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Proposed Registration Decision

PRD2019-09

Mefentrifluconazole and related end-use products

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Overview

Proposed Registration Decision for Mefentrifluconazole

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 Revysol Fungicide Technical, BAS 752 RC, Belyan, Cevya, Lenvyor, Maxtima, and Relenya, containing the technical grade active ingredient mefentrifluconazole, to control various fungal pests in field crops, fruits, specialty crops and golf course turf.

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 mefentrifluconazole and related end-use products.

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides portion of Canada.ca.

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."

Before making a final registration decision on mefentrifluconazole and related end-use products, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.³ Health Canada will then publish a Registration Decision⁴ on mefentrifluconazole and related end-use products, 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 Mefentrifluconazole?

Mefentrifluconazole is a new conventional active ingredient for disease management in certain field crops, fruits, specialty crops and golf course turf. It inhibits spore germination, mycelial growth, and sporulation of the fungus on the leaf surface. Mefentrifluconazole is a systemic and selective fungicide.

Health Considerations

Can Approved Uses of Mefentrifluconazole Affect Human Health?

The end-use products, Lenvyor, Cevya, Maxtima, Relenya, Belyan and BAS 752 RC, containing mefentrifluconazole are unlikely to affect your health when used according to label directions.

Potential exposure to mefentrifluconazole may occur through the diet (food and water) or when handling and applying the end-use products. When assessing health risks, two key factors are considered: the levels where 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 where 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.

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*.

In laboratory animals, the technical grade active ingredient mefentrifluconazole was of low acute toxicity by the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and non-irritating to the skin. It caused an allergic skin reaction; consequently, the hazard statement “POTENTIAL SKIN SENSITIZER” is required on the label.

The acute toxicity of the end-use product Lenvyor was low via the oral, dermal and inhalation routes of exposure. It was moderately irritating to the skin and eyes, and in the absence of an appropriate dermal sensitization study, Lenvyor was assumed to cause an allergic skin reaction; consequently, the signal word and hazard statements “WARNING – EYE AND SKIN IRRITANT – POTENTIAL SKIN SENSITIZER” are required on the label.

The acute toxicity of the end-use products Cevya, Maxtima and Relenya was low via the oral, dermal and inhalation routes of exposure. The end-use products were non-irritating to the skin and eyes. In the absence of an appropriate dermal sensitization study, Cevya, Maxtima and Relenya were assumed to cause an allergic skin reaction; consequently, the hazard statement “POTENTIAL SKIN SENSITIZER” is required on each of the labels.

The acute toxicity of the end-use product Belyan was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and did not cause an allergic skin reaction. Belyan was mildly irritating to the skin; consequently, the signal word and hazard statement “CAUTION – SKIN IRRITANT” are required on the label.

The acute toxicity of the end-use product BAS 752 RC was low via the oral, dermal and inhalation routes of exposure. It was slightly irritating to the skin and minimally irritating to the eyes. BAS 752 RC did not cause an allergic skin reaction.

Registrant-supplied short- and long-term (lifetime) animal toxicity tests were assessed for the potential of mefentrifluconazole 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 hematology parameters, the liver and kidneys and activity level. There was no evidence of increased sensitivity of the young to mefentrifluconazole compared to adult animals. 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 were less than 6% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was children 1–2 years old.

Aggregate chronic dietary (food plus drinking water) intake estimates indicated that the general population and children 1–2 years old, the subpopulation which would ingest the most mefentrifluconazole relative to body weight, are expected to be exposed to less than 12% of the

acceptable daily intake. Based on these estimates, the chronic dietary risk from mefentrifluconazole 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 mefentrifluconazole on potatoes, sugar beets, legume vegetables, citrus fruits, pome fruits, stone fruits, grapes, tree nuts, cereals, canola and peanuts are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this document.

A number of these mefentrifluconazole products are also formulated with the active ingredients fluxapyroxad and pyraclostrobin. These co-active ingredients are already registered for these uses in Canada, and residues in treated commodities will be covered under the existing MRLs for each active ingredient.

Occupational Risks from Handling BAS 752 RC, Belyan, Cevya and Lenvyor

Occupational risks are not of concern when BAS 752 RC, Belyan, Cevya and Lenvyor are used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply BAS 752 RC, Belyan, Cevya or Lenvyor as well as workers entering freshly treated fields can come in direct contact with mefentrifluconazole residues on the skin. Therefore, the labels for BAS 752 RC, Belyan and Cevya specify that users wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. The label of Lenvyor specifies that users wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. In addition, the labels for Belyan and Lenvyor also specify that users wear protective eyewear during mixing and loading.

Furthermore, the labels for BAS 752 RC, Belyan and Lenvyor require that workers do not enter treated fields for 12 hours after application. For Cevya, it is required that workers do not enter treated fields for 12 hours after application for all activities, except for cane turning and girdling of table grapes where workers must respect a 35-day restricted-entry interval.

Standard label statements to protect against drift during application are present on the labels. Taking into consideration these label statements, the number of applications and the duration of exposure for handlers and workers, health risks to these individuals are not a concern.

Occupational Risks from Handling Maxtima

Occupational risks are not of concern when Maxtima is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Maxtima as well as workers entering freshly treated golf course turf can come in direct contact with mefentrifluconazole residues on the skin. Therefore, the label for Maxtima specifies that users wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. The restricted-entry interval on commercial golf courses treated with Maxtima is “until sprays have dried”.

Taking into consideration these label statements, the number of applications and the duration of exposure for handlers, workers and golfers, health risks to these individuals are not a concern.

Occupational Risks from Handling Relenya

Occupational risks are not of concern when Relenya is used according to the proposed label directions, which include protective measures.

Workers treating seed with Relenya in commercial facilities, by commercial mobile systems or on-farm, and workers planting treated seed can come into direct contact with mefentrifluconazole residues on the skin and through inhalation.

The Relenya label specifies that workers mixing, loading, applying, bagging, stacking and sewing bags of treated seed and involved in handling treated seed in commercial seed treating facilities or on-farm, must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested.

In addition, workers cleaning-up or maintaining and repairing seed treatment equipment must wear chemical-resistant coveralls in commercial seed treatment facilities, or coveralls on-farm, over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested.

Workers loading and planting treated seed must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. Closed transfer systems must be used in commercial seed treatment facilities and closed-cab tractors must be used while planting.

Taking into consideration these label statements, the number of applications and the duration of exposure for handlers and workers, health risks to these individuals are not a concern.

Health Risks to Bystanders

For bystanders, exposure is expected to be less than that for workers. Therefore, health risks to bystanders are not of concern.

Risks in Residential and Other Non-Occupational Environments

Risks in residential and other non-occupational environments are not of concern when mefentrifluconazole is used according to the proposed label directions and restricted-entry intervals are observed.

Adults, youth and children while golfing can come into direct contact with mefentrifluconazole residues from treated turf. Therefore, the label requires that individuals do not enter treated golf courses until sprays have dried. Taking into consideration the label statements, number of applications and the duration of exposure, risks to individuals golfing are not a concern.

Residential exposure in pick-your-own fruit scenarios in treated orchards and residential areas are not of health concern.

Environmental Considerations

What Happens When Mefentrifluconazole Is Introduced Into the Environment?

When mefentrifluconazole is used according to the label directions, the risks to the environment have been determined to be acceptable.

Mefentrifluconazole enters the environment when applied to control or suppress fungal pests on certain vegetable and fruit crops, treated seeds, and golf course turf. In the presence of sunlight, mefentrifluconazole can break down in the upper layers of clear water bodies and form breakdown products M750F005, M750F006, and M750F007. When mefentrifluconazole enters aquatic environments it is expected to move to the sediments and it can also break down to M750F001. Mefentrifluconazole is not expected to move into the air from water or moist soils and it is not expected to travel long distances from where it was applied. Mefentrifluconazole residues can carry-over into the next growing season. Mefentrifluconazole is not expected to move through soil and reach groundwater. Mefentrifluconazole is a systemic fungicide, and therefore, residues may move through plants, in addition to residues being present on leaves and flowers. Mefentrifluconazole is not likely to accumulate in tissues of organisms.

Mefentrifluconazole does not present a risk of concern to wild mammals, birds, beneficial insects, pollinators, earthworms, marine fish, or aquatic plants. When used according to labelled application rates, mefentrifluconazole may pose risks to freshwater fish, freshwater and marine invertebrates, amphibians, and terrestrial plants. Mitigation measures, including spray buffer zones and precautionary label statements, are required to reduce exposure to these organisms. When mefentrifluconazole is used according to the label and the required risk reduction measures are applied, the environmental risks are considered acceptable.

Value Considerations

What Is the Value of Lenvyor, Cevya, Maxtima, Relenya, BAS 752 RC and Belyan?

Lenvyor, Cevya, Maxtima and Relenya

Mefentrifluconazole is the active ingredient in Lenvyor, Cevya, Maxtima and Relenya. The registration of these products will provide Canadian growers with a new mode of action to manage important fungal diseases on the crops and plants specified on these product labels.

Lenvyor, Cevya, Maxtima and Relenya contain mefentrifluconazole as their sole active ingredient. Lenvyor, applied as a foliar spray, is effective against certain economically important diseases in corn (field, pop, sweet, seed), Crop Subgroup 6C (dried shelled pea and bean subgroup, except soybeans), soybeans, sugar beet, peanuts, potatoes, canola, rapeseed, mustard, flax and wheat (all types). Cevya, applied as a foliar spray, is effective against certain economically important diseases in grapes, peanuts, potatoes, sugar beet, Crop Group 11-09 (pome fruits), Crop Group 12-09 (stone fruits) and tree nuts. Maxtima, applied as a foliar spray, is effective against certain important diseases in golf course turf. Relenya, applied as a seed treatment, is effective against certain important diseases in canola, corn, Crop Subgroup 6C, soybean and wheat.

BAS 752 RC

Mefentrifluconazole and fluxapyroxad, the active ingredients in BAS 752 RC, control or suppress certain fungal diseases on canola, rapeseed, flax, dry pea, lentil, chickpea, fababean and potato.

BAS 752 RC, formulated as a foliar treatment, is effective against certain fungal diseases in canola, rapeseed, flax, dry pea, lentil, chickpea, fababean and potato.

Belyan

Mefentrifluconazole, pyraclostrobin and fluxapyroxad, the active ingredients in Belyan, control or suppress certain fungal diseases on canola, rapeseed, mustard, flax, Crop Subgroup 6C, potato, soybean and wheat (all types).

Belyan, formulated as a foliar treatment, is effective against certain fungal diseases in canola, rapeseed, mustard, flax, Crop Subgroup 6C, potato, soybean and wheat (all types).

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 labels of BAS 752 RC, Belyan, Cevya, Lenvyor, Maxtima, and Relenya to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with mefentrifluconazole on the skin or through inhalation of spray mists, the labels for BAS 752 RC, Belyan, Cevya and Maxtima specify that users wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. The label of Lenvyor specifies that users wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. In addition, the labels for Belyan and Lenvyor also specify that users wear protective eyewear during mixing and loading. Furthermore, standard label statements to protect against drift during application are present.

The labels for BAS 752 RC, Belyan and Lenvyor also require that workers do not enter treated fields for 12 hours after application. For Cevya, it is required that workers do not enter treated fields for 12 hours after application for all activities, except for cane turning and girdling activity in treated vineyards of table grapes where workers do not enter for 35 days after application. For the Maxtima label, the restricted-entry interval on treated commercial golf courses is “until sprays have dried”.

The label for Relenya specifies that workers mixing, loading, applying, bagging, stacking and sewing bags of treated seed or any other activities involving handling treated seed in commercial or on-farm seed treating facilities, must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. In addition, workers cleaning-up or maintaining and repairing seed treatment equipment must wear chemical-resistant coveralls in commercial seed treatment facilities and coveralls during on-farm seed treatment, over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. Workers loading and planting treated seed must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. In addition, closed transfer systems must be used in commercial seed treatment facilities and closed-cab tractors must be used while planting.

Taking into consideration these label statements, the number of applications and the duration of exposure for handlers, workers and golfers, health risks to these individuals are not a concern.

Next Steps

Before making a final registration decision on mefentrifluconazole and related end-use products, 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 Health Canada makes its registration decision, it will publish a Registration Decision on Revysol Fungicide Technical, containing the new active ingredient mefentrifluconazole, and on the associated end-use products BAS 752 RC, Belyan, Cevya, Lenvyor, Maxtima, and Relenya (based on the Science Evaluation section 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

Mefentrifluconazole and Related End-Use Products

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance Mefentrifluconazole

Function Fungicide

Chemical name

1. International Union of Pure and Applied Chemistry (IUPAC) (2*RS*)-2-[4-(4-chlorophenoxy)- α,α,α -trifluoro-*o*-tolyl]-1-(1*H*-1,2,4-triazol-1-yl)propan-2-ol

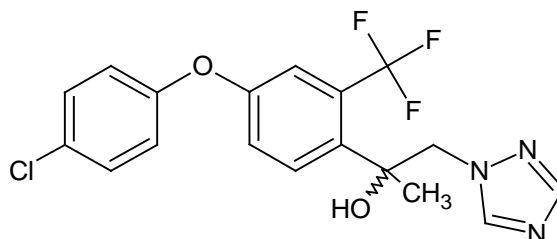
2. Chemical Abstracts Service (CAS) α -[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]- α -methyl-1*H*-1,2,4-triazole-1-ethanol

CAS number 1417782-03-6

Molecular formula C₁₈H₁₅ClF₃N₃O₂

Molecular weight 397.8 g/mol

Structural formula



Purity of the active ingredient 98.5

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product — Mefentrifluconazole Technical

Property	Result
Colour and physical state	off-white, solid
Odour	moderate thiolic
Melting range	126°C
Boiling point or range	decomposes
Density	1.468 g/cm ³

Property	Result																
Vapour pressure at 20°C	3.2×10^{-6} Pa																
Ultraviolet (UV)-visible spectrum	<table> <tr> <th>λ (nm)</th><th>ϵ (L/(mol cm))</th></tr> <tr> <td>194</td><td>5.5×10^4</td></tr> <tr> <td>231</td><td>1.7×10^4</td></tr> <tr> <td>275</td><td>2.8×10^3</td></tr> <tr> <td>290</td><td>1.5×10^3</td></tr> <tr> <td>295</td><td>4.2×10^2</td></tr> </table>	λ (nm)	ϵ (L/(mol cm))	194	5.5×10^4	231	1.7×10^4	275	2.8×10^3	290	1.5×10^3	295	4.2×10^2				
λ (nm)	ϵ (L/(mol cm))																
194	5.5×10^4																
231	1.7×10^4																
275	2.8×10^3																
290	1.5×10^3																
295	4.2×10^2																
Solubility in water at 20°C	0.81 mg/L																
Solubility in organic solvents at 20°C	<table> <tr> <th>Solvent</th><th>Solubility (g/L)</th></tr> <tr> <td>ethyl acetate</td><td>116.2</td></tr> <tr> <td>acetone</td><td>93.2</td></tr> <tr> <td>methanol</td><td>73.2</td></tr> <tr> <td>1,2-dichloroethane</td><td>55.3</td></tr> <tr> <td>acetonitrile</td><td>49.4</td></tr> <tr> <td>xylene</td><td>8.5</td></tr> <tr> <td>n-heptane</td><td>0.09</td></tr> </table>	Solvent	Solubility (g/L)	ethyl acetate	116.2	acetone	93.2	methanol	73.2	1,2-dichloroethane	55.3	acetonitrile	49.4	xylene	8.5	n-heptane	0.09
Solvent	Solubility (g/L)																
ethyl acetate	116.2																
acetone	93.2																
methanol	73.2																
1,2-dichloroethane	55.3																
acetonitrile	49.4																
xylene	8.5																
n-heptane	0.09																
<i>n</i> -Octanol-water partition coefficient (K_{ow})	$\log K_{ow}$ 3.4																
Dissociation constant (pK_a)	not applicable - molecule will be unionized at environmental pH																
Stability (temperature, metal)	Technical material was found to be stable in contact with metals (iron and aluminum) and metal salts (iron acetate and aluminum acetate), and when stored at normal and elevated (~54°C) temperatures.																

End-Use Product—Cevya

Property	Result
Colour	off-white, solid
Odour	faint smoky
Physical state	liquid
Formulation type	SU (suspension)
Label concentration	Mefentrifluconazole 400 g/L
Container material and description	HDPE jugs, drums or totes
Density	1.147 g/cm ³
pH of 1% dispersion in water	7.1 (1% in deionized water)
Oxidizing or reducing action	No significant oxidizing or reducing action
Storage stability	Stable on storage for 2 weeks at 54°C in HDPE containers
Corrosion characteristics	Not corrosive to commercial container material
Explosibility	Not explosive

End-Use Product — Maxtima

Property	Result
Colour	off-white
Odour	faint smoky
Physical state	liquid
Formulation type	SU (suspension)
Label concentration	Mefentrifluconazole 400 g/L
Container material and description	HDPE jugs, drums or totes
Density	1.147 g/cm ³
pH of 1% dispersion in water	7.1 (1% in deionized water)
Oxidizing or reducing action	No significant oxidizing or reducing action
Storage stability	Stable on storage for 2 weeks at 54°C in HDPE containers
Corrosion characteristics	Not corrosive to commercial container material
Explodability	Not explosive

End-Use Product — Relenya

Property	Result
Colour	off-white
Odour	faint smoky
Physical state	liquid
Formulation type	SU (suspension)
Label concentration	Mefentrifluconazole 400 g/L
Container material and description	HDPE jugs, drums or totes
Density	1.147 g/cm ³
pH of 1% dispersion in water	7.1 (1% in deionized water)
Oxidizing or reducing action	No significant oxidizing or reducing action
Storage stability	Stable on storage for 2 weeks at 54°C in HDPE containers
Corrosion characteristics	Not corrosive to commercial container material
Explodability	Not explosive

End-Use Product — Lenvyor

Property	Result
Colour	yellow
Odour	faintly fishy
Physical state	clear liquid
Formulation type	EC (emulsifiable concentrate)
Label concentration	Mefentrifluconazole 100 g/L
Container material and description	PA/PE coextruded jugs, drums or totes
Density	0.993 g/cm ³
pH of 1% dispersion in water	6.8 (1% dispersion in deionized water)
Oxidizing or reducing action	No significant oxidizing or reducing action
Storage stability	Stable on storage for 2 weeks at 54°C in PA/PE containers
Corrosion characteristics	Not corrosive to commercial container material
Explodability	Not explosive

End-Use Product — BAS 752 RC

Property	Result
Colour	off-white
Odour	odourless
Physical state	liquid
Formulation type	SU (suspension)
Label concentration	Mefentrifluconazole 200 g/L Fluxapyroxad 200 g/L
Container material and description	HDPE jugs, drums or totes
Density	1.152 g/cm ³
pH of 1% dispersion in water	6.9 (1% in deionized water)
Oxidizing or reducing action	No significant oxidizing or reducing action
Storage stability	Stable on storage for 2 weeks at 54°C in HDPE containers
Corrosion characteristics	Not corrosive to commercial container material
Explodability	Not explosive

End-Use Product — Belyan

Property	Result
Colour	Creamy white
Odour	Odourless
Physical state	Liquid
Formulation type	SU (suspension)
Label concentration	Mefentrifluconazole 133.3 g/L Fluxapyroxad 88.9 g/L Pyraclostrobin 177.8 g/L
Container material and description	HDPE jugs, drums or totes
Density	1.136 g/cm ³
pH of 1% dispersion in water	6.56 (1% in deionized water)
Oxidizing or reducing action	No significant oxidizing or reducing action
Storage stability	Stable on storage for one year at 25°C in HDPE containers
Corrosion characteristics	Not corrosive to commercial container material
Explodability	Not explosive

1.3 Directions for Use

Lenvyor may be applied as a preventative foliar treatment at 0.5 to 1.5 L product/ha, and in accordance with the label, for the control or suppression of certain fungal diseases on corn (field, pop, sweet, seed), Crop Subgroup 6C (dried shelled pea and bean subgroup, except soybeans), soybeans, sugar beet, peanuts, potatoes, canola, rapeseed, mustard, flax and wheat (all types).

Cevya may be applied as a preventative foliar treatment at 0.19 to 0.375 L product/ha, and in accordance with the label, for the control or suppression of certain fungal diseases on grapes, peanuts, potatoes, sugar beet, Crop Group 11-09 (pome fruits), Crop Group 12-09 (stone fruits) and tree nuts,

Maxtima may be applied as a preventative foliar treatment at 6.25 to 25 mL product/100 m², and in accordance with the label, for the control or suppression of certain fungal diseases on golf course turf.

Relenya may be applied as a seed treatment at 12.5 to 50 mL product/100 kg seed, and in accordance with the label, for the control of certain seed and seedling diseases on canola, corn, Crop Subgroup 6C, soybean and wheat.

BAS 752 RC may be applied as a preventative foliar treatment at a rate of 0.375 L product/ha, and in accordance with the label, for the control or suppression of certain fungal diseases on canola, rapeseed, flax, dry pea, lentil, chickpea, fababean and potato.

Belyan may be applied as a preventative foliar treatment at a rate range of 0.45 – 0.56 L product/ha, and in accordance with the label, for the control or suppression of certain fungal diseases on canola, rapeseed, mustard, flax, Crop Subgroup 6C, potato, soybean and wheat (all types).

1.4 Mode of Action

Mefentrifluconazole is classified as a Group 3 fungicide by the Fungicide Resistance Action Committee (FRAC). It inhibits sterol biosynthesis in certain fungi. Specifically, mefentrifluconazole inhibits spore germination, mycelial growth, and sporulation of the fungus on the leaf surface. It is a systemic fungicide that is best used as a preventative treatment.

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 for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation 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; Methods D1511/01 and L0295/01 in plant matrices and Methods L0272/01 and D1704/01 in animal matrices) were developed and proposed for mefentrifluconazole for data generation and enforcement purposes. Additionally, gas chromatographic methods with mass spectrometric detection (GC-MS; L0309/01 and L0309/02) were developed and proposed for the metabolite M750F022 and its conjugates for data generation purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) for mefentrifluconazole were obtained in plant and animal matrices, and for the metabolite M750F022 in animal matrices. The proposed enforcement methods (L0295/01 in plant matrices and L0272/01 in animal matrices) for mefentrifluconazole were each successfully validated by an independent laboratory. Adequate extraction efficiencies were demonstrated using radiolabelled crop and animal matrices.

Methods for residue analysis are summarized in Appendix I, Table 8.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Mefentrifluconazole is a fungicide belonging to the triazole group of chemicals. The parent compound consisted of a 1:1 mixture of S- and R-isomers. The primary pesticidal mode of action of mefentrifluconazole is the inhibition of cytochrome P450 sterol 14 α -demethylase, also known as CYP51, leading to an accumulation of dysfunctional sterols. This results in growth inhibition and membrane disruption of the fungus. A detailed review of the toxicological database for mefentrifluconazole was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. In addition, an acute oral toxicity, a 28-day oral (dietary) toxicity, and three in vitro genotoxicity studies, as well as a quantitative structure-activity relationship (QSAR) analysis were provided on the poultry metabolite M750F022. Acute oral toxicity and in vitro genotoxicity studies, as well as QSAR analyses were provided on the mefentrifluconazole metabolites M750F037, M750F006, and M750F002. An acute oral toxicity and an in vitro genotoxicity study were provided on the mefentrifluconazole metabolite M750F036. The studies were carried out in accordance with 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 mefentrifluconazole.

Toxicokinetic studies were performed by oral gavage to characterize the absorption, distribution, metabolism and elimination of radiolabelled mefentrifluconazole in rats, as well as absorption in mice. The rat studies included bile duct-cannulated animals as well as animals that received intravenous injections of the radiolabelled test compound. An in vitro study comparing mefentrifluconazole metabolism in rat, mouse and human hepatocytes was also available. Three radiolabels were used in the course of the investigations and were located on the chlorophenyl ring (C-label), trifluoromethyl ring (TFMP-label) or triazole moiety (T-label).

Mefentrifluconazole was extensively absorbed from the gastrointestinal tract after oral administration to rats, regardless of the label position tested. Based on the bile excretion data, an oral single low dose was well-absorbed in both sexes. Absorption was slightly lower with an oral single high dose; suggesting saturation of the absorption at the high dose. The time required to reach the plasma peak concentration occurred 1 to 5 hrs post-dosing with the C-label and 1 hr post-dosing with the T-label at both the single low or high dose level. A second plasma peak concentration occurred at 8 or 24 hrs at the single mid-high (females) and high (both sexes) dose levels with the T-label. Such peaks were not observed with the other labels in the rat, but multiple peaks were observed in the mouse using the same T-label suggesting an enterohepatic recirculation of the triazole moiety. The plasma kinetic data showed that internal exposure of male rats to radiolabelled test compound, as reflected by the area under curve (AUC), was greater than the internal exposure observed in female rats. In the mouse, the AUC data were similar in both sexes and proportional to the dose.

Oral gavage studies with the C- and T-labels in the rat showed that radioactivity was distributed to all organs and tissues with the highest levels being found in liver, plasma, adrenal glands and kidneys. Radioactivity progressively decreased in organs and tissues in parallel to the radioactive residues in plasma at the low and high dose levels.

The test substance was eliminated predominantly via the feces in the rat following oral gavage administration for all three label positions. Bile duct cannulation studies showed that a significant amount of radioactivity was excreted via the bile with all labels. Urinary excretion was comparable at all doses and labels tested with the exception of the T-labelled compound, for which urinary elimination was slightly increased. Specifically, a higher urinary elimination was observed in male compared to female animals at the low-dose level. The elimination of C- and TFMP-labels showed similar time-course patterns at all doses tested in both sexes. Exhalation accounted for the elimination of less than 2% of the administered dose (AD). At a high-dose level, repeated oral administration of the T-labelled mefentrifluconazole showed only slightly increased amounts of radioactivity excreted via urine compared to single oral administration. The urinary elimination in the groups administered a repeated high-dose level using the other radiolabels was comparable to the single high-dose group. There was no evidence of tissue retention 3 days post-dosing for any dosing regimen.

Mefentrifluconazole was extensively metabolized with more than 60 metabolites identified in rats. The isomeric ratio remained stable in feces at both dose levels. In the liver, kidney and plasma, a shift of the S- versus R-enantiomer ratio towards lower relative amounts of the S-enantiomer was observed (1:4). The metabolic reactions included phase I conversion of mefentrifluconazole via hydroxylation (mono, di- and tri-), chlorine shift, methylation, and cleavage of the ether group or of the triazole ring from mefentrifluconazole. These were followed by phase II reactions including sulfation, glucuronidation and /or glutathione adduction with corresponding decomposition products (see Appendix I, Table 1 for identification of select metabolites).

In urine, the overall metabolic profile was comparable for all radiolabels in both sexes and consisted mostly of glucuronide and sulphate conjugates of hydroxylated phase I compounds. Unchanged mefentrifluconazole was not detected in urine samples. With the C-labelled compound, M750F049 and M750F023 were the major urinary metabolites detected. All other metabolites were detected at less than 1.1% of the AD in all dose regimens. Female animals presented a more diversified metabolite profile compared to male animals (12 metabolites in males versus 17 in females). For the TFMP-label (single high oral dose), the major urinary metabolites in both sexes were M750F071, M750F054 and M750F049 / M750F003. For the T-labelled compound (all dose regimens), the major urinary metabolite was M750F001.

In feces, unchanged mefentrifluconazole and cleaved parent hydroxylated compounds were identified. All tested dose levels and labels showed a comparable metabolite pattern with M750F015, M750F016/M750F017 and the unchanged mefentrifluconazole as the major fecal components. Unchanged mefentrifluconazole was the most abundant component for the T-label except at the low-dose level in both sexes. For the C- and TFMP-labels, M750F015 and/or M750F016/ M750F017 were usually more abundant than the parent compound. The metabolic profiles in both sexes and for all labels were not remarkably different in feces. In bile,

metabolites M750F035, M750F044, M750F045, M750F049 (including isomers) and M750F087 were identified as the major radiolabelled residues for all tested labels. These metabolites were mefentrifluconazole-hydroxylated products, which were then glucuronidated. An exception occurred in males at the high dose level with TFMP-label and males (low- and high-dose) and females (low-dose) with the T-label, where these metabolites were not detected. In tissues and plasma, most of the metabolites detected were hydroxylated mefentrifluconazole or unchanged mefentrifluconazole.

An in vitro comparative metabolism study performed with mouse, rat and human hepatocytes showed that over a 180-minute incubation period, human hepatocytes metabolized mefentrifluconazole to an unidentified compound that was also detected in rat hepatocytes, although the metabolic reaction(s) occurred at a faster rate in rat hepatocytes compared to human hepatocytes.

Over the same period, no significant biotransformation of the test compound was observed in mouse hepatocytes suggesting a slower or absent metabolism for mouse hepatocytes compared to human and rat hepatocytes.

In acute toxicity testing, the technical grade active ingredient mefentrifluconazole 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. Mefentrifluconazole was positive for dermal sensitization in guinea pigs when tested in the Maximization assay.

The end-use products Lenvyor, Cevya, Maxtima, Relenya, Belyan, and BAS 752 RC containing mefentrifluconazole were of low acute toxicity via the oral, dermal and inhalation routes in rats. Lenvyor was moderately irritating to the skin and the eyes of rabbits. Cevya, Maxtima and Relenya were non-irritating to the skin and eyes of rabbits. In absence of adequate dermal sensitization studies, Lenvyor, Cevya, Maxtima and Relenya were assumed to be potential skin sensitizers. Belyan and BAS 752 RC were mildly and slightly irritating to the skin of rabbits, respectively. Belyan and BAS 752 RC were minimally irritating to the eyes of rabbits and neither were dermal sensitizers in guinea pigs when tested with the Buehler method.

Following repeated dermal exposure to mefentrifluconazole in rats, there were no systemic effects noted in either sex. The requirement for a repeat-dose inhalation toxicity study with mefentrifluconazole was waived on the basis of physical-chemical properties and overall toxicity profile.

Repeat-dose oral toxicity studies with mefentrifluconazole were available in mice (diet), rats (diet) and dogs (capsule). In these studies, the most sensitive species for toxicity was the mouse, followed by the rat and dog. This species sensitivity may be the result of slower or absent metabolism and increased exposure to unchanged mefentrifluconazole in mice compared to rats as suggested by the results of the in vitro comparative metabolism study. The most sensitive endpoints in mice were an increased incidence of fatty change of the liver as well as decreased kidney weight and decreased kidney tubular vacuolation in males and decreased body weight and body weight gain in females occurring at the LOAEL in the 18-month dietary oncogenicity study. Other effects noted in the mouse included hepatocellular hypertrophy, increased alkaline

phosphatase and decreased cholesterol levels, minimal liver cell necrosis, and increased white blood cell counts. Most of the effects observed in the mouse were also observed in rats and dogs given repeated dose of mefentrifluconazole, but rats also showed increased gamma-glutamyl transpeptidase levels while dogs presented hepatocellular eosinophilic change and subcapsular fibrosis and lymphoid infiltration of the kidney. Minimal multifocal hepatocellular necrosis was also observed in short-term mouse and rat studies. Overall, in the repeat-dose oral toxicity studies in mice, there was an increase in toxicity with increased duration of dosing.

There was no evidence of genotoxicity in a battery of in vitro and in vivo genotoxicity studies conducted with mefentrifluconazole, nor was there evidence of oncogenicity in mice or rats after long-term dietary administration.

In a rat dietary 2-generation reproductive toxicity study with mefentrifluconazole, a decreased number of implantation sites in F1 dams was observed. Consequently, a decreased number of pups delivered per dam as well as a decreased gestation index in F1 dams were also observed. This serious effect occurred in the presence of other adverse effects in the F1 parental animals (decreased body weight and body weight gain, and liver toxicity). Along with decreased body weights and body weight gains in the offspring of both sexes and generations, the female F2 offspring had an increased incidence of renal pelvis dilation. These effects also occurred in the presence of parental toxicity.

In a gavage developmental toxicity study in the rat, developmental toxicity was observed at the highest dose tested and included increased incidences of renal pelvis dilation in both sexes and decreased female fetal weight. However, these effects occurred at the limit dose only and in the presence of decreased body weight and body weight gain in the dams. No adverse effects were noted in maternal animals or fetuses in the rabbit gavage developmental toxicity study up to the limit dose of testing. In a rabbit gavage developmental toxicity dose range-finding study using non-pregnant rabbits, decreased body weights and body weight gains, reduced food consumption and moribund condition leading to sacrifice were observed at higher dose levels than in the main study. Overall, there was no evidence of sensitivity of the young or evidence of treatment-related malformations in rats or rabbits in the developmental toxicity studies.

The toxicity of metabolite M750F022 (poultry metabolite) was investigated as it was not identified in the rat metabolism studies. M750F022 was of low acute toxicity via the oral route in rats. In a 28-day repeat-dose dietary study in the mouse, liver toxicity was comparable to what was observed in mice dosed with the parent compound, although higher NOAELs were observed with the metabolite. The genotoxicity studies performed, namely a reverse mutation assay, an in vitro gene mutation test and an in vivo micronucleus assay, all yielded negative results. Therefore, M750F022 was not considered to be more toxic than the parent compound.

The identification of select metabolites is presented in Appendix I, Table 1. Results of the toxicology studies conducted on laboratory animals with mefentrifluconazole and its associated end-use products are summarized in Appendix I, Tables 2 to 6. The toxicological reference values for use in the human health risk assessment are summarized in Appendix I, Table 7.

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 toxicity database for mefentrifluconazole 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 2-generation reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, no evidence of sensitivity of the young was observed in the dietary 2-generation reproductive toxicity study with mefentrifluconazole. Both maternal animals and offspring demonstrated a decrease in body weight at the same dose level. In addition, a serious effect was observed in the form of a decreased number of implantation sites in F1 dams. This had a resulting impact on the number of pups delivered and gestation index, but only at a maternally toxic dose level. In the rabbit gavage developmental toxicity study with mefentrifluconazole, there were no effects observed in fetuses or dams up to the highest dose level tested. In the rat gavage developmental toxicity study with mefentrifluconazole, increased placental weight and an increased incidence of renal pelvis dilation in fetuses of both sexes and decreased fetal weight in females were observed at the high-dose level only, and occurred in the presence of maternal toxicity.

Overall, the database is adequate for determining the sensitivity of the young. There is a low concern for sensitivity of the young and effects on the young are well-characterized. The decreased number of implantation sites in F1 dams was considered a serious endpoint, although the concern was tempered by the presence of maternal toxicity. On the basis of this information, the *Pest Control Products Act* factor (PCPA factor) would be reduced to three-fold if this endpoint was used for the point of departure for risk assessment. However, the toxicological reference values selected for risk assessment provide an intrinsic margin to the endpoint of decreased implantations. Consequently, the PCPA factor was reduced to one-fold.

3.2 Acute Reference Dose (ARfD)

To estimate acute dietary risk, the acute gavage neurotoxicity study in rats with a NOAEL of 200 mg/kg bw was selected for risk assessment. At the LOAEL of 600 mg/kg bw, decreased motor activity in both sexes and increased foot splay in male animals were observed on the day of dosing. These effects were the result of 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 one-fold. **The composite assessment factor (CAF) is thus 100.**

The ARfD is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{200 \text{ mg/kg bw}}{100} = 2.0 \text{ mg/kg bw of mefentrifluconazole}$$

3.3 Acceptable Daily Intake (ADI)

To estimate risk following repeated dietary exposure, the NOAEL of 3.5 mg/kg bw/day from the 18-month oncogenicity study in the mouse was selected. At the LOAEL of 9 mg/kg bw/day, adverse effects in the liver and kidneys were observed in males and decreased body weight was observed in females. This study provides the lowest NOAEL in the database. 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 one-fold. **The CAF is thus 100.**

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{3.5 \text{ mg/kg bw/day}}{100} = 0.04 \text{ mg/kg bw/day of mefentrifluconazole}$$

The ADI provides a margin of over 1800 to the NOAEL for decreased number of implantation sites in F1 dams were observed in a 2-generation reproductive toxicity study in rats and is considered protective of pregnant women and their fetuses.

Cancer Assessment

There was no evidence of carcinogenicity and therefore, a cancer risk assessment was not necessary.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Reference Values

Occupational exposure to mefentrifluconazole is characterized as short- to intermediate-term in duration and is predominantly by the dermal and inhalation routes.

Short- and Intermediate-term Dermal

For short- and intermediate-term dermal risk assessment, a NOAEL of 11 mg/kg bw/day from the 90-day dietary toxicity study in mice was selected. The existing short-term dermal toxicity study was not conducted in the most sensitive species, thus necessitating the use for the oral mouse study. At the LOAEL of 58 mg/kg bw/day, liver toxicity was observed.

For residential scenarios, the MOE selected for this endpoint is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. As outlined in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to one-fold. The selection of this study and target MOE is considered to be protective of all populations including the unborn children of exposed women.

For occupational scenarios, the target MOE for this endpoint is 100, which includes standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The selection of this study and target MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Short- and Intermediate-term Inhalation

For short- and intermediate-term inhalation risk assessment, a NOAEL of 11 mg/kg bw/day from the 90-day dietary toxicity study in mice was selected. A repeat-dose inhalation toxicity study was not available and thus, use of a NOAEL from an oral study was appropriate. At the LOAEL of 58 mg/kg bw/day, liver toxicity was observed.

For residential scenarios, the target margin of exposure (MOE) selected for this endpoint is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. As outlined in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to one-fold. The selection of this study and target MOE is considered to be protective of all populations including the unborn children of exposed women.

For occupational scenarios, the target MOE for this endpoint is 100, which includes standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The selection of this study and target MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Aggregate Short- and Intermediate-term 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).

Short- and intermediate-term aggregate exposure to mefentrifluconazole may be comprised of food, drinking water and residential exposure via the oral and dermal routes. The toxicological endpoint selected for aggregation for all populations was liver toxicity. For the oral and dermal routes, the NOAEL of 11 mg/kg bw/day from the 90-day dietary study in the mouse was selected with a target MOE of 100. The PCPA factor for all routes was one-fold as set out in the *Pest Control Products Act* Hazard Characterization section.

Cumulative Risk Assessment

The PCPA requires the Agency to consider the cumulative effects of pest control products that have a common mechanism of toxicity. Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken for mefentrifluconazole.

Mefentrifluconazole belongs to a group of pesticides known as the conazole fungicides. These pesticides are structurally similar and contain a triazole moiety. As a result of these structural similarities, triazole fungicides share common metabolites including 1,2,4-triazole and triazole conjugates. Variable toxicological responses are found for conazoles including: hepatotoxicity and hepatocarcinogenicity in mice, thyroid tumors in rats, as well as developmental, reproductive, and neurological effects in rodents.

No clear common mechanism for toxicity has been confirmed on which to base a cumulative assessment for any of these effects. However, a cumulative risk assessment for the common triazole metabolites will be addressed in a separate document.

Dermal Absorption

In the in vivo rat dermal absorption study, the dermal absorption of mefentrifluconazole was examined after a single dermal application of BAS 750 01 F formulation concentrate (100 g/L mefentrifluconazole), or spray dilutions of concentrate in tap water, at 1.5, 15 or 1000 µg/cm² doses. One hundred microliters of each dose was applied to a 10 cm² skin area to three groups of four animals each. Each dose was washed after 8 hours of exposure and groups of animals were sacrificed at 8 hours, 24 hours or 120 hours. An additional skin wash was conducted prior to sacrifice for the groups that were observed for an additional 24 hours or 120 hours. The application site from all groups was subjected to tape stripping immediately after sacrifice. Recovery of the applied dose (mass balance) was acceptable at all dose levels (93–103%).

