₅₀ >0.134 mg a.i./L (overlying water) LC ₅₀ >1.34 mg a.i./L (pore water) LC ₅₀ >71.1 mg a.i./kg (dry sediment)	Highly toxic	2924102 2924103
	Acute (10-day spiked sediment)	TP: M850H004	LC ₅₀ >0.0628 mg/L (overlying water) LC ₅₀ >1.56 mg/L (pore water) LC ₅₀ >72.8 mg/kg (dry sediment)	Very highly toxic	2924104 2924105
	Chronic (28-day spiked sediment)	TFX	NOEC ≥ 0.00792 mg a.i./L (overlying water) NOEC ≥ 0.0296 mg a.i./L (pore water) NOEC ≥ 0.408 mg a.i./kg (sediment)	na	2924106 2924107
<i>Oncorhynchus mykiss</i>	Acute (96-h flow-through)	TFX	LC ₅₀ >1.76 mg a.i./L	Moderately toxic	2924059 2924060
	Acute (96-h static)	BAS 850 00H formulation (40.9% TFX)	LC ₅₀ >43.26 mg a.i./L	Slightly toxic	2924158 2924159
	Acute (96-h static-renewal)	TP: M850H001	LC ₅₀ >9.71 mg/L	Moderately toxic	2924065 2924066
	Acute (96-h static-renewal)	TP: M850H004	LC ₅₀ >0.588 mg/L	Highly toxic	2924067 2924068
<i>Pimephales promelas</i>	Acute (96-h, flow-through)	TFX	LC ₅₀ >3.3 mg a.i./L	Moderately toxic	2924061 2924062
	ELS (32-day, flow-through)	TFX	NOEC = 12 µg a.i./L NOEC = 0.82 µg a.i./L ^A	na	2924069 2924070
<i>Cyprinus carpio</i>	Acute (96-h flow-through)	TFX	LC ₅₀ >1.68 mg a.i./L	Moderately toxic	2924063 2924064
<i>Pseudokirchneriella subcapitata</i>	Acute (96-h static)	TFX	EC ₅₀ = 0.459 µg a.i./L (yield) EC ₅₀ = 0.753 µg a.i./L (growth rate) EC ₅₀ = 0.482 µg a.i./L (AUC)	Very highly toxic	2924089 2924115
	Acute (96-h static)	BAS 850 00H formulation (40.9% TFX)	EC ₅₀ = 0.389 µg a.i./L (yield) EC ₅₀ = 0.583 µg a.i./L (growth rate) EC ₅₀ = 0.356 µg a.i./L (AUC)	Very highly toxic	2924162 2924163
	Acute (96-h static)	BAS 851 00H formulation (11.2% TFX)	EC ₅₀ = 3.6 µg end-use product/L (yield) EC ₅₀ = 8.0 µg end-use product/L (growth rate)	Very highly toxic	2924229 2924230

Organism	Study (exposure)	Test substance	Endpoint value	Degree of toxicity	PMRA Study #
		21.5% SFF)	EC ₅₀ = 3.8 µg end-use product/L (AUC)		
	Acute (96-h static)	TP: M850H001	EC ₅₀ = 7.48 µg/L (yield) EC ₅₀ = 11.1 µg/L (growth rate) EC ₅₀ = 7.35 µg/L (AUC)	Moderately toxic to highly toxic	2924093 2924094
	Acute (96-h static)	TP: M850H002	EC ₅₀ = 2.80 µg/L (yield) EC ₅₀ = 3.63 µg/L (growth rate) EC ₅₀ = 2.69 µg/L (AUC)	Moderately toxic	2924098 2924099
	Acute (96-h static)	TP: M850H004	EC ₅₀ = 8.47 µg/L (yield) EC ₅₀ = 12.7 µg/L (growth rate) EC ₅₀ = 8.31 µg/L (AUC)	Moderately toxic	2924096 2924097
<i>Anabaena flos-aquae</i>	Acute (96-h static)	TFX	EC ₅₀ >1.41 mg a.i./L	Moderately toxic	2924087 2924088
<i>Navicula pelliculosa</i>	Acute (96-h static)	TFX	EC ₅₀ = 0.200 µg a.i./L (yield) EC ₅₀ = 0.603 µg a.i./L (growth rate) EC ₅₀ = 0.230 µg a.i./L (AUC)	Very highly toxic	2924091 2924092
<i>Lemna gibba</i>	7-day static-renewal	TFX	EC ₅₀ = 0.129 µg a.i./L (frond number yield) EC ₅₀ = 1.17 µg a.i./L (frond number growth rate) EC ₅₀ = 0.115 µg a.i./L (final biomass) EC ₅₀ = 0.779 µg a.i./L (biomass growth rate)	Very highly toxic	2924114 2924115
	7-day static-renewal	BAS 850 00H formulation (40.9% TFX)	EC ₅₀ = 0.215 µg a.i./L (frond number yield) EC ₅₀ > 0.237 µg a.i./L (frond number growth rate) EC ₅₀ = 0.116 µg a.i./L (final biomass) EC ₅₀ > 0.237 µg a.i./L (biomass growth rate)	Very highly toxic	2924175 2924176
	7-day static-renewal	BAS 851 00H formulation (11.2% TFX 21.5% SFF)	EC ₅₀ = 2.6 µg end-use product/L (frond number yield) EC ₅₀ = 9.4 µg end-use product/L (frond number growth rate) EC ₅₀ = 1.8 µg end-use product/L (final biomass) EC ₅₀ = 7.2 µg end-use product/L (biomass growth rate)	Very highly toxic	2924243 2924244
	7-day static-renewal	TP: M850H001	EC ₅₀ = 0.0039 mg/L (frond number yield) EC ₅₀ = 0.0094 mg/L (frond number growth rate) EC ₅₀ = 0.0038 mg/L (final biomass) EC ₅₀ = 0.0088 mg/L (biomass growth rate)	Very highly toxic	2924112 2924113
	7-day static-renewal	TP: M850H002	EC ₅₀ = 0.0218 mg/L (frond number yield) EC ₅₀ = 0.0542 mg/L (frond number growth rate) EC ₅₀ = 0.0326 mg/L (final biomass)	Very highly toxic	2924108 2924109

Organism	Study (exposure)	Test substance	Endpoint value	Degree of toxicity	PMRA Study #
			EC ₅₀ = 0.0705 mg/L (biomass growth rate)		
	7-day static-renewal	TP: M850H004	EC ₅₀ = 0.0146 mg/L (frond number yield) EC ₅₀ = 0.0597 mg/L (frond number growth rate) EC ₅₀ = 0.0168 mg/L (final biomass) EC ₅₀ = 0.0742 mg/L (biomass growth rate)	Very highly toxic	2924110 2924111
<i>Cyprinodon variegatus</i>	Acute (96-h, flow-through)	TFX	LC ₅₀ >2.9 mg a.i./L	Moderately toxic	2924037 2924038
<i>Cyprinodon variegatus</i>	ELS (34-day, flow-through)	TFX	NOEC = 2.7 µg a.i./L NOEC = 0.82 µg a.i./L ^A	na	2924071 2924072
<i>Cyprinodon variegatus</i>	ELS (34-day, flow-through)	TP: M850H001	NOEC = 0.041 mg/L	na	2924073 2924074
<i>Americamysis bahia</i>	Acute (96-h)	TFX	LC ₅₀ = 0.371 mg a.i./L	Highly toxic	2924039 2924040
<i>Americamysis bahia</i>	Life-cycle (28-day, flow-through)	TFX	NOEC = 52.5 µg a.i./L	na	2924043 2924044
<i>Leptocheirus plumulosus</i>	Subchronic (10-day)	TFX	LC ₅₀ >0.347 mg a.i./L (overlying water) LC ₅₀ >2.02 mg a.i./L (pore water) LC ₅₀ >492 mg a.i./kg (dry sediment)	Highly toxic	2924045 2924046
<i>Crassostrea virginica</i>	Acute (96-h)	TFX	IC ₅₀ >2.88 mg a.i./L	Moderately toxic	2924041 2924042
<i>Skeletonema costatum</i>	Acute (96-h static)	TFX	EC ₅₀ >0.330 mg a.i./L	Highly toxic	2924035 2924036

^ANOEC based on USEPA's molar threshold approach as trifludimoxazin is an inhibitor of protoporphyrinogen oxidase (PPO) and these chemicals may have enhanced toxicity under UV light. The ELS NOEC using the USEPA's molar threshold would be 0.82 µg/L (0.002 µmol/L*412.3 g/mol*1 mol/1000000 µmol*1000000 µg/g). The USEPA has [guidance for light-dependent peroxidizing herbicides for chronic fish](#).

Table 14 Endpoints considered in the risk assessment

Organism	Exposure	Test Substance	Toxicity endpoint	Uncertainty factor	Assessment endpoint	Study# /
Earthworm (<i>Eisenia foetida</i>)	Acute (14-day)	TFX	LC ₅₀ >985 mg a.i./kg soil	2	492.5 mg a.i./kg soil	2924127
	Acute (14-day)	BAS 851 00H (11.2% TFX 21.5% SFF)	LC ₅₀ >1000 mg end-use product/kg soil	2	500 mg/kg soil	2924237
	Chronic (56-day)	TFX	NOEC (reprod.) = 308.6 mg a.i./kg soil	1	308.6 mg a.i./kg soil	2924129
Bee (<i>Apis mellifera</i>)	Acute oral (48-h)	TFX	LD ₅₀ >10.0 µg a.i./bee	na	10.0 µg a.i./bee	2924116
	Acute contact (48-h)	TFX	LD ₅₀ >100.0 µg a.i./bee	na	100.0 µg a.i./bee	2924116
	Acute oral (48-h)	BAS 851 00H (11.2% TFX 21.5% SFF)	LD ₅₀ >309.9 µg end-use product/bee	na	309.9 µg end-use product/bee	2924231
	Acute contact (48-h)	BAS 851 00H (11.2% TFX 21.5% SFF)	LD ₅₀ >309.9 µg end-use product/bee	na	309.9 µg end-use product/bee	2924231
	Acute larval (8-day)	BAS 850 00H (40.9% TFX)	LD ₅₀ >256.7 µg end-use product/larva (LD ₅₀ >105 µg a.i./larva)	na	105 µg a.i./larva	2924120
	Chronic adult (10-day)	TFX	NOAEL = 9.6 µg a.i./bee/day	1	9.6 µg a.i./bee/day	2924122
	Chronic larval	TFX	LD ₅₀ = 9.0 µg a.i./larva/day (larvae)	1	7.9 µg	2924124

Organism	Exposure	Test Substance	Toxicity endpoint	Uncertainty factor	Assessment endpoint	Study# /
	(22-day repeat dose)		LD ₅₀ = 11.0 µg a.i./larva/day (pupae) ED ₅₀ = 7.9 µg a.i./larva/day (adult emergence)		a.i./larva/day (adult emergence)	
Predatory mite (<i>Typhlodromus pyri</i>)	Acute (7-day) glass plates	BAS 850 00H (40.9% TFX)	LR ₅₀ >1085.8 g end-use product/ha (LR ₅₀ >444.1 g a.i./ha)	2	222.1 g a.i./ha	2924164
	Acute (7-day) glass plates	BAS 851 00H (11.2% TFX 21.5% SFF)	LR ₅₀ >696.6 g end-use product/ha (LR ₅₀ >78.0 g TFX/ha) (LR ₅₀ >149.8 g SFF/ha)	2	348.3 g end-use product/ha	2924235
Bobwhite quail	Acute oral (14-day)	TFX	LD ₅₀ >2000 mg a.i./kg bw	10	200 mg a.i./kg bw	2924013
	Acute dietary (5-day)	TFX	LD ₅₀ >441 mg a.i./kg bw/day	10	44.1 mg a.i./kg bw/day	2924021
	Reproduction (20-wk.)	TFX	NOAEC = 12.0 mg a.i./kg bw	1	12.0 mg a.i./kg bw	2924024
Mammals (Rat)	Acute		LD ₅₀	10		
	Reproduction		NOEC	1		
Terrestrial plants	Vegetative vigor (21-day)	BAS 850 A0 H (514 g TFX/L)	HC ₅ of IC ₅₀ (dry wt.) = 0.13 g a.i./ha ER ₂₅ (dry wt.) = 0.049 g a.i./ha (soybean)	1	0.13 g a.i./ha	2924049
Freshwater invertebrate <i>Hyalella azteca</i>	Acute (10-day)	TFX	LC ₅₀ >0.072 mg a.i./L (overlying water)	2	0.036 mg a.i./L	2924100
Freshwater invertebrate <i>Daphnia magna</i>	Acute (48-h static)	BAS 851 00H (11.2% TFX 21.5% SFF)	EC ₅₀ >86 mg end-use product/L	2	43 mg end-use product/L	2924227
Freshwater invertebrate <i>Chironomus dilutus</i>	Chronic (28-day spiked sediment)	TFX	NOEC = 0.00792 mg a.i./L (overlying water)	1	0.00792 mg a.i./L	2924106
Freshwater fish <i>Cyprinus carpio</i>	Acute (96-h flow-through)	TFX	LC ₅₀ >1.68 mg a.i./L	10	0.168 mg a.i./L	2924063
Freshwater fish <i>Pimephales promelas</i>	ELS (32-day, flow-through)	TFX	NOEC = 0.82 µg a.i./L ^A	1	12 µg a.i./L	2924069
Amphibians (surrogate species <i>Cyprinus carpio</i>)	Acute (96-h flow-through)	TFX	LC ₅₀ >1.68 mg a.i./L	10	0.168 mg a.i./L	2924063
Amphibians (surrogate species <i>Pimephales promelas</i>)	ELS (32-day, flow-through)	TFX	NOEC = 12 µg a.i./L	1	12 µg a.i./L	2924069
Aquatic vascular plants (<i>Lemna gibba</i>)	Acute (7-day static/renewal)	TFX	EC ₅₀ = 0.115 µg a.i./L (final biomass)	2	0.058 µg a.i./L	2924114
Aquatic vascular plants (<i>Lemna gibba</i>)	Acute (7-day static/renewal)	BAS 851 00H formulation (11.2% TFX 21.5% SFF)	EC ₅₀ = 1.8 µg end-use product/L (final biomass)	2	0.9 µg end-use product/L	2924243
Freshwater algae <i>Navicula pelliculosa</i>	Acute (96-h static)	TFX	EC ₅₀ = 0.20 µg a.i./L (yield)	2	0.10 µg a.i./L	2924091
Freshwater algae <i>Pseudokirchneriella subcapitata</i>	Acute (96-h static)	BAS 851 00H (11.2% TFX 21.5% SFF)	EC ₅₀ = 3.6 µg end-use product/L (yield)	2	1.8 µg end-use product/L	2924229
Marine invertebrates (<i>Leptocheirus plumulosus</i>)	Subchronic (10-day)	TFX	LC ₅₀ >0.347 mg a.i./L (overlying water)	2	0.174 mg a.i./L	2924045
Marine invertebrates (<i>Americamysis bahia</i>)	Life-cycle (28-day, flow-through)	TFX	NOEC = 52.5 µg a.i./L	1	52.5 µg a.i./L	2924043
Marine fish (<i>Cyprinodon variegatus</i>)	Acute (96-h, flow-through)	TFX	LC ₅₀ >2.9 mg a.i./L	10	0.29 mg a.i./L	2924037
Marine fish (<i>Cyprinodon variegatus</i>)	ELS (34-day, flow-through)	TFX	NOEC = 0.82 µg a.i./L ^A	1	2.7 µg a.i./L	2924071
Marine algae (<i>Skeletonema costatum</i>)	Acute (96-h static)	TFX	EC ₅₀ >0.330 mg a.i./L	2	0.165 mg a.i./L	2924035

^ANOEC based on USEPA's molar threshold approach as trifludimoxazin is an inhibitor of protoporphyrinogen oxidase (PPO) and these chemicals

may have enhanced toxicity under UV light. The ELS NOEC using the USEPA's molar threshold would be 0.82 µg/L (0.002 µmol/L*412.3 g/mol*1 mol/1000000 µmol*1000000 µg/g). The USEPA has [guidance for light-dependent peroxidizing herbicides for chronic fish](#).

Table 15 Screening level risk to terrestrial organisms other than birds and mammals

Organism	Test substance	Exposure	Endpoint value	EEC ¹	RQ ²	LOC ³ exceeded
Earthworm	TFX	Acute	LC _{50/2} >492.5 mg a.i./kg soil (NOEC ≥ 985 mg a.i./kg soil)	0.017 mg a.i./kg soil	0.000035	No
	BAS 851 00H (11.2% TFX 21.5% SFF)	Acute	LC _{50/2} >500 mg end-use product/kg soil	0.074 mg end-use product/kg soil	0.00015	No
	TFX	Chronic	NOEC = 308.6 mg a.i./kg soil	0.017 mg a.i./kg soil	0.000055	No
Honey bee	TFX	Adult oral acute	LD ₅₀ >10.0 µg a.i./bee	1.07 µg a.i./bee	0.11	No
	BAS 851 00H (11.2% TFX 21.5% SFF)	Adult oral acute	LD ₅₀ >318.1 µg end-use product/bee	4.78 µg end-use product/bee	0.015	No
	TFX	Adult contact acute	LD ₅₀ >100.0 µg a.i./bee	0.09 µg a.i./bee	0.0009	No
	BAS 851 00H (11.2% TFX 21.5% SFF)	Adult contact acute	LD ₅₀ >309.9 µg end-use product/bee	0.40 µg end-use product/bee	0.001	No
	TFX	Adult oral chronic	NOAEL = 9.6 µg a.i./bee/day	1.07 µg a.i./bee	0.11	No
	BAS 850 00H (40.9% TFX)	Larvae oral acute	LD ₅₀ >105 µg a.i./larva	0.06 µg a.i./bee	0.00057	No
	TFX	Larvae oral chronic	ED ₅₀ = 7.9 µg a.i./larva/day (adult emerg)	0.06 µg a.i./bee	0.008	No
Predatory mite	BAS 850 00H (40.9% TFX)	Acute contact (glass plates)	LR _{50/2} >542.9 g a.i./ha	37.5 g a.i./ha	0.07	No
	BAS 851 00H (11.2% TFX 21.5% SFF)	Acute contact (glass plates)	LR _{50/2} >300 g end-use product/ha	167 g end-use product/ha	0.56	No
Parasitic wasp	BAS 850 00H (40.9% TFX)	Acute contact (glass plates)	LR _{50/2} >542.9 g a.i./ha	37.5 g a.i./ha	0.07	No
	BAS 851 00H (11.2% TFX 21.5% SFF)	Acute contact (glass plates)	LR _{50/2} >300 g end-use product/ha	167 g end-use product/ha	0.56	No
Vascular plants	BAS 850 A0 H	Vegetative vigour	HC ₅ of IC ₅₀ (dry wt.) = 0.13 g a.i./ha	37.5 g a.i./ha	288.5	Yes

Organism	Test substance	Exposure	Endpoint value	EEC ¹	RQ ²	LOC ³ exceeded
	(514 g TFX/L)	(21-day)				

¹EEC = Estimated Environmental Concentration. The EEC in soil was determined using the maximum single application rate of 37.5 g a.i./ha and assumes a soil bulk density of 1.5 g/cm³, a soil depth of 15 cm. EEC for bees = application rate (0.0375 kg a.i./ha) × adjustment factor (2.4 µg a.i./bee/kg a.i./ha for adult contact, and 28.6 µg a.i./bee/kg a.i./ha for adult oral and 12.15 µg a.i./larva/kg a.i./ha for larvae).

²RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value).

³LOC = Level of Concern. The RQ is compared to the LOC. The LOC = 1 is for earthworms, chronic exposure in bees, predatory mite, parasitic wasp and vascular plants. The LOC = 0.4 is for acute exposure in bees.

Table 16 Screening level risk assessment of trifludimoxazin for birds

			Maximum nomogram residues ^T				Mean nomogram residues			
			On-field		Off field		On-field		Off field	
	Toxicity (mg ai/kg bw/d)	Food Guild (food item)	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ
Small Bird (0.02 kg)										
Acute	200	Insectivore	3.0524	0.0153	0.1831	0.0009	2.1076	0.0105	0.1265	0.0006
	200	Granivore (grain and seeds)	0.4724	0.0024	0.0283	0.0001	0.2253	0.0011	0.0135	0.0001
	200	Frugivore (fruit)	0.9448	0.0047	0.0567	0.0003	0.4506	0.0023	0.0270	0.0001
Dietary	44.1	Insectivore	3.0524	0.0692	0.1831	0.0042	2.1076	0.0478	0.1265	0.0029
	44.1	Granivore (grain and seeds)	0.4724	0.0107	0.0283	0.0006	0.2253	0.0051	0.0135	0.0003
	44.1	Frugivore (fruit)	0.9448	0.0214	0.0567	0.0013	0.4506	0.0102	0.0270	0.0006
Reproduction	12	Insectivore	3.0524	0.2544	0.1831	0.0153	2.1076	0.1756	0.1265	0.0105
	12	Granivore (grain and seeds)	0.4724	0.0394	0.0283	0.0024	0.2253	0.0188	0.0135	0.0011
	12	Frugivore (fruit)	0.9448	0.0787	0.0567	0.0047	0.4506	0.0375	0.0270	0.0023
Medium-sized Bird (0.1 kg)										
Acute	200	Insectivore	2.3820	0.0119	0.1429	0.0007	1.6447	0.0082	0.0987	0.0005
	200	Granivore (grain and seeds)	0.3686	0.0018	0.0221	0.0001	0.1758	0.0009	0.0105	0.0001
	200	Frugivore (fruit)	0.7373	0.0037	0.0442	0.0002	0.3516	0.0018	0.0211	0.0001
Dietary	44.1	Insectivore	2.3820	0.0540	0.1429	0.0032	1.6447	0.0373	0.0987	0.0022
	44.1	Granivore (grain and seeds)	0.3686	0.0084	0.0221	0.0005	0.1758	0.0040	0.0105	0.0002
	44.1	Frugivore (fruit)	0.7373	0.0167	0.0442	0.0010	0.3516	0.0080	0.0211	0.0005
Reproduction	12	Insectivore	2.3820	0.1985	0.1429	0.0119	1.6447	0.1371	0.0987	0.0082
	12	Granivore (grain and seeds)	0.3686	0.0307	0.0221	0.0018	0.1758	0.0147	0.0105	0.0009
	12.00	Frugivore (fruit)	0.7373	0.0614	0.0442	0.0037	0.3516	0.0293	0.0211	0.0018

			Maximum nomogram residues ^T				Mean nomogram residues			
			On-field		Off field		On-field		Off field	
	Toxicity (mg ai/kg bw/d)	Food Guild (food item)	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ
Large-sized Bird (1 kg)										
Acute	200.00	Insectivore	0.6955	0.0035	0.0417	0.0002	0.4802	0.0024	0.0288	0.0001
	200.00	Granivore (grain and seeds)	0.1076	0.0005	0.0065	0.0000	0.0513	0.0003	0.0031	0.0000
	200.00	Frugivore (fruit)	0.2153	0.0011	0.0129	0.0001	0.1027	0.0005	0.0062	0.0000
	200.00	Herbivore (short grass)	1.5387	0.0077	0.0923	0.0005	0.5464	0.0027	0.0328	0.0002
	200.00	Herbivore (long grass)	0.9395	0.0047	0.0564	0.0003	0.3068	0.0015	0.0184	0.0001
	200.00	Herbivore (Broadleaf plants)	1.4236	0.0071	0.0854	0.0004	0.4706	0.0024	0.0282	0.0001
Dietary	44.10	Insectivore	0.6955	0.0158	0.0417	0.0009	0.4802	0.0109	0.0288	0.0007
	44.10	Granivore (grain and seeds)	0.1076	0.0024	0.0065	0.0001	0.0513	0.0012	0.0031	0.0001
	44.10	Frugivore (fruit)	0.2153	0.0049	0.0129	0.0003	0.1027	0.0023	0.0062	0.0001
	44.10	Herbivore (short grass)	1.5387	0.0349	0.0923	0.0021	0.5464	0.0124	0.0328	0.0007
	44.10	Herbivore (long grass)	0.9395	0.0213	0.0564	0.0013	0.3068	0.0070	0.0184	0.0004
	44.10	Herbivore (Broadleaf plants)	1.4236	0.0323	0.0854	0.0019	0.4706	0.0107	0.0282	0.0006
Reproduction	12.00	Insectivore	0.6955	0.0580	0.0417	0.0035	0.4802	0.0400	0.0288	0.0024
	12.00	Granivore (grain and seeds)	0.1076	0.0090	0.0065	0.0005	0.0513	0.0043	0.0031	0.0003
	12.00	Frugivore (fruit)	0.2153	0.0179	0.0129	0.0011	0.1027	0.0086	0.0062	0.0005
	12.00	Herbivore (short grass)	1.5387	0.1282	0.0923	0.0077	0.5464	0.0455	0.0328	0.0027
	12.00	Herbivore (long grass)	0.9395	0.0783	0.0564	0.0047	0.3068	0.0256	0.0184	0.0015
	12.00	Herbivore (Broadleaf plants)	1.4236	0.1186	0.0854	0.0071	0.4706	0.0392	0.0282	0.0024