The majority of the administered dose was not absorbed and was recovered in the first skin wash after 8 hours of exposure at all dose levels (69.5–81.8%). Small amounts (<2.6%) were recovered after the second skin wash at 24 hours and 120 hours before sacrifice.

There was an inverse relationship between the dose level and the mean percentage of the applied dose that was absorbed. The total potentially absorbable dose (which was the sum of excreta including cage wash, blood and carcass, the surrounding skin, plus the residues at the application site) was 19.4% (8 hours), 15.5% (24 hours) and 15.7% (120 hours) in the 1.5 µg/cm² low dose group; 10.5% (8 hours), 11.9% (24 hours) and 11.3% (120 hours) in the 15µg/cm² mid dose group; and 12.6% (8 hours), 8.0% (24 hours) and 5.6% (120 hours) in the 1000 µg/cm² high dose group.

The dermal absorption value of 16% from the low dose group sacrificed at 120 hours after 8 hours of exposure was chosen to be the most appropriate dermal absorption value.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment for BAS 752 RC, Belyan, Cevya and Lenvyor

Individuals have the potential for exposure to BAS 752 RC, Belyan, Cevya or Lenvyor during mixing, loading and application, clean-up and repair. Exposure to workers mixing, loading and applying BAS 752 RC, Belyan, Cevya or Lenvyor, is expected to be short- to intermediate-term in duration and to occur primarily by the dermal or inhalation routes.

Exposure estimates were derived for mixers/loaders/applicators applying BAS 752 RC, Belyan, Lenvyor or Cevya at the proposed use rate to canola/rapeseed, flax, mustard, crop subgroup 6C (dry shelled peas and beans), soybean, potato, wheat, corn (field, pop and sweet), peanut or sugar beet using groundboom equipment. In addition, exposure estimates were also derived for mixers/loaders/applicators applying to canola/rapeseed, flax, mustard, crop subgroup 6C crops, soybean, potato, wheat, corn (field, pop and sweet) and sugar beet using aerial equipment.

Finally, exposure estimates were also derived for mixers/loaders/applicators applying Cevya at the proposed use rate to grapes, pome fruits, stone fruits or tree nuts using airblast equipment.

The exposure estimates are based on workers wearing a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Dermal and inhalation exposure estimates for workers were generated using the unit exposure values from the Agricultural Handlers Exposure Task Force (AHETF) database.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value of 16%. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day 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 selected toxicological reference value to obtain the margin of exposure (MOE); the target MOE is 100. Dermal and inhalation MOEs were combined, since the dermal and inhalation endpoints are based on the same toxicological effects. Calculated MOEs are above the target MOE of 100 for all chemical handler scenarios for agriculture crops and are therefore not of concern (Appendix I, Table 11).

3.4.2.2 Exposure and Risk Assessment for Workers Entering Fields Treated with BAS 752 RC, Belyan, Cevya and Lenvyor

There is potential for exposure to workers entering areas treated with BAS 752 RC, Belyan, Lenvyor or Cevya to complete tasks such as setting irrigation lines, scouting, hand harvesting, pruning, thinning, hand weeding, rouging, transplanting, detasseling, cane turning and girdling, orchard maintenance, and trellis repair. The duration of exposure is considered to be short- to intermediate-term for all uses. Given the nature of activities performed, dermal contact with treated foliage is expected to be primarily via the dermal route of exposure. Inhalation exposure is not considered to be a significant route of exposure for workers entering treated areas compared to the dermal route, as mefentrifluconazole is considered non-volatile with a vapour pressure of 6.5×10^{-9} kPa (25°C), which is less than the NAFTA criterion for a non-volatile product for outdoor uses [1×10^{-4} kPa (7.5×10^{-4} mm Hg) at 20-30° C]. As such, an inhalation risk assessment was not required.

3.4.2.2.1 Dislodgeable Foliar Residue for Mefentrifluconazole

Chemical-specific dislodgeable foliar residue (DFR) data on grapes were submitted. This DFR study was designed to collect data to calculate DFR dissipation curves for mefentrifluconazole from treated grape foliage following application of BAS 750 02 F, a suspension concentrate formulation containing 400 g of mefentrifluconazole/L. Three field trial test sites: Dundee (NY), Fresno (CA) and Ephrata (WA) were monitored with triplicate foliage samples per sampling time per site. Each treated plot received three foliar spray applications at a 10-day retreatment interval at the target rate of 150 g a.i./ha. Applications were made using a truck-mounted airblast sprayer and spray volumes of 931 - 939 L/ha of spray solution. DFR samples consisted of 2.54 cm diameter leaf disks. Grape leaf samples were collected prior to, and 4 hours after, each application, 8 hours after the last application, and at 1, 2, 3, 4, 5, 6, 7, 10, 13/14, 21, 28 and 35 days after the last application.

Successively higher DFR levels were found consistently after each application at each site, followed by a gradual decline from the final application through 35 days after last application (DALA). All measured residues were corrected for the average of the highest concurrent field fortification recovery level (93.4% for NY, 80.7% for CA, and 72.6% for WA) which was closest to the residue levels measured in field samples. Sampling was conducted until 35 days after the application; however, all DFR values did not decline below the limit of quantitation (LOQ) by the end of the sampling period.

At the NY site, the average corrected mefentrifluconazole residue (and percent of application rate) available for dislodging from grape foliage was $0.326 \mu\text{g}/\text{cm}^2$ (21.7%) after the first application, $0.423 \mu\text{g}/\text{cm}^2$ (28.3%) after the second application, $0.502 \mu\text{g}/\text{cm}^2$ (33.5%) after the third application, and declining to $0.170 \mu\text{g}/\text{cm}^2$ (11.3%) by the last day of sampling (35DAT).

At the CA site, the average corrected mefentrifluconazole residue (and percent of application rate) available for dislodging from grape foliage was $0.182 \mu\text{g}/\text{cm}^2$ (12.2%) after the first application, $0.284 \mu\text{g}/\text{cm}^2$ (18.8%) after the second application, and $0.382 \mu\text{g}/\text{cm}^2$ (25.7%) after the third application. The average mefentrifluconazole residue (and percent of application rate) was highest at 3DAT at $0.382 \mu\text{g}/\text{cm}^2$ (25.7%) and declining to $0.202 \mu\text{g}/\text{cm}^2$ (13.5%) by the last day of sampling (35DAT).

At the WA site, the average corrected mefentrifluconazole residue (and percent of application rate) available for dislodging from grape foliage was $0.404 \mu\text{g}/\text{cm}^2$ (27.0%) after the first application, $0.592 \mu\text{g}/\text{cm}^2$ (39.8%) after the second application, $0.752 \mu\text{g}/\text{cm}^2$ (50.6%) after the third application, and declining to $0.412 \mu\text{g}/\text{cm}^2$ (27.7%) by the last day of sampling (35DAT).

First-order dissipation kinetics was assumed to generate dissipation curves for mefentrifluconazole. Based on linear regression of the natural log transformed data, the calculated half-life for mefentrifluconazole on grape leaves is 22 days ($R^2 = 0.9047$) for the NY site, 53 days ($R^2=0.6044$) for the CA site, and 58 days ($R^2=0.4753$) for the WA site.

No major limitations were identified and the results are considered acceptable for risk assessment purposes. Minor limitations were noted: 1) only two field fortification levels were used which were up to 30-fold lower than the anticipated sample residue levels. 2) As the test substance did not dissipate fully after 35 days, longer than 35 days sampling should have been monitored. 3) The study did not discuss the production of metabolites or breakdown of products of mefentrifluconazole. 4) The storage stability of residue samples stored for up to 109 days was assessed by recovery of field fortification samples stored for up to 84 days only.

As the R^2 values for the dissipation curves for the CA and WA sites were less than 0.85, predicted values from these sites are not appropriate for risk assessment. Therefore, the measured actual DFR data from the WA site with the highest measured average Day 0 residue and the slowest dissipation are considered the most appropriate for occupational postapplication risk assessment for grapes and other crops.

3.4.2.2.2 Postapplication Exposure and Risk for BAS 752 RC, Belyan, Cevya and Lenvyor

A postapplication dermal exposure risk assessment was conducted for BAS 752 RC, Belyan, Cevya or Lenvyor for each postapplication activity for each crop at the maximum rate per application, the number of applications and the maximum proposed rate for the year.

The results of the DFR study discussed above showed that the highest peak residue of 0.752 $\mu\text{g}/\text{cm}^2$ was measured at the WA test site after three applications of mefentrifluconazole at the application rate of 150 g a.i./ha with the retreatment interval of 10 days. Moreover, the results also demonstrated that mefentrifluconazole deposition increased after each application and dissipated slowly after each application. At the WA test site, the residue deposition after the first application was 27% and the dissipation was 1.2% per day after three applications, which represented the most conservative dissipation when compared to the other two sites (CA and NY). Even though the data at the WA site did not demonstrate a linear dissipation, these data are still appropriate for estimating the Day 0 DFR for all crops treated according to the proposed use pattern. Therefore, the Day 0 DFR, based on the grape DFR and dissipation at WA site data, was calculated and used to generate the postapplication exposure and risk estimates for each postapplication activity for each crop, and for each agricultural end-use product. For grapes, the highest peak residue from the WA site is considered as the appropriate Day 0 DFR for estimating postapplication exposure and risk.

Postapplication worker dermal exposure for each crop was calculated using the Day 0 DFR estimated for each postapplication activity, the Agricultural Re-entry Task Force (ARTF) transfer coefficients (TCs), the dermal absorption of 16% and the exposure duration of an 8-hour workday. The MOEs were calculated using the toxicological reference value specified for mefentrifluconazole. These estimates are presented in Appendix I, Table 12. Calculated MOEs for all activities for all crops, except for cane turning and girdling in table grapes and hand harvesting in sweet corn, were above the target MOE of 100 on day zero after the maximum number of applications. For sweet corn, the MOE reached the target MOE after 13 days following the last application; however, as the preharvest interval (PHI) for sweet corn is 21 days, an REI for harvesting is not required. The MOE for cane turning and girdling table grapes was 47 on day zero after the second application (< the target MOE of 100). The MOE for cane turning and girdling table grapes was calculated for day 35 after three applications using the actual measured DFR value of 0.412 $\mu\text{g}/\text{cm}^2$ at the WA site. The resulting MOE of 86 (Appendix I, Table 12) is considered acceptable based on the fact that it is a conservative estimate of exposure generated using the maximum application rate and shortest spray interval. Furthermore, the cane turning and girdling grape activity occurs during fruit set in table grapes only. Therefore, an REI of 35 days for cane turning and girdling is required for table grapes. For all other crops activities, the REI of 12 hours is adequate.

3.4.2.3 Mixer/Loader/Applicator Exposure and Risk Assessment for Maxtima

Individuals have the potential for exposure to Maxtima during mixing, loading and application, clean-up and repair. Exposure to workers mixing, loading and applying Maxtima is expected to be short- to intermediate-term in duration and to occur primarily by the dermal or inhalation routes. The exposure estimates are based on workers wearing a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair.

Dermal and inhalation exposure estimates for workers were generated using the unit exposure values from the AHETF database, the Pesticide Handlers Exposure Database (PHED, version 1.1) or the Outdoor Residential Exposure Task Force (ORETF) database. Exposure estimates were derived for mixers/loaders/applicators applying Maxtima according to the proposed use pattern to commercial golf course turf using groundboom, handgun sprayer or backpack sprayer equipment.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value of 16%. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day and assuming 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight. Exposure estimates were compared to the selected toxicological reference value to obtain the MOE; the target MOE is 100. Dermal and inhalation MOEs were combined, since the dermal and inhalation endpoints are based on the same toxicological effects. Calculated MOEs are above the target MOE of 100 for all chemical handler scenarios for golf course turf, and are therefore not of concern (Appendix I, Table 11).

3.4.2.4 Postapplication Exposure and Risk for Maxtima

A postapplication dermal exposure risk assessment was conducted for Maxtima for each postapplication activity at the maximum rate per application, the number of applications and the maximum proposed rate.

A turf transferable residue (TTR) dissipation study was not submitted. Therefore, for estimating exposure during postapplication activities on treated turf, the default of 1% of the application rate dislodged from treated turf, with the 1.2% slowest dissipation rate of mefentrifluconazole from the grape DFR study, were used to estimate day zero TTR after the last application. Postapplication worker dermal exposure for each postapplication activity was calculated with the Day 0 DFR, the TC value for each activity, the dermal absorption of 16% and the exposure duration of an 8-hour workday. The MOEs were calculated using the toxicological reference value specified for mefentrifluconazole. Calculated MOEs for all postapplication activities on treated turf are above the target MOE of 100 on Day 0, after the maximum number of applications, and are therefore not of concern (Appendix I, Table 12).

3.4.2.5 Commercial Seed Treatment Exposure Risk Assessment for Relenya

Wheat, triticale, corn, soybean, canola/rapeseed and crop subgroup (CSG 6C) seeds can be treated with Relenya in commercial seed treatment facilities, by mobile treaters or on-farm. Individuals have the potential for exposure to mefentrifluconazole while treating seed in commercial seed treatment facilities or by commercial mobile treaters using closed transfer equipment, as well as while bagging, sewing and stacking bags of treated seed and during cleaning and repair of equipment. Potential exposure can also occur when using open or closed transfer equipment during on-farm seed treatment. Occupational exposure to Relenya is characterized as short- to intermediate-term in duration for seed treatment workers and occurs predominantly by the dermal and inhalation routes.

3.4.2.5.1 Dust-off Study

A dust-off study was conducted to compare the dust-off potential of various seeds (soybean, winter wheat, winter barley, maize (corn), winter oilseed rape/canola, field peas and lentils) untreated and treated with BAS 750 02F and several known surrogate seed treatment formulations.

The various seeds were treated with slurry of each seed treatment formulation and dust-off levels from untreated and treated seed samples were measured using a Heubach dust measurement apparatus.

Winter barley seeds were the dustiest, with the level of dustiness (grams of dust/100 kg seed) from untreated seed as follows: winter barley > soybean > winter wheat > maize > field peas > lentils > winter oilseed rape.

Compared to dust-off levels from untreated seeds, BAS 750 02 F treatment reduced the dust-off levels from soybean, winter wheat, winter barley and field peas; and increased the dust-off levels from maize, winter oilseed rape and lentils. The order of dustiness (grams of dust/100 kg seed) after treatment with BAS 750 02 F mixed with water was winter barley > winter wheat > maize > winter oilseed rape > soybean > lentils > field peas.

The dust-off levels from various seeds treated with BAS 750 02 F and several surrogate known seed treatment formulations in various combinations were lower than the dust-off levels from untreated seeds of soybean, winter wheat, winter barley and field peas, and were variable, depending on the products used, in maize, winter oilseed rape and lentils. Thus, the dust-off levels from various seeds after treatment with various combinations of known products were comparable to the dust-off levels from seeds treated with BAS 750 02 F.

Therefore, based on the dust-off data, the selected surrogate passive dosimetry exposure studies are not expected to underestimate occupational exposures to treated wheat, triticale, corn, soybean, canola/rapeseed, and CSG 6C seeds.

3.4.2.5.2 Commercial Seed Treatment Facilities Including Mobile Treaters

Based on the dust-off study data discussed in Section 3.4.2.5.1, after treatment with mefentrifluconazole and water, the dust-off levels in corn (maize) were higher than the levels in winter oilseed rape, soybean, lentils and field peas. Therefore, a surrogate passive dosimetry study conducted on corn and canola/rapeseed was used to estimate exposure for corn, soybean, canola/rapeseed and CSG 6C crops using the corn unit exposure data. As canola seeds were separately monitored in this study, unit exposure data for canola were used to generate exposure and risk estimates for canola/rapeseed and soybean seeds.

For wheat and triticale, to estimate exposure for treaters and cleaners, a wheat passive dosimetry study with the highest unit exposure compared to other surrogate passive dosimetry studies on wheat was selected. For workers bagging treated wheat and triticale seed, the cereals passive dosimetry study was selected as this study has the highest unit exposure and highest number of workers and sites monitored compared to other surrogate seed treatment studies on cereals.

Dermal and inhalation exposure estimates were derived for workers commercially treating various seeds using closed transfer commercial treating equipment, as well as workers bagging, sewing and stacking bags. The estimates are based on treaters wearing coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

In addition, workers cleaning-up or maintaining and repairing seed treatment equipment must wear chemical-resistant coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day. The dermal absorption value of 16% was used for the dermal exposure assessment. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day and assuming 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight. Dermal and inhalation exposures can be combined as there are common toxicological effects for both exposure routes. Exposure estimates were compared to the toxicological reference value to obtain the MOE; the target MOE is 100 for dermal as well as inhalation exposure. The combined dermal and inhalation exposures are presented in Appendix I, Table 13. As calculated MOEs are above the target MOE of 100, no health risks of concern are expected for workers treating various seeds with Relenya in commercial treatment facilities or using mobile treaters provided workers wear the PPE specified in the respective surrogate studies selected for each crop, and that seed treatment is conducted using closed transfer equipment.

3.4.2.6 On-farm Seed Treatment Exposure and Risk Assessment for Relenya

Wheat, triticale, corn, soybean, canola/rapeseed and CSG 6C seeds can be treated on-farm with Relenya. To estimate exposure for workers conducting on-farm seed treatment, the wheat passive dosimetry study was selected as the surrogate seed treatment study since it is a well conducted study on wheat. The dust-off data submitted for mefentrifluconazole discussed earlier showed that after treatment with mefentrifluconazole, dust-off levels were highest in wheat seed,

excluding barley seed, compared to other seed types. Thus, based on the results of the dust-off study and comparing the parameters of the selected wheat surrogate on-farm treatment study with the proposed use of Relenya on various seeds, this passive dosimetry study is appropriate for the risk assessment of workers treating seed on-farm, using either an open or a closed transfer system. The exposure and risk estimates for on-farm treaters are presented in Appendix I, Table 14. As the calculated MOEs are above the target MOE of 100, there are no health risks of concern for on-farm mixers, loaders, applicators and workers cleaning-up or maintaining and repairing seed treatment equipment when wearing coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

3.4.2.7 Planting of Relenya Treated Seeds

Commercially treated seeds are either bagged or stored in bulk. During planting, workers load the treated seed into a planter from bags or from bulk containers using an auger. Workers have the potential for exposure to Relenya while loading and planting treated seed. Surrogate planting exposure data were used to estimate risk to workers planting treated seed.

Using the same rationale of the dust-off levels discussed earlier for the selection of surrogate studies to estimate exposure for commercial and on-farm seed treatment workers, the unit exposures from 1) the planting study for corn, soybean, canola/rapeseed and CSG 6C crops, 2) the planting study for bagged cereal seeds, and 3) the planting study for bulk cereal seeds, are considered appropriate for the exposure assessment for planting Relenya-treated seed.

The passive dosimetry study determined the dermal and inhalation exposure to agricultural workers opening bags of corn seed, loading the treated seed into hoppers, and planting with a closed-cab tractor. The revised arithmetic mean unit exposure values from planting corn were used to estimate exposure and risk from planting Relenya treated seeds.

To estimate exposure from planting wheat and triticale seeds treated with Relenya, the surrogate planting studies, conducted for loading and planting of bagged or bulk treated wheat seeds with a closed-cab were considered appropriate.

Dermal and inhalation exposure estimates were derived for workers planting Relenya treated wheat, triticale, corn, soybean, canola/rapeseed and CSG 6C crops using closed-cab tractors. The exposure duration for planters is short-term. The exposure estimates were based on planters wearing coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. Dermal exposure was estimated by coupling the unit exposure values with the amount of treated seed planted per day. The dermal absorption value of 16% was used for the planter's exposure assessment. Inhalation exposure was estimated by coupling the unit exposure values with the amount of treated seed planted per day and assuming 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight. Dermal and inhalation exposures can be combined as there are common toxicological endpoints of concern for both exposure routes. Exposure estimates were compared to the selected toxicological reference value to obtain the MOE; the target MOE is 100 for dermal and inhalation exposures.

The exposure and risk estimates for workers planting various seeds treated with Relenya are presented in Appendix I, Table 15. The calculated MOEs are well above the target MOE of 100, and are therefore not of concern. As the selected planting surrogate exposure studies were conducted with a closed-cab planter, the label will reflect this requirement.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

As mefentrifluconazole end-use products are proposed as commercial class products, a residential handler exposure risk assessment was not required.

3.4.3.2 Postapplication Residential Exposure and Risk

3.4.3.2.1 Pick-Your-Own (PYO) Activities

Given that pome and stone fruits can be treated with mefentrifluconazole, there is potential for exposure from pick-your-own activities. The postapplication occupational risk assessment is protective of the risk associated with dermal exposure to this scenario.

3.4.3.2.2 Trees Treated with Cevya in Residential Areas

Although Cevya is a commercial end-use product of mefentrifluconazole, commercial applicators may apply Cevya to pome fruits, stone fruits and nut trees in residential areas. As such, there is a potential for residential postapplication exposure for adults and youth who harvest treated fruits and nuts or come in contact with the treated foliage. The postapplication occupational risk assessment is protective of the risk associated with dermal exposure to this scenario.

3.4.3.2.3 Commercial Golf Courses Treated with Maxtima

Since Maxtima is for use on golf courses, there is the potential for recreational postapplication exposure to mefentrifluconazole for golfers (adults, youth and children) entering golf course turf areas treated with mefentrifluconazole. The primary route of exposure for these individuals is through the dermal route. The duration of exposure for golfing is expected to be of short- to intermediate-term in duration.

Dermal exposure to golfers is estimated by coupling the TTR value with the activity specific transfer coefficient based on ARTF studies data from the 2012 United States Environmental Protection Agency Residential Standard Operating Procedures. TTR was calculated by using 1% of the application rate with the 1.2% dissipation rate from the grape DFR study for the maximum number of applications. Exposure estimates after correcting for the dermal absorption of 16% were compared to the toxicological reference value to obtain the MOE; the target MOE is 100 for mefentrifluconazole. The calculated MOEs for dermal exposure are presented in Appendix I, Table 16. The estimated MOEs were all above the target MOE of 100. Therefore, health risks are not of concern for golfers entering treated golf courses after the sprays have dried.

3.4.4 Bystander Exposure and Risk

Bystander exposure is expected to be negligible since the potential for drift is expected to be minimal and label restrictions to minimize drift are included.

3.4.5 Aggregate Exposure and Risk

There is potential for individuals to be exposed to mefentrifluconazole via different routes and sources of exposure. As such, the aggregation of these exposures was considered when conducting the health risk assessments.

Given that pome and stone fruits can be treated with mefentrifluconazole, there is potential for aggregate exposure to mefentrifluconazole during pick-your-own activities and during harvesting of fruits from trees in residential settings that may have been treated. Aggregation of dietary and dermal exposure from pick-your-own activities was not conducted, as the risk estimated for each individual route of exposure is well below the level of concern and therefore protective of the scenario.

For golfers, an aggregate risk assessment was conducted combining dermal exposure while golfing as well as dietary exposure from eating foods treated with mefentrifluconazole. The dietary chronic exposure (food plus drinking water) estimates for children 6 - <11 years old, children 11 - <16 years old, and adults (16+ years old) were calculated and aggregated with the residential exposure from playing golf on treated turf. The aggregated exposure estimates were compared to the selected toxicological aggregate reference value which exceeded the target MOE of 100. Therefore, the aggregated exposure and health risks are not of concern (Appendix I, Table 17).

3.5 Exposure from Drinking Water

Concentrations in Drinking Water

The residue definition for drinking water includes mefentrifluconazole and three phototransformation products, M750F005, M750F006, and M750F007, and the aquatic biotransformation product 1,2,4-triazole (M750F001). Estimated environmental concentrations (EECs) in water for the combined residues of mefentrifluconazole and three of its transformation products were calculated for use in human health risk assessments using the Pesticide Water Calculator (PWC, version 1.52). For the human health assessment, EECs in potential drinking water sources are calculated for both groundwater and surface water.

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

Level 1 EECs for surface water were calculated based on a single standard scenario. Level 1 EECs in groundwater were calculated for several scenarios representing different regions of Canada; only the highest EECs from across these scenarios are reported (tables 3.5.1 and 3.5.2). Level 2 EECs were calculated using turf-specific application rates, timing and method as well as turf specific scenarios for both surface water and groundwater. All surface water scenarios were run for 50 years, whereas those for groundwater were run for 100 years. The level 1 EECs used for drinking water assessment are reported in Table 3.5.2 below.

Table 3.5.1 Major Groundwater and Surface Water Model Inputs for Level 1 Assessment of Mefentrifluconazole

Parameter	Ecological	Surface water	Groundwater	
	Residue Definition ^a	Residue Definition ^b	Mefentrifluc onazole	M750F001
Mol. wt. (g/mole)	397.8	397.8	397.8	397.8
Vap. pres. (mm Hg) at 20°C	2.4E-8	2.4E-8	2.4E-8	0.603
Solubility (mg/L) in water	0.71	0.71	0.71	4.24E+5
Henry's law constant (unitless)	7.23E-7	7.23E-7	7.23E-7	3.04E-5
Photolysis half-life (day) at 40°N latitude	26.4	292	NA	NA
Hydrolysis at pH 7	stable	stable	stable	stable
K _{oc} (L/kg)	3047 ^c	3047 ^c	3047	5.0
Soil half-life (day) at 20°C	577 ^d	577 ^d	577/441 ^g	13.3 ^g
Aerobic aquatic half-life (day) at 20°C	222 ^e	222 ^e	NA	NA
Anaerobic aquatic half-life (day) at 20°C	3990 ^f	3990 ^f	NA	NA

a. Residue Definition = mefentrifluconazole + M750F006

b. Residue Definition = mefentrifluconazole + M750F005 + M750F006 + M750F007

c. The K_{oc} for the most mobile constituent of the combined residue was selected. The K_{oc} of M750F001 was used when the residue definition included this compound. In other cases, the 20th percentile of eight available adsorption values for the parent was used.

d. Calculated from the 90 percent upper confidence bound on the mean of available half-lives. The half-life of 577 days is that of the parent since M750F005 + M750F006 + M750F007 were not formed in soil. The half-life of 6.58E5 days was calculated for the combined residues of mefentrifluconazole + M750F001.

e. Longer of two half-lives in whole system calculated for the combined residues.

f. Longer of two half-lives in whole system calculated for the combined residues.

g. The half-life of 577 days is the 90 percent upper confidence bound on the mean of half-lives for the parent compound, as calculated using only measured concentrations of mefentrifluconazole. The half-life of 441 days and 13.3 days for the parent compound and M750F001, respectively, were obtained from parent-daughter curve fitting taking into account measured concentrations for both mefentrifluconazole and M750F001.

Table 3.5.2 Level 1 Estimated Environmental Concentrations of the Combined Residue of Mefentrifluconazole, M750F005, M750F006 and M750F007 in Potential Sources of Drinking Water as the Parent Equivalent

Use Pattern	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
	Daily	Yearly	Daily	Yearly
Turf and all agricultural crops/ 3 applications of 1000 g a.i./ha at 7-day interval	4.6	4.6	92	34
All agricultural crops/3 applications of 150 g a.i./ha at 7-day interval	0.69	0.69	14	4.5

3.6 Food Residues Exposure Assessment

3.6.1 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products is mefentrifluconazole. In animal commodities, the residue definition is mefentrifluconazole for enforcement, and for risk assessment includes the metabolite M750F022 and its conjugates (poultry only). The data gathering/enforcement analytical methods are valid for the quantitation of mefentrifluconazole residues in crop matrices (Method D1511/01 for data gathering; Method L0295/01 for enforcement) and in livestock matrices (Method L0272/01 for both data gathering and enforcement). Residues of mefentrifluconazole are stable in representative matrices from five crop categories (high water, high oil, high protein, high starch and high acid content) for up to 24 months when stored at $\leq -18^{\circ}\text{C}$. Therefore, mefentrifluconazole residues are considered stable in all frozen crop matrices and processed crop fractions for up to 24 months. Residues of mefentrifluconazole and the metabolite M750F022 are stable in animal matrices for up to 6 months when stored at $\leq -18^{\circ}\text{C}$. The raw agricultural commodities potatoes, sugar beets, soybean, orange, apple, plum, grape, barley, field corn and wheat were processed. Separate MRLs are only required for orange oil, raisins and dried prune plums. Adequate feeding studies were carried out to assess the anticipated residues in livestock matrices resulting from the current uses. Crop field trials conducted throughout Canada and the United States using end-use products containing mefentrifluconazole at approved or exaggerated (peanut only) rates in or on potatoes, sugar beets, legume vegetables, citrus fruits, pome fruits, stone fruits, grapes, tree nuts, cereals, canola and peanuts are sufficient to support the proposed maximum residue limits. A field rotational crop study was conducted in/on lettuce, radish and wheat. The data are adequate to demonstrate that a 30-day plant-back interval is appropriate for non-labelled crops.

3.6.2 Dietary Risk Assessment

Acute and chronic 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 mefentrifluconazole: 100% crop treated, default processing factors, residues in/on crops and animal commodities at MRL levels. The basic acute dietary exposure (food alone) for all supported mefentrifluconazole registered commodities is estimated to be 1.3% of the ARfD for the general population and 5.2% of the ARfD for the highest exposed population subgroup, children 1–2 years old. Aggregate exposure from food and drinking water is considered acceptable at 5.3% of the ARfD for the highest exposed population subgroup children 1-2 years old.

3.6.2.2 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the refined chronic analysis for mefentrifluconazole: 100% crop treated, default and experimental processing factors (where available), residues of potatoes, sugar beets, legume vegetables, citrus fruits, pome fruits, stone fruits, grapes, tree nuts, cereals, canola and peanuts based on supervised trial median residue values, and the lower Canadian MRLs for animal commodities (where applicable). The refined chronic dietary exposure from all supported mefentrifluconazole food uses (alone) for the total population, including infants and children, and all representative population subgroups, is less than 9% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to mefentrifluconazole from food and drinking water is 4.1% (0.0016 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 11.3% (0.0045 mg/kg bw/day) of the ADI.

3.6.3 Maximum Residue Limits

Table 3.6.1 Proposed Maximum Residue Limits

MRL (ppm)	Food Commodity
15	Citrus oil
4.0	Cherries (crop subgroup 12-09A), cereal grains (crop group 15, except wheat, triticale and corn), dried prune plums, raisins
2.0	Plums (crop subgroup 12-09C), dry lentils
1.5	Pome fruits (crop group 11-09), peaches (crop subgroup 12-09B), small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F)
1.0	Lemons (crop subgroup 10B, revised), oilseeds (crop subgroup 20A, revised)
0.6	Oranges (crop subgroup 10A, revised), sugar beet roots
0.5	Grapefruits (crop subgroup 10C, revised)
0.4	Dry soybeans
0.3	Wheat; meat byproducts of cattle, goats, horses and sheep; triticale

MRL (ppm)	Food Commodity
0.2	Fat of cattle, goats, horses and sheep
0.15	Legume vegetables, succulent or dried (crop subgroup 6), except dry lentils and dry soybeans
0.1	Milk fat
0.06	Tree nuts (crop group 14-11)
0.04	Tuberous and corm vegetables (crop group 1C)
0.03	Sweet corn kernels plus cobs with husks removed
0.02	Meat of cattle, goats, horses and sheep; milk
0.01	Field corn; peanuts; popcorn grain; fat, meat and meat byproducts of hogs and poultry; eggs

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the [Residue Chemistry Crop Groups](#) webpage in the Pesticides and Pest Management section of Health Canada's website.

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 acute and chronic dietary risk estimates are summarized in Appendix I, Tables 8, 9 and 10.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Terrestrial Environment

Hydrolysis is not expected to be an important route of dissipation of mefentrifluconazole in the environment. Mefentrifluconazole is effectively stable to hydrolysis at pH 4, 5, 7, and 9 at 25°C. The phototransformation half-life on soil is long (326 days), and as such, phototransformation on soil is not expected to contribute significantly to the dissipation of mefentrifluconazole.

Volatilization is not expected to be an important route of dissipation of mefentrifluconazole in the terrestrial environment as indicated by its low vapour pressure and Henry's law constant.

Biotransformation of mefentrifluconazole occurs slowly in the terrestrial environment.

Mefentrifluconazole is persistent in soil, with half-lives in the laboratory ranging from 355 to 626 days under aerobic conditions, and from 325 to greater than 10,000 days under anaerobic conditions. Minor transformation products M750F001 (1,2,4-triazole) and M750F003 were both detected under aerobic conditions, while no transformation products were detected under anaerobic conditions. Carbon dioxide was detected at 9.7% or less of the applied radioactivity under aerobic conditions and 2.16% or less under anaerobic conditions. Consistent with results of laboratory studies, mefentrifluconazole dissipates slowly under terrestrial field conditions relevant to Canada (representative field DT50s of 251 to 1,177 days).

Mefentrifluconazole has the potential to accumulate in soil and carry over to the next growing season based on carry-over values greater than 30% at approximately one year after application. The transformation products M750F001 (1,2,4-triazole) and M750F003 were observed in the field studies as they were in the laboratory studies. Levels of both 1,2,4-triazole and M750F003 declined over the course of the studies.

The linear adsorption coefficient, K_d , and associated K_{OC} values for mefentrifluconazole (K_d : 26.4 to 128.9 L/kg soil; K_{OC} : 2,163 to 4,631 L/kg OC) indicate that it is expected to have slight mobility in a variety of soil types. Correlation was noted between the adsorption of mefentrifluconazole to soil and percent organic carbon content, while there were no correlations between adsorption to soil and clay content or cationic exchange capacity (CEC). The criteria of Cohen et al. (1984), the groundwater ubiquity score of Gustafson (1989), and conservative multi-year modelling indicate mefentrifluconazole has a low potential to leach in soil.

Mefentrifluconazole may enter the aquatic environment through spray drift or run-off. It is sparingly soluble in water and has low potential to volatilize from moist soils or from water. Mefentrifluconazole is effectively stable to hydrolysis. Although the UV/Visible absorption spectra indicate no absorption above a wavelength of 300 nm, mefentrifluconazole phototransformed in aqueous buffer solution and in sterile natural water by indirect photolysis, with DT50 values of 2.5 and 6.6 days (continuous radiation), respectively, under spring sunlight at 40°N. Up to nine transformation products were identified in the irradiated treatments. Mefentrifluconazole was photodegraded to major (>10%) transformation products M750F005, M750F006, and M750F007 in aqueous buffer solution, and to M750F006 in natural sterile water. Minor transformation products include M750F001 (1,2,4-triazole), M750F002, M750F003, M750F008, M750F036, and M750F037 in natural sterile water.

Mefentrifluconazole is persistent in water-sediment systems under both aerobic and anaerobic conditions (total system half-lives of 192 to 729 days), with slower degradation under anaerobic conditions. One major transformation product was formed (M750F001) in one of the aerobic water-sediment systems. Minor transformation products M750F001, M750F003, M750F032, and carbon dioxide were detected under aerobic conditions, while carbon dioxide was the only minor transformation product under anaerobic conditions. Mefentrifluconazole was associated mainly with the sediment phase over time. The radioactivity attributed to mefentrifluconazole itself in the sediment ranged from 45.6 to 79.9% of the applied radioactivity after 100 days under aerobic or anaerobic conditions.

Based on the octanol-water partitioning coefficient ($\log K_{OW}$) value of 3.4, there is potential for mefentrifluconazole to bioaccumulate. However, a bioconcentration study in fish indicates that mefentrifluconazole does not accumulate to a large degree in fish (whole fish steady state BCF normalised to 5% lipid: 350 L/kg). The time for 50% depuration is estimated to be 14 hours for the whole fish.

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 environmental exposure concentrations (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 ($RQ = \text{exposure/toxicity}$), and the risk quotient is then compared to the level of concern (LOC = 1 or most species, 0.4 for acute risk to pollinators, and 2 for glass plate studies using the standard beneficial arthropod test species, *Typhlodromus pyri* and *Aphidius rhopalosiphii*; LOC = 1 is used for higher tier tests of the standard arthropod test species and for other arthropod test species). 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.

As there were large differences in the end-use product proposed application rates (turf rate of 1,000 g a.i./ha compared with orchard/vegetable crop rate of 150 g a.i./ha), end-use product-specific estimated exposure concentrations (EECs) were determined and used when end-use product-specific ecotoxicity data were available.

4.2.1 Risks to Terrestrial Organisms

A risk assessment for mefentrifluconazole was conducted for terrestrial organisms. For acute toxicity studies, uncertainty factors of 1/2 of the EC₅₀ (LC₅₀) are typically used in modifying the toxicity values for terrestrial invertebrates, and of 1/10 the EC₅₀ (LC₅₀) for birds and mammals when calculating risk quotients. No uncertainty factors are applied to chronic NOEC endpoints.

A summary of terrestrial toxicity data for mefentrifluconazole and end-use products (Lenvyor, Cevya, Maxtima, BAS 752 RC (containing mefentrifluconazole and fluxapyroxad, and Belyan (containing mefentrifluconazole, pyraclostrobin and fluxapyroxad) is presented in Appendix I, Table 21. The use rates and pattern for pyraclostrobin and fluxapyroxad are within registered use patterns for these active ingredients. The terrestrial risk assessment for mefentrifluconazole is presented in Appendix I, Table 22 for terrestrial organisms other than birds and mammals, Table 23 and 24 for pollinators, and Table 25 to 28 for birds and mammals.

Earthworms: Earthworms and other soil dwelling invertebrates can be exposed to mefentrifluconazole on the soil following spray applications.

Mefentrifluconazole was not toxic to earthworms on an acute basis at concentrations up to 1,000 mg a.i./kg soil dw. The end-use products Cevya, Maxtima, and BAS 752 RC were not acutely toxic at the concentrations tested (up to 1,000 mg formulation/kg soil dw). The end-use products Lenvyor and Belyan were acutely toxic, with LC50s of 707 and 787 mg formulation/kg soil dw, respectively. Chronic exposure to technical mefentrifluconazole resulted in effects on earthworm reproduction at concentrations of 16 mg a.i./kg soil dw, while no effects were noted at the highest concentration tested of Lenvyor of 80 mg formulation/kg soil dw (8.1 mg a.i./kg soil dw).

The risk quotients for earthworms resulting from acute and chronic exposure to mefentrifluconazole or from acute exposure to end-use products containing mefentrifluconazole do not exceed the level of concern at the screening level. The use of mefentrifluconazole is expected to pose a negligible acute and chronic risk to earthworms.

Other soil-dwelling invertebrates: Chronic exposure to collembolans did not result in effects on survival or reproduction at the concentrations tested of up to 400 mg a.i./kg soil dw for mefentrifluconazole, and up to 24.3 mg a.i./kg soil dw for Lenvyor. The risk quotients for the reproduction of collembola (*Folsomia candida*) resulting from exposure to mefentrifluconazole and to Lenvyor or Maxtima do not exceed the level of concern at the screening level. The use of mefentrifluconazole is expected to pose a negligible risk to the reproduction of the soil-dwelling invertebrate collembola.

Bees: Adult bees can be exposed during foliar application by spray droplets while foraging, and both adult and larval bees can consume contaminated pollen and/or nectar when mefentrifluconazole is applied as a foliar spray or seed treatment.

Results of acute laboratory studies with mefentrifluconazole and its end-use products, Lenvyor, Cevya, Maxtima, BAS 752 RC, and Belyan, indicate that it is practically non-toxic to larval and adult honey bees and adult bumble bees on an acute oral and contact basis. Sublethal effects including morbidity and impaired locomotion were noted in the tests with the end-use product Lenvyor. Chronic exposure to mefentrifluconazole resulted in no significant sublethal behavioural effects in adult bees with NOED values of 110.5 µg a.i./bee/day (highest dose tested), while effects on larvae, pupae, and adult emergence were limited to the highest dose tested resulting in a NOED of 6.4 µg a.i./larva/day.

At the screening level, risk quotients did not exceed the level of concern for acute oral and contact exposure to adult bees and larvae (considering both lethal and sublethal endpoints) for foliar or seed treatment uses. Risk quotients for chronic exposure did not exceed the level of concern for adult bees for foliar or seed treatment uses, or for larvae seed treatment uses. Only chronic exposure to larvae resulting from use on golf course turf had risk quotients slightly exceeding the level of concern (RQ of 1.9).

The turf exposure scenario is not considered realistic for pollinators, as food sources are limited on golf courses. The more realistic scenario of foliar application to orchard crops resulted in risk quotients that did not exceed the level of concern for larvae.

Beneficial arthropods: Beneficial arthropods (other than bees) can also be exposed to residues of mefentrifluconazole on plant surfaces or on the soil, following spray applications.

Acute exposure to Lenvyor on glass plates affected survival of *Typhlodromus pyri*, while exposure to Cevya, Maxtima or BAS 752 RC did not significantly affect survival. In 48-hour glass plate contact tests, Lenvyor showed the greatest toxicity (LR50 of 9.44 g a.i./ha) to the parasitic wasp *Aphidius rhopalosiphi* of Lenvyor, Cevya, Maxtima, and BAS 752 RC end-use products.

At the screening level, the risk quotients for *T. pyri* resulting from glass plate exposure to Lenvyor, Cevya, and Maxtima exceeded the level of concern for in-field exposures only. The potential risk from Cevya, Maxtima was based on limited effects observed at the highest dose tested, and, as such, is a conservative estimate of risk. The risk quotients for *A. rhopalosiphi* exceeded the level of concern for glass plate exposure to Lenvyor both in-field and off-field, and to Cevya, Maxtima for in-field exposure only (based on limited effects observed at the highest dose tested). The risk quotients resulting from exposure to BAS 752 RC did not exceed the level of concern for in- or off-field exposures for *T. pyri* and *A. rhopalosiphi*. As the EECs for Belyan are similar to those of BAS 752 RC, the level of concern for risk is also not expected to be exceeded for Belyan for *T. pyri* and *A. rhopalosiphi*.

The survival and reproduction of the predatory soil mite *Hypoaspis aculeifer* were not significantly affected by mefentrifluconazole or Lenvyor at the concentrations tested (1,000 mg a.i./kg soil dw and 27.2 mg a.i./kg soil dw, respectively). The risk quotients resulting from exposure of *H. aculeifer* to mefentrifluconazole and to Lenvyor on artificial soil did not exceed the level of concern.

The risk to predatory and parasitic arthropods was further characterized using results from higher tier (extended laboratory) toxicity studies with *T. pyri* and *A. rhopalosiphi*, and other terrestrial arthropod species. Risk quotients for higher tier studies with predatory and parasitic arthropods are shown in Appendix I, Table 33.

Lenvyor affected the survival of *T. pyri* in the extended laboratory study with sprayed leaves at rates above 75 g a.i./ha, but did not affect reproduction at rates up to 300 g a.i./ha. Survival and reproduction of *A. rhopalosiphi* and to the predatory insect *Chrysoperla carnea* (green lacewing) were not affected by exposure to Lenvyor on plants. The risk quotients resulting from exposure

to Lenvyor of *A. rhopalosiphi* and *C. carnea* did not exceed the level of concern for in-field or off-field exposures ($RQs \leq 0.58$). The risk quotient did exceed the level of concern for in-field exposure to the predatory mite *T. pyri* ($RQ\ 2.3$) when considering the No Observed Effect Rate (NOER) for mortality, but not for the LR50 endpoint. Off-field exposures did not result in risk quotients exceeding the level of concern ($RQ < 0.54$).

Use of the NOER endpoint for mortality is conservative, with 1.6% mortality observed at this rate. In the field, this low level of mortality would not be expected to affect populations of beneficial arthropods. As such, the concern for risk to *T. pyri*, *A. rhopalosiphi*, and *C. carnea* from exposure to Lenvyor is considered low.

An extended laboratory study with sprayed leaves for Belyan showed no significant effects on survival or reproduction for *T. pyri* at the highest rate tested of 456 g mefentrifluconazole/ha. Extended laboratory tests on plants showed that survival was a more sensitive endpoint than reproduction for *A. rhopalosiphi* exposed to Belyan with 31% mortality noted at 152 g a.i./ha (the LOER for survival). Exposure of *T. pyri* to Belyan did not result in risk quotients that exceeded the level of concern for in- or off-field exposures. Exposure of *A. rhopalosiphi* to Belyan resulted in a risk quotient that slightly exceeded the level of concern for in-field exposure when considering the NOER for mortality only (RQ of 2.2). Off-field and in-field exposures considering the LR50 endpoint did not result in a risk quotient exceeding the level of concern ($RQ \leq 0.67$). Although the level of concern was exceeded for in-field exposure, the endpoint for which this exceedance was noted is conservative. The concern for risk to *T. pyri* and *A. rhopalosiphi* from exposure to Belyan is low.

No extended laboratory tests were conducted for these species for a formulation representing Maxtima (400 g a.i./L). The magnitude of the risk quotients for Maxtima at the screening level is related to the high application rate for turf and the high cumulative application rate that results. The proposed label for Maxtima indicates that no more than two sequential applications with this product are to be made before alternating to a different group of fungicide (a non-Group 3 fungicide). The EECs have been determined assuming three sequential applications of the end-use product to turf as a conservative estimate of cumulative exposure. This results in a higher cumulative exposure estimate than can be expected for the use pattern when following the label instructions. A single application of Maxtima results in a risk quotient of less than 2.2 for in-field exposure (1,000 g a.i./ha / > 450 g a.i./ha). As such, the risk quotients are likely lower than those calculated during screening. In addition, the extended laboratory tests available for *T. pyri*, *A. rhopalosiphi*, and *C. carnea* conducted with other formulations containing mefentrifluconazole gave risk quotients that did not exceed the level of concern for in-field or off-field exposures in most cases. The other extended laboratory tests with *T. pyri*, *A. rhopalosiphi*, and *C. carnea* indicate a low concern for risk under more realistic exposure scenarios. In addition, there is conservatism built into the exposure estimates for the screening level assessment. It is, therefore, expected that in-field exposures during application to turf will result in low risk to predatory and parasitic arthropods.

Overall conclusions about potential risks to predatory and parasitic arthropods: Under more realistic exposures on excised leaves or plants, the concern for risks to predatory and parasitic arthropods is acceptable.

Birds: Birds can be exposed to residues of mefentrifluconazole when they ingest food items such as vegetation or insects that may have been sprayed during foliar application. In addition, birds can ingest seeds treated with mefentrifluconazole.

In general, mefentrifluconazole exhibited low acute toxicity to birds (bobwhite quail, mallard duck and canary) via oral and dietary routes, and the end-use products Cevya, Maxtima, BAS 752 RC, and Belyan also showed low acute oral toxicity up to the highest dose tested. Chronic studies with mefentrifluconazole indicated effects on the reproduction and offspring of bobwhite quail at 531 mg a.i./kg diet, namely, egg production, 14-day survivors of eggs hatched, and hatchling and survivor body weights, resulting in a NOAEC of 278 mg a.i./kg diet (NOAEL of 24.8 mg a.i./kg bw/day). In a reproduction study with the mallard duck, a statistically significant reduction in adult female body weight and body weight gain was observed at the highest dose tested (616 mg a.i./kg diet), resulting in a NOAEC of 302 mg a.i./kg diet (NOAEL of 44 mg a.i./kg bw/day).

The risk quotients for birds resulting from exposure to mefentrifluconazole exceeded the level of concern at the screening level for foliar applications for the turf use (RQs from 2.5 to <5.3). For foliar orchard uses, the risk quotient slightly exceeded the level of concern for acute exposure to small birds only (RQ of <1.0). The risk quotients for small- and medium-sized birds resulting from exposure to mefentrifluconazole also exceeded the level of concern at the screening level for seed treatment applications (RQs from 1.6 to <2.2).

The risks to birds were further characterized considering feeding guilds, maximum and mean residue levels, and in-field and off-field exposures (Appendix I, Table 29). Looking at multiple feeding guilds, risk quotients exceeded the level of concern for insect- and fruit-eating small- and medium-sized birds, and insect- and plant-eating large-sized birds when considering maximum food residues in-field from turf applications. The maximum risk quotients were for insectivorous small birds (RQs of < 5.3 and 5.0 for acute and reproductive effects, respectively). Assuming that food items all contain maximum residue levels is conservative, as levels will likely vary. When considering mean residues of mefentrifluconazole in food items, risk quotients exceeded the level of concern for small and medium insectivores exposed on the field (RQs of <3.6 and < 2.83).

Risks from off-field exposure were investigated assuming 6% drift from ground boom sprayer (medium droplet) applications on turf (Appendix I, Table 29). Risk quotients for off-field exposure did not exceed the level of concern for any feeding guild assuming maximum residue levels on food items from turf use ($RQ \leq 0.3$). Although spray drift is higher for orchard applications (74% for airblast, early season, fine droplet), the application rate is much lower for these applications (turf: single application of 1,000 g a.i./ha; orchard: single application of 150 g a.i./ha), resulting in lower risk quotients for birds. Only small insect-eating birds showed a risk quotient that slightly exceeded the level of concern for maximum residues in-field for orchard use (RQ of 1.0). Risk quotients calculated using mean residues of mefentrifluconazole from orchard applications did not exceed the level of concern for small insectivores in-field (RQ of <0.71).

Small- and medium-sized birds showed risk quotients that exceeded the level of concern for mefentrifluconazole use as a seed treatment on peas/beans during the screening assessment (RQs from 1.6 to <2.2). When the acute oral LD50 for mefentrifluconazole of 816 mg a.i./kg bw is used to calculate risk quotients, the level of concern is not exceeded for any size of bird for acute exposures. The NOAEL for the bobwhite quail reproduction study was used during the screening assessment. The LOAEL of 47.3 mg a.i./kg bw/day was used to calculate risk quotients to bracket the risk. This results in a risk quotient slightly exceeding the level of concern for small birds only for reproduction (RQ of 1.1; Appendix I, Table 31).

The screening assessment for birds assumes that the diet consists entirely of treated seeds, that all of the treated seeds that are planted are available for consumption over an extended period of time, and that birds feed exclusively in one area. Variables of feed preference, availability of treated seeds, or potential avoidance behaviour toward treated seed are not considered at the screening level. For small birds, they would need to eat 14 to 38 seeds in order to reach the reproductive toxicity LOAEL, an amount which would represent the entire diet for a small bird. In addition, this consumption would need to continue for several days in order to reach levels similar to those fed to birds in the reproductive toxicity study. Seed planting practices, such as precision drilling, also place the seeds fairly deep into the soil, making the treated seeds less accessible to small birds. All of these factors, considered together, indicate that the risk to small birds can be expected to be low from use of mefentrifluconazole as a seed treatment (see Appendix I, Table 32).

Overall conclusion about potential risks to birds: Levels on food items are likely variable, and thus, assuming that 100% of food items contain maximum residue levels is conservative. No risk quotient exceeded the level of concern when considering maximum and mean residues off-field. Seed treatment uses of mefentrifluconazole are expected to result in low risk to birds. Based on these results, the risks of mefentrifluconazole to birds are acceptable.

Mammals: Mammals can be exposed to residues of mefentrifluconazole when they ingest food items such as vegetation or insects that may have been sprayed during foliar application. In addition, mammals can ingest seeds treated with mefentrifluconazole.

Mefentrifluconazole and the end-use products Lenvyor, Cevya, Maxtima, BAS 752 RC, and Belyan were all of low acute oral toxicity to rats. A two-generation reproduction study with rats resulted in a NOAEL of 72 mg/kg bw/day, due to body weight and reproductive effects.

The screening level risk quotients for mammals resulting from longer term exposure to mefentrifluconazole through foliar applications slightly exceeded the level of concern for medium- and large-sized mammals for turf use in-field (RQs of 1.9 and 1.0, respectively). This determination uses maximum residues on food items for calculation of EECs which is a conservative assumption. When considering mean residues on food items, the risk quotients do not exceed the level of concern (RQs of up to 0.68 and 0.36, respectively for medium- and large-sized mammals; see Appendix I, Table 28). In addition, off-field exposures for the turf use do not exceed the level of concern for any feeding guild for the maximum residues on food items. Therefore, it is expected that the foliar turf use of mefentrifluconazole will pose a low risk to

medium- and large-sized mammals. The risk quotients for mammals resulting from acute and longer term exposure to mefentrifluconazole through foliar orchard applications and seed treatment applications did not exceed the level of concern for any feeding guild at the screening level. Mefentrifluconazole is expected to pose negligible risk to mammals from foliar orchard use and use as a seed treatment.

Overall conclusion about potential risks to mammals: Assuming that all food items consumed by mammals contain maximum residues of mefentrifluconazole is conservative. Levels on food items are likely variable. No risk quotient exceeded the level of concern when considering mean residues. Seed treatment uses of mefentrifluconazole are expected to result in negligible risk to mammals. Based on these results, the risks of mefentrifluconazole to mammals are acceptable.

Terrestrial vascular plants: Lenvyor, Cevya, Maxtima affected seedling emergence and vegetative vigour in some plant species, however no effects greater than 25% were observed in the seedling emergence or vegetative vigour studies for plants exposed up to 157 g a.i./ha for Lenvyor, or up to 527 g a.i./ha for Cevya (orchard) / Maxtima (turf). Effects were similar (up to 16% inhibition) at both 157 and 527 g a.i./ha for seedling emergence, and no significant effects were noted up to 527 g a.i./ha in the vegetative vigour studies.

Because the estimated exposure concentrations for Cevya, Maxtima, and Lenvyor are higher than those for BAS 752 RC and Belyan, the risk assessment of Cevya, Maxtima, and Lenvyor also covers use of BAS 752 RC and Belyan. At the screening level, the calculated risk quotients exceed the level of concern for in-field exposure only for seedling emergence and vegetative vigour for both Lenvyor and Cevya, Maxtima (RQs of < 1.1 to < 5.6).

The highest cumulative application rates for orchard use for Cevya, Lenvyor, BAS 752 RC, and Belyan were estimated to be 446 g a.i./ha at the soil surface and 299 g a.i./ha at the leaf surface. These EECs are lower than the higher study application rate for seedling emergence and vegetative vigour of 527 g a.i./ha which resulted in no effects above 25%. As such, the potential risk to non-target terrestrial plants is considered low. The highest cumulative application rates for the turf end-use product Maxtima are 2,950 g a.i./ha (soil surface) and 1,523 g a.i./ha (leaf surface). The single application rate for Maxtima is 1,000 g a.i./ha. The cumulative and single rates are much higher than the higher application rate used in the plant studies. Effects, although less than 25%, were noted at rates of 527 g a.i./ha. As such, there may be potential risk to non-target terrestrial plants when mefentrifluconazole is used for application on turf.

Overall conclusion about potential risks to terrestrial vascular plants: There may be a potential risk to non-target plants from use of mefentrifluconazole on turf, and therefore, terrestrial buffer zones were calculated for the label of Maxtima end-use product. The risk to plants is acceptable for the remaining proposed uses of mefentrifluconazole, including orchard and field foliar uses and seed treatment uses.

4.2.2 Risks to Aquatic Organisms

Aquatic organisms can be exposed to mefentrifluconazole and its transformation products through spray drift or run-off into aquatic habitats. A risk assessment for mefentrifluconazole, the transformation products M750F002, M750F003, M750F005, M750F006, M750F007, M750F008, M750F036, and M750F037, and end-use products (Lenvyor, Cevya, Maxtima, BAS 752 RC, and Belyan) was conducted for freshwater and marine aquatic organisms based on available toxicity data. A summary of aquatic toxicity data is presented in Appendix I, Table 34. For acute toxicity studies, uncertainty factors of 1/2 of the EC50 (LC50) are typically used for aquatic plants and invertebrates, and of 1/10 the EC50 (LC50) fish species when calculating risk quotients. No uncertainty factors are applied to chronic NOEC endpoints. For groups where the LOC is exceeded (thus, if $RQ \geq 1$), a refined Tier 1 assessment is conducted to determine risk resulting from spray drift and run-off separately. Risk quotients for mefentrifluconazole and its transformation products were calculated based on the highest maximum seasonal application rate for all uses. The screening level risk quotients for mefentrifluconazole are summarized in Appendix I, Table 35. The risk quotients for the refined risk assessment of mefentrifluconazole are presented in Appendix I, Table 36 (spray drift) and Table 21 (run-off).

Invertebrates: Mefentrifluconazole was highly toxic to daphnids on an acute basis. The transformation products ranged from practically non-toxic to moderately toxic, with M750F006 showing the greatest acute toxicity to daphnids. Most other transformation products showed minimal toxicity at the highest dose tested. The end-use product Belyan (coformulation with two other active ingredients, pyraclostrobin and fluxapyroxad) was the most acutely toxic of Lenvyor, Cevya, Maxtima, and Belyan to daphnids. The blank formulation of Lenvyor showed less toxicity to daphnids than Lenvyor. During chronic exposures, *Daphnia magna* was the most sensitive daphnid tested. Levels of 18.3 µg a.i./L affected reproduction by reducing the number of live offspring per parent and decreasing the successful birth rate. Survival of the amphipod *Hyalella azteca* and the midge *Chironomus dilutus* was not significantly affected up to mefentrifluconazole concentrations of 0.2 mg a.i./L in overlying water (1.7 mg a.i./L in pore water) when exposed for 10 days, following application to sediment. Chronic exposures (for 63 days) through spiked sediment resulted in decreases in emergence for both *Chironomus dilutus* and *Chironomus riparius* at mefentrifluconazole levels of less than 10 µg a.i./L in overlying water. Mefentrifluconazole was moderately to highly toxic to marine invertebrates *Leptocheirus plumulosus*, mysid shrimp, and Eastern oyster following acute exposures. No effects were noted in mysid shrimp during chronic exposure to mefentrifluconazole.

At the screening level, the risk quotients for acute exposure of *Daphnia magna* to mefentrifluconazole, its transformation products, or Lenvyor, Cevya, and Maxtima end-use products did not exceed the level of concern at the screening level. The risk quotient for *D. magna* resulting from acute exposure to the coformulated end-use product Belyan exceeded the level of concern at the screening level (RQ of 6.4). The risk quotient for chronic exposure of *D. magna* to mefentrifluconazole exceeded the level of concern (RQ of 40). The risk quotients for chronic exposure of *D. pulex* and *D. longispina* to mefentrifluconazole exceeded the level of concern at the screening level (RQs of 13 and 11, respectively). The risk quotient for acute exposure of the amphipod, *Hyalella azteca*, to mefentrifluconazole exceeded the level of concern at the screening level (RQ of < 3.6) for overlying water, but did not exceed the level of concern

for pore water exposures (RQ of < 0.43). The risk quotients for acute and chronic exposure to the midge, *Chironomus dilutus*, to mefentrifluconazole exceeded the level of concern at the screening level (RQ of < 4.0 for acute, RQ of 74 for chronic) for exposure to overlying water and for chronic exposure to pore water (RQ of 4.1). The risk quotient for chronic exposure to the midge, *Chironomus riparius*, exceeded the level of concern at the screening level for overlying water and pore water exposure (RQ of 340 and 243, respectively). For marine/estuarine invertebrates, acute exposure to the crustacean *Leptocheirus plumulosus* results in a risk quotient that exceeds the level of concern for overlying water (RQ of < 2.4).

Chronic exposure to the mysid shrimp results in risk quotients that also exceed the level of concern (RQ of < 28). Acute exposure to mysid shrimp did not result in a risk quotient that exceeds the level of concern. The risks to aquatic invertebrates from spray drift and run-off were further characterized.

The refined risk quotients indicate that the level of concern from mefentrifluconazole exposure due to spray drift is exceeded for the freshwater invertebrates *D. magna*, *D. pulex*, and *D. longispina*, and for the marine crustacean mysid shrimp. Spray buffer zones are required to mitigate potential effects of mefentrifluconazole drift on aquatic organisms in adjacent freshwater and marine habitats. The spray buffer zones for mefentrifluconazole are application type and rate-specific for the product labels and will range from 0 to 650 m for freshwater and from 1 to 5 m for marine waters.

Exposure through surface run-off was estimated using the PWC model, which simulates pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. The water body consists of a 1 ha wetland with an average depth of 80 cm and a drainage area of 10 ha. EECs in pore water were also generated to assess the risk to sediment-dwelling organisms. The most conservative EECs obtained from the modelling are reported in Appendix I, Table 37. The risk quotients using more refined EECs for run-off (Appendix I, Table 38) slightly exceed the level of concern for chronic effects to freshwater invertebrates (*D. magna*, *C. dilutus*, and *C. riparius*) and for the marine crustacean mysid shrimp. The run-off EECs for both freshwater and marine exposures are based on the yearly cumulative application rate and are modelled without outflow.

For the marine exposure scenario, this is a particularly conservative assessment since the EECs do not account for tides / dilution that would be present in the Canadian marine environment. Standard best management practice label statements to reduce run-off are required on the labels of mefentrifluconazole end-use products.

Overall conclusion about potential risks to aquatic invertebrates: The risk to aquatic invertebrates from drift and run-off into surface waters is considered acceptable with proposed mitigation.

Fish: Mefentrifluconazole was highly toxic to the freshwater fish species rainbow trout, zebrafish, fathead minnow, and also to marine species sheepshead minnow. Mefentrifluconazole was moderately toxic to carp after acute exposures. The transformation products M750F006 and M750F007 were approximately ten times less acutely toxic to rainbow trout than

mefentrifluconazole. Freshwater fish showed greater sensitivity to Belyan than to Lenvyor or Cevya, Maxtima following acute exposures to these end-use products. The blank formulation of Lenvyor showed less toxicity to rainbow trout than Lenvyor. In chronic tests with zebrafish exposed to mefentrifluconazole, F1 survival was the most sensitive endpoint. Sheepshead minnow did not show significant effects at the concentrations tested in chronic testing with mefentrifluconazole.

The risk quotients for freshwater fish resulting from acute and chronic exposure to mefentrifluconazole exceeded the level of concern at the screening level (RQs of 3.2 to 16). The risk quotients resulting from acute exposure to the transformation products M750F006 and M750F007 did not exceed the level of concern at the screening level (RQs of 0.55 or less). The risk quotients resulting from acute exposure to the end-use products Lenvyor, Cevya, Maxtima and Belyan also exceeded the level of concern at the screening level (RQs of <3.5 to 68). The risk to freshwater fish will be further characterized. The risk quotient for marine fish resulting from acute exposure to mefentrifluconazole did not exceed the level of concern. The risk quotient from early life stage exposure was less than 2.5. This value was derived using a cumulative EEC in an 80-cm deep body of water, and an endpoint of greater than or equal to 0.147 mg a.i./L (NOAEC) for the sheepshead minnow. Based on the relatively low risk quotient, the low water solubility of mefentrifluconazole, and because no effects were observed up to the highest concentration tested in the chronic test, a risk to marine or estuarine fish is not expected.

The refined risk quotients for freshwater fish indicate that the level of concern from mefentrifluconazole exposure due to spray drift is exceeded for zebrafish for chronic exposures, and for rainbow trout exposed to Lenvyor and Belyan. Spray buffer zones will be required to mitigate potential effects of mefentrifluconazole drift on aquatic organisms in adjacent aquatic habitats. The spray buffer zones for mefentrifluconazole are application type and rate-specific for the product labels and will range from 0 to 650 m for freshwater.

The risk quotients using more refined EECs for run-off (EECs: Table 37; risk quotients: Appendix I, Table 38) are at the level of concern for freshwater fish (RQ of 1.0) for chronic exposure to mefentrifluconazole. The run-off EECs are conservatively based on the yearly cumulative application rate and are modelled without outflow.

Overall there is minimal risk to fish from run-off. Standard best management practice label statements to reduce run-off are required on the labels of mefentrifluconazole end-use products.

Overall conclusion about potential risks to fish: The risk to fish from drift and run-off into surface waters is considered acceptable with proposed mitigation.

Amphibians: Using endpoints for freshwater fish as a surrogate for amphibian ecotoxicity data, in addition to EECs for a 15-cm deep body of water, the screening level risk quotients for amphibians resulting from acute and chronic exposure to mefentrifluconazole exceeded the level of concern in each case (RQs of 36 to 87).

The risk quotients for amphibians also exceeded the level of concern for exposure to the transformation products M750F006 and M750F007 (RQs of 2.9 and < 2.3, respectively). The risk quotients for amphibians resulting from acute exposure to the end-use products Lenvyor, Cevya, Maxtima, and Belyan exceeded the level of concern at the screening level.

The refined risk quotients accounting for spray drift indicate that the level of concern from mefentrifluconazole exposure is exceeded for amphibians exposed to either active ingredient or end-use products. Spray buffer zones are required to mitigate potential effects of mefentrifluconazole drift on aquatic organisms including amphibians in adjacent aquatic habitats.

The spray buffer zones for mefentrifluconazole are application type- and rate-specific for the product labels and will range from 0 to 650 m for freshwater. The highest buffer zone of 650 m is for freshwater habitats of less than 1 m depth.

Exposure through surface run-off was refined using the PWC for a scaled down version of a permanent water body (1 ha of wetland and drainage area of 10 ha), but having a water depth of 15 cm using the PWC model. The most conservative EECs obtained from the modelling are reported in Appendix I, Table 37. The risk quotients using the refined EECs for run-off (Table 38) slightly exceed the level of concern for amphibians exposed to the active ingredient. The run-off EECs are based on the yearly cumulative application rate and are modelled without outflow which is a conservative approach. Standard best management practice label statements to reduce run-off are required on the labels of mefentrifluconazole end-use products.

Overall conclusion about potential risks to amphibians: The risk to amphibians from drift and run-off into surface waters is considered acceptable with proposed mitigation.

Algae: Freshwater and marine algal growth was inhibited after acute exposures to mefentrifluconazole. The transformation product M750F006 was the most acutely toxic to freshwater algae of all of the aqueous transformation products. The end-use products Lenvyor, Cevya, Maxtima, and Belyan showed similar or greater acute toxicity than mefentrifluconazole to freshwater algae.

The risk quotients for freshwater algae from acute exposure to mefentrifluconazole or the end-use products Lenvyor, Cevya, Maxtima, and Belyan did not exceed the level of concern at the screening level. The risk quotients resulting from exposure to the transformation products did not exceed the level of concern, with the exception of M750F006 (RQ of 3.7). The refined risk quotients for both spray drift and run-off did not exceed the level of concern for algae exposed to the transformation product M750F006. The use of mefentrifluconazole is expected to pose a negligible risk to freshwater and marine algae.

Aquatic vascular plants: The aquatic vascular plant *Lemna gibba* was not affected by seven days of exposure at the concentrations tested of up to 1.9 mg a.i./L. The risk quotient for aquatic vascular plants resulting from exposure to mefentrifluconazole did not exceed the level of concern at the screening level. The use of mefentrifluconazole is expected to pose a negligible risk to aquatic vascular plants.

4.2.3 Incident Reports

Mefentrifluconazole is a new active ingredient pending registration for use in Canada and as of February 28, 2019, there were no human, domestic animal or environment incident reports. Once products containing mefentrifluconazole are registered, the PMRA will monitor for incident reports.

For pyraclostrobin, the PMRA Incident Reporting database contains two minor fish incident reports and one minor bird incident report that were potentially the result of spray drift. Additionally, there were 10 bee incident reports and one major fish incident report considered unlikely to be caused by pyraclostrobin. The USEPA's Ecological Incident Information System (EIS) reported some environmental incidents, however, very few details were outlined in the reports. Exposure from spray drift has been mitigated for the end-use product containing pyraclostrobin, with the development of appropriate spray buffer zones.

5.0 Value

Mefentrifluconazole is a new conventional active ingredient for disease management in Canada, which will provide Canadian growers with a new mode of action to manage important fungal diseases on the crops and plants specified on the product labels for Lenvyor, Cevya, Maxtima, Relenya, BAS 752 RC and Belyan.

Efficacy of Lenvyor, Cevya and Maxtima in controlling or suppressing various fungal diseases when applied as preventative applications in crops and plants listed on the product labels was demonstrated. Similarly, Relenya, a seed treatment fungicide, was shown to control various seed or seedling diseases in crops listed on the label. For both BAS 752 RC and Belyan, information demonstrated control or suppression of various fungal diseases when applied as preventative applications in crops listed on the labels. There was no phytotoxicity or injury to any of the crops evaluated in the trial studies. When used according to label directions, application of these products is not expected to result in any non-safety adverse effects to any of the labelled crops.

Details of the supported uses are provided in Appendix I, Table 40.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) 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 [those that meet all four criteria outlined in the policy, in other words, 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*].

During the review process, mefentrifluconazole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Mefentrifluconazole does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Table 38 for comparison with Track 1 criteria.
- Mefentrifluconazole does not form any transformation products that meet all Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*⁶. The list is used as described in the PMRA Notice of Intent NOI2005-01⁷ and is based on existing policies and regulations including: DIR99-03; and DIR2006-02⁸, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- The formulated end-use products contain toluene and dimethylformamide as impurities at concentrations that do not pose a risk to the environment, therefore, environmental risk management measures are not required for any of the impurities at the reported levels.
- The formulated product Lenvyor contains aromatic petroleum distillates, therefore, the label for this end-use product will include the statement “This product contains aromatic petroleum distillates that are toxic to aquatic organisms.”

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02⁹.

⁵ DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

⁶ SI/2005-114

⁷ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*

⁸ DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

⁹ DIR2006-02, PMRA Formulants Policy.

7.0 Summary

7.1 Human Health and Safety

The toxicology database is adequate to characterize the potential health hazards associated with mefentrifluconazole. There was no evidence of carcinogenicity in rats or mice after long-term dosing. There was no evidence of increased sensitivity of the young in reproductive or developmental toxicity studies. Mefentrifluconazole was not selectively neurotoxic. In short-term and chronic studies on laboratory animals, the primary target was the liver. Effects on the kidneys, hematology parameters, body weight and activity level were also observed. 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.

The nature of the residues in plants and animals is adequately understood. The residue definition for enforcement is mefentrifluconazole in plant products and in animal matrices. The proposed use of mefentrifluconazole on potatoes, sugar beets, CSG 6C, soybeans, pome fruits, stone fruits, grapes, tree nuts, corn (field, pop, sweet and seed corn), wheat (spring, winter and durum), triticale, canola, flax, mustard, rapeseed and peanuts, and the imported commodities do 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. Sufficient crop residue data were available to propose MRLs. The PMRA proposes that the following MRLs be specified for residues of mefentrifluconazole.

MRL (ppm)	Food Commodity
15	Citrus oil
4.0	Cherries (crop subgroup 12-09A), cereal grains (crop group 15, except wheat, triticale and corn), dried prune plums, raisins
2.0	Plums (crop subgroup 12-09C), dry lentils
1.5	Pome fruits (crop group 11-09), peaches (crop subgroup 12-09B), small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F)
1.0	Lemons (crop subgroup 10B, revised), oilseeds (crop subgroup 20A, revised)
0.6	Oranges (crop subgroup 10A, revised), sugar beet roots
0.5	Grapefruits (crop subgroup 10C, revised)
0.4	Dry soybeans
0.3	Wheat; meat byproducts of cattle, goats, horses and sheep; triticale
0.2	Fat of cattle, goats, horses and sheep
0.15	Legume vegetables, succulent or dried (crop subgroup 6), except dry lentils and dry soybeans
0.1	Milk fat
0.06	Tree nuts (crop group 14-11)

MRL (ppm)	Food Commodity
0.04	Tuberous and corm vegetables (crop group 1C)
0.03	Sweet corn kernels plus cobs with husks removed
0.02	Meat of cattle, goats, horses and sheep; milk
0.01	Field corn; peanuts; popcorn grain; fat, meat and meat byproducts of hogs and poultry; eggs

Risks are acceptable for mixers, loaders and applicators handling BAS 752 RC, Belyan, Cevya, Lenvyor, Maxtima and Relenya and for workers entering freshly treated fields, areas or golf courses or planting treated seed when these mefentrifluconazole end-use products are used according to label directions. The personal protective equipment on the labels for BAS 752 RC, Belyan, Cevya and Maxtima specify that users wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. The label of Lenvyor specifies that users wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. In addition, the labels for Belyan and Lenvyor also specify that users wear protective eyewear during mixing and loading. The label for Relenya specifies that workers mixing, loading, applying, bagging, sewing bags of treated seed, stacking or performing any other activity involving the handling of treated seed must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested. In addition, workers cleaning-up, or maintaining and repairing seed treatment equipment must wear chemical-resistant coveralls in a commercial seed treatment facility, or during on-farm seed treatment, clean-up, maintenance and repair, coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a NIOSH-approved N95 (minimum) filtering face piece respirator (dust mask) that is properly fit tested. Workers loading and planting treated seed must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes, socks, and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask). In addition, closed transfer systems must be used in commercial seed treatment facilities and closed cab tractors must be used while planting treated seed.

Residential exposure is acceptable for individuals 1) involved in pick-your-own activities, or performing tasks around treated trees in residential areas when Cevya is used according to label directions, 2) playing golf on treated golf courses when Maxtima is used according to label directions.

7.2 Environmental Risk

When used according to the label directions, mefentrifluconazole does not present a risk of concern to wild mammals, birds, beneficial insects, pollinators, earthworms, marine fish, and aquatic plants. Mefentrifluconazole may pose risks of concern to freshwater fish, freshwater and marine invertebrates, amphibians, and terrestrial plants.

To minimize exposure and reduce risks to these organisms, spray buffer zones and precautionary label statements are required. When mefentrifluconazole is used in accordance with the label and the required risk reduction measures are applied, the reduced environmental exposure is deemed adequate and risks are considered to be acceptable.

7.3 Value

Mefentrifluconazole, the sole active ingredient of Lenvyor, Cevya, Maxtima and Relenya, is effective against various important fungal diseases in listed field crops, specialty crops, fruits and turf grasses. These products can be used as a preventative foliar treatment (in other words, Lenvyor, Cevya and Maxtima) or as a seed treatment (in other words, Relenya) in conjunction with good disease management practices. Two pre-mix products, BAS 752 RC and Belyan, are effective against certain important fungal diseases in labelled crops. The availability of these products will provide Canadian growers with a new mode of action to manage some important fungal diseases on the crops and plants specified on the respective product labels.

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 Revysol Fungicide Technical, BAS 752 RC, Belyan, Cevya, Lenvyor, Maxtima, and Relenya, containing the technical grade active ingredient mefentrifluconazole, to control various fungal pests in field crops, fruits, specialty crops and golf course turf.

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

µg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
abs	absolute
AD	administered dose
ADI	acceptable daily intake
ADME	absorption, distribution, metabolism and excretion
AHETF	Agriculture Handler Exposure Task Force
ALP	alkaline phosphatase
ALT	alanine aminotransferase
aPTT	activated partial prothrombin time
ARTF	Agriculture Re-entry Task Force
ARfD	acute reference dose
AST	aspartate aminotransferase
AUC _{0-x}	area under curve for a given time interval
bw	body weight
bwg	body weight gain
BBCH	Biologische Bundesanstalt, Bundessortenamt and Chemical industry
BCF	bioaccumulation factor
CAS	Chemical Abstracts Service
cm	centimetres
CSG	crop subgroup
C _{max}	maximum plasmatic concentration
DALA	Days After Last Treatment
DAT	Days After Treatment
DAT3	Days After Treatment 3
DF	dry flowable
DFR	Dislodgeable Foliar Residue
DNA	deoxyribonucleic acid
DA1A	days after first application
DFOP	double first order in parallel
DMSO	dimethyl sulphoxide
DT ₅₀	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT ₉₀	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC ₂₅	effective concentration on 25% of the population
EC ₅₀	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
ER ₂₅	effective rate for 25% of the population
Eq	equivalent
F0	parental generation
F1	first generation
F2	second generation

fc	food consumption
GD	gestation day
GGT	gamma glutamyl transpeptidase
GIT	gastrointestinal tract
HB	hemoglobin
HCT	hematocrit
hr(s)	hour(s)
K _d	adsorption quotient
K _F	Freundlich adsorption coefficient
K _{F-des}	Freundlich desorption coefficient
K _{FOC}	Freundlich adsorption coefficient normalized to organic carbon
K _{oc}	adsorption quotient normalized to organic carbon
K _{ow}	octanol water partition coefficient
kg	kilogram(s)
i.v.	intravenous
L	litre(s)
LC50	lethal concentration required to kill 50% of the test group
LOC	level of concern
LOQ	limit of quantification
LOEC	lowest observed effect concentration
LOER	lowest observed effect rate
LR50	median lethal rate on 50% of the population
LD	lactation day
LD50	lethal dose required to kill 50% of the test group
LOAEC	lowest observed adverse effect concentration
LOAEL	lowest observed adverse effect level
M/L/A	Mixer/Loader/Applicator
MCH	medium cellular hemoglobin
mg	milligram(s)
µg	microgram(s)
µM	micromolar
MAS	maximum average score for 24, 48 and 72 hrs
MIS	maximum irritation score
MOE	margin of exposure
MTD	Maximum tolerated dose
nm	nanometer
NOAEC	no observed adverse effect concentration
NOAED	no observed adverse effect dose
NOAEL	no observed adverse effect level
NOAER	no observed adverse effect rate
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
NZW	New Zealand white
ORETF	Outdoor Residential Exposure Task Force
PCPA	Pest Control Product Act
PBI	plant-back interval

PHED	Pesticide Handler Exposure Database
PHI	preharvest interval
PLT	platelet
PMRA	Pest Management Regulatory Agency
PND	postnatal day
PYO	Pick Your Own
QuEchERS	Quick, easy, cheap, effective rugged and safe multi-residue method
RAC	raw agricultural commodity
RBC	red blood cell
RD	residue definition
REI	Restricted-Entry Interval
rel	relative
tmax	time to reach maximum plasmatic concentration
TC	Transfer coefficient
t _{1/2}	half-life
t _R	representative half-life
TRR	total radioactive residue
TG	triglyceride
TTR	Turf Transferable Residue
TGAI	technical grade active ingredient
wk(s)	week(s)
wt(s)	weight(s)
WBC	white blood cells
♂	males
♀	females
↑	increased
↓	decreased

Appendix I Tables and Figures

Table 1 Identification of Mefentrifluconazole and Select Metabolites.