Table 17 Screening level risk assessment of trifludimoxazin for mammals

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off field	
	Toxicity (mg ai/kg bw/d)	Food guild (food item)	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ
Small Mammal (0.015 kg)										
Acute	200.00	Insectivore	1.75560	0.00878	0.10534	0.00053	1.21220	0.00606	0.07273	0.00036
	200.00	Granivore (grain and seeds)	0.27170	0.00136	0.01630	0.00008	0.12958	0.00065	0.00777	0.00004
	200.00	Frugivore (fruit)	0.54340	0.00272	0.03260	0.00016	0.25916	0.00130	0.01555	0.00008
Reproduction	6.40	Insectivore	1.75560	0.27431	0.10534	0.01646	1.21220	0.18941	0.07273	0.01136
	6.40	Granivore (grain and seeds)	0.27170	0.04245	0.01630	0.00255	0.12958	0.02025	0.00777	0.00121
	6.40	Frugivore (fruit)	0.54340	0.08491	0.03260	0.00509	0.25916	0.04049	0.01555	0.00243
Medium-sized Mammal (0.035 kg)										
Acute	200.00	Insectivore	1.53900	0.00770	0.09234	0.00046	1.06264	0.00531	0.06376	0.00032
	200.00	Granivore (grain and seeds)	0.23818	0.00119	0.01429	0.00007	0.11359	0.00057	0.00682	0.00003
	200.00	Frugivore (fruit)	0.47636	0.00238	0.02858	0.00014	0.22719	0.00114	0.01363	0.00007
	200.00	Herbivore (short grass)	3.40496	0.01702	0.20430	0.00102	1.20924	0.00605	0.07255	0.00036
	200.00	Herbivore (long grass)	2.07900	0.01039	0.12474	0.00062	0.67886	0.00339	0.04073	0.00020
	200.00	Herbivore (forage crops)	3.15032	0.01575	0.18902	0.00095	1.04143	0.00521	0.06249	0.00031
Reproduction	6.40	Insectivore	1.53900	0.24047	0.09234	0.01443	1.06264	0.16604	0.06376	0.00996
	6.40	Granivore (grain and seeds)	0.23818	0.03722	0.01429	0.00223	0.11359	0.01775	0.00682	0.00106
	6.40	Frugivore (fruit)	0.47636	0.07443	0.02858	0.00447	0.22719	0.03550	0.01363	0.00213
	6.40	Herbivore (short grass)	3.40496	0.53203	0.20430	0.03192	1.20924	0.18894	0.07255	0.01134
	6.40	Herbivore (long grass)	2.07900	0.32484	0.12474	0.01949	0.67886	0.10607	0.04073	0.00636
	6.40	Herbivore (Broadleaf plants)	3.15032	0.49224	0.18902	0.02953	1.04143	0.16272	0.06249	0.00976
Large-sized Mammal (1 kg)										
Acute	200.00	Insectivore	0.82234	0.00411	0.04934	0.00025	0.56781	0.00284	0.03407	0.00017
	200.00	Granivore (grain and seeds)	0.12727	0.00064	0.00764	0.00004	0.06070	0.00030	0.00364	0.00002
	200.00	Frugivore (fruit)	0.25453	0.00127	0.01527	0.00008	0.12139	0.00061	0.00728	0.00004
	200.00	Herbivore (short grass)	1.81939	0.00910	0.10916	0.00055	0.64614	0.00323	0.03877	0.00019
	200.00	Herbivore	1.11088	0.00555	0.06665	0.00033	0.36274	0.00181	0.02176	0.00011

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off field	
	Toxicity (mg ai/kg bw/d)	Food guild (food item)	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ
		(long grass)								
	200.00	Herbivore (Broadleaf plants)	1.68332	0.00842	0.10100	0.00050	0.55647	0.00278	0.03339	0.00017
Reproduction	6.40	Insectivore	0.82234	0.12849	0.04934	0.00771	0.56781	0.08872	0.03407	0.00532
	6.40	Granivore (grain and seeds)	0.12727	0.01989	0.00764	0.00119	0.06070	0.00948	0.00364	0.00057
	6.40	Frugivore (fruit)	0.25453	0.03977	0.01527	0.00239	0.12139	0.01897	0.00728	0.00114
	6.40	Herbivore (short grass)	1.81939	0.28428	0.10916	0.01706	0.64614	0.10096	0.03877	0.00606
	6.40	Herbivore (long grass)	1.11088	0.17357	0.06665	0.01041	0.36274	0.05668	0.02176	0.00340
	6.40	Herbivore (Broadleaf plants)	1.68332	0.26302	0.10100	0.01578	0.55647	0.08695	0.03339	0.00522

Table 18 Further characterization of risk to terrestrial non-target plants

Organism	Exposure	Endpoint value (g a.i./ha)	EEC - spray drift (g a.i./ha) ¹	RQ ²	LOC ³ exceeded
Crop species	Vegetative vigour	HC ₅ of IC ₅₀ (dry wt.) = 0.13 g a.i./ha	2.25	17.3	Yes

¹EEC = Estimated Environmental Concentration. The EEC resulting from spray drift was determined by assuming approximately 6% of the application rate at one metre downwind from the point of application for field sprayers if the spray quality (droplet size distribution) used is classified as ASAE medium.

²RQ = Risk quotient. The RQ is calculated by dividing the EEC from spray drift by the endpoint value (RQ = EEC/endpoint value).

³LOC = Level of concern. The RQ is compared to the LOC (LOC = 1).

Table 19 Screening level risk assessment of trifludimoxazin for aquatic species

Organism	Exposure	Substance	Endpoint value (µg a.i./L)	EEC (µg a.i./L) ¹	RQ ²	LOC exceeded ³
Freshwater species						
<i>Hyalella azteca</i>	Acute	TFX	EC ₅₀ /2 = 36	4.7	0.13	No
<i>Daphnia magna</i>	Acute	BAS 851 00H (11.2% TFX 21.5% SFF)	EC ₅₀ /2 = 43000	21	0.0004	No
<i>Chironomus dilutus</i>	Chronic	TFX	NOEC = 7.92	4.7	0.59	No
Common carp <i>Cyprinus carpio</i>	Acute	TFX	LC ₅₀ /10 = 168	4.7	0.03	No
Fathead minnow <i>Pimephales promelas</i>	Chronic (ELS)	TFX	NOEC = 12 NOEC = 0.82 ^a	4.7	0.39 5.7	No Yes
Amphibian (surrogate species <i>Cyprinus carpio</i>)	Acute	TFX	LC ₅₀ /10 = 168	25	0.15	No
Amphibians (surrogate species <i>Pimephales promelas</i>)	Chronic	TFX	NOEC = 12 NOEC = 0.82 ^a	25	2.1 30.5	Yes
Aquatic vascular plants (<i>Lemna gibba</i>)	Acute	TFX	EC ₅₀ /2 = 0.058	4.7	81	Yes
Aquatic vascular plants	Acute	BAS 851 00H	EC ₅₀ /2 = 0.9 µg end-	21	23.3	Yes

Organism	Exposure	Substance	Endpoint value ($\mu\text{g a.i./L}$)	EEC ($\mu\text{g a.i./L}$) ¹	RQ ²	LOC exceeded ³
<i>(Lemna gibba)</i>		(11.2% TFX 21.5% SFF)	use product/L (final biomass)			
Freshwater algae <i>Navicula pelliculosa</i>	Acute (96-h static)	TFX	EC _{50/2} = 0.10 μg a.i./L	4.7	47	Yes
Freshwater algae <i>Pseudokirchneriella subcapitata</i>	Acute	BAS 851 00H (11.2% TFX 21.5% SFF)	EC _{50/2} = 1.8 μg end- use product/L	21	11.7	Yes
Marine species						
Marine invertebrates <i>(Leptocheirus plumulosus)</i>	Subchronic	TFX	EC _{50/2} = 174	4.7	0.03	No
Marine invertebrates <i>(Americamysis bahia)</i>	Chronic	TFX	NOEC = 52.5	4.7	0.09	No
Marine fish <i>(Cyprinodon variegatus)</i>	Acute	TFX	LC _{50/10} = 290	4.7	0.016	No
Marine fish <i>(Cyprinodon variegatus)</i>	Chronic	TFX	NOEC = 2.7 NOEC = 0.82 ^a	4.7	1.7 5.7	Yes Yes
Marine algae <i>(Skeletonema costatum)</i>	Acute	TFX	EC _{50/2} = 165	4.7	0.03	No

¹EEC = Estimated Environmental Concentration.

The EEC in a 80-cm deep pond is 4.7 $\mu\text{g a.i./L}$ for Vulcarus and 21 μg end-use product/L for Voraxor.

The EEC in a 15-cm deep pond is 25 $\mu\text{g a.i./L}$ for Vulcarus.

The EEC is calculated by assuming a direct overspray to water with the maximum application rate.

²RQ = Risk quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value).

³LOC = Level of concern. The RQ is compared to the LOC (LOC = 1). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary.

^aNOEC based on USEPA's molar threshold approach as trifludimoxazin is an inhibitor of protoporphyrinogen oxidase (PPO) and these chemicals may have enhanced toxicity under UV light. The ELS NOEC using the USEPA's molar threshold would be 0.82 $\mu\text{g/L}$ (0.002 $\mu\text{mol/L}$ *412.3 g/mol*1 mol/1000000 μmol *1000000 $\mu\text{g/g}$). The USEPA has [guidance for light-dependent peroxidizing herbicides for chronic fish](#).

Table 20 Further characterization of risk to aquatic organisms

Organism	Exposure	Substance	Endpoint value ($\mu\text{g a.i./L}$)	EEC in water ($\mu\text{g a.i./L}$) ¹		RQ ²		Spray drift – LOC exceeded ³	Runoff – LOC exceeded ³
				Drift	Runoff	Drift	Runoff		
Freshwater fish	Chronic	TFX	NOEC = 0.82 ^a	0.28	2.3	0.34	2.8	No	Yes
Amphibian	Chronic	TFX	NOEC = 12 NOEC = 0.82 ^a	1.5	8.8	0.13 1.8	0.73 10.7	No Yes	No Yes
Vascular plant	Acute	TFX	EC _{50/2} = 0.058	0.28	2.5	4.8	43.1	Yes	Yes
Vascular plant	Acute	BAS 851 00H (11.2% TFX 21.5% SFF)	EC _{50/2} = 0.10 ^b	0.14	1.2	1.4	12	Yes	Yes
Freshwater algae	Acute	TFX	EC _{50/2} = 0.10	0.28	2.5	2.8	25	Yes	Yes
Freshwater algae	Acute	BAS 851 00H (11.2% TFX 21.5% SFF)	EC _{50/2} = 0.20 ^b	0.14	1.2	0.7	6	No	Yes
Marine fish	Chronic	TFX	NOEC = 2.7 NOEC = 0.82 ^a	0.28	2.3	0.10 0.34	0.85 2.8	No No	No Yes

¹EEC = Estimated Environmental Concentration based on water modelling of the use-pattern for Prince Edward Island (PEI).

²RQ = Risk quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value).

³LOC = Level of concern; the RQ is compared to the LOC (LOC = 1).

^aNOEC based on the USEPA's molar threshold approach as trifludimoxazin is an inhibitor of protoporphyrinogen oxidase (PPO) and these chemicals may have enhanced toxicity under UV light. The ELS NOEC using the USEPA's molar threshold would be 0.82 $\mu\text{g/L}$ (0.002 $\mu\text{mol/L}$ *412.3 g/mol*1 mol/1 000 000 μmol *1 000 000 $\mu\text{g/g}$). The USEPA has [guidance for light-dependent peroxidizing herbicides for chronic fish](#). ^bEndpoint value for BAS 851 00H expressed in terms of trifludimoxazin.