Name and/or Synonym, Code Name	Chemical name
Mefentrifluconazole, Revysol, BAS 750 F	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
M750F001	1,2,4-(1H)-triazole
M750F003	4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenol
M750F015	2-chloro-4-{4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy}phenol
M750F016	2-chloro-5-{4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy}phenol
M750F017	5-chloro-2-{4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy}phenol
M750F022	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]propane-1,2-diol
M750F023	2-(4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl)-2-hydroxypropyl (9Z,11Z)-octadeca-9,11-dienoate
M750F035	5-chloro-2-{4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy}phenyl hexopyranosiduronic acid
M750F044	2-chloro-4-{4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy}phenyl hexopyranosiduronic acid
M750F045	2-chloro-5-{4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy}phenyl hexopyranosiduronic acid

Table 2 Toxicity Profile of Lenvyor (BAS 750 01 F) Containing Mefentrifluconazole

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute Oral Toxicity	LD ₅₀ ♀ > 2000 mg/kg bw
Rat, Wistar	Low toxicity
PMRA #2789329	
Acute Dermal Toxicity	LD ₅₀ > 5000 mg/kg bw
Rat, Wistar	Low toxicity
PMRA #2789330	

Study Type/Animal/PMRA #	Study Results
Acute Inhalation Toxicity (nose-only) Rat, Wistar PMRA #2789331	LC ₅₀ > 2.4 mg/L Low toxicity
Dermal Irritation Rabbit, NZW PMRA #2789332	MAS* = 4.22/8 MIS = 4.67/8 at 7 days Moderately irritating
Eye Irritation Rabbit, NZW PMRA #2789333	MAS = 36.7/110 MIS = 39/110 at 1 hr Moderately irritating

* MAS = Maximum Average Score for 72 hrs, 7 and 14 days
MIS = Maximum Irritation Score

Table 3 Toxicity Profile of Cevya, Maxtima and Relenya (BAS 750 02 F) Containing Mefentrifluconazole

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute Oral Toxicity Rat, Sprague-Dawley PMRA #2789211	LD ₅₀ ♀ > 2000 mg/kg bw Low toxicity
Acute Dermal Toxicity Rats, Sprague-Dawley PMRA #2789212	LD ₅₀ > 5000 mg/kg bw Low toxicity
Acute Inhalation Toxicity (nose-only) Rat, Wistar PMRA #2789213	LC ₅₀ > 5.48 mg/L Low toxicity

Study Type/Animal/PMRA #	Study Results
Dermal Irritation	MAS = 0/8 MIS = 0/8
Rabbit, NZW	Non-irritating
PMRA #2789214	
Eye Irritation	MAS = 0/110 MIS = 0/110
Rabbit, NZW	Non-irritating
PMRA #2789215	

Table 4 Toxicity Profile of Belyan (BAS 753 02 F) Containing Mefentrifluconazole, Fluxapyroxad and Pyraclostrobin

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute Oral Toxicity	LD ₅₀ ♀ > 2000 mg/kg bw
Rat, Wistar	Low toxicity
PMRA #2789112	
Acute Dermal Toxicity	LD ₅₀ > 5000 mg/kg bw
Rat, Wistar	Low toxicity
PMRA #2789113	
Acute Inhalation Toxicity (nose-only)	LC ₅₀ ♂ = 6.684 mg/L LC ₅₀ ♀ = 4.309 mg/L LC ₅₀ ♂♀ = 5.052 mg/L
Rat, Wistar	Low toxicity
PMRA #2789114	
Dermal Irritation	MAS = 2.56/8 MIS = 2.67/8 at 24 and 48 hrs
Rabbit, NZW	Mildly irritating
PMRA #2789115	
Eye Irritation	MAS = 0.89/110 MIS = 3.33/110 at 1 hr
Rabbit, NZW	Minimally irritating
PMRA #2789116	

Study Type/Animal/PMRA #	Study Results
Dermal Sensitization (Buehler)	Negative
Guinea pigs, Dunkin-Hartley	
PMRA #2789117	

Table 5 Toxicity Profile of BAS 752 RC (BAS 752 01 F) Containing Mefentrifluconazole and Fluxapyroxad

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute Oral Toxicity	LD ₅₀ ♀ > 2000 mg/kg bw Low toxicity
Rat, Sprague-Dawley	
PMRA #2788356	
Acute Dermal Toxicity	LD ₅₀ > 5000 mg/kg bw Low toxicity
Rat, Sprague-Dawley	
PMRA #2788357	
Acute Inhalation Toxicity (nose-only)	LC ₅₀ = 5.196 mg/L Low toxicity
Rat, Wistar	
PMRA #2788358	

Study Type/Animal/PMRA #	Study Results
Dermal Irritation Rabbit, NZW PMRA #2788359	MAS = 0.67/8 MIS = 1.33/8 at 48 hrs Slightly irritating
Eye Irritation Rabbit, NZW PMRA #2788360	MAS = 0.22/110 MIS = 4.67/110 at 1 hr Minimally irritating
Dermal Sensitization (Buehler test) Guinea pig, Dunkin-Hartley PMRA #2788361	Negative

Table 6 Toxicity Profile of Technical Mefentrifluconazole

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted. Effects above the LOAEL(s) were not reported in this table for most studies for reasons of brevity).

Study Type/Animal/PMRA #	Study Results
Toxicokinetic Studies	
Absorption, distribution, metabolism, elimination and plasma kinetics of mefentrifluconazole (racemic mixture), were investigated in male and female Wistar rats (PMRA #2789570, 2789568 and 2789569). Three radiolabels were used in the course of these investigations: chlorophenyl ring (C-label), trifluoromethyl ring (TFMP-label) or triazole moiety (T-label).	
After single oral gavage administration at 5 and 180 mg/kg bw, plasma kinetics were measured from 0.5 to 168 hrs post-dosing (C-label). Mass balance and biliary excretion studies were performed up to 168 hrs (C- and TFMP-labels) and tissue distribution studies up to 53 hrs (C-label) after administration.	
Plasma kinetics were investigated with T-labelled mefentrifluconazole after single oral gavage at doses of 5, 40, 120 or 360 mg/kg bw or intravenous administration at 0.4 mg/kg bw. Mass balance (from 0 to 168 hrs), biliary excretion (from 0 to 72 hrs) and tissue distribution (from 1 to 24 hrs at the low dose or from 1 to 34-48 hrs at the high dose) studies were performed with single or repeated administration at doses of 5 or 180 mg/kg bw with the T-label.	

Study Type/Animal/PMRA #	Study Results
	<p>Metabolism and elimination studies after oral administration of a single dose of 5 or 180 mg/kg bw of T-labelled mefentrifluconazole or after repeated oral gavage administration of unlabelled mefentrifluconazole at a dose of 180 mg/kg bw/day for 14 days followed by 1 day administration of T-labelled mefentrifluconazole at a dose of 180 mg/kg bw were performed. For the metabolism study with the T-label, urine, feces, tissue and plasma samples were collected up to 168 hrs post-dosing (single high dose) or at 1 hr (single low and high doses).</p>
	<p>Absorption: Mefentrifluconazole was extensively absorbed from the gastrointestinal tract after oral administration to rats regardless of the label position tested (~82% of the administered dose [AD]). From the bile excretion data, an oral single low dose was well-absorbed in both sexes. Absorption was slightly lower with an oral single high dose (~68% of the AD); suggesting a saturation of the absorption at the high dose. The time required to reach the plasma peak concentration occurred 1 to 5 hrs post-dosing with the C-label and 1 hr post-dosing with the T-label at the single low or high dose levels. A second plasma peak concentration occurred at 8 or 24 hrs at the single mid-high (females) and high (both sexes) dose levels with the T-label. Such peaks were not observed with the other labels in the rat, but multiple peaks were observed in the mouse using the same T-label suggesting an enterohepatic recirculation of the triazole moiety. The plasma kinetic data showed that internal exposure of male rats to radiolabelled test compound, as reflected by the area under curve (AUC), was greater than the internal exposure observed in female rats.</p> <p>Distribution: Oral gavage studies with the C- and T-labels in the rat showed that radioactivity was distributed to all organs and tissues with the highest levels being found in liver (up to 7.3% of the AD), plasma, adrenal glands and kidneys (all at less than 1% of the AD). Radioactivity progressively decreased in organs and tissues in parallel to the radioactive residues in plasma at the low and high dose levels.</p> <p>Elimination: The test substance was eliminated predominantly via the feces (70-90% of the AD) following oral gavage administration for all three label positions. Bile duct cannulation studies showed that a significant amount of radioactivity was excreted via the bile (34-76% of the AD) with all labels. Urinary excretion was comparable at all doses and labels tested with the exception of the T-labelled compound, for which urinary elimination was slightly increased. Specifically, a higher urinary elimination was observed in male compared to female animals with at the low-dose level (41% versus 15% of the AD). The elimination of C- and TFMP-labels showed similar time-course patterns at all doses tested in both sexes. Exhalation accounted for the elimination of less than 2% of the AD. At a high-dose level, repeated oral administration of the T-labelled mefentrifluconazole showed only slightly increased amounts of radioactivity excreted via urine compared to single oral administration (+ 6% of the AD). The urinary elimination in the groups administered a repeated high-dose level using the other radiolabels was comparable to the single high-dose group. There was no evidence of tissue retention 3 days post-dosing for any dosing regimen.</p> <p>Metabolism: Mefentrifluconazole was extensively metabolized with more than 60 metabolites identified in rats. The isomeric ratio remained stable in feces at both dose levels. In the liver, kidney and plasma, a shift of the S- versus R-enantiomer ratio towards lower relative amounts</p>

Study Type/Animal/PMRA #	Study Results
	<p>of the S-enantiomer was observed (1:4). The metabolic reactions included phase I conversion of mefentrifluconazole via hydroxylation (mono, di- and tri-), chlorine shift, methylation, and cleavage of the ether group or of the triazole ring from mefentrifluconazole. These were followed by phase II reactions including sulfation, glucuronidation and /or glutathione adduction with corresponding decomposition products.</p> <p>In urine, the overall metabolic profile was comparable for all radiolabels in both sexes and consisted mostly of glucuronide and sulphate conjugates of hydroxylated phase I compounds. Unchanged mefentrifluconazole was not detected in urine samples. With the C-labelled compound, M750F049 and M750F023 were the major urinary metabolites detected (up to 2.6% of the AD). All other metabolites were detected at less than 1.1% of the AD in all dose regimens. Female animals presented a more diversified metabolite profile compared to male animals (12 metabolites in males versus 17 in females). For the TFMP-label (single high oral dose), the major urinary metabolites in both sexes were M750F071, M750F054 and M750F049 / M750F003 (up to 6.7% of the AD). For the T-labelled compound (all dose regimens), the major urinary metabolite was M750F001 (up to 20% of the AD).</p> <p>In feces, unchanged mefentrifluconazole and cleaved mefentrifluconazole-hydroxylated compounds were identified. All tested dose levels and labels showed a comparable metabolite pattern with M750F015 (up to 41% of the AD), M750F016/M750F017 (up to 32% of the AD) and unchanged mefentrifluconazole (up to 35% of the AD) as the major fecal components. Unchanged mefentrifluconazole was the most abundant component for the T-label except at the low-dose level in both sexes. For the C- and TFMP-labels, M750F015 and/or M750F016/ M750F017 (up to 41% of the AD) were usually more abundant than unchanged mefentrifluconazole. The metabolic profiles in both sexes and for all labels were not remarkably different in feces. In bile, metabolites M750F035, M750F044, M750F045, M750F049 (including isomers) and M750F087 were identified as the major radiolabelled residues for all tested labels (up to 53% of the AD). An exception occurred in males at the high dose level with TFMP-label and males (low- and high-dose) and females (low-dose) with the T-label, where they were not detected. These metabolites were mefentrifluconazole-hydroxylated products, which were then glucuronidated. In tissues and plasma, most of the metabolites detected were hydroxylated mefentrifluconazole or unchanged mefentrifluconazole.</p> <p>Note on the enantiomer ratio of mefentrifluconazole: The relative amounts of the isomers were 1:1 in the test material and remained at 1:1 in the fecal extracts. In feces, at the single low dose level (T-label) during the 0-24 hour time interval, the S- versus R-enantiomer ratio was 46:54. At the high dose level and up to 72 hours, the ratio was 1:1. In the liver and kidney extracts as well as in plasma, the S- versus R-enantiomer ratio shifted towards a higher relative amount of the R-enantiomer (1:4).</p>
Metabolism/ Toxicokinetics in Mammals (oral, gavage, supplemental)	Mefentrifluconazole, labelled at the triazole moiety (T-label) was administered to mice. Blood samples were taken at 0, 0.5, 1, 3, (or 2, 4), 8, 24, 72, 96, 120, 144 and 168 h after test substance administration. After administration of the test substance in single doses of 10, 50 or 75 mg/kg bw

Study Type/Animal/PMRA #	Study Results
Mouse, C57BL/6 PMRA #2789567	<p>C_{max} showed a sublinear dose-response relationship. At the high dose, multiple peak values were observed: 24.80, 26.02 and 26.85 $\mu\text{g Eq/g}$ at sampling time points of 0.5, 3 and 8 h post dosing for ♂ animals. In ♀ animals peaks values were 21.48 and 26.62 $\mu\text{g Eq/g}$ at sampling time points of 0.5 and 8 h post dosing. At the mid dose, C_{max} value was 19.78 $\mu\text{g Eq/g}$ with another peak at 19.18 $\mu\text{g Eq/g}$ for ♂ at 1 and 8 hrs, respectively. In ♀ animals, C_{max} was 17.24 $\mu\text{g Eq/g}$ and occurred at 8 h post dosing. At the low dose, C_{max} values were 5.66 $\mu\text{g Eq/g}$ in ♂ animals and occurred 8 h post dosing whereas in ♀ a first peak of 3.98 $\mu\text{g Eq/g}$ was observed at 1 h and C_{max} values of 5.31 $\mu\text{g Eq/g}$ was observed at 4 h post dosing. The observation of more than one peak value indicated a potential enterohepatic recirculation of the test substance and/or metabolites.</p> <p>A comparable time course for radioactivity concentration was observed in blood as well as in plasma in both sexes with the tendency to slightly higher blood to plasma ratios at later sampling time points, indicating that parts of the test substance and/or its metabolites may be bound to blood constituents.</p> <p>The systemic exposure, as measured by the area under curve ($AUC_{0-\infty}$) were 151, 694 and 958 for ♂ and 127, 478 and 1012 $\mu\text{g Eq} \times \text{hr/g}$ for ♀ at doses of 10, 50 and 75 mg/kg bw, respectively. The internal dose was generally correlated with the oral dose administered.</p>
Metabolism/ Toxicokinetics in Mammals (in vitro, supplemental) Mouse, C57BL/6, hepatocytes Rats, Wistar, hepatocytes Human, hepatocytes PMRA #2841412	<p>2×10^6 hepatocytes/mL (human, rat or mouse) tested with mefentrifluconazole at 1 μM in incubation medium and incubated for 10, 30, 60 or 180 min.</p> <p>In mouse hepatocytes, no significant biotransformation of mefentrifluconazole was observed over a 180-minute period. In human hepatocytes, a peak occurred at the 180-minute time point comprising up to 21% of the AD. The same peak was observed in rat hepatocytes at each time point and comprised up to 43% of the AD at 180 minutes. This showed that in vitro biotransformation of mefentrifluconazole in mouse hepatocytes was absent or slower than in human hepatocytes and much slower than in rat hepatocytes (rat >> human > mouse). No unique human metabolite was observed.</p>
Acute Toxicity Studies	
Acute Oral, Acute Toxic Class Assay Rat, Wistar PMRA #2789573	<p>$LD_{50} \text{♀} > 2000 \text{ mg/kg bw}$</p> <p>Low toxicity</p>

Study Type/Animal/PMRA #	Study Results
Acute Dermal Rat, Wistar PMRA #2789574	LD ₅₀ ♂/♀ > 5000 mg/kg bw Low toxicity
Acute Inhalation, nose-only Rat, Wistar PMRA #2789575	LC ₅₀ ♂/♀ > 5.3 mg/L Low toxicity
Primary Skin Irritation Rabbit, NZW PMRA #2789576	MAS = 0/8, MIS = 0/8 Non-irritating
Primary Eye Irritation Rabbit, NZW PMRA #2789577	MAS _{at 24, 48 and 72 hrs} = 0.9/110 MIS _{at 1 hr} = 3.3/110 Minimally irritating
Dermal Sensitization (Maximization assay) Guinea pig, Dunkin Hartley PMRA #2789578	Positive Potential dermal sensitizer
Short-Term Toxicity Studies	
28-Day Oral Toxicity (diet) Mouse, C57BL/6 PMRA #2789579	NOAEL= 4.8/19 mg/kg bw/day ♂/♀ LOAEL= 16/61 mg/kg bw/day ♂/♀ Effects at the LOAEL: ↑ monocyte counts, ↓ cholesterol, ↓ TG, ↑ liver wt; slight centrilobular hepatocellular hypertrophy, ↑ ALP, ↓ bilirubin (♂); slight to moderate diffuse hepatocellular hypertrophy, ↑ thymus wt (♀)
90-Day Oral Toxicity (diet) Mouse, C57BL/6 PMRA #2789582	NOAEL= 11/15 mg/kg bw/day ♂/♀ LOAEL= 58/67 mg/kg bw/day ♂/♀

Study Type/Animal/PMRA #	Study Results
	Effects at the LOAEL: ↑ liver wt, centrilobular or diffuse hepatocellular hypertrophy, ↓ cholesterol, ↓ kidney wt, ↑ WBC (lymphocytes, monocytes, eosinophils, basophils), ↓ total protein, ↓ albumin, ↓ total globulin; minimal liver cell necrosis, minimal cytoplasmic alteration (hyaline globules/vacuoles), ↑ HB, HCT, MCH, RBC and platelet counts (hemoconcentration) (♂); ↑ liver fatty change, ↓ albumin/globulin ratio (♀)
28-Day Oral Toxicity (diet) Rat, Wistar PMRA #2789581	NOAEL= 135/138 mg/kg bw/day ♂/♀ LOAEL= 388/334 mg/kg bw/day ♂/♀ Effects at the LOAEL: ↓ bw, ↓ bwg, ↑ minimal centrilobular hepatocyte hypertrophy; ↓ abs kidney wt (♂); ↓ fc, ↑ liver wt, ↑ GGT, ↑ cholesterol, ↓ albumin, ↓ total bilirubin (♀)
90-Day Oral Toxicity (diet) Rat, Wistar PMRA #2789583	NOAEL= 76/91 mg/kg bw/day ♂/♀ LOAEL= 256/314 mg/kg bw/day ♂/♀ Effects at the LOAEL: ↓ bw, ↓ bwg, ↑ ALP, ↑ rel liver wt, ↑ minimal centrilobular hepatocellular hypertrophy, ↑ urea, ↓ glucose; ↑ cholesterol, ↓ albumin, ↓ total protein, ↑ GGT, minimal multifocal hepatocellular necrosis in 1 ♀ (♀) No evidence of treatment-related adverse effects in Functional Observational Battery or Motor Activity assessments
28-Day Oral Toxicity (capsule) Dog, Beagle PMRA #2789580	Supplemental Treatment was interrupted 24 to 48 hrs post-dosing due to severe clinical signs in males and females and then continued on Day 7/Day 3 in ♂/♀ at lower dose levels ≥ 300 mg/kg bw/day: severe clinical signs in all dogs including vomitus, impaired general condition, unsteady gait and reduced food intake (Days 0-1/Day 0 in ♂/♀) ≥ 125 (reduced from 300) mg/kg bw/day from Day 7/3 in ♂/♀: ↓ terminal bw, ↑ liver wt, minimal to slight centrilobular hepatocellular hypertrophy and eosinophilic change, ↓ cholesterol; 1 ♂ with vomiting on 3 of 28 days, ↓ bwg (♂); ↓ fc in 1 animal (♀) 250 (reduced from 1000 /500 ♂/♀) mg/kg bw/day from Day 7/3 in ♂/♀: ↓ fc, isolated vomiting, single occurrence of unsteady gait and poor general condition; ↓ TG (♂); ↑ AST and ALT (1 animal) (♀)
90-Day Oral Toxicity (capsule)	NOAEL= 15/90 mg/kg bw/day ♂/♀ LOAEL= 90/180 mg/kg bw/day ♂/♀

Study Type/Animal/PMRA #	Study Results
Dog, Beagle PMRA #2789584	Effects at the LOAEL: ↑ ALP, ↑ liver wt, minimal centrilobular hepatocellular hypertrophy and eosinophilic change; ↓ bw, ↓ bwg, vomiting and delayed fc, ↓ total protein, ↓ fc, ↑ kidney wt (♀)
12-Month Oral Toxicity (capsule) Dog, Beagle PMRA #2789585	NOAEL= 30 mg/kg bw/day ♂/♀ LOAEL= 150 mg/kg bw/day ♂/♀ Effects at the LOAEL: ↓ bw, ↓ bwg, ↑ liver wt, minimal to slight centrilobular hepatocellular or diffuse hepatocellular hypertrophy and minimal eosinophilic change, ↑ ALP; ↑ incidence of minimal to moderate liver subcapsular fibrosis (♂); ↓ cholesterol, ↑ rel kidney wt, ↓ kidney vacuolation, minimal kidney tubular dilation, minimal kidney lymphoid infiltration (♀)
28-Day Dermal Toxicity Rat, Wistar PMRA #2789587	NOAEL= 1000 mg/kg bw/day LOAEL not observed No adverse effects at the highest dose tested including Functional Observational Battery or Motor Activity assessments
90-Day Inhalation Toxicity Waiver Request PMRA #2789586	Granted on the basis of physical-chemical properties and overall toxicity profile
Chronic Toxicity/Oncogenicity Studies	
18-Month Oncogenicity (diet) Mouse, C57BL/6 PMRA #2789596	NOAEL= 3.5/4.9 mg/kg bw/day ♂/♀ LOAEL= 9.1/13 mg/kg bw/day ♂/♀ Effects at the LOAEL: ↑ liver wt, ↑ incidence of minimal to marked hepatocellular fatty change (diffuse and macrovesicular), ↓ abs kidney wt, ↓ kidney tubular vacuolation (♂); ↓ bw, ↓ bwg (♀) No evidence of oncogenicity
24-Month Chronic/Toxicity Oncogenicity (diet) Rat, Wistar PMRA #2789595	NOAEL= 25/38 mg/kg bw/day ♂/♀ LOAEL= 163/302 mg/kg bw/day ♂/♀ Effects at the LOAEL: ↓ bw, ↓ bwg, ↑ rel liver wt, minimal to slight centrilobular hepatocellular hypertrophy, (↓ aPTT, ↑ ALP, ↑ urea, ↑ cholesterol, ↓ glucose at 52 wks); ↓ PLT at 52 wks (♂); (↓ albumin, ↓ globulin, ↓ total protein at 52 wks) (♀) No evidence of oncogenicity

Study Type/Animal/PMRA #	Study Results
Developmental/Reproductive Toxicity Studies	
<p>2-Generation Reproductive Toxicity (diet)</p> <p>Rat, Wistar</p> <p>PMRA #2789597</p>	<p>Parental toxicity NOAEL= 72/73 mg/kg bw/day ♂/♀ LOAEL= 191/194 mg/kg bw/day ♂/♀</p> <p>Effects at the LOAEL: ↓ bw (pre-mating, mating and post-mating, F0♂ and F1♂♀; at gestation; at lactation), ↓ bwg (pre-mating, F0♂ and F1♂♀; F0 gestation), ↑ rel liver wt (F0 and F1), ↑ ALP (F1); ↑ minimal centrilobular hepatocellular hypertrophy (F0 and F1), ↑ cholesterol (♂); ↓ fc (F0 lactation and F1 gestation), ↑ abs liver wt, ↑ GGT, ↑ TG (♀)</p> <p>Offspring toxicity NOAEL= 73 mg/kg bw/day ♀ LOAEL= 194 mg/kg bw/day ♀</p> <p>Effects at the LOAEL: ↓ bw (F1 and F2), ↓ bwg (F1 and F2); ↑ incidence of renal pelvis dilation (F2) (♀)</p> <p>Reproductive toxicity NOAEL= 72/73 mg/kg bw/day ♂/♀ LOAEL= 192/193 mg/kg bw/day ♂/♀</p> <p>Effects at the LOAEL: ↓ number implantation sites (F1), ↓ number of pup delivered per dam (F1), ↓ gestation index of all dams (F1)</p> <p>No evidence of sensitivity of the young</p>
<p>Developmental Toxicity (gavage)</p> <p>Rat, Wistar</p> <p>PMRA #2789598</p>	<p>Maternal NOAEL= 150 mg/kg bw/day LOAEL= 400 mg/kg bw/day</p> <p>Effects at the LOAEL: ↓ bw (GD 19-20), ↓ bwg (GD 6-19), ↓ corrected bwg, ↓ fc</p> <p>Developmental NOAEL= 150 mg/kg bw/day LOAEL= 400 mg/kg bw/day</p> <p>Effects at the LOAEL: ↑ incidence of renal pelvis dilation; ↓ fetal wt (♀)</p> <p>No evidence of treatment-related malformations</p> <p>No evidence of sensitivity of the young</p>

Study Type/Animal/PMRA #	Study Results
<p>Developmental Toxicity (gavage), Dose Range-Finding Study</p> <p>Non-pregnant Rabbit, NZW dosed for 21 days</p> <p>PMRA #2789599</p>	<p>Supplemental</p> <p>25 mg/kg bw/day: 1 animal with ↓ bw, ↓ bwg, ↓ fc, sacrificed moribund on day 17 (reduced or no feces, empty small and large intestine, and rectum)</p> <p>50 mg/kg bw/day: ↓ bw, ↓ bwg, ↓ fc, 2/3 does sacrificed moribund on days 14 and 20 (reduced nutritional condition, no or reduced feces, lateral position)</p> <p>≥150 mg/kg bw/day: ↓ bw, ↓ bwg, ↓ fc, all animals were sacrificed moribund on days 2 to 4 with earlier and more severe signs than at lower dose (reduced nutritional condition, no or reduced feces, lateral position)</p> <p>400 mg/kg bw/day: 1 animal found dead on day 2</p>
<p>Developmental Toxicity (gavage)</p> <p>Rabbit, NZW</p> <p>PMRA #2789599</p>	<p>Maternal NOAEL= 25 mg/kg bw/day LOAEL not observed</p> <p>No treatment-related adverse effects at the highest dose tested</p> <p>Developmental NOAEL= 25 mg/kg bw/day LOAEL not observed</p> <p>No treatment-related adverse effects at the highest dose tested</p> <p>No evidence of treatment-related malformations</p> <p>No evidence of sensitivity of the young</p>
Genotoxicity Studies	
<p>In Vitro Reverse Mutation Assay in Bacteria</p> <p><i>S. Typhimurium</i> Strains TA 1535, TA 1537, TA 98, TA 100</p> <p><i>E. Coli</i> Strain WP2 uvrA</p> <p>PMRA #2789588</p>	<p>Negative ± metabolic activation</p> <p>Tested up to a limit concentration</p>
<p>In Vitro Reverse Mutation Assay in Bacteria</p> <p><i>S. Typhimurium</i> Stains TA</p>	<p>Negative ± metabolic activation</p> <p>Tested up to a limit concentration</p>

Study Type/Animal/PMRA #	Study Results
1535, TA 1537, TA 98, TA 100 E. Coli Strain WP2 uvrA PMRA #2789589	
In Vitro Forward Mutation Assay in Mammalian Cells Mouse Lymphoma L5178Y Cells PMRA #2789593	Negative ± metabolic activation Tested up to a cytotoxic concentration
In vitro Forward Mutation Assay in Mammalian Cells Mouse Lymphoma L5178Y Cells PMRA #2789590	Negative ± metabolic activation Tested up to a cytotoxic concentration
In Vitro Cytogenicity Assay in Mammalian Cells (Micronucleus test) Hamster, V79 Chinese Lung Fibroblast Cells PMRA #2789591	Negative ± metabolic activation Tested up to a cytotoxic concentration
In vitro Cytogenicity Assay in Mammalian Cells (Micronucleus test) Human Lymphocytes PMRA #2789592	Negative ± metabolic activation Tested up to a cytotoxic concentration
In Vivo Cytogenicity Assay in Mammalian Cells (Micronucleus Test) Mouse, NMRI PMRA #2789594	Negative
Neurotoxicity Studies	
Acute Neurotoxicity (gavage)	NOAEL= 200 mg/kg bw LOAEL= 600 mg/kg bw

Study Type/Animal/PMRA #	Study Results
Rat, Wistar PMRA #2854736	Effects at the LOAEL: ↓ motor activity on day of dosing; ↑ landing foot splay on day of dosing (♂) No evidence of selective neurotoxicity
Other/Metabolite Studies	
MF750F022 (Poultry Metabolite)	
Acute Oral, Acute Toxic Class Assay MF750F022 Rat, Wistar PMRA #2789608	LD ₅₀ ♀ > 2000 mg/kg bw Low toxicity
28-Day Oral Toxicity (diet) MF750F022 Mouse, C57BL/6 PMRA #2789617	NOAEL= 20/249 mg/kg bw/day ♂/♀ LOAEL= 180/718 mg/kg bw/day ♂/♀ Effects at the LOAEL: hepatocellular hypertrophy and necrosis; ↑ rel liver wt, decreased liver fat storage, ↓ TG (♂); ↓ bw, ↓ bwg, ↑ ALP, dark discoloration of liver with fine granular eosinophilic cytoplasm, ↑ abs liver wt (♀)
In Vitro Reverse Mutation Assay in Bacteria MF750F022 <i>S. Typhimurium</i> Strains TA 1535, TA 1537, TA 98, TA 100 and E. Coli Strain WP2 uvrA PMRA #2789609	Negative ± metabolic activation Tested up to a limit concentration
In vitro Forward Mutation Assay in Mammalian Cells MF750F022 Mouse lymphoma L5178Y cells PMRA #2789607	Negative ± metabolic activation Tested up to a cytotoxic concentration
In vitro Cytogenicity Assay in Mammalian Cells (Micronucleus test)	Negative ± metabolic activation Tested up to a cytotoxic concentration

Study Type/Animal/PMRA #	Study Results
Human Lymphocytes MF750F022 PMRA #2789602	
QSAR: Derek Nexus Report MF750F022 PMRA #2789603	No new alerts were triggered for the following endpoints: Carcinogenicity, Genotoxicity, Irritation, Miscellaneous Endpoints, Neurotoxicity, Organ Toxicity, Reproductive Toxicity, Respiratory Sensitisation, Skin Sensitisation.
M750F037	
Acute Oral, Acute Toxic Class Assay M750F037 Rat, Wistar PMRA #2789614	LD ₅₀ ♀ > 5000 mg/kg bw Low toxicity
In Vitro Reverse Mutation Assay in Bacteria M750F037 <i>S. Typhimurium</i> Strains TA 1535, TA 1537, TA 98, TA 100 and <i>E. Coli</i> Strain WP2 uvrA PMRA #2789612	Negative ± metabolic activation Tested up to a limit concentration
QSAR: Derek Nexus Report M750F037 PMRA #2789604	No new alerts were triggered for the following endpoints: Carcinogenicity, Genotoxicity, Irritation, Miscellaneous Endpoints, Neurotoxicity, Organ Toxicity, Reproductive Toxicity, Respiratory Sensitisation, Skin Sensitisation.
M750F006	
Acute Oral, Acute Toxic Class Assay M750F006	LD ₅₀ ♀ > 500 mg/kg bw Moderate toxicity

Study Type/Animal/PMRA #	Study Results
Rat, Wistar PMRA #2789618	
In Vitro Reverse Mutation Assay in Bacteria M750F006 <i>S. Typhimurium</i> Strains TA 1535, TA 1537, TA 98, TA 100 and E. Coli Strain WP2 uvrA PMRA #2789610	Negative ± metabolic activation Tested up to a cytotoxic concentration and/or test substance precipitation
QSAR: Derek Nexus Report M750F006 PMRA #2789605	No new alerts were triggered for the following endpoints: Carcinogenicity, Genotoxicity, Irritation, Miscellaneous Endpoints, Neurotoxicity, Organ Toxicity, Reproductive Toxicity, Respiratory Sensitisation, Skin Sensitisation.
M750F002	
Acute Oral, Acute Toxic Class Assay M750F002 Rat, Wistar PMRA #2789613	LD ₅₀ ♀ > 5000 mg/kg bw Low toxicity
In Vitro Reverse Mutation Assay in Bacteria M750F002 <i>S. Typhimurium</i> Strains TA 1535, TA 1537, TA 98, TA 100 and E. Coli Strain WP2 uvrA PMRA #2789611	Negative ± metabolic activation Tested up to a cytotoxic or limit concentration
QSAR: Derek Nexus Report M750F002	No new alerts were triggered for the following endpoints: Carcinogenicity, Genotoxicity, Irritation, Miscellaneous Endpoints, Neurotoxicity, Organ Toxicity, Reproductive Toxicity, Respiratory Sensitisation, Skin Sensitisation.

Study Type/Animal/PMRA #	Study Results
PMRA #2789606	
M750F036	
Acute Oral, Acute Toxic Class Assay	LD ₅₀ ♀ > 2000 mg/kg bw
M750F036	Low toxicity
Rat, Wistar	
PMRA #2789616	
In Vitro Reverse Mutation Assay in Bacteria	Negative ± metabolic activation
M750F036	Tested up to a cytotoxic or limit concentration
<i>S. Typhimurium</i> Strains TA 1535, TA 1537, TA 98, TA 100 and <i>E. Coli</i> Strain WP2 uvrA	
PMRA #2789615	

Table 7 Toxicology Reference Values for Use in Health Risk Assessment for Mefentrifluconazole

Exposure Scenario	Study	Point of Departure and Endpoint	CAF ¹ or Target MOE
Acute dietary	Acute neurotoxicity in rat (gavage)	NOAEL= 200 mg/kg bw Decreased motor activity in both sexes and increased foot splay in males on day of dosing	100
	ARfD = 2.0 mg/kg bw		
Repeated dietary	Oncogenicity in mouse (diet)	NOAEL= 3.5 mg/kg bw/day Liver and kidney effects	100
	ADI = 0.04 mg/kg bw/day		
Short- and Intermediate-term dermal ²	90-Day toxicity in mouse (diet)	NOAEL= 11 mg/kg bw/day Liver toxicity	100
Short- and Intermediate-term inhalation ³	90-Day toxicity in mouse (diet)	NOAEL= 11 mg/kg bw/day Liver toxicity	100

Exposure Scenario	Study	Point of Departure and Endpoint	CAF ¹ or Target MOE
Aggregate dermal ² and oral routes (short- to intermediate-term)	90-Day toxicity in mouse (diet)	Common endpoint: Liver toxicity NOAEL= 11 mg/kg bw/day	100
Cancer	There was no evidence of oncogenic potential of mefentrifluconazole in rodents		

¹ CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary assessments; MOE refers to a target MOE for occupational and residential assessments

² Since an oral NOAEL was selected, a dermal absorption factor of 16% was used in 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 8 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference (PMRA #)
Plant	D1511/01 [Data gathering]	Mefentrifluconazole [BAS 750 F]	LC-MS/MS	0.01 ppm	Validated in grape, apple, wheat grain, dried bean seed, canola seed.	2789544 2789547
	L0295/01, based on QuEChERS [Enforcement]	Mefentrifluconazole [BAS 750 F]	LC-MS/MS	0.01 ppm	Validated in tomato, orange, dry bean seeds, wheat grain and dry soybean seeds.	2789550 2789541 2789552
Animal	L0272/01 [Data gathering; enforcement]	Mefentrifluconazole [BAS 750 F]	LC-MS/MS	0.01 ppm	Validated in bovine muscle, liver, kidney, fat, milk and cream; and egg.	2789549 2789546 2789542
	L0309/01 [Data gathering]	Diol metabolite [M750F022]	GC-MS	0.01 ppm	Validated in bovine muscle, liver, kidney, fat and milk; and egg.	2789548 2789546 2789543
	L0309/02 [Data gathering]	Diol metabolite [M750F022], including its fatty acid conjugates [M750F025]	GC-MS	0.01 ppm	Validated in poultry fat, liver, muscle and egg.	2789645
	D1704/01, based on QuEChERS [Data gathering]	Mefentrifluconazole	LC-MS/MS	0.01 ppm	Validated in bovine liver, kidney, muscle, fat, milk and egg.	2789545 2789546
Soil / Sediment	D1513/01	active	HPLC-MS/MS	2 µg /kg		2789555 2789554
		M750F003		2 µg /kg		
		1,2,4-triazole		2 µg /kg		
Water	L0359/01	active	HPLC-MS/MS	0.03 µg/L		2789559 2789557
		M750F003		0.03 µg/L		
		M750F005		0.03 µg/L		
		M750F006		0.03 µg/L		
		M750F007		0.03 µg/L		
		M750F008		0.03 µg/L		

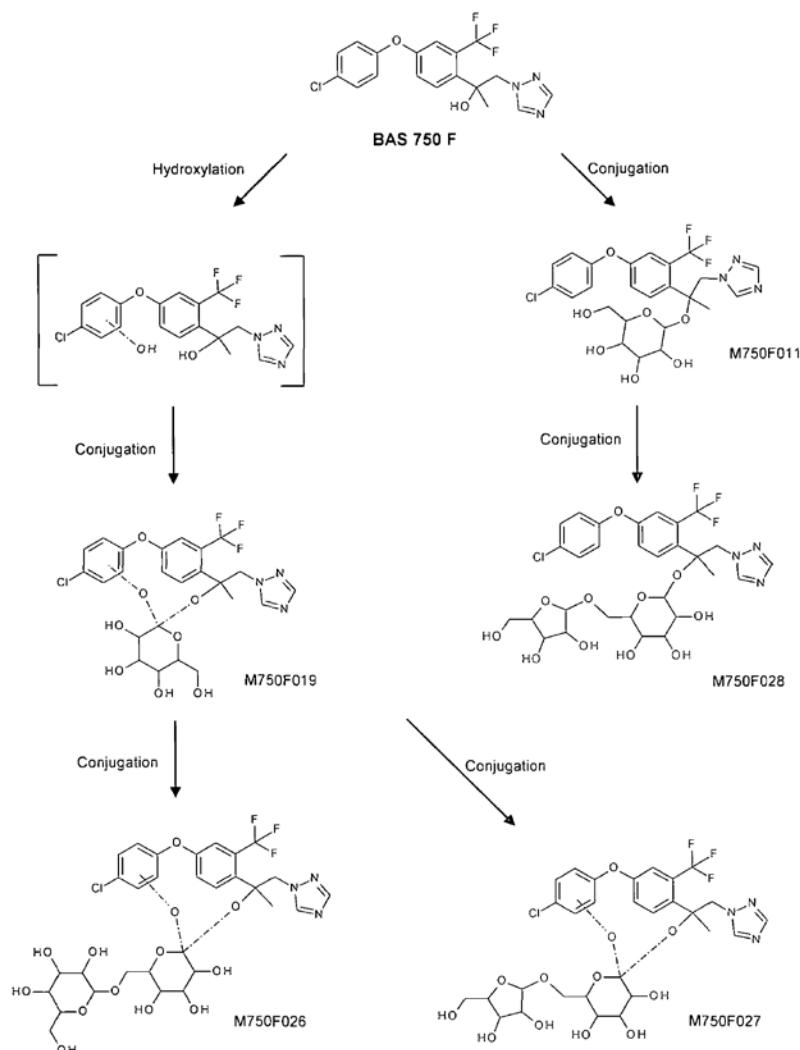
Matrix	Method ID	Analyte	Method Type	LOQ	Reference (PMRA #)
	D1605/01	M750F002		0.03 µg/L	2789558
		M750F036		0.03 µg/L	2789556
		M750F037		0.03 µg/L	
	L0199/01	1,2,4-triazole		0.05 µg/L	2789560

Table 9 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN GRAPE				PMRA # 2789630	
Radiolabel Position	Chlorophenyl label (C-label): 1: 1 mixture of [14C-U-chlorophenyl]-mefentrifluconazole and [13C-1-chlorophenyl]-mefentrifluconazole. Triazole label (T-label): 2:1 mixture of [14C-3(5)-triazole]-mefentrifluconazole and [C13-3(5)-triazole]-mefentrifluconazole.				
Test Site	Grape plants were cultivated in outdoor test plots.				
Treatment	Three foliar spray applications were made with either formulated C- or T-labelled mefentrifluconazole.				
Total Rate	C-label: 1st at 151.6 g a.i./ha, 2nd at 150.1 g a.i./ha and the 3rd at 150.1 g a.i./ha for a total of 451.8 g a.i./ha. T-label: 1st at 153.2 g a.i./ha, 2nd at 151.7 g a.i./ha and 3rd at 151.7 g a.i./ha, for a total of 465.5 g a.i./ha.				
Formulation	The type of formulation used was not specified.				
Matrices	PHI (days)	C-label TRRs (ppm)		T-label TRRs (ppm)	
		Measured	Calculated	Measured	Calculated
Leaf	12	8.860	7.371	7.245	7.312
Stalk	12	0.674	0.648	1.214	1.136
Grape	12	0.435	0.349	0.400	0.428
The TRRs were determined directly by combustion/LSC analysis, and indirectly as the sum of the extractable and non-extractable radioactive residues.					
Metabolites Identified	Major Metabolites (>10% of the TRRs)				
Radiolabel Position	C-label			T-label	
Leaf	Mefentrifluconazole; M750F019			Mefentrifluconazole; M750F019	
Stalk	Mefentrifluconazole			Mefentrifluconazole	
Grape	Mefentrifluconazole			mefentrifluconazole	
Radioactive residues were identified by HPLC-MS as well as by HPLC retention time comparisons with standards. Enantiomer-specific HPLC analyses for mefentrifluconazole in the application solution as well as in samples of grape (C-label) and leaf (T-label) indicated that the racemic mixture (approximately 1:1 ratio of S-enantiomer and R-enantiomer) of the application formulation was maintained.					
Proposed Metabolic Scheme in Grape					
In grape, mefentrifluconazole undergoes the following transformations:					

O-conjugation of the 2-hydroxy on the propyl chain in the unchanged mefentrifluconazole with sugars C-ring hydroxylation followed by sugar conjugation

There was no cleavage of the diphenyl ether, or of the propyl-triazole moiety.

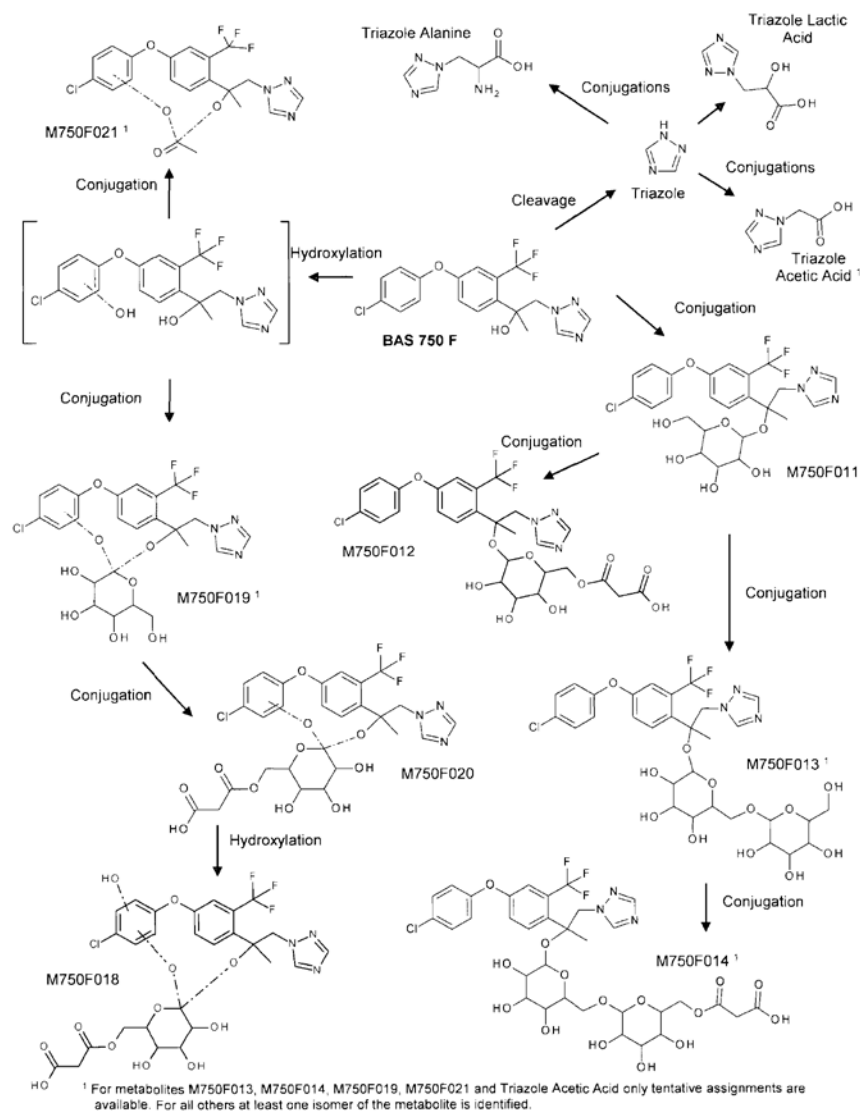


NATURE OF THE RESIDUE IN SOYBEAN	PMRA # 2789628
Radiolabel Position	<p>Chlorophenyl label (C-label): 1: 1 mixture of [14C-U-chlorophenyl]-mefentrifluconazole and [13C-1-chlorophenyl]-mefentrifluconazole.</p> <p>Triazole label (T-label): 2:1 mixture of [14C-3(5)-triazole]-mefentrifluconazole and [C13-3(5)-triazole]-mefentrifluconazole.</p>
Test Site	<p>Soybean plants were cultivated in containers with sandy loam soil. The containers were initially located in a vegetation hall with a glass roof, and after treatment with the test formulation, the containers were transferred to climatic chambers (phytotrons).</p>

Treatment	Three foliar spray applications were made with either formulated C- or T-labelled mefentrifluconazole. The growth stages at the 1st, 2nd and 3rd applications corresponding to BBCH 60, BBCH 72 and BBCH 77, respectively.				
Total Rate	C-label: 1st at 128.4 g a.i./ha, 2nd at 127.6 g a.i./ha and the 3rd at 127.5 g a.i./ha for a total of 383.5 g a.i./ha. T-label: 1st at 127.0 g a.i./ha, 2nd at 127.1 g a.i./ha and 3rd at 126.6 g a.i./ha, for a total of 380.7 g a.i./ha.				
Formulation	The type of formulation used was not specified.				
Matrices	PHI1 (days)	C-label TRRs (ppm)		T-label TRRs (ppm)	
		Measured	Calculated	Measured	Calculated
Forage	19	6.516	6.575	4.416	4.609
Rest-of-plant	47-48	16.016	16.459	19.934	19.264
Hull	47-48	3.735	3.838	3.890	4.122
Green pod	47-48	8.857	8.721	16.005	16.006
Seed	47-48	0.109	0.129	2.592	3.063
1 Forage was harvested 19 days after the first application, all other matrices were harvested 47 days (C-label) or 48-days (T-label) after the last application. The TRRs were determined directly by combustion/LSC analysis, and indirectly as the sum of the extractable and non-extractable radioactive residues.					
Metabolites Identified	Major Metabolites (>10% of the TRRs)				
Radiolabel Position	C-label		T-label		
Forage	Mefentrifluconazole		Mefentrifluconazole		
Rest-of-plant	Mefentrifluconazole		Mefentrifluconazole		
Hull	Mefentrifluconazole		Mefentrifluconazole		
Green pod	Mefentrifluconazole		None		
Seed	None		M750F029 (TA)		
Radioactive residues were identified by HPLC-MS as well as by HPLC co-chromatography and comparison of retention times with components of the methanol extract of T-labelled straw from the wheat metabolism study (PMRA No. 2789629).					
Cleavage of mefentrifluconazole at the triazole-bridge leads to T (M750F001), TA (M750F029) and TLA (M750F031). These metabolites are part of the triazole-derived metabolites which are associated with azole fungicides (1,2,4-triazole = T; triazolylalanine = TA and triazole acetic acid = TAA).					
Enantiomer-specific HPLC analyses for mefentrifluconazole in the application solution as well as in samples from both radiolabels of forage, hull and rest of plant indicated that the racemic mixture (approximately 1:1 ratio of S-enantiomer and R-enantiomer) of the application formulation was maintained.					
Proposed Metabolic Scheme in Soybean					
Mefentrifluconazole undergoes metabolism in three major areas: O-conjugation of the unchanged mefentrifluconazole (at propyl-triazole moiety) with sugars; C-ring hydroxylation of mefentrifluconazole followed by conjugation with sugars; and					

T-bridge cleavage of mefentrifluconazole backbone (at the propyl backbone linking the trifluoromethylphenyl-ring and the T-ring).

There was no cleavage of the diphenyl ether, or hydroxylation of the trifluoromethylphenyl (TFMP) ring.



NATURE OF THE RESIDUE IN WHEAT

PMRA # 2789629

Radiolabel Position

Chlorophenyl label (C-label):

1: 1 mixture of [14C-U-chlorophenyl]-mefentrifluconazole and [13C-1-chlorophenyl]-mefentrifluconazole.

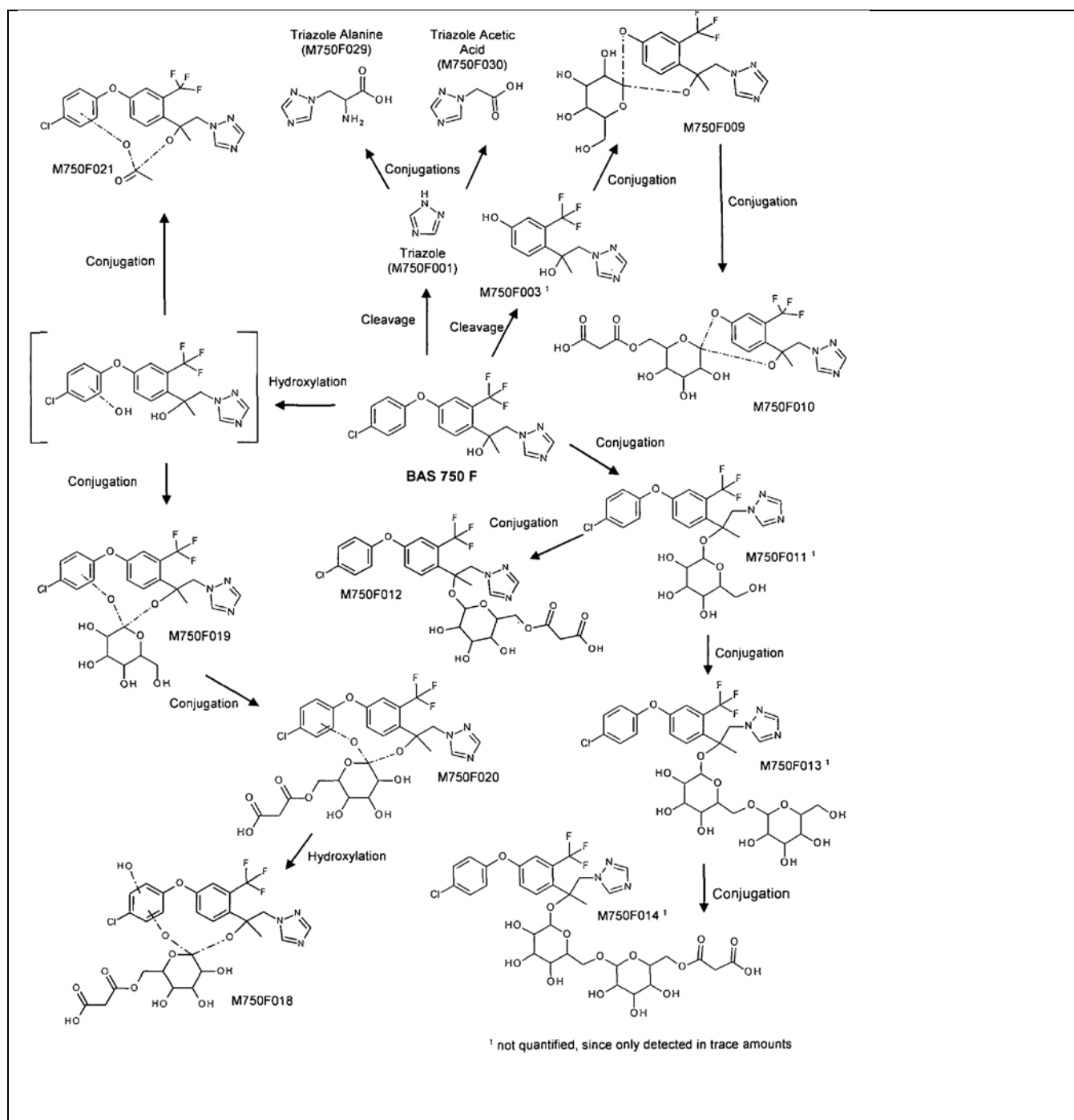
Triazole label (T-label):

2:1 mixture of [14C-3(5)-triazole]-mefentrifluconazole and [13C-3(5)-triazole]-mefentrifluconazole.

Test Site

Spring wheat plants were cultivated in containers with sandy loam soil.

	The containers were initially located in a vegetation hall with a glass roof and temporarily in a greenhouse. The plant uptake portion of the study was conducted in phytotrons.				
Treatment	Two foliar spray applications were made with either formulated C- or T-labelled mefentrifluconazole. The growth stages at the 1st and 2nd applications corresponding to BBCH 49 and BBCH 69, respectively.				
Total Rate	C-label: 1st at 151.8 g a.i./ha and the 2nd at 150.8 g a.i./ha, for a total of 302.6 g a.i./ha. T-label: 1st at 152.1 g a.i./ha and 2nd at 150.4 g a.i./ha, for a total of 302.5 g a.i./ha.				
Formulation	The type of formulation used was not specified.				
Matrices	PHI1 (days)	C-label TRRs (ppm)		T-label TRRs (ppm)	
		Measured	Calculated	Measured	Calculated
Forage	15	2.472	2.378	2.634	2.310
Grain	35	0.065	0.062	0.619	0.620
Straw	35	24.305	24.380	14.339	13.984
1 Forage was harvested 15 days after the first application, all other matrices were harvested 35 days after the last application. The TRRs were determined directly by combustion/LSC analysis, and indirectly as the sum of the extractable and non-extractable radioactive residues.					
Metabolites Identified	Major Metabolites (>10% of the TRRs)				
Radiolabel Position	C-label		T-label		
Forage	Mefentrifluconazole		Mefentrifluconazole		
Grain	None		M750F029 (TA); M750F030 (TAA)		
Straw	Mefentrifluconazole		Mefentrifluconazole		
Radioactive residues were identified by HPLC-MS as well as by HPLC co-chromatography and HPLC retention time comparisons with standards.					
Cleavage of mefentrifluconazole at the triazole-bridge leads to T (M750F001), TA (M750F029) and TLA (M750F031). These metabolites are part of the triazole-derived metabolites which are associated with azole fungicides (1,2,4-triazole = T; triazolylalanine = TA and triazole acetic acid = TAA).					
Enantiomer-specific HPLC analyses for mefentrifluconazole in the application solution as well as in samples from both radiolabels of forage and straw indicated that the racemic mixture (approximately 1:1 ratio of S-enantiomer and R-enantiomer) of the application formulation was maintained.					
Proposed Metabolic Pathway in Wheat					
Mefentrifluconazole undergoes the following transformations: O-conjugation of the 2-hydroxyl moiety on the propyl chain of mefentrifluconazole with sugars; C-ring hydroxylation, which can then be followed by sugar conjugation; Cleavage of the propyl group from the 1-position of the triazole ring of mefentrifluconazole; and Cleavage of the diphenyl ether (minor pathway).					



CONFINED ACCUMULATION IN ROTATIONAL CROPS –
Spinach, radish and wheat

PMRA # 2789658

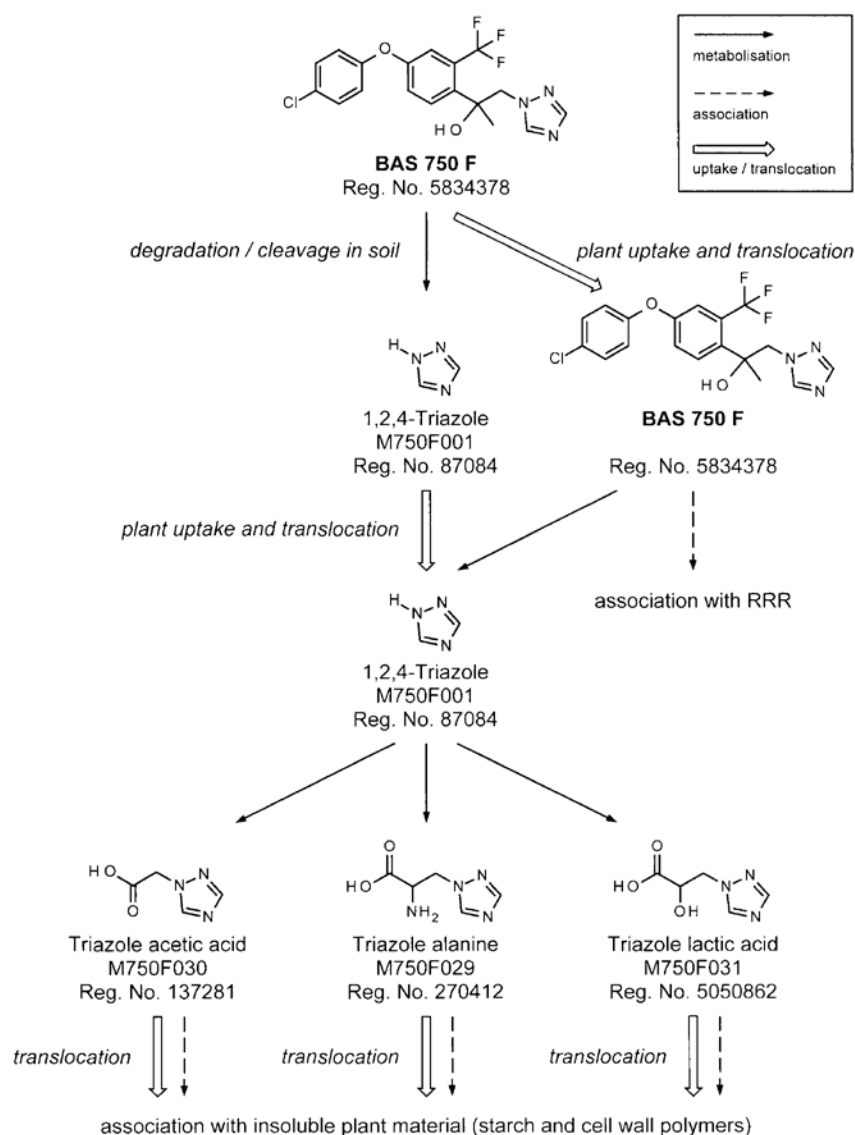
Radiolabel Position

Chlorophenyl label (C-label):
1: 1 mixture of [14C-U-chlorophenyl]-mefentrifluconazole and [13C-1-chlorophenyl]-mefentrifluconazole.
Triazole label (T-label):
2: 1 mixture of [14C-3(5)-triazole]-mefentrifluconazole and [13C-3(5)-triazole]-mefentrifluconazole.

Test site		The aging of the soil and the cultivation of the crop took place under natural climatic conditions in a glass roofed vegetation hall, in phytotrons or in the glass house.	
Formulation		Emulsifiable concentrate (EC)	
Application rate and timing		Bare sandy loam soil was treated at 300 g a.i./ha, and aged for 30/31, 120/122 and 364/365 days.	
Metabolites Identified		Major Metabolites (>10% of the TRRs)	
Matrices	PBI (days)	C-label	T-label
Spinach (immature)	30/31	Mefentrifluconazole	Mefentrifluconazole; T; TA
	120/122	Mefentrifluconazole	TA; TLA
	364/365	Sample not extracted	TA; TLA
Spinach (mature)	30/31	Mefentrifluconazole	Mefentrifluconazole; TA; TLA
	120/122	Mefentrifluconazole	T; TA; TLA
	364/365	Sample not extracted	TA; TLA
Radish top	30/31	Mefentrifluconazole	TA; TLA
	120/122	Sample not analyzed	TA
	364/365	Sample not extracted	TA; TLA
Radish root	30/31	Mefentrifluconazole	TA; TLA
	120/122	Sample not analyzed	TA; TLA
	364/365	Sample not extracted	TA; TLA
Wheat forage	30/31	Mefentrifluconazole	TA; TAA; TLA
	120/122	Mefentrifluconazole	TA; TLA
	364/365	Mefentrifluconazole	TA; TLA
Wheat hay	30/31	Mefentrifluconazole	TA; TAA; TLA
	120/122	Mefentrifluconazole	TA; TLA
	364/365	Mefentrifluconazole	TA; TAA; TLA
Wheat straw	30/31	Mefentrifluconazole	TA; TAA; TLA
	120/122	Mefentrifluconazole	TA; TAA; TLA
	364/365	Mefentrifluconazole	TA; TAA; TLA
Wheat grain	30/31	Mefentrifluconazole	T; TA; TAA; TLA
	120/122	Mefentrifluconazole	TA; TAA
	364/365	Mefentrifluconazole	TA; TAA
1,2,4-triazole = T; triazolyllalanine = TA and triazole acetic acid = TAA; triazole lactic acid = TLA			

Proposed Metabolic Pathway in Rotational Crops

In rotational crops cultivated on mefentrifluconazole treated soil, the residue includes mainly two components: mefentrifluconazole and the triazole-derived metabolites (TMDs). The TMDs are generated by cleavage of mefentrifluconazole at the 1-position of the triazole ring. This cleavage step can occur both in the plant or in the soil, followed by uptake of the cleavage products into the plant. In addition, a small proportion of the radioactive residues appear to be associated with insoluble plant cell constituents being released only after solubilization treatments. No components specific to rotational crops were detected.



NATURE OF THE RESIDUE IN LAYING HEN							PMRA # 2789631		
Thirty laying hens (10 animals per label) were dosed orally with mefentrifluconazole radiolabelled in either the chlorophenyl ring (C-label), trifluoromethylphenyl ring (TFMP-label) or in the triazole ring (T-label) by gelatin capsule once daily for fourteen consecutive days. The nominal dose was 12 ppm per dry weight diet per day. The actual mean doses were 16.74 ppm (C-label), 15.90 ppm (TFMP-label) and 14.98 ppm (T-label), corresponding to 1.09, 1.07 and 1.08 mg/kg body weight/day, respectively.									
Samples of excreta were collected once daily. Samples of eggs were collected twice daily. The hens were euthanized 3-6 hours after administration of the final dose.									
Chlorophenyl label (C-label): 1:1:2 ratio of [14C-U-chlorophenyl]-mefentrifluconazole, [13C-1-chlorophenyl]-mefentrifluconazole and unlabelled mefentrifluconazole.									
Trifluoromethylphenyl ring (TFMP-label): 1:2:2 ratio of [14C-U-trifluoromethylphenyl]-mefentrifluconazole [13C-2-propyl]-mefentrifluconazole and unlabelled mefentrifluconazole.									
Triazole label (T-label): 1:1:1 mixture of [14C-3(5)-triazole]-mefentrifluconazole and [C13-3(5)-triazole]-mefentrifluconazole.									
Matrices	C-label			TFMP-label			T-label		
	TRRs (ppm)		% AD	TRR1 (ppm)		% AD	TRRs (ppm)		% AD
	Measure d	Calculate d ¹		Measure d	Calculated ¹		Measure d	Calculated ¹	
Excreta (Days 1-14)	2.924	3.439	75.30	Not measure d	Not extracted	86.59	6.341	7.405	88.91
Egg white (Days 1-13)	0.008	0.009	0.01	0.010	0.005	0.02	0.386	0.357	0.55
Egg Yolk (Days 1-13)	0.281	0.477	0.22	0.571	0.618	0.28	0.263	0.269	0.17
Partially formed eggs	Not determin ed	Not extracted	0.08	Not determin ed	Not extracted	0.14	Not determin ed	Not extracted	0.09
Muscle	0.054	0.050	0.03	0.078	0.066	0.05	0.377	0.353	0.23
Liver	0.307	0.320	0.06	0.611	0.582	0.13	0.146	0.480	0.03
Kidney	0.431	0.427	0.01	0.612	0.610	0.01	0.590	0.565	0.01
Fat	0.679	0.702	0.13	1.227	0.893	0.10	0.183	0.190	0.01
Gastro-intestina l tract and contents	Not determin ed	Not extracted	1.14	Not determin ed	Not extracted	2.41	Not determin ed	Not extracted	1.62

Bile	Not determined	Not extracted	0.01	Not determined	Not extracted	0.02	Not determined	Not extracted	<0.01
Blood	Not determined	Not extracted	<0.01	Not determined	Not extracted	<0.01	Not determined	Not extracted	<0.01
Cage wash	Not determined	Not extracted	2.53	Not determined	Not extracted	2.61	Not determined	Not extracted	2.37
Total Recovery	--	--	79.52	--	--	92.36	--	--	93.99

Note: The TRRs were determined directly by combustion/LSC analysis, and indirectly as the sum of the extractable and non-extractable radioactive residues.

%AD = percent of the administered dose.

1 The calculated TRRs in egg yolks and egg whites, and in excreta were determined from the respective samples pooled on Days 7-12.

2 The %AD and measured TRRs were determined individually for thigh and breast muscle. The values reported above represent the sum of the individual values for breast and thigh muscle. For the analysis of radioactive residues, the entire breast and thigh muscle samples were pooled for each treatment.

3 The %AD and measured TRRs were determined individually for omental, subcutaneous and renal fat. The values reported above represent the sum of the individual values for each fat. For the analysis of radioactive residues, the entire omental, subcutaneous and renal fat samples were pooled for each treatment.

Metabolites Identified	Major Metabolites (>10% of the TRRs)		
Radiolabel Position	C-label	TFMP-label	T-label
Egg yolk (Days 7-12)	M750F022; M750F024	Mefentrifluconazole; M750F022;	Mefentrifluconazole; M750F001 (1,2,4-T)
Egg white (Day 7-12)	Sample not extracted	Sample not extracted	M750F001 (1,2,4-T)
Muscle	M750F022	M750F022	M750F001 (1,2,4-T)
Liver	M750F022	M75F034; M750F022	M750F001 (1,2,4-T)
Kidney	M750F022	M750F022	M750F001 (1,2,4-T)
Fat	M750F022; M750F023; M750F024; M750F025	Mefentrifluconazole; M750F022; M750F023; M750F025	Mefentrifluconazole ; M750F001 (1,2,4-T)
Excreta (Days 7-12)	M750F022	Extract not analyzed	Samples not extracted

Radioactive residues were identified primarily by co-chromatography with reference standards, and by HPLC-MS and HPLC-MS/MS analysis of selected isolated fractions.

Cleavage of mefentrifluconazole at the triazole-bridge leads to M750F001 (1,2,4-triazole).

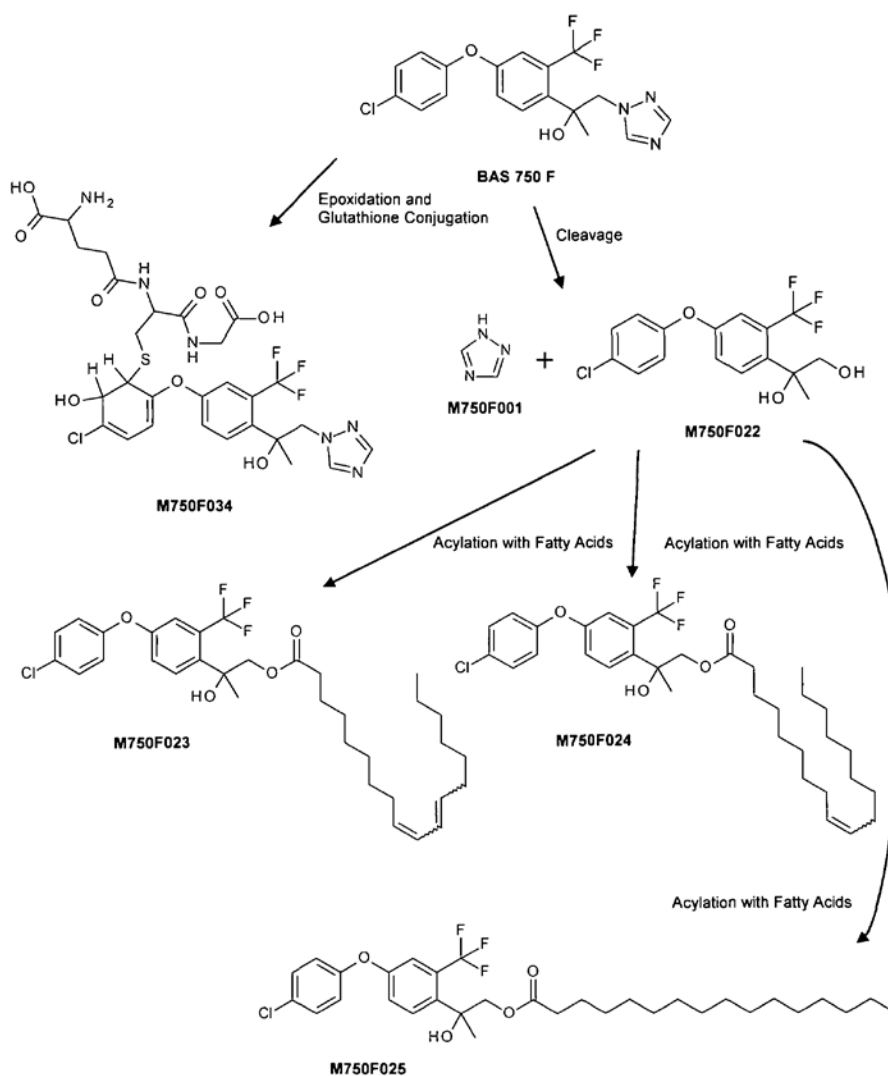
Enantiomer-specific HPLC analyses for mefentrifluconazole in the administered dose as well as in samples of egg yolk (T-label) and fat (T-label) indicated no significant change of the isomer ratio.

Proposed Metabolic Scheme in Hen

Mefentrifluconazole is metabolized by two main transformation reactions:

Cleavage of mefentrifluconazole at the azo-bridge of the propyl-triazole moiety results in the metabolites M750F001 and M750F022. Metabolite M750F022 is further conjugated with fatty acids forming M750F023, M750F024 and M750F025.

Hydroxylation of mefentrifluconazole followed by epoxidation and conjugation with glutathione leads to the formation of the liver-specific metabolite M750F034.



NATURE OF THE RESIDUE IN LACTATING GOAT						PMRA # 2789632			
Five lactating goats (2 animals each for C- and T-labels and 1 animal for the TFMP-label) were dosed orally once daily with mefentrifluconazole labelled in either the chlorophenyl ring (C-label), trifluoromethylphenyl ring (TFMP-label) or in the triazole ring (T-label) for 12 consecutive days (TFMP-label) or 14 consecutive days (C- and T-labels). The nominal dose was 12 ppm per dry weight diet per day. The actual mean doses were 15.5 ppm (C-label), 23.4 ppm (TFMP-label) and 17.5 ppm (T-label), corresponding to 0.36, 0.40 and 0.43 mg/kg body weight/day, respectively.									
Samples of urine and feces were collected once daily. Samples of milk were collected twice daily. The goats were euthanized 23 hours after administration of the final dose.									
Chlorophenyl label (C-label): 1:1:2 ratio of [14C-U-chlorophenyl]-mefentrifluconazole, [13C-1-chlorophenyl]-mefentrifluconazole and unlabelled mefentrifluconazole.									
Trifluoromethylphenyl ring (TFMP-label): 1:2:2 ratio of [14C-U-trifluoromethylphenyl]-mefentrifluconazole [13C-2-propyl]-mefentrifluconazole and unlabelled mefentrifluconazole.									
Triazole label (T-label): 1:1:1 mixture of [14C-3(5)-triazole]-mefentrifluconazole and [C13-3(5)-triazole]-mefentrifluconazole.									
Matrices	C-label			TFMP-label			T-label		
	TRRs (ppm)		Mean % AD	TRRs (ppm)		% AD	TRRs (ppm)		Mean % AD
	Measured	Calculated ¹		Measured	Calculated ¹		Measured	Calculated ¹	
Whole milk ²	0.029	0.029	0.25	0.065	0.062	0.35	0.284	0.273	2.16
Skim milk ²	0.016	0.016	Not determined	0.031	0.036	Not Determined	0.286	0.270	Not determined
Cream ²	0.204	0.207	Not determined	0.491	0.521	Not Determined	0.266	0.289	Not determined
Liver	1.122	1.085	0.40	1.468	1.332	0.52	0.655	0.650	0.25
Kidney	0.353	0.352	0.01	0.436	0.422	0.02	0.386	0.396	0.01
Muscle ³	0.044	0.047	0.03	0.099	0.098	0.10	0.222	0.223	0.18
Fat ⁴	0.307	0.309	0.34	0.515	0.532	0.98	0.215	0.213	0.18
Gastrointestinal Tract contents	Not determined	Not extracted	3.35	Not determined	Not extracted	3.76	Not determined	Not extracted	2.63
Gastrointestinal Tract	Not determined	Not extracted	1.70	Not determined	Not extracted	1.08	Not determined	Not extracted	1.24

Bile	7.393	Not extracted	0.02	11.687	Not extracted	0.22	3.974	Not extracted	0.02
Whole blood	Not determined	Not extracted	<0.01	Not determined	Not extracted	<0.01	Not determined	Not extracted	Not determined
Urine ¹	4.154	Not extracted	25.86	5.329	Not extracted	40.21	2.941	Not extracted	26.90
Feces ¹	3.823	5.174	47.89	4.569	5.543	34.49	3.077	3.206	49.59
Cage wash	Not determined	Not extracted	0.94	Not determined	Not extracted	0.87	Not determined	Not extracted	0.53
Total Recovery	--	--	80.76	--	--	82.60	--	--	83.65

Note: The TRRs were determined directly by combustion/LSC analysis, and indirectly as the sum of the extractable and non-extractable radioactive residues.

%AD = percent of the administered dose.

1 The calculated TRRs in milk (whole, skim and cream) and in urine and excreta were determined from the respective samples pooled on Days 6-12.

2 Composite milk sample separated by centrifugation into fat (cream) and aqueous (skim milk) fraction.

3 The %AD and measured TRRs were determined individually for loin and flank muscle. The values reported above represent the sum of the individual values for loin and flank muscle. For the analysis of radioactive residues, loin and flank muscle samples were pooled (2:1; w:w) between animals in the same treatment group.

4 The %AD and measured TRRs were determined individually for omental, subcutaneous and renal fat. The values reported above represent the sum of the individual values for each fat. For the analysis of radioactive residues, omental, subcutaneous and renal fat samples were pooled (2:1:1; w:w:w) between animals in the same treatment group.

Metabolites Identified	Major Metabolites (>10% of the TRRs)		
Radiolabel Position	C-label	TFMP-label	T-label
Whole milk	M750F043	Mefentrifluconazole; M750F043	M750F001
Skim milk	Mefentrifluconazole; M750F041; M750F072; M750F043	Mefentrifluconazole; M750F041; M750F043	M750F001
Cream	Mefentrifluconazole	Mefentrifluconazole; M750F043	Mefentrifluconazole; M750F001
Muscle	Mefentrifluconazole	Mefentrifluconazole	Mefentrifluconazole; M750F001
Liver	Mefentrifluconazole; M750F016	Mefentrifluconazole; M750F016; M750F038	Mefentrifluconazole; M750F001/derivate
Kidney	Mefentrifluconazole; M750F068; M750F038/ M750F064	Mefentrifluconazole; M750F022; M750F038	Mefentrifluconazole; M750F001
Fat	Mefentrifluconazole	Mefentrifluconazole	Mefentrifluconazole

Urine	M750F015/ M750F043; M750F022; M750F038/ M750F042	M750F063; M750F038/ M750F064	M750F001; M750F003
Feces	Mefentrifluconazole	Mefentrifluconazole; M750F016	Mefentrifluconazole;
Bile	M750F063; M750F038	M750F063;	M750F063
<p>Radioactive residues were identified primarily by co-chromatography with reference standards, and by HPLC-MS and HPLC-MS/MS analysis of selected isolated fractions.</p> <p>Cleavage of mefentrifluconazole at the triazole-bridge leads to M750F001 (1,2,4-triazole = 1,2,4-T).</p> <p>Enantiomer-specific HPLC analyses for mefentrifluconazole in the administered dose as well as in samples of muscle and kidney (TFMP-label), and in cream, liver, fat and feces for the T-label, indicated a significant change in the ratio in most matrices, with the proportion of the R-enantiomer being 70-80% in cream, muscle, liver, kidney and fat, indicating preferential metabolism of the S-enantiomer. In contrast, the enantiomer ratio in feces was similar to that of the dosing material.</p>			

Proposed Metabolic Scheme in Goats

Mefentrifluconazole is metabolized by two main transformation reactions:

Hydroxylation of the chlorophenyl ring followed by conjugation.