Table 21 Further characterization of risk to aquatic vascular plants and algae from surface runoff of Vulcarus

Organism	Exposure	Substance	Endpoint value ($\mu\text{g a.i./L}$)	Site	Scenario	EEC in water ($\mu\text{g a.i./L}$) ¹	RQ ²	Runoff – LOC exceeded ³
Vascular plant	Acute	TFX	$EC_{50}/2 = 0.058$	Crop	Barley-AB	0.6	10.3	Yes
				Crop	Corn-ON	1.3	22.4	Yes
				Crop	Corn-QC	1.8	31.0	Yes
				Crop	Potato-PEI	2.5	43.1	Yes
				Crop	Rasp-BC	0.3	5.2	Yes
				Crop	Sugarbeet-AB	0.9	15.5	Yes
				Crop	Wheat-MB	0.8	13.8	Yes
				Fallow	Barley-AB	1.0	17.2	Yes
				Fallow	Sugarbeet-AB	1.1	19.0	Yes
Freshwater algae	Acute	TFX	$EC_{50}/2 = 0.10$	Crop	Barley-AB	0.6	6.0	Yes
				Crop	Corn-ON	1.3	13.0	Yes
				Crop	Corn-QC	1.8	18.0	Yes
				Crop	Potato-PEI	2.5	25.0	Yes
				Crop	Rasp-BC	0.3	3.0	Yes
				Crop	Sugarbeet-AB	0.9	9.0	Yes
				Crop	Wheat-MB	0.8	8.0	Yes
				Fallow	Barley-AB	1.0	10.0	Yes
				Fallow	Sugarbeet-AB	1.1	11.0	Yes
Fallow	Wheat-MB	0.9	9.0	Yes				

¹EEC = 96-hour estimated environmental concentrations for a 1-ha, 80-cm deep pond.

²RQ = Risk quotient. The RQ is calculated by dividing the EEC by the endpoint value ($RQ = EEC/\text{endpoint value}$).

³LOC = Level of concern; the RQ is compared to the LOC ($LOC = 1$).

Table 22 Further characterization of risk to aquatic vascular plants and algae from surface runoff of Voraxor

Organism	Exposure	Substance	Endpoint value ($\mu\text{g a.i./L}$)	Site	Scenario	EEC in water ($\mu\text{g a.i./L}$) ¹	RQ ²	Runoff – LOC exceeded ³
Vascular plant	Acute	BAS 851 00H	$EC_{50}/2 = 0.10^a$	Crop	Barley-AB	0.29	2.9	Yes
				Crop	Corn-ON	0.62	6.2	Yes
				Crop	Corn-QC	0.86	8.6	Yes
				Crop	Potato-PEI	1.19	11.9	Yes
				Crop	Raspberry-BC	0.14	1.4	Yes
				Crop	Sugarbeet-AB	0.43	4.3	Yes
				Crop	Wheat-MB	0.38	3.8	Yes
				Fallow	Barley-AB	0.48	4.8	Yes
				Fallow	Sugarbeet-AB	0.52	5.2	Yes
Freshwater algae	Acute	BAS 851 00H	$EC_{50}/2 = 0.20^a$	Crop	Barley-AB	0.29	1.4	Yes
				Crop	Corn-ON	0.62	3.1	Yes
				Crop	Corn-QC	0.86	4.3	Yes
				Crop	Potato-PEI	1.19	6.0	Yes
				Crop	Raspberry-BC	0.14	0.7	No
				Crop	Sugarbeet-AB	0.43	2.1	Yes
				Crop	Wheat-MB	0.38	1.9	Yes
				Fallow	Barley-AB	0.48	2.4	Yes
				Fallow	Sugarbeet-AB	0.52	2.6	Yes
Fallow	Wheat-MB	0.43	2.1	Yes				

¹EEC = 96-hour estimated environmental concentrations for a 1-ha, 80-cm deep pond.

²RQ = Risk quotient. The RQ is calculated by dividing the EEC by the endpoint value ($RQ = EEC/\text{endpoint value}$).

³LOC = Level of concern; the RQ is compared to the LOC ($LOC = 1$).

^aEndpoint value for BAS 851 00H expressed in terms of trifludimoxazin.

Table 23 Toxic substances management policy considerations-comparison to TSMP track 1 criteria

TSMP track 1 criteria	TSMP track 1 criterion value		Active ingredient endpoints
CEPA toxic or CEPA toxic equivalent ¹	Yes		Yes
Predominantly anthropogenic ²	Yes		Yes
Persistence ³ :	Soil	Half-life ≥ 182 days	Half-life = 87.4 days
	Water	Half-life ≥ 182 days	Half-life = 94.8 days
	Sediment	Half-life ≥ 365 days	Not available
	Air	Half-life ≥ 2 days or evidence of long range transport	Not expected to be found in air
Bioaccumulation ⁴	Log K_{ow} ≥ 5		3.33
	BCF ≥ 5000		51.9–81.5
	BAF ≥ 5000		Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.
<p>¹All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).</p> <p>²The policy considers a substance “predominantly anthropogenic” if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.</p> <p>³ If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.</p> <p>⁴Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{ow}).</p>			

Table 24 List of supported uses for Vulcarus

Items	Label claims that are supported
Application rate	Pre-plant and pre-emergent applications at 50–75 mL/ha.
Adjuvant	Merge Adjuvant at 0.5% v/v.
Efficacy claim	Burndown control of cleavers, kochia (suppression only), lamb’s-quarters, volunteer canola (all types including Roundup Ready), and wild buckwheat (suppression only at 75 mL/ha). Suppression of secondary flushes of kochia, lamb’s-quarters, redroot pigweed, volunteer canola, and wild mustard.
Tank mixture	Glyphosate herbicides at 450–900 g a.e./ha.
Hosts and use site	Barley, field corn, field peas, soybeans, and wheat (including spring, durum, and winter) and chemfallow. The application of Vulcarus may result in injury to field pea, but should not affect grain yield.
Application method and timing	Pre-plant and pre-emergent application to the crop and post-emergence to the weed. Apply in 50–100 L water/ha using ground application equipment.
Rotational restriction	If the initial planting of labelled crop fails, the following crops can be planted in the same season: barley, field corn, dry field pea, soybean, and wheat (spring, durum, and winter).

Items	Label claims that are supported
	<p>Winter wheat can be grown 3 months after application.</p> <p>The following crops can be planted anytime in the following season: barley, canola, field corn, dry common bean, dry field pea, flax, lentil, mustard, soybean, and wheat (spring and durum).</p>

Table 25 List of supported uses for Voraxor

Items	Label claims that are supported
Application rate	Pre-seed and pre-emergent applications at 48–72 mL/ha for burndown weed control and at 100–144 mL/ha for burndown weed control and further suppression of their secondary weed flushes.
Adjuvant	Merge Adjuvant at 0.5% v/v.
Efficacy claim	<p>Burndown control of Canada fleabane, cleavers, kochia, lamb's-quarters, narrow-leaved hawk's beard, redroot pigweed, round-leaved mallow, shepherd's purse (suppression), stinkweed, volunteer canola (all types including Roundup Ready), wild buckwheat, and wild mustard.</p> <p>Burndown control and suppression of secondary flushes of cleavers, kochia, lamb's-quarters, redroot pigweed, stinkweed, volunteer canola (all types including Roundup Ready), wild buckwheat, and wild mustard.</p>
Tank mixture	Glyphosate herbicides at 450–900 g a.e./ha, Zidua SC at 120–240 mL/ha, or Zidua SC + glyphosate herbicides.
Hosts and use site	<p>Lentil at 48 mL/ha; field corn and soybean at 48–100 mL/ha; wheat (spring, durum, and winter), field pea and barley at 48–144 mL/ha; and chemfallow at 48-72 mL/ha.</p> <p><i>The application of Voraxor may result in injury to field pea, but should not affect grain yield.</i></p>
Application method and timing	Pre-seed and pre-emergent applications to the crop and post-emergence to the weed. Apply in 50–100 L water/ha using ground application equipment.
Rotational restriction	<p>If the initial planting of labelled crop fails, the following crops can be planted in the same season: barley, field corn, lentil, dry field pea, soybean, and wheat (spring, durum, and winter).</p> <p>Winter wheat can be grown 3 months after application.</p> <p>The following crops can be planted anytime in the following season: barley, canola, field corn, dry common bean, dry field pea, flax, lentil, mustard, soybean, and wheat (spring and durum).</p>

Appendix II Supplemental maximum residue limit information— international situation and trade implications

Trifludimoxazin is a new active ingredient which is concurrently being registered in Canada and the United States. The MRLs proposed for trifludimoxazin in Canada are the same as corresponding tolerances to be promulgated in the United States, except for certain (livestock) commodities, in accordance with Table 1, for which differences in MRLs/tolerances are due to different legislative frameworks.

Once established, the American tolerances for trifludimoxazin will be listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs²⁸ listed for trifludimoxazin in or on any commodity on the Codex Alimentarius [Pesticide Index](#) website.

Table 1 compares the MRLs proposed for trifludimoxazin in Canada with corresponding American tolerances.

Table 1 Comparison of Canadian MRLs and American tolerances (where different)

Food commodity	Canadian MRL (ppm)	American tolerance (ppm)
Eggs, fat, meat, meat byproducts of cattle, goats, hogs, horses, poultry and sheep, milk	0.01	Not required ¹

¹as per Category 3 of 40 CFR 180.6(a) for livestock

²⁸ The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2923775	2018, Tier II Chapter 4.4: Description of methods for analysis of soil (parent and metabolites), DACO: 12.7, Document M
2923834	2017, Preliminary analysis of BAS 850 H, DACO: 2.13.3, IIA 1.11.1 CBI
2923838	2018, Confirmation of identity of active substance and technical impurities in technical grade BAS 850 H, DACO: 2.16, IIA 1.12 CBI
2923841	2013, Physical properties of Reg.No. 5654329 - pure active ingredient (PAI), DACO: 2.14.1, 2.14.2, 2.14.3, 2.14.4, 2.14.9, IIA 2.1.1, IIA 2.3.1, IIA 2.4.1, IIA 2.4.2
2923843	2013, Evaluation of physical and chemical properties according to Directive 94/37/EC (Regulation (EC) No 440/2008), DACO: 2.16, IIA 2.13
2923844	2018, BAS 850 H: Determination of oxidation/reduction, chemical incompatibility, DACO: 2.16, IIA 2.15
2923845	2013, Physical and chemical properties of Reg.No. 5654329 technical active ingredient TC - accelerated storage stability up to 2 weeks at 54°C, DACO: 2.14.1, 2.14.14, 2.14.2, 2.14.3, 2.14.6, 2.16, IIA 2.16, IIA 2.17.1, IIA 2.2, IIA 2.4.1, IIA 2.4.2
2923846	2017, Storage stability of BAS 850 H (Reg.No. 5654329) TC when stored for 4 years at 20°C and 30°C, DACO: 2.14.14, IIA 2.17.1
2923847	2018, Trifludimoxazin (BAS 850 H) Technical Grade Active Ingredient (TC/TGAI) - Storage stability and corrosion characteristics in commercial type containers when stored for up to 2 weeks at 54°C, DACO: 2.14.14, IIA 2.17.1
2923848	2018, BAS 850 H (TGAI): Stability to normal and elevated temperature, metal and metal ions, DACO: 2.14.13, IIA 2.17.2
2923850	2013, Henry's law constant for BAS 850 H (Reg.No. 5654329), DACO: 2.16, IIA 2.3.2
2923851	2013, Mass, NMR, IR and UV/Vis spectra of BAS 850 H (Reg.No. 5654329), DACO: 2.13.2, 2.14.12, IIA 2.5.1.1, IIA 2.5.1.2, IIA 2.5.1.3, IIA 2.5.1.4
2923852	2013, Water solubility of BAS 850 H (Reg.No. 5654329), DACO: 2.14.7, IIA 2.6
2923858	2013, Solubility of BAS 850 H (Reg. No. 5654329) in organic solvents, DACO: 2.14.8, IIA 2.7
2923859	2013, Partition coefficient of BAS 850 H (Reg.No. 5654329), HPLC-method, DACO: 2.14.11, IIA 2.8.1
2923865	2013, Dissociation constant of BAS 850 H (Reg.No. 5654329) in water, DACO: 2.14.10, 8.2.3.2, IIA 2.9.5
2923869	2012, Determination of active ingredient Reg.No. 5654329 in BAS 850 H technical grade active ingredient (TGAI) by means of [CBI Removed], DACO: 2.13.1, IIA 4.2.1 CBI
2923871	2014, Validation of analytical method AFR0090/01: Determination of [CBI Removed] in BAS 850 H TGAI by [CBI Removed], DACO: 2.13.4, IIA 4.2.3 CBI
2923872	2014, GLP Validation of analytical method AFR0091/01: Determination of [CBI Removed] in BAS 850 H TGAI by [CBI removed], DACO: 2.13.4, IIA 4.2.3 CBI
2923873	2014, Determination of [CBI Removed] in BAS 850 H TGAI by [CBI Removed], DACO: 2.13.4, IIA 4.2.3 CBI

PMRA Document Number	Reference
2923874	2014, Determination of [CBI Removed] in BAS 850 H TGAI by [CBI Removed], DACO: 2.13.4,IIA 4.2.3 CBI
2923875	2016, Determination of technical impurities in Trifludimoxazin TGAI (BAS 850 H), DACO: 2.13.4,IIA 4.2.3 CBI
2923876	2016, Validation of analytical method AFR0118/01 for the determination of minor impurities in BAS 850 H, DACO: 2.13.4,IIA 4.2.3 CBI
2923878	2017, Validation of analytical method AFR0122/01 for the determination of [CBI Removed] in BAS 850 H by [CBI Removed], DACO: 2.13.4,IIA 4.2.3 CBI
2923887	2017, Independent laboratory validation of BASF analytical method D1401/02: Analytical method for the determination of residues of BAS 850 H and its four metabolites, [CBI Removed] in soil by [CBI Removed], DACO: 8.2.2.1,IIA 4.4
2923888	2018, Method of analysis of BAS 850 H and its relevant metabolites in soil with limit of determination (LOD) calculation (Method D1401/02), DACO: 8.2.2.1,IIA 4.4
2923890	2018, Independent laboratory validation of BASF analytical method D1724/01: Method for the determination of BAS 850 H (Reg. No. 5654329), [CBI Removed] in surface and drinking water by[CBI Removed], DACO: 8.2.2.3,IIA 4.5
2923891	2018, Methods of analysis of BAS 850 H and its relevant metabolites in water with limit of determination (LOD) calculation (method D1724/01), DACO: 8.2.2.3,IIA 4.5
2923893	2018, Method of analysis of BAS 850 H metabolite in water with limit of determination (LOD) calculation (method R0048/01), DACO: 8.2.2.3,IIA 4.5
2924156	2018, Tirexor TM Herbicide - Group A - Product identity, composition and analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.5.4,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 1.5 CBI
2924177	2018, Physical and chemical properties of formula BAS 850 01 H including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C), DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.9,3.7,8.2.2.1,8.2.3.6,IIIA 2.1,IIIA 2.13,IIIA 2.14,IIIA 2.4.2,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.7.1,IIIA 2.7.4,IIIA 2.8.2,IIIA 2.8.3.1,IIIA 2.8.3.2,IIIA 2.8.5.2,IIIA 2.8.6.1,IIIA 2.8.8.2
2924181	2018, BAS 850 01 H: Determination of oxidation/reduction, chemical incompatibility, DACO: 3.5.8,IIIA 2.2.2
2924182	2018, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11,3.5.12,IIIA 2.2.1,IIIA 2.3.1,IIIA 2.3.3
2924252	2017, Validation of analytical method AFL0963/01: Determination of the active ingredients Trifludimoxazin (BAS 850 H) and Saflufenacil (BAS 800 H) in formulations by [CBI Removed], DACO: 3.4.1,IIIA 5.2.2
2924223	2018, BAS 851 01 H Group A - Product identity, composition and analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.5.4,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 1.5 CBI
2924245	2018, Physical and chemical properties of BAS 851 01 H including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C), DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9,3.7,8.2.2.1,8.2.3.6,IIIA 2.1,IIIA 2.13,IIIA 2.4.2,IIIA 2.5.1,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.7.1,IIIA 2.7.4,IIIA 2.8.2,IIIA 2.8.3.1,IIIA 2.8.3.2,IIIA 2.8.5.2,IIIA 2.8.6.1,IIIA 2.8.8.2
2924249	2018, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11,3.5.12,IIIA 2.2.1,IIIA 2.3.1,IIIA 2.3.2

PMRA Document Number	Reference
2924250	2018, BAS 851 01 H: Determination of oxidation/reduction, chemical incompatibility, DACO: 3.5.8,IIIA 2.2.2
3085296	2020, Chemical Analysis of Five Batches of BAS 850 H, DACO: 2.13.3 CBI
3085297	2020, Trifludimoxazin TGAI Announcement of an Additional Source and Documentation of Equivalency, DACO: 2.11.2,2.11.3,2.11.4 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
2923894	2017, Excretion and metabolism of 14C-BAS 850 H after oral administration in rats, DACO: 4.5.9,IIA 5.1.1,IIA 5.1.3
2923895	2017, 14C-BAS 850 H - Study on kinetics in Wistar rats after oral and intravenous administration, DACO: 4.5.9,IIA 5.1.1,IIA 5.1.3
2923901	2018, BAS 850 H - Acute oral toxicity study in rats (Including amendment no. 1 and analytical report), DACO: 4.2.1,IIA 5.2.1
2923902	2013, BAS 850 H - Acute dermal toxicity study in rats (Including analytical report), DACO: 4.2.2,IIA 5.2.2
2923903	2013, BAS 850 H - Acute inhalation toxicity study in Wistar rats - 4-hour dust exposure (head-nose only), DACO: 4.2.3,IIA 5.2.3
2923904	2013, BAS 850 H - Acute dermal irritation / corrosion in rabbits, DACO: 4.2.5,IIA 5.2.4
2923905	2013, BAS 850 H - Acute eye irritation in rabbits, DACO: 4.2.4,IIA 5.2.5
2923906	2018, BAS 850 H - Assessment of sensitising properties on albino guinea pigs - Maximisation test according to Magnusson and Kligman (Including amendment no. 1 and analytical report), DACO: 4.2.6,IIA 5.2.6
2923907	2018, BAS 850 H - Repeated-dose 28-day oral toxicity study in C57BL/6JRj mice - Administration via the diet, DACO: 4.3.3,IIA 5.3.1
2923908	2017, BAS 850 H - Repeated-dose 28-day toxicity study in Wistar rats - Administration via the diet, DACO: 4.3.3,IIA 5.3.1
2923909	2018, BAS 850 H - Repeated-dose 28-day oral toxicity study in Beagle dogs - Oral administration (capsule) (Including Amendment No. 1), DACO: 4.3.3,IIA 5.3.1
2923910	2018, BAS 850 H - Repeated-dose 90-day oral toxicity study in C57BL/6 J Rj mice - Administration via the diet, DACO: 4.3.1,IIA 5.3.2
2923911	2018, BAS 850 H - Repeated-dose 90-day toxicity study in Wistar rats - Administration via the diet, DACO: 4.3.1,IIA 5.3.2
2923912	2018, BAS 850 H - Repeated-dose 90-day toxicity study in female Wistar rats - Administration via diet, DACO: 4.3.1,IIA 5.3.2
2923913	2018, BAS 850 H - Repeated-dose 90-day oral toxicity study in Beagle dogs - Oral administration (capsule), DACO: 4.3.2,IIA 5.3.3
2923915	2017, BAS 850 H - Repeated-dose 12-month toxicity study in Beagle dogs - Oral administration (capsule), DACO: 4.3.2,IIA 5.3.4
2923916	2013, BAS 850 H - Repeated dose 28-day dermal toxicity study in Wistar rats, DACO: 4.3.5,IIA 5.3.7
2923917	2013, BAS 850 H - Salmonella typhimurium / Escherichia coli Reverse mutation assay, DACO: 4.5.4,IIA 5.4.1
2923918	2017, BAS 850 H - Salmonella typhimurium/ Escherichia coli reverse mutation assay, DACO: 4.5.4,IIA 5.4.1

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2923919	2017, BAS 850 H - Salmonella typhimurium /Escherichia coli reverse mutation assay, DACO: 4.5.4,IIA 5.4.1
2923920	2013, BAS 850 H - In vitro gene mutation test in L5178Y mouse lymphoma cells (TK+/- locus assay, microwell version), DACO: 4.5.6,IIA 5.4.2
2923921	2013, BAS 850 H - In vitro chromosome aberration assay in V79 cells, DACO: 4.5.5,IIA 5.4.3
2923922	2010, Reg.No. 5654329 - Micronucleus test in bone marrow cells of the mouse, DACO: 4.5.7,IIA 5.4.4
2923923	2018, BAS 850 H - Combined chronic toxicity/carcinogenicity study in Wistar rats - Administration via the diet up to 24 months (Including amendment no. 1), DACO: 4.4.1,4.4.2,4.4.4,IIA 5.5.1,IIA 5.5.2
2923924	2018, BAS 850 H - Combined chronic toxicity/carcinogenicity study in Wistar rats - Administration via the diet up to 24 months (Including amendment no. 1), DACO: 4.4.1,4.4.2,4.4.4,IIA 5.5.1,IIA 5.5.2
2923925	2018, BAS 850 H - Combined chronic toxicity/carcinogenicity study in Wistar rats - Administration via the diet up to 24 months (Including amendment no. 1), DACO: 4.4.1,4.4.2,4.4.4,IIA 5.5.1,IIA 5.5.2
2923926	2018, BAS 850 H - Carcinogenicity study in C57BL/6 J Rj mice - Administration via the diet up to 18 months, DACO: 4.4.3,IIA 5.5.3
2923927	2018, BAS 850 H - Carcinogenicity study in C57BL/6 J Rj mice - Administration via the diet up to 18 months, DACO: 4.4.3,IIA 5.5.3
2923928	2018, BAS 850 H - Carcinogenicity study in C57BL/6 J Rj mice - Administration via the diet up to 18 months, DACO: 4.4.3,IIA 5.5.3
2923929	2018, BAS 850 H - Enzyme induction in liver Wistar rats - Administration via the diet for 14 days, DACO: 4.8,IIA 5.5.4
2923930	2018, BAS 850 H - Thyroid function test in Wistar rats using Perchlorate discharge as a diagnostic test - Administration via the diet over 14 days, DACO: 4.8,IIA 5.5.4
2923932	2018, BAS 850 H - Enhanced one-generation reproduction toxicity study in Wistar rats - Range-finding study - Administration via the diet, DACO: 4.5.1,IIA 5.6.1
2923933	2018, BAS 850 H - Modified extended one-generation reproduction toxicity study in Wistar rats - Administration via the diet, DACO: 4.2.9,4.3.8,4.4.5,4.5.1,4.5.13,4.5.14,4.5.8,4.8,IIA 5.10,IIA 5.6.1,IIA 5.7.4,IIA 5.7.5
2923934	2018, BAS 850 H - Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage), DACO: 4.5.2,IIA 5.6.10
2923935	2018, BAS 850 H - Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage), DACO: 4.5.2,IIA 5.6.10
2923936	2018, BAS 850 H - Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage) (Including amendment no. 1), DACO: 4.5.2,IIA 5.6.10
2923937	2018, BAS 850 H - Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage), DACO: 4.5.3,IIA 5.6.11
2923938	2018, BAS 850 H - Acute oral neurotoxicity study in Wistar rats - Administration by gavage, DACO: 4.5.12,IIA 5.7.1
2923939	2012, Reg.No. 5757726 - In vitro gene mutation test in L5178Y mouse lymphoma cells (TK+/- locus assay, microwell version), DACO: 4.8,IIA 5.8
2923940	2012, Reg.No. 5757726 - Salmonella typhimurium / Escherichia coli reverse mutation assay, DACO: 4.8,IIA 5.8
2923941	2012, Reg.No. 5757726 - In vitro chromosome aberration assay in V79 cells, DACO: 4.8,IIA 5.8