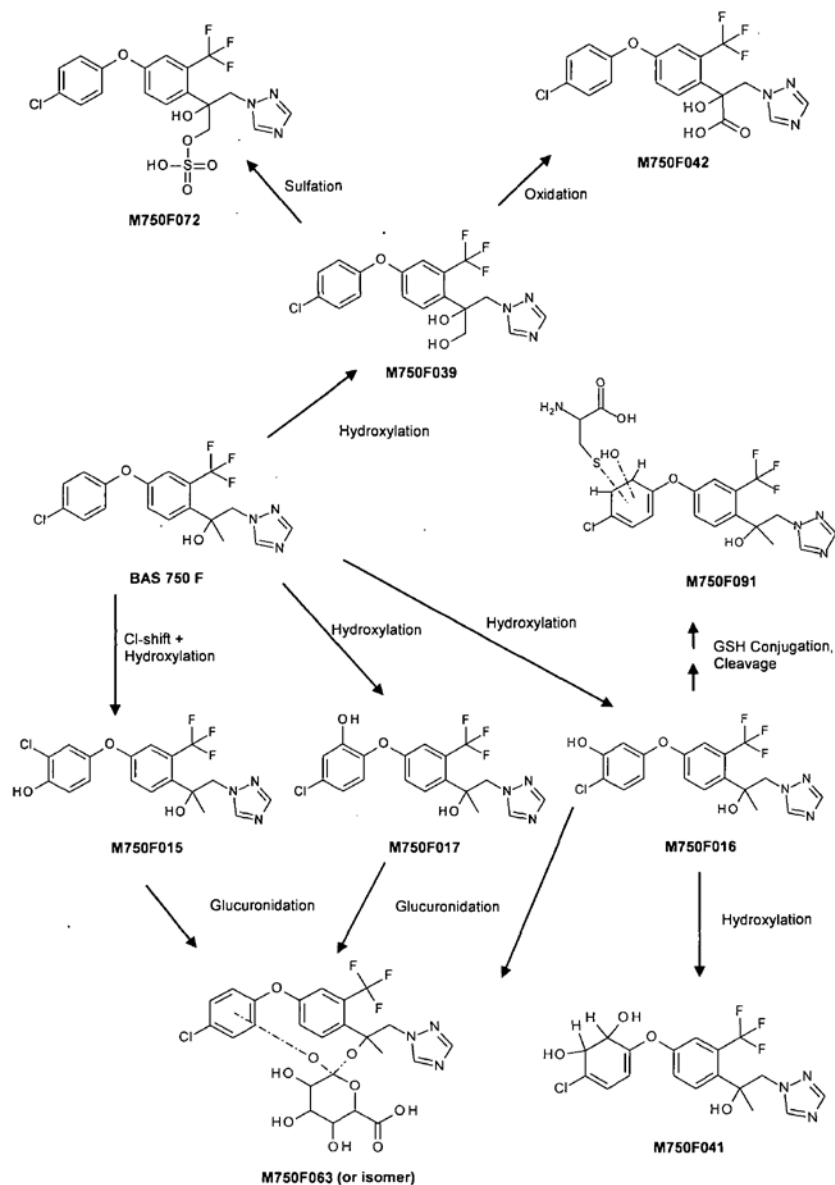
Cleavage of the propyl chain at the 1-position of the triazole, followed by conjugation.

In addition, minor transformations were also observed:

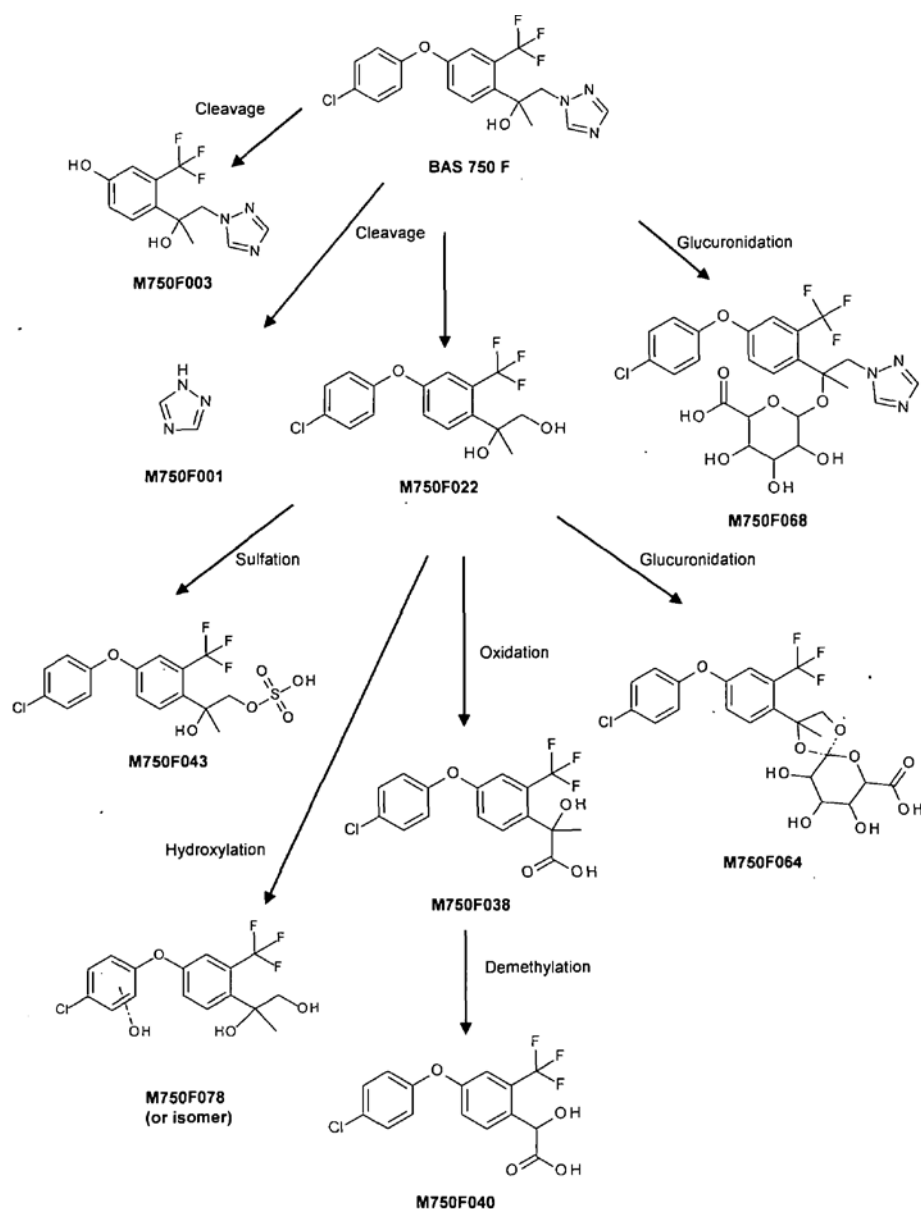
Cleavage at the diphenyl ether.

Hydroxylation of the methyl group, followed by conjugation.

Part 1



Part 2 Cleavage and Conjugation



FREEZER STORAGE STABILITY

PMRA # 2789621, 2789622,
2789623

Plant matrices: Apple fruit, grape fruit, lemon fruit, tomato fruit, wheat grain, straw and whole plant, dried bean, dried pea, soybean seed, rape seed and potato tuber

The freezer storage stability data indicate that residues of mefentrifluconazole are stable at <-18°C for twenty-four months.

Animal matrices: Muscle, liver, kidney, fat, milk, cream and eggs

The freezer storage stability data indicate that residues of mefentrifluconazole and the metabolite M750F022 are stable at <-18°C for six months.

CROP FIELD TRIALS & RESIDUE DECLINE ON POTATO						PMRA # 2789641		
Potato is the representative commodity for Crop Subgroup 1C (tuberous and corm vegetables).								
Field trials were conducted in 2015 in Canada and the United States in growing regions 1(5 trials), 2 (1 trial), 3 (1 trial), 5 (5 trials), 7A (1 trial), 9 (1 trial), 10 (1 trial), 11 (4 trials), 14 (1 trial) for a total of twenty trials. Trial R150057 (growing region 11) was lost due to the inability to collect protocol specified samples. An EC formulation of mefentrifluconazole was applied three times as foliar broadcast sprays at a rate of 146-164 g a.i./ha/application for a seasonal application rate of 442-476 g a.i./ha. The applications were made at 6- to 8-day intervals with the last application occurring 6-7 days before harvest. An adjuvant was added to the spray mixture for all applications.								
Residue decline data show that residues of mefentrifluconazole were <LOQ (<0.01 ppm) at each sampling interval for one trial (Trial ID: R150043), and for the second trial (Trial ID: R150051), residues of mefentrifluconazole were relatively constant over the sampling period (per trial averages of 0.03 ppm, 0.02 ppm, 0.02 ppm, 0.02 ppm and 0.04 ppm at PHIs of 0, 3, 7, 10 and 14 days, respectively).								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Potato tuber	442-476	6-7	19	<0.01	0.02	0.01	0.01	0.002
LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ. n = number of independent field trials.								
CROP FIELD TRIALS & RESIDUE DECLINE ON SUGAR BEET						PMRA # 2789643		
Field trials were conducted in 2014 and 2015 in Canada and the United States in growing regions 5 (5 trials), 7 (1 trial), 7A (2 trials), 8 (1 trial), 10 (1 trial), 11 (2 trials), and 14 (1 trial) for a total of thirteen trials. An EC formulation of mefentrifluconazole was applied two times as foliar broadcast sprays at a rate of 146-161 g a.i./ha/application for a seasonal application rate of 298-318 g a.i./ha. The applications were made at 6- to 7-day intervals with the last application occurring 20-23 days before harvest. An adjuvant was added to the spray mixture for all applications, except for three of the thirteen trials.								
Residue decline data for sugar beets show that residues of mefentrifluconazole decreased with increasing pre-harvest intervals in both roots and tops.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Sugar beet root	293-318	20-23	13	0.02	0.40	0.06	0.11	0.11
Sugar beet top			13	0.48	6.94	1.84	2.09	1.63
LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ. n = number of independent field trials.								

CROP FIELD TRIALS & RESIDUE DECLINE ON LEGUME VEGETABLES – SUCCULENT OR DRIED	PMRA # 2789636 and 2789637
<p>The representative commodities for Crop group 6 (legume vegetables - succulent or dried) are bean (<i>Phaseolus</i> spp.; any one succulent cultivar and any one dried cultivar); pea (<i>Pisum</i> spp.; any one succulent cultivar and any one dried cultivar); and soybean.</p> <p>Field trials for mefentrifluconazole on legume vegetables were conducted in 2014 and 2015 in Canada and the United States in the following growing regions for a total of sixty-five trials:</p> <p>Bean, succulent podded – Six trials: 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (2 trials) and 11 (1 trial).</p> <p>Bean, succulent shelled – Six trials: 2 (3 trials), 5 (1 trial), 10 (1 trial) and 11 (1 trial).</p> <p>Pea, succulent with and without pod – Nine trials: 1 (1 trial), 5 (5 trials), 7A (1 trial), 11 (1 trial) and 12 (1 trial).</p> <p>Bean, dry – Ten trials: 1 (1 trial), 5 (3 trials), 7 (1 trial), 7A (1 trial), 8 (1 trial), 10 (1 trial), 11 (1 trial) and 14 (1 trial).</p> <p>Cowpea – Three trials: 5 (2 trials) and 11 (1 trial).</p> <p>Pea, dry – Eight trials: 7 (3 trials), 11 (3 trials), 14 (1 trial) and 14 (1 trial).</p> <p>Lentil, dry – Three trials: 7 (1 trial), 7A (1 trial) and 14 (1 trial).</p> <p>Soybean – Twenty trials: 2 (2 trials), 4 (3 trials) and 5 (15 trials).</p> <p>At each test location (except for the cowpea and soybean trials), the treated plot received three broadcast foliar ground applications of an EC formulation of mefentrifluconazole, the first of which made 33-36 days prior to cutting/harvest at 145-155 g a.i./ha, the second was made 27-28 days prior to cutting/harvest at 145-159 g a.i./ha, and the last application was made 20-22 days prior to cutting/harvest at 142-160 g a.i./ha. The total application rates were 436.4-466.6 g a.i./ha. An adjuvant was included in the spray mixture for all applications. A residue decline trial was conducted for each legume crop commodity during which samples were harvested at PHIs of 0, 7, 14, 21 and 28 days.</p> <p>At each cowpea trial, two treated plots (Plot 2 for forage and Plot 3 for hay) were established. Plot 2 received three broadcast foliar ground applications of an EC formulation of mefentrifluconazole, the first of which was made 35-36 days prior to cutting/harvest at 149-155 g a.i./ha, the second was 28 days prior to cutting/harvest at 148-167 g a.i./ha, and the last application was 21 days prior to cutting/harvest at 147-152 g a.i./ha. The total application rate for Plot 2 was 445.0-469.3 g a.i./ha. Plot 3 received three broadcast foliar ground applications of an EC formulation of mefentrifluconazole, the first of which was 35 days prior to cutting/harvest at 150-152 g a.i./ha, the second was 27-28 days prior to cutting/harvest at 146-150 g a.i./ha, and the last application was 21 days prior to cutting/harvest at 146-151 g a.i./ha. The total application rate for Plot 3 was 446.4-451.4 g a.i./ha. For all applications, an adjuvant was included in the spray mixture.</p>	

At each soybean trial, two treated plots (Plots 2 and 3) were established. Plot 2 received two broadcast foliar ground applications of an EC formulation of mefentrifluconazole, the first of which was 27-30 days prior to forage/hay harvest at 146-156 g a.i./ha, and the last application was made 21-22 days prior to forage/hay harvest at 148-156 g a.i./ha. The total application rate for Plot 2 was 293.5-306.3 g a.i./ha. Plot 3 received two broadcast foliar ground applications of an EC formulation of mefentrifluconazole, the first of which was 27-29 days prior to dry seed harvest at 147-156 g a.i./ha, and the last applications was 20-22 days prior to dry seed harvest at 148-156 g a.i./ha. The total application rate for Plot 3 was 297.9-309.1 g a.i./ha. For all applications, an adjuvant was included in the spray mixture. Two residue decline trials were conducted for each soybean commodity during which samples of forage, hay and seed were harvested at PHIs of 0, 7, 13-14, 21 and 28 days.

The residue decline data showed that residues of mefentrifluconazole were <LOQ (<0.01 ppm) in all samples of succulent shelled bean, succulent pea without pod and dry bean. In succulent podded bean, residues of mefentrifluconazole were relatively constant over the sampling period. In succulent pea with pod, residues of mefentrifluconazole decreased over the sampling period. For dry pea, residues of mefentrifluconazole generally decreased in hay, decreased in vines, and in dry seed were quantifiable at the 0-day PHI and <LOQ (<0.01 ppm) at each subsequent sampling interval. In dry lentil seed, residues of mefentrifluconazole were constant up to the 14-day interval, but decreased at each subsequent interval. For soybean, residues of mefentrifluconazole decreased in forage and hay, and in dry seed residues of mefentrifluconazole were quantifiable at the 0-day PHI, but were <LOQ (<0.01 ppm) at each subsequent interval.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Bean, fresh	449.5-466.6	21	6	<0.01	0.02	0.010	0.011	0.004
Bean, succulent (green) seed	445.4-455.5	21	6	<0.01	0.02	0.010	0.012	0.004
Pea (green) with pod	443.8-459.5	21	9	<0.01	0.08	0.01	0.023	0.023
Pea, succulent (green) seeds	443.8-459.5	21	9	<0.01	<0.01	<0.01	<0.01	0
Bean, dry seed	436.4-460.7	21	10	<0.01	0.05	0.010	0.016	0.013
Cowpea forage	445.0-469.3	21	3	0.04	0.09	0.05	0.06	0.026
Cowpea hay	446.4-451.4	21	3	0.44	1.61	0.87	0.97	0.59
Dry pea hay	449.2-460.3	21-22	8	3.59	9.01	7.53	6.79	2.1
Dry pea vines	449.2-460.3	21-22	8	0.82	10.18	3.53	4.81	3.73
Dry pea seed	449.2-460.3	21-22	8	<0.01	0.09	<0.015	<0.024	0.027
Dry lentil seed	447.4-453.1	20-21	3	0.06	0.68	0.14	0.29	0.34
Soybean forage	293.5-306.3	21-22	20	0.18	2.67	1.15	1.21	0.72
Soybean hay	293.5-306.3	21-22	20	0.68	7.32	3.01	3.45	1.95

Soybean seed	297.9-309.1	20-22	20	<0.01	0.31	<0.010	<0.031	0.067
LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ. n = number of independent field trials.								
CROP FIELD TRIALS & RESIDUE DECLINE ON CITRUS FRUITS						PMRA # 2789397		
The representative commodities of the revised Crop Group 10 (citrus fruits) are orange or tangerine, lemon or lime and grapefruit.								
Field trials for mefentrifluconazole were conducted on citrus fruits in 2016 and 2017 in the United States in the following growing regions for a total of twenty-five trials: Orange – Twelve trials: 3 (8 trials); 6 (1 trial); 10 (3 trials). Grapefruit – Six trials: 3 (3 trials), 6 (1 trial); and 10 (2 trials). Lemon – Six trials: 3 (2 trials) and 10 (4 trials).								
The treated plots received three foliar airblast applications of an EC formulation of mefentrifluconazole targeting 150 g a.i./ha/application, with a 14-day retreatment interval, totaling 450 g a.i./ha. The actual total application rates were 443-466 g a.i./ha, with 13- to 16-day intervals. The applications were made with a concentrate spray volume for Plot 2 (505-889 L/ha) and a with a dilute spray volume for Plot 3 (1502-3695 L/ha). An adjuvant was added to the spray mixture for all applications. The application timings varied according to crop and ranged between BBCH 73 to BBCH 89. For all trials, fruit samples were collected immediately after the last application (PHI = 0 days). For the decline trials (1 trial each for orange, lemon and grapefruit), additional treated samples were targeted for collection at PHIs of 7, 14, 21 and 28 days.								
There were no significant differences in residue levels between the concentrate and dilute spray applications from the orange and grapefruit trials. Residues were generally higher in lemons following treatment with the concentrate spray compared to the dilute spray. In the residue decline trials, following dilute spray applications residues of mefentrifluconazole decreased in oranges, lemons and grapefruit. With the concentrate spray applications, residues of mefentrifluconazole increased in oranges, and decreased in lemons and grapefruit over the sampling period.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Orange whole fruit	443-460 [concentrate spray]	0	12	0.139	0.464	0.191	0.225	0.094
	447-462 [dilute spray]	0	12	0.133	0.226	0.167	0.171	0.027
	443-462 [concentrate + dilute sprays]	0	12	0.146	0.314	0.189	0.198	0.049
Grapefruit whole fruit	444-466 [concentrate spray]	0	6	0.099	0.204	0.173	0.162	0.039
	444-463 [dilute spray]	0	6	0.071	0.235	0.113	0.123	0.060
	444-466 [concentrate + dilute sprays]	0	6	0.085	0.211	0.136	0.142	0.044

Lemon whole fruit	447-454 [concentrate spray]	0	6	0.268	0.604	0.352	0.385	0.122
	445-456 [dilute spray]	0	6	0.167	0.326	0.249	0.255	0.066
	445-456 [concentrate + dilute sprays]	0	6	0.254	0.409	0.302	0.319	0.062

The residue data were summarized separately for the plots that were treated with concentrate (Plot 2) and dilute spray (Plot 3) applications, respectively, and also for when samples from Plot 2 and Plot 3 were treated as replicates.

LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation.

Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ.

n = number of independent field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON POME FRUITS

PMRA # 2789638

The representative commodities for the revised Crop Group 11-09 (pome fruits) are apple and pear.

Field trials for mefentrifluconazole were conducted on pome fruits in 2014 and 2015 in Canada and the United States in the following growing regions for a total of twenty four trials:

Pear – Nine trials: 1 (1 trial); 5 (3 trials), 10 (2 trials), and 11 (3 trials).

Apple – Fifteen trials: 1 (3 trials), 2 (1 trial), 5 (5 trials), 9 (1 trial), 10 (1 trial) and 11 (4 trials).

The treated plots received three broadcast foliar airblast applications of a suspension concentrate (SC) formulation of mefentrifluconazole targeting 150 g a.i./ha/application at a 6- to 8-day intervals totaling 450 g a.i./ha. The actual total application rates were 428-459 g a.i./ha. The applications were made with a concentrate spray volume for Plot 2 (466-1110 L/ha) and a with a dilute spray volume for Plot 3 (1403-3011 L/ha). An adjuvant was added to the spray mixture for all applications.

At each location, apple and pear samples were harvested 0, 7 and 14 days after the last application (DALA); 0-, 7- and 14-day pre-harvest intervals (PHIs). The 0-day PHI sample timing was selected as the worst case scenario. As such, the 7-day and 14-day PHI samples were not analyzed unless the trial was a residue decline trial. Three residue decline trials (PHIs = 0, 3, 7, 14 and 21 days) were conducted: one trial for pears and two trials for apples.

There were no significant differences in residue levels between the concentrate and dilute spray applications from the pear and apple trials. In the pear residue decline trials, residues of mefentrifluconazole generally increased with increasing preharvest intervals for the concentrate spray, and for the dilute spray, residues of mefentrifluconazole were variable over the sampling period. In the apple residue decline trials, residues of mefentrifluconazole decreased over the sampling period.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Apple fruit	437-457 [concentrate spray]	0	15	<0.01	0.55	0.37	0.34	0.140
	434-457 [dilute spray]	0	15	<0.01	0.47	0.30	0.27	0.12

	434-457 [concentrate and dilute sprays]	0	15	<0.010	0.47	0.34	0.30	0.122
Pear fruit	428-458 [concentrate spray]	0	9	<0.01	0.76	0.34	0.37	0.24
	429-459 [dilute spray]	0	9	0.01	0.92	0.27	0.35	0.25
	428-459 [concentrate and dilute sprays]	0	9	<0.01	0.84	0.30	0.36	0.24

The residue data were summarized separately for the plots that were treated with concentrate (Plot 2) and dilute spray (Plot 3) applications, respectively, and also for when samples from Plot 2 and Plot 3 were treated as replicates.

LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation.
Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ.
n = number of independent field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON STONE FRUITS

PMRA # 2789639

The representative commodities for the revised Crop Group 12-09 (stone fruits) are sweet cherry or tart cherry, peach and plum or prune plum.

Field trials for mefentrifluconazole were conducted in 2014-2015 in Canada and the United States in the following growing regions for a total of thirty-one trials:

Cherry - Eight trials: 5 (3 trials), 10 (3 trials) and 11 (2 trials).

Peach - Thirteen trials: 1 (1 trial), 2 (3 trials), 5 (4 trials), 6 (1 trial), 10 (3 trials), 11 (1 trial).

Plum - Ten trials: 1 (1 trial), 5 (3 trials), 10 (4 trials), 11 (1 trial) and 12 (1 trial).

The treated plots received three broadcast foliar applications of a SC formulation of mefentrifluconazole targeting 150 g a.i./ha/application at 6- to 9-day intervals, totaling 450 g a.i./ha. The actual total application rates were 437-566 g a.i./ha. An adjuvant was included to the spray mixture for all applications. The applications were made with a concentrate spray volume for Plot 2 (464-898 L/ha) and with a dilute spray volume for Plot 3 (962-3604 L/ha). During one of the peach trials (R140429), the second spray application for Plot 3 was ~178% of the target amount (269 g a.i./ha).

At each location, stone fruit samples were harvested 0, 7 and 14 DALA; 0-, 7- and 14-day PHIs. The 0-day PHI sample timing was selected as the worst case scenario. As such, the 7-day and 14-days samples were not analyzed unless the trial was a residue decline trial. One residue decline trial was conducted at PHIs of 0, 3, 7 and 14 days for each cherry, plum, and peach.

The residue data from the stone fruits trials are summarized below. There were no significant differences in residue levels between the concentrate and dilute spray applications from the cherry, peach and plum trials. In the residue decline trials, mefentrifluconazole decreased with increasing pre-harvest intervals for cherry, peach and plum.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Cherry fruit	446-462 [concentrate spray]	0	8	0.04	1.55	0.955	0.879	1.66
	445-462 [dilute spray]	0	8	0.03	2.25	1.07	1.21	0.698
	445-462 [concentrate + dilute sprays]	0	8	0.03	1.9	0.98	1.04	0.590
Peach fruit	445-458 [concentrate spray]	0	13	0.22	0.81	0.35	0.39	0.15
	444-566 [dilute spray]	0	13	0.34	0.96	0.50	0.57	0.21
	444-566 [concentrate + dilute sprays]	0	13	0.31	0.73	0.44	0.48	0.13
Plum fruit	437-461 [concentrate spray]	0	10	<0.01	0.90	0.24	0.30	0.30
	438-460 [dilute spray]	0	10	0.01	0.98	0.23	0.34	0.36
	437-461 [concentrate + dilute sprays]	0	10	<0.01	0.94	0.24	0.32	0.32
<p>The residue data were summarized separately for the plots that were treated with concentrate (Plot 2) and dilute spray (Plot 3) applications, respectively, and also for when samples from Plot 2 and Plot 3 were treated as replicates.</p> <p>LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation.</p> <p>Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ.</p> <p>n = number of independent field trials.</p>								

CROP FIELD TRIALS & RESIDUE DECLINE ON GRAPE						PMRA # 2789642		
Grape is the representative commodity for Crop Subgroup 13-07F (small fruits vine climbing, except fuzzy kiwifruit).								
Field trials for mefentrifluconazole on grapes were conducted in 2014 in Canada and the United States in growing regions 1 (2 trials), 5 (1 trial), 10 (7 trials), 11 (1 trial) and 12 (1 trial) for a total of twelve trials.								
The treated plots received three broadcast foliar applications of a SC formulation of mefentrifluconazole targeting 150 g a.i./ha/application, with 8- to 11-day intervals, totaling 450 g a.i./ha/season. The actual total application rates were 440.9-467.7 g a.i./ha. The applications were made in concentrate spray volumes (423.77-748.78 L/ha) for Plot 2 or in dilute spray volumes for Plot 3 (1872.97-2700.03 L/ha). An adjuvant was included in the spray mixture for all applications.								
Grape RAC samples were harvested 14 and 21 days after the last application (14 and 21 DALA; 14 and 21 day PHIs) of the test substance. At two trial locations, grape samples were collected from each treated plot at 0, 3, 7, 14 and 21 DALA to monitor residue decline.								
There were no significant differences in residue levels between the concentrate and dilute spray applications from the grape trials. In the residue decline trials, mefentrifluconazole generally decreased with increasing pre-harvest intervals in grapes.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Grape fruit	447.8-460.5 [concentrate spray]	14	12	0.110	1.07	0.410	0.439	0.270
	440.9-467.7 [dilute spray]	14	12	0.280	1.03	0.430	0.517	0.259
	440.9-467.7 [concentrate + dilute sprays]	14	12	0.090	0.980	0.420	0.477	0.245
Grape fruit	447.8-460.5 [concentrate spray]	21	11	0.070	0.760	0.310	0.374	0.239
	440.9-467.7 [dilute spray]	21	11	0.11	0.77	0.290	0.419	0.259
	440.9-467.7 [concentrate and dilute sprays]	21	11	0.18	0.76	0.300	0.395	0.236
The residue data were summarized separately for the plots that were treated with concentrate (Plot 2) and dilute spray (Plot 3) applications, respectively, and also for when samples from Plot 2 and Plot 3 were treated as replicates.								
For trial R40826-ON, samples were not taken at the 21-day PHI due to wind damage to the grape crop.								
LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation.								
Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ.								
n = number of independent field trials.								

CROP FIELD TRIALS & RESIDUE DECLINE ON TREE NUTS						PMRA # 2789633		
The representative commodities for the revised Crop Group 14-11 (tree nuts) are almond and pecan.								
Field trials for mefentrifluconazole on representative tree nuts were conducted in 2014 in the United States encompassing the following growing regions for a total of thirteen trials: Pecan – Five trials: 2 (2 trials), 4 (1 trial), 6 (1 trial) and 8 (1 trial). Pistachio – Three trials: 10. Almond – Five trials: 10.								
The treated plots received three foliar airblast applications of a SC formulation of mefentrifluconazole targeting 150 g a.i./ha/application applied nominally 28 days (27-30 days actual), 21 days (19-23 days actual) and 14 days (13-15 days actual) prior to harvest (PHI). The actual seasonal application rates ranged from 444-462 g a.i./ha. The applications were made using ground equipment and in spray volumes of 486-1019 L/ha for Plot 2 (concentrate spray volume) and 1150-2881 L/ha for Plot 3 (dilute spray volume). An adjuvant was added to the spray mixture for all applications.								
At each location, the tree nut samples were harvested 13-15 days DALA. In addition, at one pecan trial, one pistachio trial, and one almond trial, tree nut samples were collected 0, 3, 7 and 21 DALA in addition to the targeted 14-day PHI to examine residue decline.								
There were no significant differences in residue levels between the concentrate and dilute spray applications from the tree nuts trials. In the residue decline trials, residues of mefentrifluconazole were mostly <LOQ (<0.01 ppm) in all nutmeat samples. In almond hulls, residues of mefentrifluconazole were variable over the sampling period for the concentrate spray, and for the dilute spray mefentrifluconazole residues decreased with increasing PHIs.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Pecan nutmeat	446-456 [concentrate spray]	13-15	5	<0.01	0.012	0.010	0.010	0.0009
	446-454 [dilute spray]	13-15	5	<0.01	<0.01	<0.01	<0.01	0
	446-456 [concentrate + dilute sprays]	13-15	5	<0.01	0.011	0.010	0.010	0.0004
Pistachio nutmeat	445-453 [concentrate spray]	14	3	<0.01	0.044	0.010	0.021	0.020
	445-458 [dilute spray]	14	3	<0.01	0.011	0.011	0.011	0.0006
	444-458 [dilute and concentrate sprays]	14	3	<0.01	0.027	0.011	0.016	0.010

Almond nutmeat	445-458 [dilute spray]	14-15	5	<0.01	<0.01	<0.01	<0.01	0
	445-462 [concentrate spray]	14-15	5	<0.01	0.021	0.010	0.012	0.005
	445-462 [dilute + concentrate sprays]	14-15	5	<0.01	0.016	0.010	0.011	0.003
Almond hulls	445-458 [dilute spray]	14-15	5	0.27	1.13	1.1	0.85	0.36
	445-462 [concentrate spray]	14-15	5	0.76	1.68	1.49	1.34	0.40
	445-462 [dilute + concentrate spray]	14-15	5	0.95	1.38	1.08	1.15	0.21

The residue data were summarized separately for the plots that were treated with concentrate (Plot 2) and dilute spray (Plot 3) applications, respectively, and also for when samples from Plot 2 and Plot 3 were treated as replicates.

LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation.

Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ.

n = number of independent field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON CEREALS	PMRA # 2789634 and 2789635
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The representative commodities of Crop Group 15 (cereal grains) are corn (fresh sweet corn and dried field corn), barley and wheat.

Field trials for mefentrifluconazole on cereals were conducted in 2014-2015 in Canada and the United States encompassing growing regions for a total of eighty-nine trials:

Barley: 10 trials - 1 (1 trial in NY), 5 (1 trial in MN), 7 (1 trial in NE), 10 (1 trial in CA), 11 (1 trial in ID) and 14 (5 trials: 2 trial in MB, 2 trials in SK, and 1 trial in AB).

Field Corn: 20 trials - 1 (1 trial in NY), 2 (1 trial in GA), 5 (17 trials: 3 trials in WI, 2 trials in ND, 1 trial in KS, 2 trials in NE, 4 trials in MN, 2 trials in IA, and 3 trials in MO) and 6 (1 trial in TX).

Rice: 12 trials - 4 (7 trials: 4 trials in AR, 1 trial in LA and 2 trials in MO), 5 (1 trial in MO), 6 (2 trials in TX) and 10 (2 trials in CA).

Grain sorghum: 9 trials - 5 (4 trials: 1 trial each in AR, MN, IA, and MO), 6 (1 trial in TX and 1 trial in OK), 7 (1 trial in NE), and 8 (2 trials in TX).

Wheat: 25 trials - 2 (1 trial in GA), 4 (1 trial in AR), 5 (4 trials: 1 in ND, 2 in MN and 1 in MO), 6 (1 trial in TX), 7 (5 trials: 2 trials in NE, 1 trial in SK, and 2 trials in ND), 7A (1 trial in AB), 8 (4 trials: 3 trials in TX and 1 trial in KS), 11 (1 trial in ID) and 14 (7 trials: 3 trials in MB, 2 trials in SK and 2 trials in AB).

Sweet corn: 13 trials - 1 (2 trials in NY), 2 (1 trial in GA), 3 (1 trial in FL), 5 (5 trials: 2 trials each in WI and MN and 1 trial in NE), 7A (1 trial in AB), 10 (1 trial in CA), 11 (1 trial in ID) and 12 (1 trial in BC).

Barley, field corn, rice and wheat

One treated plot (Plot 2) at all rice sites, and two treated plots (Plot 2 and Plot 3) were established at all barley, field corn, sorghum and wheat trial sites. The treated plots received two broadcast foliar applications of an EC formulation of mefentrifluconazole targeting 150 g a.i./ha/application, with 14-day retreatment intervals, totaling 300 g a.i./ha/season.

The actual total application rates were 289-309 g a.i./ha for barley, 294-308 g a.i./ha for field corn, 294-307 g a.i./ha for rice, 296-312 g a.i./ha for sorghum and 294-307 g a.i./ha for wheat, and at intervals of 13-15 days, except for plot 3 of Trial R140307, which had an interval of 20 days. All applications were made with an adjuvant added to the spray mixture.

The spray timings varied according to crop and ranged between: BBCH 11 to BBCH 85 (one leaf soft dough) stages of growth for barley in Plot 2 (hay) and from BBCH 52 to BBCH 89 (early heading to fully ripe) stages of growth for barley in Plot 3 (grain and straw); BBCH 45 to BBCH 83 (V11 to early dough) stages of growth for field corn in Plot 2 (forage) and from BBCH 52 to BBCH 89 (early heading to fully ripe) stages of growth for field corn in Plot 3 (grain and stover); BBCH 43 to BBCH 87 (mid-boot to hard dough) stages of growth for rice; BBCH 36 to BBCH 85 (V6 to soft dough) stages of growth for sorghum in Plot 2 (forage) and from BBCH 55 to BBCH 89 (heading to fully ripe) stages of growth for sorghum in Plot 3 (grain and stover); and BBCH 10 to BBCH 53 (one leaf to boot/early heading) stages of growth for wheat in Plot 2 (forage and hay) and from BBCH 35 to BBCH 92 (jointing to over-ripe) stages of growth for wheat in Plot 3 (grain and straw).

Sweet Corn

For sweet corn, one untreated control (Plot 1) and one treated plot (Plot 2) were established at each site. The treated plots received three broadcast foliar applications of an emulsifiable formulation of mefentrifluconazole targeting 150 g a.i./ha/application, with 7-day retreatment intervals, totaling 450 g a.i./ha/season. The actual total application rates were 448-480 g a.i./ha within $\pm 5\%$ of the target rate, with 6-8 day retreatment intervals. The applications were made with spray volumes of 140 to 446 L/ha using ground (airblast) equipment, and an adjuvant added to the spray mixture for all applications. The spray timings varied according to crop and ranged between BBCH 38 to BBCH 73 (flag leaf visible, unrolled to early milk) for sweet corn stages of growth.

Sweet corn forage and kernel plus cob with husk removed (K+CWHR) samples were harvested at 21 days after the last application. Sweet corn stover samples were harvested when the stover contained 80 to 85% dry matter or at approximately one month after forage harvest, whichever came first. In addition, at one of the trial sites treated forage and K+CWHR samples were collected at 0, 14, 28 and 35 days after the last application and treated stover samples were collected at 0, 14, 21, 28 and 35 days after the stover reached 80 to 85% dry matter (52, 66, 73, 80 and 87 days after the last application).

Residue decline

In cereal commodities, residues of mefentrifluconazole generally decreased with increasing preharvest intervals.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Barley hay	300-309	21	9	0.40	6.5	4.78	4.54	1.71
Barley grain	289-309	21	10	<0.01	1.67	0.43	0.54	0.46
Barley straw	289-309	21	10	<0.01	15.41	6.07	7.4	5.7
Field corn forage	294-308	20-22	20	<0.01	2.15	0.67	0.87	0.60
Field corn grain	295-305	19-22	20	<0.01	<0.01	<0.01	<0.01	0
Field corn stover	295-305	19-22	20	<0.01	5.66	2.04	2.4	1.6
Rice grain	294-307	21-23	12	<0.01	1.84	0.99	0.95	0.69
Rice straw	294-307	21-23	12	<0.01	6.67	2.1	2.2	1.8
Sorghum forage	297-312	20-21	9	<0.01	1.63	0.44	0.64	0.58

Sorghum grain	296-311	21-22	9	<0.01	1.06	0.41	0.44	0.32
Sorghum stover	296-311	21-22	9	<0.01	2.56	1.21	1.09	0.803
Wheat forage	294-307	21-22	25	<0.01	2.42	0.65	0.79	0.74
Wheat hay	294-307	21-22	25	<0.01	4.44	1.68	1.67	1.42
Wheat grain	295-305	20-21	24	<0.01	0.27	0.090	0.087	0.054
Wheat straw	295-305	20-21	24	<0.01	19.25	6.94	7.30	4.53

LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation.
Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ.
n = number of independent field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON CANOLA

PMRA # 2789644

Rapeseed (canola varieties only) is the representative commodity for crop subgroup 20A.

Field trials for mefentrifluconazole on canola were conducted in 2014-2015 in Canada and the United States in growing regions 2 (1 trial), 5 (2 trials), 7 (1 trial), 11 (2 trials), and 14 (7 trials) for a total of thirteen trials. Two broadcast foliar spray applications of an EC formulation of mefentrifluconazole targeting 150 g a.i./ha/application. The applications were timed to occur 35 and 21 days prior to harvest of mature seed. The actual application rate 145-170 g a.i./ha/application, with a 20 to 22 day retreatment interval, for a total rate of 294-327 g a.i./ha/season. An adjuvant was added to the spray mixture for all applications. Canola samples were harvested at 20-22 days after the last application (20-22-day PHI). At one trial location, samples were collected 7, 10, 14, 21, and 28 DALA to generate residue decline data.

The residue decline data (per trial average) indicated that residues of mefentrifluconazole were stable up to the 14-day PHI (0.30-0.31 ppm), increased to 0.74 ppm at the 21-day PHI and then decreased to 0.41 ppm at the 28-day PHI.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Canola seed	294-327	20-22	13	<0.01	0.74	0.060	0.14	0.20

LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation.
Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ.
n = number of independent field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON PEANUT

PMRA # 2789640

Field trials for mefentrifluconazole on peanuts were conducted in 2014 in the United States in growing regions 2 (6 trials) 3 (1 trial), 6 (2 trials) and 8 (1 trial in TX) for a total of ten trials.

Three broadcast foliar ground applications of an EC formulation of mefentrifluconazole were made targeting 200 g a.i./ha, with a 14-day retreatment interval. The actual total application rates were 587-601 g a.i./ha with 13-16 retreatment intervals. All applications were made with an adjuvant. The timing of the applications ranged from the beginning of pod development through 60% pod maturity (about 80% of pods developed to final size are ripe) at approximately BBCH 71 to BBCH 88. Peanut nutmeat and hay samples were collected at crop maturity (BBCH 89) targeting 14-day PHI. The actual PHIs were 13-15 days. For the decline trial, peanut nutmeat and hay samples were collected at 8, 10, 14, 17 and 22 DALA.