PMRA Document Number	Reference
2923942	2014, Reg.No. 5757726 - Micronucleus test in bone marrow cells of the mouse, DACO: 4.8,IIA 5.8
2923943	2014, Reg.No. 5797901 - Salmonella typhimurium / Escherichia coli reverse mutation assay, DACO: 4.8,IIA 5.8
2923944	2014, Reg.No. 5797901 - Acute oral toxicity study in rats (Including analytical method), DACO: 4.8,IIA 5.8
2923945	2017, Reg.No. 5797901 - Acute inhalation toxicity study in Wistar rats 4-hour dust aerosol exposure (nose only), DACO: 4.8,IIA 5.8
2924191	2018, BAS 850 01 H - Acute oral toxicity study in rats, DACO: 4.6.1,IIIA 7.1.1
2924192	2018, BAS 850 01 H - Acute dermal toxicity study in rats (Including amendment no. 1 and amendment no. 2), DACO: 4.6.2,IIIA 7.1.2
2924193	2018, BAS 850 01 H - Acute inhalation toxicity study in Wistar rats - 4-hour liquid aerosol exposure (nose only), DACO: 4.6.3,IIIA 7.1.3
2924194	2018, BAS 850 01 H - Acute dermal irritation / corrosion in rabbits, DACO: 4.6.5,IIIA 7.1.4
2924195	2018, BAS 850 01 H - Acute eye irritation in rabbits, DACO: 4.6.4,IIIA 7.1.5
2924196	2018, BAS 850 01 H - BUEHLER test in guinea pigs (Including analytical report), DACO: 4.6.6,IIIA 7.1.6
2924259	2017, BAS 851 01 H - Acute oral toxicity study in rats, DACO: 4.6.1,IIIA 7.1.1
2924260	2017, BAS 851 01 H - Acute dermal toxicity study in rats, DACO: 4.6.2,IIIA 7.1.2
2924261	2018, BAS 851 01 H - Acute inhalation toxicity study in Wistar rats - 4-hour liquid aerosol exposure (nose only), DACO: 4.6.3,IIIA 7.1.3
2924262	2017, BAS 851 00 H - Acute dermal irritation / corrosion in rabbits, DACO: 4.6.5,IIIA 7.1.4
2924263	2017, BAS 851 01 H - Acute eye irritation in rabbits, DACO: 4.6.4,IIIA 7.1.5
2924264	2017, BAS 851 01 H - BUEHLER Test in guinea pigs, DACO: 4.6.6,IIIA 7.1.6

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2924251	2018, Use Site Description for Voraxor Herbicide Containing the New Active Ingredient Trifludimoxazin, DACO: 10.2.2,5.2,IIIA 3.3.1
2923899	2018, Handler and post-application exposure assessments to support the proposed uses of Trifludimoxazin (BAS 850 H) in Canada, DACO: 4.2.9,4.3.8,4.4.5,4.5.8,4.8,5.3,5.6,IIA 5.10
2923947	2017, 14C-BAS 850 H in BAS 850 00 H - Study of dermal absorption in rats, DACO: 5.8,IIA 5.9.9
3087345	2020, Trifludimoxazin: BASF Response to PMRA's January 2020 Inquiry Regarding Dermal Absorption in Rats (BAS Reg. Doc. No. 2017/1064931), DACO: 5.8
3087346	2017, Data Dose Group 1 - High Dose, DACO: 5.8
3087347	2017, Data Dose Group 2 - mid dose, DACO: 5.8
3087348	2017, Data Dose Group 3 - low dose, DACO: 5.8
3087349	2020, Mid Dose - raw data, DACO: 5.8
3087350	2020, High Dose - raw data, DACO: 5.8
3087351	2020, Low Dose - raw data, DACO: 5.8

PMRA Document	Reference
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Number	
2923880	2018, Validation of BASF analytical method D1407/02: Analytical method for the determination of residues of BAS 850 H and its metabolites, M850H001, M850H003, M850H006 and M850H012, in plant matrices by LC-MS/MS, DACO: 7.2.1,7.2.4, IIA 4.3
2923881	2018, Independent laboratory validation of: BASF analytical method D1407/02 for the determination of residues of BAS 850 H in plant matrices by LC-MS/MS for enforcement, DACO: 7.2.1,7.2.4, IIA 4.3
2923883	2018, Validation of method D1718/01: Analytical method for the determination of BAS 850 H (Reg. No. 5654329) and M850H001 (Reg. No. 5749359) in animal matrices by LC-MS/MS, DACO: 7.2.1,7.2.4, IIA 4.3
2923886	2018, Independent laboratory validation of analytical method for the determination of BAS 850 H (Reg. 5654329) and M850H001 (Reg. No. 5749359) in animal matrices by LC-MS/MS, DACO: 7.2.1,7.2.4, IIA 4.3
2923948	2018, Freezer storage stability of BAS 850 H and its four metabolites, M850H001, M850H003, M850H006, M850H0012 in plant matrices, DACO: 7.3, IIA 6.1.1
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2923952	2016, Metabolism of ¹⁴ C-BAS 850 H in soybean, DACO: 6.3, IIA 6.2.1
2923953	2017, Metabolism of BAS 850 H in corn - Part 2: Analysis, DACO: 6.3, IIA 6.2.1
2923954	2016, Plant metabolism of BAS 850 H in potato, DACO: 6.3, IIA 6.2.1
2923955	2017, The metabolism of ¹⁴ C-Reg.No. 5654329 (BAS 850 H) in laying hens, DACO: 6.2, IIA 6.2.2
2923956	2017, Identification of BAS 850 H goat metabolite M850H038, DACO: 6.2, IIA 6.2.3
2923957	2017, The metabolism of [¹⁴ C]-Reg. No. 5654329 (BAS 850 H) in lactating goats, DACO: 6.2,IIA 6.2.3
2923958	2016, Magnitude of the residues of BAS 850 H in citrus raw agricultural commodities, DACO: 7.4.1,7.4.2,7.4.6, IIA 6.3.1
2923959	2016, Magnitude of the residues of BAS 850 H in pome fruit raw agricultural commodities, DACO: 7.4.1,7.4.2,7.4.6, IIA 6.3.2
2923960	2017, Magnitude of the residues of BAS 850 H in tree nut raw agricultural commodities, DACO: 7.4.1,7.4.2,7.4.6, IIA 6.3.3
2923963	2017, Magnitude of the residues of BAS 850 H in cereal grains following pre-emergent application of BAS 850 00 H, DACO: IIA 6.3.4
2923964	2017, Magnitude of the residues of BAS 850 H in legumes (crop group 6) following applications of BAS 850 00 H, DACO: IIA 6.3.4
2923965	2018, Magnitude of the residues of BAS 850 H in peanut following a pre-emergent application of BAS 850 00 H, DACO: IIA 6.3.4
2923966	2015, High temperature hydrolysis of ¹⁴ C-BAS 850 H at 90°C, 100°C, and 120°C, DACO: 7.4.5, IIA 6.5.1
2923967	2017, Magnitude of the residues of BAS 850 H in barley processed commodities following applications of BAS 850 00 H, DACO: 7.4.5, IIA 6.5.3
2923971	2017, Magnitude of the residues of BAS 850 H in wheat processed commodities following applications of BAS 850 00 H, DACO: 7.4.5, IIA 6.5.3
2923972	2017, Magnitude of the residues of BAS 850 H in sweet sorghum processed fractions following applications of BAS 850 00 H, DACO: 7.4.5, IIA 6.5.3
2923973	2016, Magnitude of the residues of BAS 850 H in rice processed fractions, DACO: 7.4.5, IIA 6.5.3
2923974	2016, Magnitude of the residue of BAS 850 H in soybean processed commodities

	following applications of BAS 850 00 H, DACO: 7.4.5, IIA 6.5.3
2923975	2018, Evaluation of processed food/feed (PF) residues of BAS 850 H in oranges, DACO: 7.4.5, IIA 6.5.3
2923976	2018, Magnitude of the residues of BAS 850 H and its metabolites in or on field corn processed commodities following one preemergence application of BAS 850 00 H, DACO: 7.4.5, IIA 6.5.3
2923977	2016, Confined rotational crop study with ¹⁴ C-BAS 850 H, DACO: 7.4.4, IIA 6.6.2
2923978	2017, Field accumulation studies on rotational crops: Magnitude of the residue of BAS 850 H and its metabolites in/on lettuce, radish and wheat as a rotated crop following a primary crop treated with BAS 850 00 H, DACO: 7.4.4, IIA 6.6.3

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2923861	2017, Hydrolysis of 14C-BAS 850 H, DACO: 8.2.3.2, IIA 2.9.1, IIA 7.5
2923862	2017, Hydrolysis of 14C-BAS 850 H, DACO: 8.2.3.2, IIA 2.9.1, IIA 7.5
2923863	2017, BAS 850H - Photo-transformation of [14C]-BAS 850 H in sterile buffered aqueous solution under artificial sunlight, DACO: 8.2.3.3.2, IIA 2.9.2, IIA 7.6
2923864	2017, BAS 850H - Photo-transformation of [14C]-BAS 850 H in sterile buffered aqueous solution under artificial sunlight, DACO: 8.2.3.3.2, IIA 2.9.2, IIA 7.6
2923868	2018, DACO 8.4.1 Storage, Disposal and Decontamination, Vulcarus Herbicide TGA1 and End Use Products, DACO: 8.4.1, IIA 3.8.2
2923981	2016, Aerobic soil metabolism of 14C-BAS 850 H, DACO: 8.2.3.4.2, IIA 7.1.1, IIA 7.2.1
2923982	2016, Aerobic soil metabolism of 14C-BAS 850 H, DACO: 8.2.3.4.2, IIA 7.1.1, IIA 7.2.1
2923983	2015, Anaerobic soil metabolism of 14C-BAS 850 H, DACO: 8.2.3.4.4, IIA 7.1.2
2923984	2015, Anaerobic soil metabolism of 14C-BAS 850 H, DACO: 8.2.3.4.4, IIA 7.1.2
2923985	2017, BAS850H - Soil photolysis of [14C]-BAS850H, DACO: 8.2.3.3.1, IIA 7.1.3
2923986	2017, BAS850H - Soil photolysis of [14C]-BAS850H, DACO: 8.2.3.3.1, IIA 7.1.3
2923989	2014, Rate of degradation of the BAS 850 H metabolite Reg.No. 5757726 in aerobic soils, DACO: 8.2.3.4.2, IIA 7.2.3
2923990	2018, M850H004: Rate of degradation under aerobic conditions in four soils at 20°C, DACO: 8.2.3.4.2, IIA 7.2.3
2923991	2017, Dissipation of an herbicide (BAS 850 H) following application to a bare soil plot at a test site located in North Dakota, DACO: 8.3.2, IIA 7.3.1
2923992	2017, Dissipation of an herbicide (BAS 850 H) following application to a bare soil plot at a test site located in North Dakota, DACO: 8.3.2, IIA 7.3.1
2923993	2017, Terrestrial field dissipation of the herbicide BAS 850 H following application of a suspension concentrate formulation to a bare-soil plot at test sites in California and Washington, DACO: 8.3.2, IIA 7.3.1
2923994	2017, Terrestrial field dissipation of the herbicide BAS 850 H following application of a suspension concentrate formulation to a bare-soil plot at test sites in California and Washington, DACO: 8.3.2, IIA 7.3.1
2923995	2017, Terrestrial field dissipation of the herbicide BAS 850 H following application of a suspension concentrate formulation to a bare-soil plot at test sites in New York, North Carolina, and Texas, DACO: 8.3.2, IIA 7.3.1
2923996	2017, Terrestrial field dissipation of the herbicide BAS 850 H following application of a suspension concentrate formulation to a bare-soil plot at test sites in New York, North Carolina, and Texas, DACO: 8.3.2, IIA 7.3.1
2923998	2018, Freezer storage stability of BAS 850 H and its four metabolites, M850H001, M850H002, M850H003, M850H004 in soil, DACO: 8.3.2, IIA 7.3.2
2923999	2014, Adsorption/desorption behavior of 14C-BAS 850 H on different US, Japanese and

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	European soils, DACO: 8.2.4.2,IIA 7.4.1
2924000	2014, Adsorption/desorption behavior of 14C-BAS 850 H on different US, Japanese and European soils, DACO: 8.2.4.2,IIA 7.4.1
2924001	2013, Adsorption/desorption behavior of 14C-LS 5749359 (metabolite of BAS 850 H) on different US, European and Japanese soils, DACO: 8.2.4.2,IIA 7.4.2
2924002	2013, Adsorption/desorption behavior of 14C-LS 5749359 (metabolite of BAS 850 H) on different US, European and Japanese soils, DACO: 8.2.4.2,IIA 7.4.2
2924003	2014, Adsorption/desorption behavior of 14C-LS 5757725 (metabolite of BAS 850 H) on different US, European and Japanese soils, DACO: 8.2.4.2,IIA 7.4.2
2924004	2014, Adsorption/desorption behavior of 14C-LS 5757725 (metabolite of BAS 850 H) on different US, European and Japanese soils, DACO: 8.2.4.2,IIA 7.4.2
2924005	2014, Adsorption/desorption behavior of 14C-LS 5757726 (metabolite of BAS 850 H) on different US, European and Japanese soils, DACO: 8.2.4.2,IIA 7.4.2
2924006	2014, Adsorption/desorption behavior of 14C-LS 5757726 (metabolite of BAS 850 H) on different US, European and Japanese soils, DACO: 8.2.4.2,IIA 7.4.2
2924007	2018, M850H004: Adsorption to and desorption from five soils, DACO: 8.2.4.2,IIA 7.4.2
2924009	2017, BAS 850 H: Aerobic aquatic metabolism of 14C-BAS 850 H, DACO: 8.2.3.5.2,8.2.3.5.4,IIA 7.8.1
2924010	2017, BAS 850 H: Aerobic aquatic metabolism of 14C-BAS 850 H, DACO: 8.2.3.5.2,8.2.3.5.4,IIA 7.8.1
2924011	2017, BAS 850 H: Anaerobic aquatic metabolism of 14C-BAS 850 H, DACO: 8.2.3.5.5,8.2.3.5.6,IIA 7.8.2
2924012	2017, BAS 850 H: Anaerobic aquatic metabolism of 14C-BAS 850 H, DACO: 8.2.3.5.5,8.2.3.5.6,IIA 7.8.2

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2924013	2013, BAS 850 H - Acute toxicity in the bobwhite quail (<i>Colinus virginianus</i>) after single oral administration (LD50), DACO: 9.6.2.1,9.6.2.2,9.6.2.3,IIA 8.1.1
2924014	2013, BAS 850 H - Acute toxicity in the bobwhite quail (<i>Colinus virginianus</i>) after single oral administration (LD50), DACO: 9.6.2.1,9.6.2.2,9.6.2.3,IIA 8.1.1
2924015	2013, BAS 850 H - Acute toxicity in the mallard duck (<i>Anas platyrhynchos</i>) after single oral administration (LD50), DACO: 9.6.2.1,9.6.2.2,9.6.2.3,IIA 8.1.1
2924016	2013, BAS 850 H - Acute toxicity in the mallard duck (<i>Anas platyrhynchos</i>) after single oral administration (LD50), DACO: 9.6.2.1,9.6.2.2,9.6.2.3,IIA 8.1.1
2924017	2014, BAS 850 H - Acute toxicity in the canary (<i>Serinus canaria</i>) after single oral administration (LD50), DACO: 9.6.2.1,9.6.2.2,9.6.2.3,IIA 8.1.1
2924018	2014, BAS 850 H - Acute toxicity in the canary (<i>Serinus canaria</i>) after single oral administration (LD50), DACO: 9.6.2.1,9.6.2.2,9.6.2.3,IIA 8.1.1
2924019	2014, BAS 850 H - Avian dietary LC50 test in ducklings of the mallard duck (<i>Anas platyrhynchos</i>), DACO: 9.6.2.4,9.6.2.5,IIA 8.1.2
2924020	2014, BAS 850 H - Avian dietary LC50 test in ducklings of the mallard duck (<i>Anas platyrhynchos</i>), DACO: 9.6.2.4,9.6.2.5,IIA 8.1.2
2924021	2014, BAS 850 H - Avian dietary toxicity test in chicks of the bobwhite quail (<i>Colinus virginianus</i>), DACO: 9.6.2.4,9.6.2.5,IIA 8.1.2
2924022	2014, BAS 850 H - Avian dietary toxicity test in chicks of the bobwhite quail (<i>Colinus virginianus</i>), DACO: 9.6.2.4,9.6.2.5,IIA 8.1.2
2924023	2015, BAS 850 H: A reproduction study with the Northern Bobwhite (Including analytical report), DACO: 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
2924024	2015, BAS 850 H: A reproduction study with the Northern Bobwhite (Including analytical report), DACO: 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4

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2924025	2016, BAS 850 H - 1-Generation reproduction study on the mallard duck (<i>Anas platyrhynchos</i>) by administration in the diet (Including analytical report), DACO: 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
2924026	2016, BAS 850 H - 1-Generation reproduction study on the mallard duck (<i>Anas platyrhynchos</i>) by administration in the diet (Including analytical report), DACO: 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
2924027	2016, BAS 850 H: A reproduction study with the mallard (Including analytical report), DACO: 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
2924028	2016, BAS 850 H: A reproduction study with the mallard (Including analytical report), DACO: 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
2924035	2014, Effect of BAS 850 H (Reg.No. 5654329) on the growth of the marine diatom <i>Skeletonema costatum</i> , DACO: 9.4.2,9.4.3,9.4.4,9.8.3,IIA 8.11.1
2924036	2014, Effect of BAS 850 H (Reg.No. 5654329) on the growth of the marine diatom <i>Skeletonema costatum</i> , DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924037	2012, BAS 850 H - Acute toxicity to Sheepshead minnow (<i>Cyprinodon variegatus</i>) under flow-through conditions, DACO: 9.4.2,9.4.3,9.4.4,9.5.2.4,IIA 8.11.1
2924038	2012, BAS 850 H - Acute toxicity to Sheepshead minnow (<i>Cyprinodon variegatus</i>) under flow-through conditions, DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924039	2012, BAS 850 H: Acute toxicity test with the saltwater mysid, <i>Americamysis bahia</i> , conducted under flow-through conditions, DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924040	2012, BAS 850 H: Acute toxicity test with the saltwater mysid, <i>Americamysis bahia</i> , conducted under flow-through conditions, DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924041	2012, BAS 850 H: Effect on new shell growth of the eastern oyster (<i>Craeastrea virginica</i>), DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924042	2012, BAS 850 H: Effect on new shell growth of the eastern oyster (<i>Craeastrea virginica</i>), DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924043	2014, BAS 850 H: Life-cycle toxicity test of the saltwater mysid, <i>Americamysis bahia</i> , conducted under flow-through test conditions, DACO: 9.4.2,9.4.3,9.4.4,9.4.5,IIA 8.11.1
2924044	2014, BAS 850 H: Life-cycle toxicity test of the saltwater mysid, <i>Americamysis bahia</i> , conducted under flow-through test conditions, DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924045	2015, BAS 850 H: Whole sediment acute toxicity to a marine amphipod (<i>Leptocheirus plumulosus</i>), DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924046	2015, BAS 850 H: Whole sediment acute toxicity to a marine amphipod (<i>Leptocheirus plumulosus</i>), DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
2924047	2013, BAS 850 H: A toxicity test to determine the effects on seedling emergence of ten species of plants, DACO: 9.8.4,IIA 8.12
2924048	2013, BAS 850 H: A toxicity test to determine the effects on seedling emergence of ten species of plants, DACO: 9.8.4,IIA 8.12
2924049	2013, BAS 850 H: A toxicity test to determine the effects on vegetative vigor of ten species of plants, DACO: 9.8.4,IIA 8.12
2924050	2013, BAS 850 H: A toxicity test to determine the effects on vegetative vigor of ten species of plants, DACO: 9.8.4,IIA 8.12
2924051	2015, BAS M850H001: A toxicity test to determine the effects on seedling emergence of ten species of plants, DACO: 9.8.4,IIA 8.12
2924052	2015, BAS M850H001: A toxicity test to determine the effects on seedling emergence of ten species of plants, DACO: 9.8.4,IIA 8.12
2924053	2018, BAS M850H002: A toxicity test to determine the effects on seedling

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	emergence of ten species of plants, DACO: 9.8.4,IIA 8.12
2924054	2018, BAS M850H002: A toxicity test to determine the effects on seedling emergence of ten species of plants, DACO: 9.8.4,IIA 8.12
2924059	2013, BAS 850 H - Acute toxicity study in the rainbow trout (<i>Oncorhynchus mykiss</i>), DACO: 9.5.2.1,9.5.2.3,IIA 8.2.1.1
2924060	2013, BAS 850 H - Acute toxicity study in the rainbow trout (<i>Oncorhynchus mykiss</i>), DACO: 9.5.2.1,9.5.2.3,IIA 8.2.1.1
2924061	2012, BAS 850 H - Acute toxicity to fathead minnow (<i>Pimephales promelas</i>) under flow-through conditions, DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
2924062	2012, BAS 850 H - Acute toxicity to fathead minnow (<i>Pimephales promelas</i>) under flow-through conditions, DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
2924063	2013, BAS 850 H - Acute toxicity study in the common carp (<i>Cyprinus carpio</i>), DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
2924064	2013, BAS 850 H - Acute toxicity study in the common carp (<i>Cyprinus carpio</i>), DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
2924065	2015, BAS 850M001H: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions, DACO: 9.5.2.1,9.5.2.3,9.5.2.4,IIA 8.2.1.3
2924066	2015, BAS 850M001H: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions, DACO: 9.5.2.3,9.5.2.4,IIA 8.2.1.3
2924067	2018, M850H004: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions, DACO: 9.5.2.1,9.5.2.3,9.5.2.4,IIA 8.2.1.3
2924068	2018, M850H004: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions, DACO: 9.5.2.3,9.5.2.4,IIA 8.2.1.3
2924069	2013, BAS 850 H - Early life-stage toxicity test with fathead minnow, <i>Pimephales promelas</i> , following OPPTS draft guideline 850.1400, DACO: 9.5.3.1,IIA 8.2.4
2924070	2013, BAS 850 H - Early life-stage toxicity test with fathead minnow, <i>Pimephales promelas</i> , following OPPTS draft guideline 850.1400, DACO: 9.5.3.1,IIA 8.2.4
2924071	2014, BAS 850 H - Early life-stage toxicity test with sheepshead minnow, <i>Cyprinodon variegatus</i> , DACO: 9.5.3.1,IIA 8.2.4
2924072	2014, BAS 850 H - Early life-stage toxicity test with sheepshead minnow, <i>Cyprinodon variegatus</i> , DACO: 9.5.3.1,IIA 8.2.4
2924073	2018, M850H001 - Early life-stage toxicity test with sheepshead minnow, <i>Cyprinodon variegatus</i> (Including analytical method), DACO: 9.5.3.1,IIA 8.2.4
2924074	2018, M850H001 - Early life-stage toxicity test with sheepshead minnow, <i>Cyprinodon variegatus</i> (Including analytical method), DACO: 9.5.3.1,IIA 8.2.4
2924075	2014, 14C-BAS 850 H (label: triazine-2,4-C14) - Bioconcentration study in the rainbow trout (<i>Oncorhynchus mykiss</i>), DACO: 9.5.6,IIA 8.2.6.1
2924076	2014, 14C-BAS 850 H (label: triazine-2,4-C14) - Bioconcentration study in the rainbow trout (<i>Oncorhynchus mykiss</i>), DACO: 9.5.6,IIA 8.2.6.1
2924077	2014, BAS 850 H - Acute toxicity (immobilisation) study in the water flea - <i>Daphnia magna</i> STRAUS, DACO: 9.3.2,IIA 8.3.1.1
2924078	2014, BAS 850 H - Acute toxicity (immobilisation) study in the water flea - <i>Daphnia magna</i> STRAUS, DACO: 9.3.2,IIA 8.3.1.1
2924079	2015, BAS 850M001H: Acute toxicity to the Cladoceran, <i>Daphnia magna</i> , determined under static-renewal test conditions, DACO: 9.3.2,IIA 8.3.1.1
2924080	2015, BAS 850M001H: Acute toxicity to the Cladoceran, <i>Daphnia magna</i> , determined under static-renewal test conditions, DACO: 9.3.2,IIA 8.3.1.1