In the residue decline trials, residues of mefentrifluconazole were <LOQ (<0.01 ppm) in all samples of peanut nutmeat, and in peanut hay, residues of mefentrifluconazole decreased with increasing PHIs.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Mefentrifluconazole (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Peanut nutmeat	587-601	13-15	10	<0.01	<0.01	<0.01	<0.01	0
Peanut hay			10	2.1	14.76	5.67	6.36	3.87
LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ. n = number of independent field trials.								
RESIDUE DATA IN ROTATIONAL CROPS						PMRA # 2789660		
Field trials were conducted in 2014-2016 in the United States. Two trials each of rotational wheat, rotational lettuce and rotational radish in growing regions 2 (3 trials) and 8 (3 trials).								
Three broadcast soil directed spray applications at 7-day intervals of an EC formulation of mefentrifluconazole were made targeting 200 g a.i./ha/application. The actual application rates for mefentrifluconazole ranged from 196 to 207 g a.i./ha/application for total application rates of 595-614 g a.i./ha. Adjuvant was added to the spray mixture for all applications at all trials.								
The test crops were planted at plantback intervals (PBIs) of 1, 3, 4, and 11-13 months following the last application to the bare soil plots. The test crops of wheat, lettuce and radish were grown and maintained according to typical agricultural practices for each geographical region. Samples of lettuce, radish tops and roots, wheat forage, hay, grain, and straw were harvested at the appropriate growth stage. Wheat hay was allowed to dry in a protected area or in the field for 3-7 days prior to collection.								
Commodity	Total Application Rate (g a.i./ha)	PBI (months)	Mefentrifluconazole Residues (ppm)					
			n	LAFT	HAFT	Median	Mean	
Lettuce leaves	596-614	1	2	<0.01	<0.01	0.01	0.01	
		3	2	<0.01	<0.01	0.01	0.01	
		4	2	<0.01	<0.01	0.01	0.01	
		12	2	<0.01	<0.01	0.01	0.01	
Radish tops	595-606	1	2	<0.01	0.07	0.04	0.04	
		3	2	<0.01	0.04	0.02	0.02	
		4	2	<0.01	0.02	0.02	0.02	
		12	2	<0.01	<0.01	0.01	0.01	
Radish roots	595-606	1	2	<0.01	0.03	0.02	0.02	
		3	2	<0.01	0.02	0.01	0.01	
		4	2	<0.01	0.02	0.01	0.01	
		12	2	<0.01	<0.01	0.01	0.01	
Wheat forage	595-603	1	2	<0.01	1.80	0.91	0.91	
		3	2	<0.01	0.63	0.32	0.32	
		4	2	<0.01	0.91	0.46	0.46	
		11-13	2	<0.01	1.37	0.69	0.69	
Wheat hay	595-603	1	2	<0.01	0.37	0.19	0.19	
		3	2	<0.01	0.75	0.38	0.38	
		4	2	<0.01	1.66	0.83	0.83	
		11-13	2	<0.01	1.36	0.69	0.69	

Wheat grain	595-603	1	2	<0.01	<0.01	0.01	0.01
		3	2	<0.01	<0.01	0.01	0.01
		4	2	<0.01	<0.01	0.01	0.01
		11-13	2	<0.01	<0.01	0.01	0.01
Wheat straw	595-603	1	2	<0.01	0.04	0.02	0.02
		3	1	<0.01	<0.01	0.01	0.01
		4	1	0.02	0.02	0.02	0.02
		11-13	2	<0.01	<0.01	0.01	0.01

LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial

Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ.

n = number of independent field trials.

Based on the results of the field accumulation study, a plant-back interval of 30 days is required for crops not appearing on the label. Crops appearing on the label can be planted back immediately after the last application of mefentrifluconazole.

HIGH-TEMPERATURE HYDROLYSIS STUDY

PMRA # 2789648

A standard hydrolysis study, performed with ¹⁴C-mefentrifluconazole labelled at the chlorophenyl ring (C-label) as well as with ¹⁴C-mefentrifluconazole labelled at the triazole ring (T-label) showed hydrolytic stability under conditions representative of the following processing procedures: pasteurization (pH 4, 20 min, 90°C), baking, brewing, boiling (pH 5, 60 min, 100°C), and sterilization (pH 6, 20 min, 120°C). High-performance liquid chromatography (HPLC) analysis showed no major loss of radioactivity upon treatment, as well as absence of any degradation product exceeding 2% of total radioactivity. Chiral high-performance liquid chromatography (HPLC) analysis confirmed absence of any notable change of the enantiomer ratio.

Conditions	Pasteurization		Baking/Brewing/Boiling		Sterilization	
	%TRR		%TRR		%TRR	
	C-label	T-label	C-label	T-label	C-label	T-label
Total (prior to treatment)	100.0	100.0	100.0	100.0	100.0	100.0
Total (post treatment)	110.2	110.2	108.3	110.2	110.1	105.2
Mefentrifluconazole	107.9	110.2	107.1	110.2	107.3	103.8
Unknown	2.3	None	1.2	None	2.8	1.4

PROCESSED FOOD AND FEED - POTATO

PMRA # 2789654

Test Site	North American growing regions 1 and 11.
Treatment	Three foliar applications
Total Seasonal Rate	2.3 kg a.i./ha
End-use product/formulation	EC formulation
Preharvest interval	6-7 DALA
Processed Commodity	Median Processing Factor
Peeled potato	<0.45x
Wet peel	<1.6x
Boiled potatoes	<0.45x
Microwave boiled (unpeeled)	<0.45x
Baked potato	<0.75x
Fried potato	<0.45x
Crisps	<0.45x
Chips	<0.45x
Granules/flakes	<0.45x
Process waste	<0.45x

Ensiled potato	0.58x
Starch	0.45x
Dried pulp	2.4x
Potato protein	1.5x
PROCESSED FOOD AND FEED – SUGAR BEET	
PMRA # 2789652	
Test Site	Representative sugar beet growing regions in Germany.
Treatment	Two foliar applications
Total Seasonal Rate	1.4 kg a.i./ha
End-use product/formulation	EC formulation
Preharvest interval	20-21 DALA
Processed Commodity	Median Processing Factor
Washed beets	0.28x
Wash water	0.38x
Cossettes	0.43x
Pressed pulp	0.75x
Press water	<0.05x
Raw juice	0.12x
Thin juice	0.08x
Thick juice	0.28x
Molasses	0.88x
Raw sugar	<0.06x
Affinated syrup	0.11x
Refined sugar	<0.06x
Dried pulp	4.8x
Ensiled pulp	0.88x
PROCESSED FOOD AND FEED – SOYBEAN	
PMRA # 2789653	
Test Site	North American growing regions 2, 4 and 5
Treatment	Two foliar applications
Total Seasonal Rate	297-306 g a.i./ha (Plot 2); 599-611 g a.i./ha (Plot 3)
End-use product/formulation	EC formulation
Preharvest interval	21-23 DALA (Plot 2*); 77-91 DALA (Plot 3)
Processed Commodity	Median Processing Factor
AGF	>188.0x
Hulls	<0.83x
Meal, toasted	<0.83x
Crude oil	1.0x
Tofu	<0.83x
Soysauce	<0.83x
Pollards	<0.83x
Flour	<0.83x
Miso	<0.83x
Soy milk	<0.83x
Refined oil	<0.83x
Meal, untoasted	<0.83x
*Bulk samples from Plot 2 were used for aspirated grain fractions.	

PROCESSED FOOD AND FEED – CITRUS		PMRA # 2789398
Test Site	North American growing regions 3 and 10	
Treatment	Three foliar applications	
Total Seasonal Rate	2 kg a.i./ha	
End-use product/formulation	EC formulations	
Preharvest interval	0 DALA	
Processed Commodity	Median Processing Factor	
Juice	<0.02x	
Wet pomace	1.74x	
Dried pomace	6.44x	
Pulp	0.02x	
Dried pulp	0.11x	
Peel	2.6x	
Peel after oil extraction	1.8x	
Oil	41.2x	
Marmalade	0.11x	
PROCESSED FOOD AND FEED – APPLE		PMRA # 2789656
Test Site	North American growing regions 1, 10 and 11	
Treatment	Three foliar applications	
Total Seasonal Rate	888-906 g a.i./ha	
End-use product/formulation	SC formulation	
Preharvest interval	0 DALA	
Processed Commodity	Median Processing Factor	
Washed, whole apples	0.75x	
Wash water	0.12x	
Canned apples	<0.13x	
Fruit syrup	0.40x	
Applesauce	0.11x	
Dried apples	0.31x	
Juice	<0.13x	
Wet pomace	3.1x	
Dried pomace	9.9x	
PROCESSED FOOD AND FEED – PLUM		PMRA # 2789657
Test Site	North American growing regions 1, 10 and 11	
Treatment	Three foliar applications	
Total Seasonal Rate	903-914 g a.i./ha	
End-use product/formulation	SC formulation	
Preharvest interval	0 DALA	
Processed Commodity	Median Processing Factor	
Dried prune	4.1x	
Depitted plums	1.1x	
Juice	0.15x	
Puree	0.56x	
Washed whole plum	1.0x	
Wash water	<0.06x	

PROCESSED FOOD AND FEED – GRAPE		PMRA # 2789651
Test Site	Representative grape growing regions in Germany.	
Treatment	Two foliar applications	
Total Seasonal Rate	870-920 g a.i./ha	
End-use product/formulation	EC formulation	
Preharvest interval	21 DALA	
Processed Commodity	Median Processing Factor	
Must, cloudy (rose)	0.13x	
Pomace (rose)	3.1x	
Must deposit (rose)	0.75x	
Must separated (rose)	0.07x	
Juice (rose)	0.05x	
Yeast deposit (rose)	0.54x	
Rose wine	0.02x	
Stalks (red)	1.64x	
Crush (red)	1.54x	
Must, cloudy (red)	0.18x	
Pomace (red)	4.3x	
Must deposit (red)	0.20x	
Must, separated (red)	0.14x	
Juice (red)	0.13x	
Yeast deposit (red)	1.1x	
Red wine	0.03x	
Raisins	3.7x	
Stalks (raisins)	6.3x	
PROCESSED FOOD AND FEED – BARLEY		PMRA # 2789649
Test Site	Representative barley growing regions in Germany	
Treatment	Two foliar applications	
Total Seasonal Rate	890-960 g a.i./ha	
End-use product/formulation	EC formulation	
Preharvest interval	43-56 DALA	
Processed Commodity	Median Processing Factor	
Pearled barley	0.12x	
Flour	3.7x	
Bran	5.0x	
Brewing malt	0.50x	
Malt sprouts	1.1x	
Beer	<0.04x	
Brewer's grain (dried)	2.4x	
Brewer's yeast	0.19x	
PROCESSED FOOD AND FEED – FIELD CORN		PMRA # 2789655
Test Site	North American growing regions 4 and 5	
Treatment	Two foliar applications	
Total Seasonal Rate	296-298 g a.i./ha for AGF; 888-892 g a.i./ha for all other processed commodities	
End-use product/formulation	EC formulation	

Preharvest interval	20-21 DALA for grain for generation of AGF; 13-17 DALA for forage for generation of silage; 52-69 DALA for grain for generation of all other processed commodities	
Processed Commodity	Median Processing Factor	
AGF	>24x	
Silage	0.86x	
Flour, wet milling	ND	
Flour, dry milling	ND	
Bran	>1.7x	
Gluten	ND	
Gluten feed meal	2.7x	
Starch, wet milling	ND	
Germ	ND	
Oil, refined, wet milling	ND	
Meal, dry milling	ND	
Grits, dry milling	ND	
Milled byproducts	>8.8x	
Oil, refined, dry milling	ND	
ND = Not determined, residues <LOQ (<0.01 ppm) in the RAC and processed commodity.		
PROCESSED FOOD AND FEED – WHEAT		PMRA # 2789650
Test Site	Representative wheat growing regions in Germany	
Treatment	Two foliar applications	
Total Seasonal Rate	850-920 g a.i./ha	
End-use product/formulation	EC formulation	
Preharvest interval	7-9 DALA for forage for generation of silage; 45-60 DALA for grain for generation of all other processed commodities	
Processed Commodity	Median Processing Factor	
AGF	39x	
Wet silage	1.2x	
Wilted silage	1.9x	
Bran	2.9x	
Flour	<0.29x	
Germ	1.1x	
Middlings	2.3x	
Shorts	3.5x	
Gluten	0.55x	
Gluten feed meal	0.29x	
Starch	0.29x	
Whole meal flour	0.79x	
Whole grain bread	0.56x	
Milled byproducts	0.62x	

LIVESTOCK FEEDING – Dairy cattle			PMRA # 2789647		
Lactating dairy cows were administered mefentrifluconazole at dose levels of 1.6 ppm, 7.5 ppm , 49 ppm and 141ppm in the feed for 28 consecutive days followed by a depuration period of 3, 7 and 14 days. The dose levels of 1.6 ppm, 7.5 ppm, 49 ppm and 141 ppm correspond to 0.2x, 1x, 7x and 19x the estimated dietary burden for dairy cattle, respectively and 0.6x, 2.9x, 19x and 54x the estimated dietary burden for beef cattle, respectively.					
Residue of mefentrifluconazole declined in milk and tissues following the cessation of dosing.					
Commodity	Feeding Level (ppm)	Mefentrifluconazole Highest Residues (ppm)	Dietary Burden (ppm)	Anticipated Residues (ppm)	
				Ruminant	Non-ruminant
Whole milk	1.6	<0.01	Ruminant [7.28 ppm for dairy cattle]	0.018	Not applicable
	7.5	0.014			
	49	0.11			
	141	0.354			
Skim milk	1.6	<0.01	Non-ruminant [0.09 ppm for swine]	0.005	Not applicable
	7.5	<0.01			
	49	0.016			
	141	0.103			
Cream	1.6	<0.01		0.098	Not applicable
	7.5	0.061			
	49	0.459			
	141	1.95			
Perirenal Fat	1.6	0.018		0.137	0.002
	7.5	0.059			
	49	0.9			
	141	2.29			
Mesenterial Fat	1.6	0.018		0.095	0.001
	7.5	0.077			
	49	0.566			
	141	1.87			
Subcutaneous Fat	1.6	0.017		0.158	0.001
	7.5	0.041			
	49	0.784			
	141	1.2			
Liver	1.6	0.034		0.218	0.003
	7.5	0.182			
	49	1.4			
	141	3.58			
Kidney	1.6	0.014		0.095	0.001
	7.5	0.074			
	49	0.505			
	141	1.88			
Muscle	1.6	<0.01		0.018	0
	7.5	<0.01			
	49	0.105			
	141	0.221			

LIVESTOCK FEEDING – Laying hens			PMRA # 2789646	
Laying hens were administered mefentrifluconazole at dose levels of 0.18 ppm, 1.7 ppm, 5.1 ppm and 17.2 ppm in the feed for 33 consecutive days followed by a depuration period of 2, 7 and 14 days. The dose levels of 0.18 ppm, 1.7 ppm, 5.1 ppm and 17.2 ppm correspond to 2x, 19x, 57x and 191x the estimated dietary burden for poultry, respectively.				
Separation of the 24-day egg samples into the yolk and white from the 17.2 ppm dosing group indicated that mefentrifluconazole residues concentrated in the yolk (maximum residue = 0.091 ppm), and not in the white (<0.01 ppm).				
Residue of mefentrifluconazole declined in eggs and tissues following the cessation of dosing.				
Commodity	Feeding Level (ppm)	Mefentrifluconazole Highest Residues (ppm)	Dietary Burden (ppm)	Anticipated Residue (ppm)
Whole Egg	0.18	Samples not analyzed	0.09 ppm for poultry	0
	1.7	<0.01		
	5.1	<0.01		
	17.2	0.042		
Fat	0.18	<0.01		0.001
	1.7	<0.01		
	5.1	0.025		
	17.2	0.25		
Liver	0.18	<0.01		0.001
	1.7	0.017		
	5.1	0.021		
	17.2	0.2		
Muscle	0.18	<0.01		0
	1.7	<0.01		
	5.1	<0.01		
	17.2	0.027		
Skin with fat	0.18	<0.01		0.001
	1.7	<0.01		
	5.1	0.011		
	17.2	0.15		

Table 10 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT Primary crops (grape, soybean, wheat) Rotational crops (lettuce, radish, wheat)	Mefentrifluconazole
RESIDUE DEFINITION FOR RISK ASSESSMENT Primary crops (grape, soybean, wheat) Rotational crops (lettuce, radish, wheat)	Mefentrifluconazole
METABOLIC PROFILE IN DIVERSE CROPS	Similar in grape, soybean and wheat

ANIMAL STUDIES			
ANIMALS		Ruminant and Poultry	
RESIDUE DEFINITION FOR ENFORCEMENT		Mefentrifluconazole	
RESIDUE DEFINITION FOR RISK ASSESSMENT		Ruminant: Mefentrifluconazole including the metabolite M750F022, expressed as parent equivalents. Poultry: Mefentrifluconazole including the metabolite M750F022 (free and conjugated), expressed as parent equivalents.	
METABOLIC PROFILE IN ANIMALS (goat, hen, rat)		The goat, hen, and rat metabolism studies taken together confirm that the metabolic pathways in livestock are comparable to the rat.	
FAT SOLUBLE RESIDUE		Yes	
DIETARY RISK FROM FOOD AND WATER			
Refind chronic dietary exposure analysis ADI = 0.04 mg/kg bw/day Estimated chronic drinking water concentration = 34 µg/L	POPULATION	ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)	
		Food Alone	Food and Drinking Water
	All infants < 1 year	3.7	10.1
	Children 1–2 years	8.9	11.3
	Children 3 to 5 years	6.0	8.0
	Children 6–12 years	3.1	4.5
	Youth 13–19 years	1.5	2.7
	Adults 20–49 years	2.0	3.7
	Adults 50+ years	1.8	3.4
	Females 13-49 years	1.5	3.2
	Total population	2.4	4.1
Basic acute dietary exposure analysis, 95th percentile ARfD = 2.0 mg/kg bw Estimated acute drinking water concentration = 92 µg/L	POPULATION	ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)	
		Food Alone	Food and Drinking Water
	All infants < 1 year	3.5	3.8
	Children 1–2 years	5.2	5.3
	Children 3 to 5 years	3.3	3.4
	Children 6–12 years	1.6	1.7
	Youth 13–19 years	0.80	0.89

	Adults 20–49 years	0.76	0.88
	Adults 50+ years	0.69	0.81
	Females 13-49 years	0.72	0.85
	Total population	1.3	1.4

Table 11 Mixer/Loader/Applicator Risk Assessment for Workers Handling BAS 752 RC, Belyan, Lenvyor, Cevya and Maxtima

Crop	Maximum Rate (kg a.i./ha)	Task	AHETF Unit Exposure (µg/kg a.i. handled)		ATPD (ha/day) ¹	Daily exposure (mg/kg bw/day) ²			MOE ³
			Dermal	Inhalation		Dermal	Inhalation	Dermal + Inhalation	Dermal + Inhalation
Ground Field Sprayer Application									
<ul style="list-style-type: none">- Canola/rapeseed, flax- Chickpeas, lentils, faba beans- Soybeans- Potato- Wheat	0.075	Farmer MLA	83.9	2.31	107	0.0014	0.0002	0.0016	6970
		Custom MLA	83.9	2.31	360	0.0045	0.0008	0.0053	2071
<ul style="list-style-type: none">- Canola/rapeseed, flax, mustard- CSG 6C: Dried shelled peas and beans- Soybeans- Potato- Wheat- Corn (field, sweet, pop)- Peanut	0.100	Farmer MLA	83.9	2.31	107	0.0018	0.0003	0.0021	5227
		Custom MLA	83.9	2.31	360	0.0060	0.0010	0.0071	1553
Sugarbeets	0.150	Farmer MLA	83.9	2.31	107	0.0027	0.0005	0.0032	3485
		Custom MLA	83.9	2.31	360	0.0091	0.0016	0.0107	1036
Airblast Application									
Grapes	0.100	MLA	3827.8	9.71	20	0.0153	0.0002	0.0155	707
<ul style="list-style-type: none">- Pome fruits- Stone fruits- Tree nuts	0.150	MLA	3827.8	9.71	20	0.0230	0.0004	0.0233	472
Aerial Application									
<ul style="list-style-type: none">- Canola, flax- Chickpeas, lentils, faba beans- Soybeans	0.075	ML	58.5	0.63	400	0.00351	0.0002	0.00375	2936
		A	2.67	0.0097	400	0.0002	0.0000	0.0001	67140

Crop	Maximum Rate (kg a.i./ha)	Task	AHETF Unit Exposure (µg/kg a.i. handled)		ATPD (ha/day) ¹	Daily exposure (mg/kg bw/day) ²			MOE ³
			Dermal	Inhalation		Dermal	Inhalation	Dermal + Inhalation	Dermal + Inhalation
- Potato - Wheat								6	
- Canola/rapeseed, flax, mustard - CSG 6C: Dried shelled peas and beans - Soybeans - Potato - Wheat - Corn (field, sweet, pop) - Peanut - Corn (field, sweet, pop)	0.100	ML	58.5	0.63	400	0.0047	0.0003	0.005	2200
		A	2.67	0.0097	400	0.0002	0.0000	0.0002 2	50354
Sugarbeets	0.150	ML	58.5	0.63	400	0.0070	0.0005	0.0075	1468
		A	2.67	0.0097	400	0.0003	0.0000	0.0003	33570
Golf Course Turf									
Using field groundboom sprayer	1.0	MLA	83.9	2.31	16	0.0027	0.0005	0.0032	3495
Using handgun sprayer	1.0	MLA	785	4	16	0.02512	0.0008	0.0259	424
Using backpack sprayer (moderate inhalation)	1.0	MLA	5445.85	62.1	0.375	0.0041	0.0003	0.0044	2500

M= mixer, L= loader, A= applicator

¹ PMRA Default Area Treated per day tables (July, 2010)

² Daily exposure: Dermal = (Unit exposure × ATPD × Rate × 16% dermal absorption) / (80 kg bw × 1000 µg/mg), and

Inhalation = (AHETF unit exposure × ATPD × Rate) / (80 kg bw × 1000 µg/mg)

³ Short- to Intermediate-term dermal and inhalation NOAEL of 11 mg/kg bw/day based on 90-day dietary study in mice, target MOE = 100

Table 12 Postapplication Exposure and Risk for BAS 752 RC, Belyan, Lenvyor, Cevya and Maxtima

Crops	# of total applications ¹ (RTI)	Rate (g a.i./ha)	DFR ($\mu\text{g}/\text{cm}^2$) ²	Postapplication activity	TC (cm^2/hr) ³	Exposure ($\text{mg}/\text{kg bw}/\text{day}$) ⁴	Calculated MOE ⁵
Canola/rapeseed, flax, mustard	2 (10-14)	75	0.382	Scouting in full foliage	1100	0.0067	1636
	3 (10-14)	100	0.7214	Scouting in full foliage	1100	0.0127	866
Dried shelled peas and beans including chickpeas, lentils and faba beans (CSG 6C)	2 (10-14)	75	0.382	Hand set irrigation	1750	0.0107	1028
				Scouting	1100	0.0067	1636
				Hand weeding chickpeas	70	0.0004	25710
	4 (10-14)	100	0.9093	Hand set irrigation	1750	0.0255	432
				Scouting	1100	0.01600	687
				Hand weeding chickpeas	70	0.0010	10801
Soybeans	2 (10-14)	75	0.382	Scouting	1100	0.0067	1636
				Hand weeding	70	0.0004	25710
	3 (10-14)	100	0.7214	Scouting	1100	0.0127	866
				Hand weeding	70	0.0008	13614
Potato	4 (7-14)	75	0.7168	Hand set irrigation	1750	0.0201	548
				Rouging	1100	0.0126	872
				Scouting	210	0.0024	4567
	4 (7-14)	100	0.9557	Hand set irrigation	1750	0.0268	411
				Rouging	1100	0.0168	654
				Scouting	210	0.0032	3426
Wheat [all types]	2 (10-14)	75	0.382	Scouting	1100	0.0067	1636
				Hand pruning, hand weeding, propagating, trellis repair	70	0.0004	25711
	3 (10-14)	100	0.7214	Scouting, irrigating in full foliage	1100	0.0127	866
				Hand weeding	70	0.0008	13614
Field corn, seed corn and popcorn	3 (10-14)	100	0.7214	Hand detasseling seed corn, hand harvesting	8800	0.1016	108
				Hand set irrigating	1750	0.0202	544

Crops	# of total applications ¹ (RTI)	Rate (g a.i./ha)	DFR ($\mu\text{g}/\text{cm}^2$) ²	Postapplication activity	TC (cm^2/hr) ³	Exposure ($\text{mg}/\text{kg bw}/\text{day}$) ⁴	Calculated MOE ⁵
				in full foliage			
				Scouting in full foliage	1100	0.0127	866
				Hand weeding	70	0.0008	13614
Sweet Corn	4 (10-14)	100	0.9093	Hand harvesting (21-day PHI)	8800	0.1280	86
			0.7773 (13 DALA)		8800	0.1094	100 (No REI required as PHI is 21 days)
			0.9093	Hand set irrigating in full foliage	1750	0.0255	432
			0.9093	Scouting in full foliage	1100	0.0160	687
			0.9093	Hand weeding	70	0.0010	10801
Peanut	4 (10-14)	100	0.9093	Scouting and irrigating in full foliage	210	0.0031	3600
				Hand weeding	70	0.0010	10801
Sugarbeets	2 (14)	150	0.747	Scouting and irrigating in full foliage	210	0.0025	4383
				Hand harvesting (21-day PHI)	1100	0.0132	837
				Hand weeding in full foliage and thinning plants	70	0.0008	13148
Grapes (Wine and Table)	3 (14)	100	0.752 (Highest Peak residue at the WA site)	Cane turning and girdling table grapes	19300	0.2322	47
			0.412 (Actual value measured 35 DALA at the WA site)		19300	0.1270	86 (35-day REI required)
			0.752	Tying/training, hand harvesting (14-day PHI) and	8500	0.1023	108

Crops	# of total applications ¹ (RTI)	Rate (g a.i./ha)	DFR ($\mu\text{g}/\text{cm}^2$) ²	Postapplication activity	TC (cm^2/hr) ³	Exposure ($\text{mg}/\text{kg bw}/\text{day}$) ⁴	Calculated MOE ⁵
				leaf pulling			
			0.752	Hand set irrigation	1750	0.0211	522
			0.752	Bird control, hand pruning, hand weeding, scouting, trellis repair, propagating	640	0.0077	1429
			0.752	Transplanting	230	0.0028	3975
Pome fruits (CG 11)	3 (7-10)	150	1.12	Fruit thinning	3000	0.0538	205
				Hand harvesting (0-day PHI)	1400	0.0251	439
				Hand pruning, training, scouting	580	0.0104	1058
				Hand weeding, popping, orchard maintenance	100	0.0018	6138
				Transplanting	230	0.0041	2669
Stone fruits (CG 12)	3 (7-14)	150	1.12	Fruit thinning	3000	0.0538	205
				Hand harvesting (0-day PHI)	1400	0.0251	439
				Hand pruning, training, scouting	580	0.0104	1058
				Hand weeding, popping, orchard maintenance	100	0.0018	6138
				Transplanting	230	0.0041	2669
Tree nuts	3 (7-14)	150	1.12	Scouting	580	0.0104	1058
				Transplanting	230	0.0041	2669
				Harvesting mechanical-shaking (0-day PHI)	190	0.0034	3231
				Orchard maintenance, poling, hand weeding	100	0.0018	6138

Crops	# of total applications ¹ (RTI)	Rate (g a.i./ha)	DFR ($\mu\text{g}/\text{cm}^2$) ²	Postapplication activity	TC (cm^2/hr) ³	Exposure ($\text{mg}/\text{kg bw}/\text{day}$) ⁴	Calculated MOE ⁵
Golf course turf	3 (14-28)	1000	0.2558	Transplanting, planting, harvesting	6700	0.0274	401
				Mowing, watering/irrigation, repair, grooming	3500	0.0143	768
				Scouting, hand pruning, mechanical weeding, seeding	1000	0.0041	2687

¹ Based on maximum efficacy rate per year

² For all crop activities except in grapes and for golf course turf: DFR values calculated on Day 0 after maximum number of applications (27% DFR on Day 0 of the first application, and 1.2% dissipation per day from the grape DFR study data). For grapes: the DFR on Day 0 is the maximum peak residue as measured at the WA site from the DFR study. For golf course turf, Day 0 TTR after third application, calculated as default 1% TTR after first application and 1.2% dissipation per day.

³ ARTF Transfer coefficients

⁴ Dermal Exposure = (Peak DFR/TTR \times TC \times 8 hr/day \times 16% dermal absorption) / (80 kg bw \times 1000 $\mu\text{g}/\text{mg}$)

⁵ Based on short- to intermediate- term NOAEL of 11 $\text{mg}/\text{kg bw}/\text{day}$, target MOE = 100

Table 13 Exposure Risk Estimates for Workers Treating Seed with Relenya in Commercial Facilities using Closed Transfer Systems

Worker Task	Unit Exposure (µg/kg a.i. handled)		Application Rate (kg a.i./kg seed)	Seeds Treated Per Day (kg) ¹	Exposure (mg/kg bw/day)		Combined Exposure (Dermal + Inhalation) (mg/kg bw/day)	MOE ⁴ Dermal + Inhalation
	Dermal	Inhalation			Dermal ²	Inhalation ³		
Corn Based on Corn Unit Exposures								
Mixer, loader	170	3.72	0.0001	125,000	4.25E-03	5.81E-04	4.83E-03	2.28E+03
Bagger, sewers, stacker	54.5	18.7	0.0001	125,000	1.36E-03	2.92E-03	4.28E-03	2.57E+03
Cleaner	87.7	24.1	10	--	1.75E-03	3.01E-03	4.77E-03	2.31E+03
CSG 6C Based on Corn Unit Exposures								
Mixer, loader	170	3.72	0.0002	216,000	1.47E-02	2.01E-03	1.67E-02	6.59E+02
Bagger, sewers, stacker	54.5	18.7	0.0002	216,000	4.71E-03	1.01E-02	1.48E-02	7.43E+02
Cleaner (canola unit exposure)	56.2	12.7	20	216,000	2.25E-03	3.18E-03	5.42E-03	2.03E+03
Canola/Rapeseed Based on Canola Unit Exposures								
Mixer, loader	53.5	1.12	0.0002	67,000	1.43E-03	1.88E-04	1.62E-03	6.78E+03

Worker Task	Unit Exposure (µg/kg a.i. handled)		Application Rate (kg a.i./kg seed)	Seeds Treated Per Day (kg) ¹	Exposure (mg/kg bw/day)		Combined Exposure (Dermal + Inhalation) (mg/kg bw/day)	MOE ⁴ Dermal + Inhalation
	Dermal	Inhalation			Dermal ²	Inhalation ³		
Bagger, sewers, stacker	7.33	1.5	0.0002	67,000	1.96E-04	2.51E-04	4.48E-04	2.46E+04
Cleaner	56.2	12.7	20	67,000	2.25E-03	3.18E-03	5.42E-03	2.03E+03
Soybean based on canola unit exposures								
Mixer, loader	53.5	1.12	0.0002	63,000	1.35E-03	1.76E-04	1.52E-03	7.22E+03
Bagger, sewers, stacker	7.33	1.5	0.0002	63,000	1.85E-04	2.36E-04	4.21E-04	2.61E+04
Cleaner	56.2	12.7	20	63,000	2.25E-03	3.18E-03	5.42E-03	2.03E+03
Wheat/Triticale Based on Wheat Unit Exposure								
Mixer, loader	83.06	6.04	0.0001	92,000	1.53E-03	6.95E-04	2.22E-03	4.95E+03
Wheat/Triticale Based on Cereals Unit Exposure								
Bagger, sewer, stacker	17.67	0.89	0.0001	92,000	3.25E-04	1.02E-04	4.27E-04	2.58E+04
Wheat/Triticale Based on Wheat Unit Exposure								
Cleaner	2.13	0.102	10	--	4.26E-05	1.28E-05	5.54E-05	1.99E+05

¹ kg seed treated per day from PMRA defaults

² Dermal Exposure = (Unit exposure × App rate × Seed treated per day × 16% dermal absorption) / (80 kg bw × 1000 µg/mg)

³ Inhalation Exposure = (Unit exposure × App rate × Seed treated per day × 100% inhalation absorption) / (80 kg bw × 1000 µg/mg)

⁴ MOE = NOAEL of 11 mg /kg bw/day for dermal and inhalation exposure ÷ Exposure (dermal + inhalation). Target MOE = 100

Table 14 Exposure and Risk for On-farm Seed Treatment with Relenya

Crop	Dermal Unit Exposure (µg/kg a.i. handled)	Inhalation Unit Exposure (µg/kg a.i. handled)	Application Rate (kg a.i./ kg seed)	Seeds Treated Per Day (kg) ¹	Dermal Exposure ² (mg/kg bw/day)	Inhalation Exposure ³ (mg/kg bw/day)	Combined Exposure (Dermal + Inhalation) (mg/kg bw/day)	MOE ⁴ (Dermal + Inhalation)
Canola/rapeseed	145.22	7.61	0.0002	600	3.48E-05	1.14E-05	4.63E-05	2.38E+05
Wheat, triticale	145.22	7.61	0.0001	60000	1.74E-03	5.71E-04	2.31E-03	4.75E+03
Corn	145.22	7.61	0.0001	1360	3.95E-05	1.29E-05	5.24E-05	2.10E+05
Soybeans	145.22	7.61	0.0002	5400	2.90E-4	9.51E-05	3.86E-04	2.85E+04
Legumes (CSG 6C)	145.22	7.61	0.0002	10000	5.80E-4	1.90E-04	7.71E-04	1.43E+04

¹ Amount of seeds treated On-farm per day (kg) average values

² Dermal Exposure = (Unit exposure × App rate × Seed treated per day × 16% dermal absorption) / (80 kg bw × 1000 µg/mg)

³ Inhalation Exposure = (Unit exposure × App rate × Seed treated per day × 100% inhalation absorption) / (80 kg bw × 1000 µg/mg)

⁴ MOE = NOAEL of 11 mg /kg bw/day for dermal and inhalation exposure ÷ Exposure (dermal + inhalation). Target MOE = 100

Table 15 Risk Estimates for Workers Planting Treated Corn, Soybean, Canola/Rapeseed, CSG 6C, Wheat/Triticale Seeds

Worker Task Planting	Unit Exposure (µg/kg a.i. handled)		App. Rate (kg a.i./ kg seed)	Seed Planted (kg seed/ day) ¹	Exposure (mg/kg bw/day)		Combined Exposure (Dermal + Inhalation)	MOE ⁴ (Dermal + Inhalation) Target 100
	Dermal	Inhalation			Dermal ²	Inhalation ³		
Canola/rapeseed	1515	82.83	0.0002	600	3.64E-04	1.24E-04	4.88E-04	2.25E+04
Corn	1515	82.83	0.0001	1350	4.09E-04	1.40E-04	5.49E-04	2.00E+04
Soybeans	1515	82.83	0.0002	9,000	5.45E-03	1.86E-03	7.32E-03	1.50E+03
CSG 6C	1515	82.83	0.0002	19,000	1.15E-02	3.93E-03	1.54E-02	7.12E+02
Cereals with bagged treated seed								
Wheat, triticale	1171.83	360.04	0.0001	13,500	3.16E-03	6.08E-03	9.24E-03	1.19E+03
Cereals with bulk treated seed								
Wheat, triticale	336	119	0.0001	13,500	9.07E-04	2.01E-03	2.92E-03	3.77E+03

¹ Average Seed Planted Per Day

² Dermal Exposure = (Unit exposure × App rate × Seed planted per day × 16% dermal absorption) / (80 kg bw × 1000 µg/mg)

³ Inhalation Exposure = (Unit exposure × App rate × Seed planted per day × 100% inhalation absorption) / (80 kg bw × 1000 µg/mg)

⁴ MOE = NOAEL of 11 mg /kg bw/day for dermal and inhalation exposure ÷ Exposure (dermal + inhalation). Target MOE = 100

Table 16 Golfer Dermal Postapplication Exposure and Risk From the Proposed Use of Maxtima

Postapplication Activity	Dermal Absorption	Peak TTR ¹ (µg/cm ²)	Age (yrs)	TC ² (cm ² /hr)	Exposure Duration (hr/day)	Body Weight (kg)	Dermal Exposure ⁵ (mg/kg bw/day)	MOE ⁶
Golfing	16%	0.2558	16+	5300	4	80	0.01085	1014
			11-<16	4400	4	57	0.01264	870
			6-<11	2900	4	32	0.01484	741

TTR = Turf Transferrable Residue

¹ 1% of the application rate and 1.2% dissipation per day from the grape DFR study data

² TC = Transfer coefficients from Residential SOPs

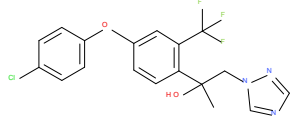
³ Dermal Exposure = (DA × TTR × TC × ED) / (BW × 1000 µg/mg)

⁴ Based on NOAEL of 11 mg/kg bw/day, target MOE = 100


Table 17 Aggregate Risk Assessment for Golfers

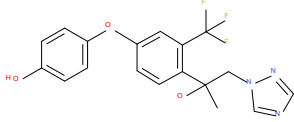
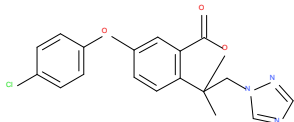
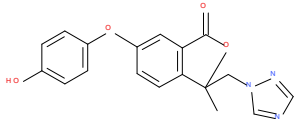
Age Group	Exposure (mg/kg bw/day)			Aggregate MOE ³ (Target = 100)
	Dermal ¹	Dietary ²	Aggregate (Dermal + Dietary)	
Adults (16+)	0.01085	0.002049	0.01290	853
Youth (11-<16)	0.01264	0.001162	0.01380	797
Children (6-<11)	0.01484	0.001409	0.01625	677

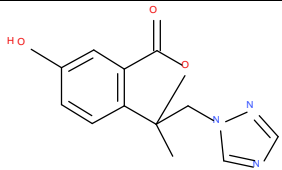
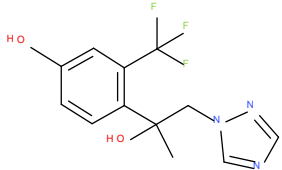
¹ Dermal exposure from Table 6 (above)² Chronic dietary (food + drinking water) exposure were derived from DEEM³ Aggregate MOE = Short- to Intermediate-term Aggregate NOAEL of 11 mg/kg bw/day from 90-day dietary mouse study
(Dermal exposure + Dietary exposure)**Table 18 Transformation Products of the Active Ingredient Mefentrifluconazole Relevant to the Environment**

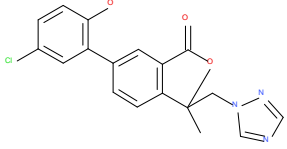
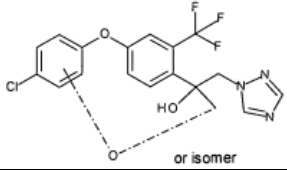
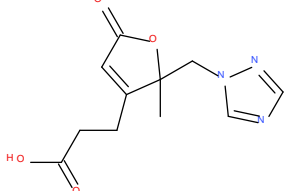
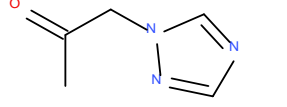
Compound	Study			Max %AR ¹ (day)	%AR ¹ at Study End (Study Length)
Mefentrifluconazole (M750F000; BAS 750 F) Formula: $C_{18}H_{15}ClF_3N_3O_2$ MW: 397.8 g/mol 	Hydrolysis	PMRA #2789692	pH 4, 25°C	Parent	93.8 (30)
			pH 5, 25°C	Parent	92.1 (30)
			pH 7, 25°C	Parent	93.3 (30)
			pH 9, 25°C	Parent	93.1 (30)
	Aqueous photolysis	PMRA# 2789694 (2 radiolabels, maximum of both)	pH 7 buffer, irradiated	Parent	1.8 (15)
			pH 7 buffer, dark	Parent	97.5 (15)
		PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	Parent	16.9 (15)
			Golden Lake, sterile, dark	Parent	94.0 (15)
	Soil photolysis	PMRA# 2789669 (2 radiolabels, maximum of both)	Nonsterile Irradiated	Parent	93.75 (15)
			Nonsterile Dark	Parent	95.83 (15)
	Aerobic aquatic		Berghäuser Altrhein chlorophenyl label	Parent	50.7 (100)
			Berghäuser Altrhein triazole label	Parent	47.9 (100)