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2924081	2018, Reg. No. 5757725 (metabolite of BAS 850 H, M850H002) - Daphnia magna, acute immobilization test, DACO: 9.3.2,IIA 8.3.1.1
2924082	2018, Reg. No. 5757725 (metabolite of BAS 850 H, M850H002) - Daphnia magna, acute immobilization test, DACO: 9.3.2,IIA 8.3.1.1
2924083	2017, Reg. No. 5833884 (metabolite of BAS 850 H, M850H004) - Daphnia magna, acute immobilization test, DACO: 9.3.2,IIA 8.3.1.1
2924084	2017, Reg. No. 5833884 (metabolite of BAS 850 H, M850H004) - Daphnia magna, acute immobilization test, DACO: 9.3.2,IIA 8.3.1.1
2924085	2014, BAS 850 H - Daphnia magna reproduction test, DACO: 9.3.3,IIA 8.3.2.1
2924086	2014, BAS 850 H - Daphnia magna reproduction test, DACO: 9.3.3,IIA 8.3.2.1
2924087	2014, BAS 850 H: Growth inhibition test with the Cyanobacterium, Anabaena flos-aquae, DACO: 9.8.2,9.8.3,IIA 8.4
2924088	2014, BAS 850 H: Growth inhibition test with the Cyanobacterium, Anabaena flos-aquae, DACO: 9.8.2,9.8.3,IIA 8.4
2924089	2014, BAS 850 H: Growth inhibition test with the unicellular green alga, Pseudokirchneriella subcapitata, DACO: 9.8.2,9.8.3,IIA 8.4
2924090	2014, BAS 850 H: Growth inhibition test with the unicellular green alga, Pseudokirchneriella subcapitata, DACO: 9.8.2,9.8.3,IIA 8.4
2924091	2015, BAS 850 H: Growth inhibition test with the freshwater diatom, Navicula pelliculosa, DACO: 9.8.2,9.8.3,IIA 8.4
2924092	2015, BAS 850 H: Growth inhibition test with the freshwater diatom, Navicula pelliculosa, DACO: 9.8.2,9.8.3,IIA 8.4
2924093	2015, M850H001: Growth inhibition test with the unicellular green alga, Pseudokirchneriella subcapitata, DACO: 9.8.2,9.8.3,IIA 8.4
2924094	2015, M850H001: Growth inhibition test with the unicellular green alga, Pseudokirchneriella subcapitata, DACO: 9.8.2,9.8.3,IIA 8.4
2924096	2017, Reg. No. 5833884 (metabolite of BAS 850 H, M850H004) - Pseudokirchneriella subcapitata SAG 61.81, growth inhibition test, DACO: 9.8.2,9.8.3,IIA 8.4
2924097	2017, Reg. No. 5833884 (metabolite of BAS 850 H, M850H004) - Pseudokirchneriella subcapitata SAG 61.81, growth inhibition test, DACO: 9.8.2,9.8.3,IIA 8.4
2924098	2018, Reg.No. 5757725 (metabolite of BAS 850 H, M850H002) - Pseudokirchneriella subcapitata SAG 61.81, growth inhibition test (Including amendment no. 1), DACO: 9.8.2,9.8.3,IIA 8.4
2924099	2018, Reg.No. 5757725 (metabolite of BAS 850 H, M850H002) - Pseudokirchneriella subcapitata SAG 61.81, growth inhibition test (Including amendment no. 1), DACO: 9.8.2,9.8.3,IIA 8.4
2924100	2016, BAS 850 H: Whole sediment acute toxicity to a freshwater amphipod (Hyalella azteca), DACO: 9.3.4,9.9,IIA 8.5.1
2924101	2016, BAS 850 H: Whole sediment acute toxicity to a freshwater amphipod (Hyalella azteca), DACO: 9.9,IIA 8.5.1
2924102	2017, BAS 850 H: Whole sediment acute toxicity test with midge larvae (Chironomus dilutus), DACO: 9.3.4,9.9,IIA 8.5.1
2924103	2017, BAS 850 H: Whole sediment acute toxicity test with midge larvae (Chironomus dilutus), DACO: 9.9,IIA 8.5.1
2924104	2018, M850H004: Whole sediment acute toxicity test with midge larvae (Chironomus dilutus), DACO: 9.3.4,9.9,IIA 8.5.1

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2924105	2018, M850H004: Whole sediment acute toxicity test with midge larvae (<i>Chironomus dilutus</i>), DACO: 9.9,IIA 8.5.1
2924106	2014, BAS 850 H: Chronic toxicity in whole sediment to freshwater midge, <i>Chironomus riparius</i> , using spiked sediment (Including method validation for BAS 850 H in formulated sediment), DACO: 9.3.4,9.9,IIA 8.5.2
2924107	2014, BAS 850 H: Chronic toxicity in whole sediment to freshwater midge, <i>Chironomus riparius</i> , using spiked sediment (Including method validation for BAS 850 H in formulated sediment), DACO: 9.9,IIA 8.5.2
2924108	2018, Reg. No. 5757725 (Metabolite of BAS 850 H, M850H002) <i>Lemna gibba</i> CPCC 310 growth inhibition test, DACO: 9.8.5,IIA 8.6
2924109	2018, Reg. No. 5757725 (Metabolite of BAS 850 H, M850H002) <i>Lemna gibba</i> CPCC 310 growth inhibition test, DACO: 9.8.5,IIA 8.6
2924110	2018, Reg. No. 5833884 (Metabolite of BAS 850 H, M850H004) <i>Lemna gibba</i> CPCC 310, Growth Inhibition Test, DACO: 9.8.5,IIA 8.6
2924111	2018, Reg. No. 5833884 (Metabolite of BAS 850 H, M850H004) <i>Lemna gibba</i> CPCC 310, Growth Inhibition Test, DACO: 9.8.5,IIA 8.6
2924112	2018, M850H001: Growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> , DACO: 9.8.5,IIA 8.6
2924113	2018, M850H001: Growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> , DACO: 9.8.5,IIA 8.6
2924114	2018, BAS 850 H: Growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> , DACO: 9.8.5,IIA 8.6
2924115	2018, BAS 850 H: Growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> , DACO: 9.8.5,IIA 8.6
2924116	2013, BAS 850 H - Acute oral and contact toxicity to the honeybee, <i>Apis mellifera</i> L. under laboratory conditions, DACO: 9.2.4.1,9.2.4.2,IIA 8.7.1,IIA 8.7.2
2924117	2013, BAS 850 H - Acute oral and contact toxicity to the honeybee, <i>Apis mellifera</i> L. under laboratory conditions, DACO: 9.2.4.1,9.2.4.2,IIA 8.7.1,IIA 8.7.2
2924118	2013, Effects of BAS 850 00 H (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory, DACO: 9.2.4.1,9.2.4.2,IIA 8.7.1,IIA 8.7.2
2924119	2013, Effects of BAS 850 00 H (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory, DACO: 9.2.4.1,9.2.4.2,IIA 8.7.1,IIA 8.7.2
2924120	2015, Acute toxicity of BAS 850 00 H to honeybee larvae <i>Apis mellifera</i> L. under laboratory conditions (in vitro), DACO: 9.2.4.1,9.2.4.3,IIA 8.7.2
2924121	2015, Acute toxicity of BAS 850 00 H to honeybee larvae <i>Apis mellifera</i> L. under laboratory conditions (in vitro), DACO: 9.2.4.1,IIA 8.7.2
2924122	2017, Chronic toxicity of BAS 850 H to the honey bee <i>Apis mellifera</i> L. under laboratory conditions, DACO: 9.2.4.1,9.2.4.4,IIA 8.7.2
2924123	2017, Chronic toxicity of BAS 850 H to the honey bee <i>Apis mellifera</i> L. under laboratory conditions, DACO: 9.2.4.1,IIA 8.7.2
2924124	2017, Repeated exposure of honey bee (<i>Apis mellifera</i>) larvae to BAS 850 H under laboratory conditions (in vitro), DACO: 9.2.4.1,9.2.4.3,IIA 8.7.2
2924126	2017, Repeated exposure of honey bee (<i>Apis mellifera</i>) larvae to BAS 850 H under laboratory conditions (in vitro), DACO: 9.2.4.1,IIA 8.7.2
2924127	2014, Acute toxicity of BAS 850 H (Reg. No. 5654329) to the earthworm <i>Eisenia fetida</i> in artificial soil with 10% peat, DACO: 9.2.3.1,IIA 8.9.1
2924128	2014, Acute toxicity of BAS 850 H (Reg. No. 5654329) to the earthworm <i>Eisenia fetida</i> in artificial soil with 10% peat, DACO: 9.2.3.1,IIA 8.9.1
2924129	2017, Sublethal effects of BAS 850 H on the earthworm <i>Eisenia andrei</i> in artificial

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2924130	2017, Sublethal effects of BAS 850 H on the earthworm <i>Eisenia andrei</i> in artificial soil (Including amendment no. 1), DACO: 9.2.3.1,IIA 8.9.2
2924158	2014, BAS 850 00 H - Rainbow trout , acute toxicity test, DACO: 9.5.4,IIIA 10.2.2.1
2924159	2014, BAS 850 00 H - Rainbow trout , acute toxicity test, DACO: 9.5.4,IIIA 10.2.2.1
2924160	2014, BAS 850 00 H - <i>Daphnia magna</i> , acute immobilization test, DACO: 9.3.2,IIIA 10.2.2.2
2924161	2014, BAS 850 00 H - <i>Daphnia magna</i> , acute immobilization test, DACO: 9.3.2,IIIA 10.2.2.2
2924162	2014, BAS 850 00H: Growth inhibition test with the unicellular green algae, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIIA 10.2.2.3
2924163	2014, BAS 850 00H: Growth inhibition test with the unicellular green algae, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIIA 10.2.2.3
2924164	2017, Effects of BAS 850 00 H on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in a laboratory test, DACO: 9.2.5,9.2.8,IIIA 10.5.2
2924165	2017, Effects of BAS 850 00 H on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in a laboratory test, DACO: 9.2.8,IIIA 10.5.2
2924166	2017, Effects of BAS 850 00 H on the parasitic wasp <i>Aphidius rhopalosiphi</i> (DESTEFANI-PEREZ) in a laboratory test, DACO: 9.2.6,9.2.8,IIIA 10.5.2
2924167	2017, Effects of BAS 850 00 H on the parasitic wasp <i>Aphidius rhopalosiphi</i> (DESTEFANI-PEREZ) in a laboratory test, DACO: 9.2.8,IIIA 10.5.2
2924168	2017, Acute toxicity of BAS 850 00 H to the earthworm <i>Eisenia andrei</i> in artificial soil with 10% peat, DACO: 9.2.8,IIIA 10.6.2
2924169	2017, Acute toxicity of BAS 850 00 H to the earthworm <i>Eisenia andrei</i> in artificial soil with 10% peat, DACO: 9.2.8,IIIA 10.6.2
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2924173	2013, Effects of BAS 850 00 H on the activity of soil microflora (Nitrogen transformation test), DACO: 9.2.8,IIIA 10.7.1
2924175	2014, BAS 850 00 H: Growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> , DACO: 9.8.6,9.8.7,IIIA 10.8.2.1
2924176	2014, BAS 850 00 H: Growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> , DACO: 9.8.6,9.8.7,IIIA 10.8.2.1
2924225	2018, BAS 851 00 H - Acute toxicity test with rainbow trout (<i>Oncorhynchus mykiss</i>) under static conditions, DACO: 9.5.4,IIIA 10.2.2.1
2924226	2018, BAS 851 00 H - Acute toxicity test with rainbow trout (<i>Oncorhynchus mykiss</i>) under static conditions, DACO: 9.5.4,IIIA 10.2.2.1
2924227	2018, BAS 851 00 H - Acute toxicity test to water fleas (<i>Daphnia magna</i>) under static conditions, DACO: 9.3.2,IIIA 10.2.2.2
2924228	2018, BAS 851 00 H - Acute toxicity test to water fleas (<i>Daphnia magna</i>) under static conditions, DACO: 9.3.2,IIIA 10.2.2.2
2924229	2018, BAS 851 00 H - 96-hour toxicity test with the freshwater green alga, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIIA 10.2.2.3
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4.0 Value

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2756064	2014, To determine the efficacy and selectivity of CHA-2738 when applied pre to soybean in 2014. DACO: 10.2.3.3(B) and 10.3.2(A).
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