Compound	Study			Max %AR ¹ (day)	%AR ¹ at Study End (Study Length)
		PMRA #2789699 (3 radiolabels, maximum of all; total for water and sediment system)	Berghäuser Altrhein trifluoromethylphenyl label	Parent	62.8 (100)
			Ranschgraben chlorophenyl label	Parent	64.8 (100)
			Ranschgraben triazole label	Parent	67.3 (100)
			Ranschgraben trifluoromethylphenyl label	Parent	70.2 (100)
	Anaerobic aquatic	PMRA #2789701 (2 radiolabels, maximum of both)	Goose River	Parent	73.2 (100)
			Golden Lake	Parent	85.5 (100)
	Aerobic soil	PMRA #2789675 (triazole label)	Germany loamy sand	Parent	83.5 (120)
			Indiana loam	Parent	87.1 (120)
		PMRA #2789663 (2 radiolabels, maximum of both)	Germany loamy sand	Parent	81.2 (121)
			New Jersey loam	Parent	67.4 (120)
		PMRA #2789665 (trifluoromethylphenyl label)	New Jersey loam	Parent	64.9 (121)
	Anaerobic soil	PMRA #2789667 (triazole label for all soils; also chlorophenyl label for NJ soil)	Indiana loam	Parent	78.7 (120)
			New Jersey loam	Parent	89.0 (120)
			Germany loamy sand	Parent	76.0 (120)
			Germany sandy loam	Parent	92.6 (120)
	Terrestrial field dissipation	PMRA #2789683	New York silt loam	Parent	19.0 (706 DALA)
			North Dakota clay	Parent	11.8 (661 DALA)
			Washington loamy sand	Parent	10.0 (693 DALA)

Compound	Study			Max %AR ¹ (day)	%AR ¹ at Study End (Study Length)
			Oklahoma sandy loam	Parent	15.4 (626 DALA)
			Illinois silty clay loam	Parent	15.4 (638 DALA)
		PMRA #2789678	Germany (Lentzke) loamy sand	Parent	22.5 (715 DALA)
			Germany (Goch-Nierswald) silt loam	Parent	20.2 (710 DALA)
			France silty clay loam	Parent	15.7 (720 DALA)
			Italy silty clay loam	Parent	50.7 (714 DALA)
			Spain loamy sand	Parent	14.8 (713 DALA)
M750F001 (1,2,4-(1H)-triazole) Formula: C ₂ H ₃ N ₃ MW: 69.1 g/mol 	Aqueous photolysis	PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	4.2 (15)	4.2 (15)
			Golden Lake, sterile, dark	0.6 (1)	<LOQ (15) (<0.297)
	Aerobic aquatic	PMRA #2789699 (3 radiolabels)	Berghäuser Altrhein triazole label	15.1 (100)	15.1 (100)
			Ranschgraben triazole label	1.1 (100)	1.1 (100)
	Aerobic soil	PMRA #2789675 (triazole label)	Germany loamy sand	1.5 (91)	1.3 (120)
			Indiana loam	1.2 (120)	1.2 (120)
		PMRA #2789663 (2 radiolabels, maximum of both)	Germany loamy sand	0.5 (121)	0.5 (121)
			New Jersey loam	5.1 (90)	4.9 (120)
	Terrestrial field dissipation	PMRA #2789683	Washington loamy sand	3.4 (6 DA1A)	0.0 (693 DALA)
		PMRA #2789678	France silty clay loam	10.0 (7 DA1A)	0.0 (720 DALA)
M750F005 Formula: C ₁₈ H ₁₆ F ₃ N ₃ O ₃ MW: 379.3 g/mol	Aqueous photolysis	PMRA #2789694 (2 radiolabels, maximum of both)	pH 7 buffer, irradiated	32.2 (6)	28.6 (15)
			pH 7 buffer, dark	0.9 (3)	<LOQ (15) (<0.312)

Compound	Study			Max %AR ¹ (day)	%AR ¹ at Study End (Study Length)
		PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	7.1 (2)	1.0 (15)
M750F006 Formula: C ₁₈ H ₁₄ ClN ₃ O ₃ MW: 355.8 g/mol  **impurity observed in dosing solutions in some studies**	Hydrolysis (impurity seen at the beginning of the test)	PMRA #2789692	pH 4, 25°C	6.2 (30)	6.2 (30)
			pH 5, 25°C	5.7 (17)	5.2 (30)
			pH 7, 25°C	5.6 (30)	5.6 (30)
			pH 9, 25°C	5.4 (3)	5.0 (30)
	Aqueous photolysis	PMRA #2789694 (2 radiolabels, maximum of both)	pH 7 buffer, irradiated	30.7 (9)	21.7 (15)
			pH 7 buffer, dark	0.4 (2, 3)	<LOQ (15) (<0.312)
		PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	25.3 (15)	25.3 (15)
			Golden Lake, sterile, dark	3.7 (15)	3.7 (15)
	Anaerobic aquatic (impurity seen at beginning of test)	PMRA #2789701	Goose River chlorophenyl label	3.4 (3)	2.2 (100)
			Goose River triazole label	2.8 (14)	1.9 (100)
			Golden Lake chlorophenyl label	3.2 (1)	2.5 (100)
			Golden Lake triazole label	3.3 (14)	2.4 (100)
M750F007 Formula: C ₁₈ H ₁₅ N ₃ O ₄ MW: 337.3 g/mol 	Aqueous photolysis	PMRA# 2789694 (2 radiolabels, maximum of both)	pH 7 buffer, irradiated	43.9 (15)	43.9 (15)
		PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	2.3 (7)	0.7 (15)
M750F002 Formula: C ₁₂ H ₁₁ N ₃ O ₃ MW: 245.2 g/mol	Aqueous photolysis	PMRA #2789694 (2 radiolabels, maximum of both)	pH 7 buffer, irradiated	3.3 (15)	3.3 (15)

Compound	Study			Max %AR ¹ (day)	%AR ¹ at Study End (Study Length)
		PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	9.7 (15)	9.7 (15)
M750F003 Formula: $C_{12}H_{12}F_3N_3O_2$ MW: 287.2 g/mol 	Aqueous photolysis	PMRA #2789694 (2 radiolabels, maximum of both)	pH 7 buffer, irradiated	1.5 (15)	1.5 (15)
		PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	4.3 (7)	2.0 (15)
			Golden Lake, sterile, dark	0.2 (0)	<LOQ (15) (<0.297)
	Aerobic aquatic	PMRA #2789699 (3 radiolabels)	Berghäuser Altrhein triazole label	4.2 (100)	4.2 (100)
			Berghäuser Altrhein trifluoromethylphenyl label	8.5 (100)	8.5 (100)
			Ranschgraben triazole label	7.1 (100)	7.1 (100)
			Ranschgraben trifluoromethylphenyl label	4.4 (100)	4.4 (100)
	Aerobic soil	PMRA #2789675 (triazole label)	Germany loamy sand	1.8 (30)	0.9 (120)
			Indiana loam	0.6 (58)	0.5 (120)
		PMRA #2789663 (2 radiolabels, maximum of both)	Germany loamy sand	0.6 (7, 14)	Not detected (121)
			New Jersey loam	1.4 (14)	0.8 (120)
		PMRA #2789665 (trifluoromethylphenyl label)	New Jersey loam	1.6 (30)	1.2 (121)
	Terrestrial field dissipation	PMRA #2789683	New York silt loam	2.1 (6 DA1A & 266 DALA)	0.6 (706 DALA)
			North Dakota clay	2.2 (32 DALA)	0.5 (661 DALA)

Compound	Study			Max %AR ¹ (day)	%AR ¹ at Study End (Study Length)
			Washington loamy sand	0.8 (6 DA1A)	0.0 (693 DALA)
			Oklahoma sandy loam	0.8 (183 DALA)	0.0 (626 DALA)
			Illinois silty clay loam	3.8 (61 DALA)	0.9 (638 DALA)
M750F008 Formula: $C_{18}H_{14}ClN_3O_3$ MW: 355.8 g/mol 	Aqueous photolysis	PMRA# 2789694 (2 radiolabels, maximum of both)	pH 7 buffer, irradiated	7.3 (13)	6.1 (15)
		PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	1.3 (2)	0.4 (15)
M750F032 Formula: $C_{18}H_{15}ClF_3N_3O_3 + H$ MW: 414.08 g/mol 	Aerobic aquatic	PMRA #2789699 (3 radiolabels)	Berghäuser Altrhein trifluoromethylphenyl label	2.9 (100)	2.9 (100)
			Ranschgraben chlorophenyl label	2.3 (30, 100)	2.3 (100)
			Ranschgraben triazole label	2.1 (56)	1.8 (100)
M750F036 Formula: $C_{11}H_{13}N_3O_4$ MW: 251.2 g/mol 	Aqueous photolysis	PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	8.4 (15)	8.4 (15)
M750F037 Formula: $C_5H_7N_3O$ MW: 125.1 g/mol 	Aqueous photolysis	PMRA #2789696 (triazole label)	Golden Lake, sterile, irradiated	9.8 (15)	9.8 (15)
CO ₂	Soil photolysis		Nonsterile Irradiated	1.1 (15)	1.1 (15)

Compound	Study			Max %AR ¹ (day)	%AR ¹ at Study End (Study Length)
Formula: CO ₂ MW: 44 g/mol $\text{O}=\text{C}=\text{O}$		PMRA# 2789669 (2 labels, maximum of both)	Nonsterile Dark	0.4 (15)	0.4 (15)
	Aerobic aquatic	PMRA #2789699 (3 radiolabels, maximum of all; total for water and sediment system)	Berghäuser Altrhein chlorophenyl label	9.6 (100)	9.6 (100)
			Berghäuser Altrhein triazole label	0.8 (100)	0.8 (100)
			Berghäuser Altrhein trifluoromethylphenyl label	1.5 (100)	1.5 (100)
			Ranschgraben chlorophenyl label	5.1 (100)	5.1 (100)
			Ranschgraben triazole label	0.5 (100)	0.5 (100)
			Ranschgraben trifluoromethylphenyl label	0.5 (100)	0.5 (100)
	Anaerobic aquatic	PMRA #2789701 (2 radiolabels, maximum of both)	Goose River	0.4 (77 & 100)	0.4 (77 & 100)
	Aerobic soil	PMRA #2789675 (triazole label)	Germany loamy sand	0.5 (120)	0.5 (120)
			Indiana loam	0.3 (120)	0.3 (120)
		PMRA #2789663 (2 radiolabels, maximum of both)	Germany loamy sand	4.7 (121)	4.7 (121)
			New Jersey loam	9.7 (120)	9.7 (120)
		PMRA #2789665 (trifluoromethylphenyl label)	New Jersey loam	5.7 (120)	5.7 (120)
	Anaerobic soil		Indiana loam	0.35 (120)	0.35 (120)
			New Jersey loam	2.16 (120)	2.16 (120)

Compound	Study			Max %AR ¹ (day)	%AR ¹ at Study End (Study Length)
		PMRA #2789667 (triazole label for all soils; also chlorophenyl label for NJ)	Germany loamy sand	0.41 (120)	0.41 (120)
			Germany sandy loam	0.38 (120)	0.38 (120)
¹ Maximum average values are reported.					

Table 19 Fate and Behaviour in the Terrestrial Environment

Property	Test Substance	Value ¹	Transformation Products	Comments	PMRA#
Abiotic Transformation					
Hydrolysis	Mefentriflu-conazole (triazole label)	Effectively stable at pH 4, 5, 7, and 9 at 25°C	Major: None identified Minor: M750F006 (impurity seen at the beginning of the test)	Hydrolysis is not expected to be an important route of dissipation of mefentrifluconazole in the environment.	2789692
Phototransformation on soil	Mefentriflu-conazole (chlorophenyl and triazole labels)	DT ₅₀ (irradiated): 210 d; DT ₅₀ (dark): 591 d (SFO – combined labels) Phototransformation half-life (based on the difference between the light and dark tests): 326 d based on continuous irradiation	Major: None identified Minor (irradiated and dark): CO ₂	Phototransformation is not expected to contribute to the dissipation of mefentrifluconazole in soil.	2789669
Phototransformation in air	Mefentrifluconazole is not expected to be volatile under field conditions based on vapour pressure, Henry’s law constant, and AOPWIN results. Transformation products of mefentrifluconazole are not expected to be volatile under field conditions based on low detection of volatile organics in soil biotransformation studies. A phototransformation study in air was not required.				
Biotransformation					
Biotransformation in aerobic soil	Mefentriflu-conazole (chlorophenyl, triazole, and trifluoromethylphenyl labels)	Germany loamy sand (Li10): DT ₅₀ : 489 d; DT ₉₀ : 1,625 d (SFO – triazole label) Indiana loam: DT50: 590 d; DT90: 1.961 d	Major: Unextracted residues Minor: M750F001 M750F003 CO ₂	Mefentrifluconazole is persistent in soil. Biotransformation in aerobic soil is not an important route of dissipation for mefentrifluconazole.	2789675

Property	Test Substance	Value ¹	Transformation Products	Comments	PMRA#
		(SFO – triazole label)			
		<u>Germany loamy sand (Lufa 5M):</u> DT50: 570 d; t_R : 626 d (DFOP slow $t_{1/2}$ – combined chlorophenyl and triazole labels)	<u>Major:</u> Unextracted residues <u>Minor:</u> M750F001 M750F003 CO ₂		2789663
		<u>New Jersey loam:</u> DT50: 264 d; t_R : 355 d (DFOP slow $t_{1/2}$ – combined chlorophenyl and triazole labels)			
Biotransformation in anaerobic soil	Mefentriflu-conazole (chlorophenyl and triazole labels)	New Jersey loam: DT50: 303 d; t_R : 454 d (DFOP slow $t_{1/2}$ – trifluoromethylphenyl label)	<u>Major:</u> Unextracted residues <u>Minor:</u> M750F003 CO ₂	Mefentrifluconazole is persistent in soil. Biotransformation in anaerobic soil is not an important route of dissipation for mefentrifluconazole.	2789665
		<u>Indiana loam:</u> DT50: 325 d; DT90: 1,080 d (SFO – triazole label)	<u>Major:</u> Unextracted residues <u>Minor:</u> CO ₂		2789667
		<u>New Jersey loam:</u> DT50: 1,105 d; DT90: 3,669 d (SFO – combined chlorophenyl and triazole labels)			
		<u>Germany loamy sand (Li10):</u> DT50: 371 d;			

Property	Test Substance	Value ¹	Transformation Products	Comments	PMRA#
		DT90: 1,233 d (SFO – triazole label) <u>Germany sandy loam (Lufa 5M):</u> DT50: 11,217 d (unreliable value) (SFO – triazole label)			
Mobility					
Adsorption / desorption in soil	Mefentriflu-conazole	<u>Indiana loam:</u> Kd: 53.9 L/kg soil Koc: 4,415 L/kg OC $K_F: 48.4 \text{ (L/kg soil)}^{-1/n}$ $K_{FOC}: 3,970 \text{ (L/kg OC)}^{-1/n}$ 1/n: 0.95 <u>New Jersey loam:</u> Kd: 37.1 L/kg soil Koc: 3,715 L/kg OC $K_F: 35.8 \text{ (L/kg soil)}^{-1/n}$ $K_{FOC}: 3,576 \text{ (L/kg OC)}^{-1/n}$ 1/n: 0.96 <u>Japan loam:</u> Kd: 128.9 L/kg soil Koc: 3,792 L/kg OC $K_F: 124.6 \text{ (L/kg soil)}^{-1/n}$ $K_{FOC}: 3,665 \text{ (L/kg OC)}^{-1/n}$ 1/n: 1.01 <u>Italy loam:</u> Kd: 35.8 L/kg soil Koc: 3,580 L/kg OC $K_F: 31.2 \text{ (L/kg soil)}^{-1/n}$ $K_{FOC}: 3,124 \text{ (L/kg OC)}^{-1/n}$ 1/n: 0.91	Not applicable	Mefentrifluconazole is classified as having slight potential for mobility in soil.	2789689

Property	Test Substance	Value ¹	Transformation Products	Comments	PMRA#
		<u>Spain sandy clay loam:</u> Kd: 26.4 L/kg soil Koc: 2,163 L/kg OC K _F : 24.4 (L/kg soil) ^{-1/n} K _{FOC} : 1,999 (L/kg OC) ^{-1/n} 1/n: 0.94 <u>Germany loamy sand (Li10):</u> Kd: 31.4 L/kg soil Koc: 3,302 L/kg OC K _F : 36.2 (L/kg soil) ^{-1/n} K _{FOC} : 3,814 (L/kg OC) ^{-1/n} 1/n: 1.02 <u>Germany sandy loam (Lufa 5M):</u> Kd: 31.6 L/kg soil Koc: 2,877 L/kg OC K _F : 36.0 (L/kg soil) ^{-1/n} K _{FOC} : 3,275 (L/kg OC) ^{-1/n} 1/n: 1.00 <u>Germany sand (Lufa 2.1):</u> Kd: 27.8 L/kg soil Koc: 4,631 L/kg OC K _F : 29.7 (L/kg soil) ^{-1/n} K _{FOC} : 4,944 (L/kg OC) ^{-1/n} 1/n: 1.00			
Soil leaching	Not required as an acceptable adsorption/desorption study was submitted.				
Volatilization	Not required based on the low vapour pressure and Henry’s law constant.				
Field Studies					
Field dissipation (only sites relevant to Canada	BAS 750 01 F (EC) – EP containing 98.9 g	<u>New York silt loam:</u> DT50: 808 d;	<u>Major:</u> None identified	Mefentrifluconazole may accumulate in soil	2789683 and

Property	Test Substance	Value ¹	Transformation Products	Comments	PMRA#
are presented here)	a.i./L, or BAS 750 UA F (SC) – EP containing 403.5 g a.i./L	<p>DT90: 2,684 d (SFO)</p> <p><u>North Dakota clay:</u> DT50: 1,017 d (SFO DT90)</p> <p><u>Washington loamy sand:</u> DT50: 318 d; DT90: 1,055 d (SFO)</p> <p><u>Oklahoma sandy loam:</u> DT50: 298 d; DT90: 991 d (SFO)</p> <p><u>Illinois silty clay loam:</u> DT50: 89.4 d; t_R: 392 d (t_R IORE)</p> <p>Detections of mefentrifluconazole or its transformation products in lower soil depths may have been due to contamination during sample preparation.</p> <p>Total residues at approximately 365 days after last application were 10.2 to 26.5% of applied radioactivity.</p>	<p><u>Minor:</u> M750F001 (1,2,4- triazole) M750F003</p>	<p>and carry over to the next growing season.</p> <p>This study may have had cross-contamination issues. As such, judging leaching potential from this study is uncertain.</p>	2789687

Property	Test Substance	Value ¹	Transformation Products	Comments	PMRA#
	EXP 5834378 F-AV – EP containing 104.7 g a.i./L	<p><u>Germany loamy sand:</u> DT50: 340 d; DT90: 1,129 d (SFO)</p> <p><u>Germany silt loam:</u> DT50: 251 d; DT90: 834 d (SFO)</p> <p><u>France silty clay loam:</u> DT50: 129 d; t_R: 344 d (DFOP slow t_{1/2})</p> <p><u>Italy silty clay loam:</u> DT50: 1,177 d; DT90: 3,911 d (SFO)</p> <p><u>Spain loamy sand:</u> DT50: 264 d; DT90: 878 d (SFO)</p> <p>No detections of parent or its transformation products below 20 cm (with exception of unreliable detection of 1,2,4-triazole at one site).</p> <p>Total residues at approximately 365 days after application were 24.2 to 46.8% of applied</p>	<p><u>Major:</u> M750F001 (1,2,4-triazole) at one site</p> <p><u>Minor:</u> None identified</p>	<p>Mefentrifluconazole may accumulate in soil and carry over to the next growing season.</p> <p>At the sites tested, neither mefentrifluconazole or its residues appeared to be susceptible to leaching.</p>	2789678 and 2789677

Property	Test Substance	Value ¹	Transformation Products	Comments	PMRA#
		radioactivity.			
Field leaching	No field leaching study with mefentrifluconazole was submitted and none is required.				
¹ DT ₅₀ and DT ₉₀ values for each fit are the times the fitted curve reaches 50% and 90%, respectively, of the fitted initial concentration. These values are used for descriptive characterization and persistence classification for soil (Goring <i>et al.</i> , 1975) and natural waters (McEwen and Stephenson, 1979).					
The representative half-life (<i>t_R</i>), is the half-life of an exponential curve which is considered to be a conservative approximation of the measured concentration decline, and is used for exposure modelling. The DT ₅₀ for the SFO model is <i>t_R</i> if the SFO model is deemed acceptable. The <i>t_R</i> value from DFOP is a half-life determined from the slow degradation rate from the DFOP model. The <i>t_R</i> value from IORE is the half-life of an exponential curve passing through the DT ₉₀ of the IORE model fit.					

Table 20 Fate and Behaviour in the Aquatic Environment

Study Type	Test Material	Value ¹	Transformation Products	Comments	PMRA#
Abiotic Transformation					
Hydrolysis	Mefentriflu-conazole (triazole label)	Effectively stable at pH 4, 5, 7, and 9 at 25°C	<u>Major:</u> None identified <u>Minor:</u> M750F006 (impurity seen at the beginning of the test)	Hydrolysis is not expected to be an important route of dissipation of mefentriflu-conazole in the environment.	2789692
Phototransformation in water	Mefentriflu-conazole (chlorophenyl and triazole labels)	<u>pH 7 aqueous buffer:</u> DT50 (irradiated): 2.14 d; t_R : 2.47 d (t_R IORE)	<u>Major:</u> M750F005 M750F006 M750F007 <u>Minor:</u> M750F002 M750F003 M750F008	Phototransformation may be an important route of dissipation for mefentrifluconazole near the surface of water bodies.	2789694
	Mefentriflu-conazole (triazole label)	<u>Sterile natural water:</u> DT50 (irradiated): 6.61 d; DT90 (irradiated): 22 d;	<u>Major:</u> M750F006		2789696

Study Type	Test Material	Value ¹	Transformation Products	Comments	PMRA#
		DT50 (dark): 1,829 d (SFO)	<u>Minor:</u> M750F001 (1,2,4-triazole) M750F002 M750F003 M750F005 M750F007 M750F008 M750F036 M750F037		
Biotransformation					
Biotransformation in aerobic water-sediment systems	Mefentrifluconazole (chlorophenyl, triazole, and trifluoromethylphenyl labels)	<u>Berhauser Altrhein water:clay loam sediment:</u> DT50: 108 d; t _R : 350 d (t _R IORE – combined chlorophenyl and triazole labels) <u>Berhauser Altrhein water:silty clay loam sediment:</u> DT50: 192 (SFO – trifluoromethylphenyl label) <u>Ranschgraben water: sand sediment:</u> DT50: 248 d; t _R : 285 d (DFOP slow t _{1/2} – combined chlorophenyl and triazole labels) <u>Ranschgraben water: sand sediment:</u> DT50: 242 d (SFO – trifluoromethylphenyl	<u>Major:</u> M750F001 (formed in one system from one label) <u>Minor:</u> M750F001 M750F003 M750F032 CO ₂	Mefentrifluconazole is persistent. Biotransformation in aerobic water-sediment systems is not an important route of dissipation.	2789699

Study Type	Test Material	Value ¹	Transformation Products	Comments	PMRA#
		label)			
Biotransformation in anaerobic water-sediment systems	Mefentrifluconazole (chlorophenyl and triazole labels)	<u>Golden Lake water:loamy sand sediment:</u> DT50: 593 d (SFO – combined labels) <u>Goose River water clay loam sediment:</u> DT50: 729 d (SFO DT90 – combined labels)	<u>Major:</u> None identified <u>Minor:</u> CO ₂	Mefentrifluconazole is persistent. Biotransformation in anaerobic water-sediment systems is not an important route of dissipation.	2789701
Field Studies					
Aquatic field dissipation	No aquatic field dissipation study with mefentrifluconazole was submitted, and data on the aquatic field dissipation of mefentrifluconazole are not required.				
Bioconcentration/Bioaccumulation					
Bioconcentration in fish	Mefentrifluconazole (triazole labelled and unlabelled)	Whole body steady state BCF: 147 L/kg Whole fish steady state BCF normalised to 5% lipid content: 350 L/kg Whole body kinetic BCF: 160 L/kg; lipid normalized and growth corrected: 385 L/kg Time to reach 50% depuration: 0.59 d for whole fish	Since the BCF <500, samples were not studied further to quantify the proportion of radioactivity attributable to metabolites.	Mefentrifluconazole is not expected to bioconcentrate in fish.	2789749

Study Type	Test Material	Value ¹	Transformation Products	Comments	PMRA#
¹ DT ₅₀ and DT ₉₀ values for each fit are the times the fitted curve reaches 50% and 90%, respectively, of the fitted initial concentration. These values are used for descriptive characterization and persistence classification for soil (Goring <i>et al.</i> , 1975) and natural waters (McEwen and Stephenson, 1979). The representative half-life (t_R), is the half-life of an exponential curve which is considered to be a conservative approximation of the measured concentration decline, and is used for exposure modelling. The DT ₅₀ for the SFO model is t_R if the SFO model is deemed acceptable. The t_R value from DFOP is a half-life determined from the slow degradation rate from the DFOP model. The t_R value from IORE is the half-life of an exponential curve passing through the DT ₉₀ of the IORE model fit.					

Table 21 Toxicity of Mefentrifluconazole to Non-target Terrestrial Organisms

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
Invertebrates					
Earthworm, <i>Eisenia fetida</i>	14-d Acute	BAS 750 F (TGAI)	LC50 > 1,000 mg a.i./kg soil dw	No classification	2789831
	14-d Acute	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	LC50 = 70.4 mg a.i./kg soil dw, or 707 mg formulation/kg soil dw	No classification	2789293
	14-d Acute	BAS 750 02 F (EP – 403.5 g a.i./L; corresponds to Cevya and Maxtima)	LC50 > 349 mg a.i./kg soil dw, or > 1,000 mg formulation/kg soil dw	No classification	2789188
	14-d Acute	BAS 752 01 F (EP – coformulation; corresponds to BAS 752 RC)	LC50 > 170.2 mg a.i./kg soil dw, or > 1,000 mg formulation/kg soil dw	No classification	2788345
	56-d Chronic	BAS 750 F (TGAI)	NOEC (reproduction) = 8 mg a.i./kg soil dw; LOEC (reproduction) = 16 mg a.i./kg soil dw	No classification	2789833
	56-d Chronic	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	NOEC ≥ 8.1 mg a.i./kg soil dw; NOEC ≥ 80 mg formulation/kg soil dw	No classification	2789295
Earthworm, <i>Eisenia andrei</i>	14-d Acute	BAS 753 02 F (EP – coformulation; corresponds to Belyan)	LC50 = 92.9 mg a.i./kg soil dw, or 787 mg formulation/kg soil dw	No classification	2789099
Collembola, <i>Folsomia</i>	28-d Reproduction (artificial soil)	BAS 750 F (TGAI)	NOEC (mortality, reproduction) ≥ 400 mg a.i./kg soil dw	No classification	2789823

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
<i>candida</i>	28-d Reproduction (artificial soil)	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	NOEC (mortality, reproduction) ≥ 24.3 mg a.i./kg soil dw, or ≥ 241.7 mg formulation/kg dry soil	No classification	2789279
Honey bee, <i>Apis mellifera</i>	48-h Oral, adults	BAS 750 F (TGAI)	LD50 > 100 μ g a.i./bee	Practically non-toxic	2789814
	48-h Oral, adults	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	LD50 = 52 μ g a.i./bee, or 519.8 μ g formulation /bee	Practically non-toxic	2789277
	48-h Oral, adults	BAS 750 02 F (EP – 403.5 g a.i./L; corresponds to Cevya and Maxtima)	LD50 > 100 μ g a.i./bee, or > 286.2 μ g formulation /bee	Practically non-toxic	2789182
	48-h Oral, adults	BAS 752 01 F (EP – coformulation; corresponds to BAS 752 RC)	LD50 > 98.7 μ g a.i./bee, or > 580 μ g formulation /bee	Practically non-toxic	2788339
	48-h Oral, adults	BAS 753 02 F (EP – coformulation; corresponds to Belyan)	LD50 > 87.0 μ g a.i./bee, or > 736.9 μ g formulation /bee	Practically non-toxic	2789089
	48-h Contact, adults	BAS 750 F (TGAI)	LD50 > 100 μ g a.i./bee	Practically non-toxic	2789814
	96-h Contact, adults	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	LD50 = 30 μ g a.i./bee, or 296.4 μ g formulation /bee	Practically non-toxic	2789277
	48-h Contact, adults	BAS 750 02 F (EP – 403.5 g a.i./L; corresponds to Cevya and Maxtima)	LD50 > 100 μ g a.i./bee, or > 286.2 μ g formulation /bee)	Practically non-toxic	2789182
	48-h Contact, adults	BAS 752 01 F (EP – coformulation; corresponds to BAS 752 RC)	LD50 > 98.7 μ g a.i./bee, or > 580 μ g formulation /bee	Practically non-toxic	2788339
	48-h Contact, adults	BAS 753 02 F (EP – coformulation; corresponds to Belyan)	LD50 > 81.1 μ g a.i./bee, or > 687.6 μ g formulation /bee	Practically non-toxic	2789089
	10-d Chronic, adults	BAS 750 F (TGAI)	NOAED ≥ 110.5 μ g a.i./bee/day	No classification	2789825
	96-h Acute oral, larvae	BAS 750 F (TGAI)	LD50 = 43.9 μ g a.i./larva	Practically non-toxic	2789827
	22-d Oral, repeated exposure, larvae	BAS 750 F (TGAI)	NOAED = 6.4 μ g a.i./larva/day (based on larval and pupal mortality and adult emergence)	No classification	2789829
Bumble bee, <i>Bombus terrestris</i>	96-h Oral, adults	BAS 750 F (TGAI)	LD50 > 195.4 μ g a.i./bee	Practically non-toxic	2789816
	96-h Contact, adults	BAS 750 F (TGAI)	LD50 > 200 μ g a.i./bee	Practically non-toxic	2789816
<i>Phacelia tanacetifolia</i> Semi-field study Application rate:	Semi-field study to determine residues in <i>Phacelia tanacetifolia</i>	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	Maximum residues: Flowers – 76.9 mg/kg; Pollen – 106 mg/kg; Nectar – 0.91 mg/kg	Not applicable	2789819

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
300 g a.i./ha, single application Foliar application applied during flowering. Flowers, pollen, and nectar were collected.					
Predatory mite, <i>Typhlodromus pyri</i>	7-d Contact (glass plates)	BAS 750 01 F (EP - 98.9 g a.i./L; corresponds to Lenvyor)	LR50 = 76.9 g a.i./ha, or 769 mL formulation/ha	No classification	2789283
	Extended laboratory with 7-d assesment of mortality and reproduction (excised leaves)	BAS 750 01 F (EP - 98.9 g a.i./L; corresponds to Lenvyor)	LR50 > 300 g a.i./ha, or ≥ 3000 mL formulation/ha; NOER (mortality) = 75 g a.i./ha, or 750 mL formulation/ha	No classification	2789291
	7-d Contact (glass plates)	BAS 750 02 F (EP – 403.5 g a.i./L; corresponds to Cevya and Maxtima)	LR50 > 450 g a.i./ha, or > 1,125 mL formulation/ha	No classification	2789184
	7-d Contact (glass plates)	BAS 752 01 F (EP – coformulation; corresponds to BAS 752 RC)	LR50 > 332 g a.i./ha, or > 1,700 mL formulation/ha	No classification	2788341
	Extended laboratory with 7-d assesment of mortality and reproduction (excised leaves)	BAS 753 02 F (EP – coformulation; corresponds to Belyan)	LR50 > 456 g a.i./ha, or > 3,390 mL formulation/ha NOER (mortality, reproduction) ≥ 456 g a.i./ha, or > 3,390 mL formulation/ha	No classification	2789092
Predatory soil mite, <i>Hypoaspis aculeifer</i>	14-d Reproduction (artificial soil)	BAS 750 F (TGAI)	EC50 (reproduction) > 1,000 mg a.i./kg soil dw; NOEC ≥ 1,000 mg a.i./kg soil dw	No classification	2789821
	14-d Reproduction (artificial soil)	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	LC50 > 27.2 mg a.i./kg soil dw, or >270 mg formulation/kg soil dw; NOEC (reproduction) = 18.1 mg a.i./kg soil dw, or 180 mg formulation/kg soil dw	No classification	2789281

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
Predatory insect green lacewing, <i>Chrysoperla carnea</i>	Extended laboratory with 21-d assesment of mortality and reproduction (excised leaves)	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	LR50 > 300 g a.i./ha, or > 3.0 L formulation/ha; NOER ≥ 300 g a.i./ha, or ≥ 3.0 L formulation/ha	No classification	2789289
Parasitic wasp, <i>Aphidius rhopalosiphi</i>	48-h Contact (glass plates)	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	LR50 = 9.44 g a.i./ha, or 95.4 mL formulation/ha)	No classification	2789285
	48-h Contact (glass plates)	BAS 750 02 F (EP – 403.5 g a.i./L; corresponds to Cevya and Maxtima)	LR50 > 450 g a.i./ha, or > 1,125 mL formulation/ha	No classification	2789185
	48-h Contact (glass plates)	BAS 752 01 F (EP – coformulation; corresponds to BAS 752 RC)	LR50 > 332 g a.i./ha, or > 1,700 mL formulation/ha	No classification	2788343
	48-h Extended laboratory with 14-d assesment of mortality and reproduction (plants)	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor)	LR50 > 300 g a.i./ha, or > 3,000 mL formulation/ha; NOER ≥ 300 g a.i./ha, or ≥ 3,000 mL formulation/ha	No classification	2789287
	48-h Extended laboratory with 14-d assesment of mortality and reproduction (plants)	BAS 753 02 F (EP – coformulation; corresponds to Belyan)	LR50 = 251 g a.i./ha, or 1,862 mL formulation/ha; NOER (mortality) = 76 g a.i./ha, or 565 mL formulation/ha	No classification	2789094
Birds					
Bobwhite quail	Acute oral	BAS 750 F (TGAI)	LD50 = 816 mg a.i./kg bw	Slightly toxic	2789707
	Acute oral	BAS 750 02 F (EP - 403.5 g a.i./L; corresponds to Cevya and Maxtima)	LD50 > 700 mg a.i./kg bw, or > 2,000 mg formulation /kg bw	a.i.: At most, slightly toxic; EP: Practically non-toxic based on formulation	2789173
	Acute oral	BAS 752 01 F (EP – coformulation; corresponds to BAS 752 RC)	LD50 > 340 mg a.i./kg bw, or > 2,000 mg formulation /kg bw	a.i.: At most, moderately toxic EP: Practically non-toxic based on formulation	2788337
	Acute oral	BAS 753 02 F (EP – coformulation; corresponds to	LD50 > 236 mg a.i./kg bw, or > 2,000 mg formulation /kg bw	a.i.: At most, moderately toxic	2789081

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
		Belyan)		EP: Practically non-toxic based on formulation	
	5-d Dietary	BAS 750 F (TGAI)	LC50 = 6,737 mg a.i./kg diet; LD50 could not be reliably derived, however mortality was 30, 10 and 70% at concentrations of 650, 769 and 653 mg/kg bw (based on ingested amount of food)	Practically non-toxic, based on dietary LC50	2789713
	21-w Dietary reproduction	BAS 750 F (TGAI)	NOAEC = 278 mg a.i./kg diet (24.8 mg a.i./kg bw/day); LOAEC = 531 mg a.i./kg diet (47.3 mg a.i./kg bw/day; based on effects on egg production, 14-day survivors per number hatched, and offspring body weights)	No classification	2789715
Mallard duck	Acute oral	BAS 750 F (TGAI)	LD50 > 2,000 mg a.i./kg bw	Practically non-toxic	2789705
	5-d Dietary	BAS 750 F (TGAI)	LC50 > 7,695 mg a.i./kg diet, or > 760.3 mg a.i./kg bw	Practically non-toxic	2789711
	20-w Dietary reproduction	BAS 750 F (TGAI)	NOAEC = 302 mg a.i./kg diet (44.0 mg a.i./kg bw/day); LOAEC = 616 mg a.i./kg diet (89.8 mg a.i./kg bw/day; based on effects on adult female body weight, body weight gain)	No classification	2789717
Canary	Acute oral	BAS 750 F (TGAI)	LD50 > 2,860 mg a.i./kg bw	Practically non-toxic	2789709
Mammals					
Rat	Acute oral	BAS 750 F (TGAI)	LD50 > 2,000 mg/kg bw (females)	Practically non-toxic	2789573
	Acute oral	BAS 750 01 F (EP – 98.9 g a.i./L; corresponds to Lenvyor	LD50 > 2,000 mg/kg bw (females)	Practically non-toxic	2789329
	Acute oral	BAS 750 02 F (EP – 403.5 g a.i./L; corresponds to Cevya and Maxtima)	LD50 > 2,000 mg/kg bw (females)	Practically non-toxic	2789211
	Acute oral	BAS 752 01 F (EP – coformulation; corresponds to BAS 752 RC	LD50 > 2,000 mg/kg bw (females)	Practically non-toxic	2788356

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
	Acute oral	BAS 753 02 F (EP – coformulation; corresponds to Belyan)	LD50 > 2,000 mg/kg bw (females)	Practically non-toxic	2789112
	2-Generation reproduction	BAS 750 F (TGAI)	NOAEL = 72 mg a.i./kg bw/day; LOAEL = 191 mg a.i./kg bw/day (based on parental and offspring toxicity and reproductive toxicity)	No classification	2789597
Vascular plants					
Monocot and dicot crop species (cabbage, carrot, corn, lettuce, oilseed rape, onion, ryegrass, soybean, tomato, and wheat)	21-d Seedling emergence	BAS 750 01 F (EP - 98.9 g a.i./L; corresponds to Lenvyor)	NOAER = 9.4 g a.i./ha (wheat, based on dry weight effects); ER25 > 157 g a.i./ha, or >1,500 mL formulation/ha	No classification	2789299
	21-d Seedling emergence	BAS 750 02 F (EP - 403.5 g a.i./L; corresponds to Cevya and Maxtima) + adjuvant	Tier I test: NOAER < 527 g a.i./ha (wheat height and dry weight and carrot emergence); NOAER and ER25 > 527 g a.i./ha (for all other plants) Tier II test: ER25 > 560 g a.i./ha (wheat and carrot), or >1,500 mL formulation/ha	No classification	2789192
Monocot and dicot crop species (cabbage, carrot, corn, lettuce, oilseed rape, onion, ryegrass, soybean, tomato, and wheat)	21-d Vegetative vigour	BAS 750 01 F (EP - 98.9 g a.i./L; corresponds to Lenvyor)	NOAER > 157 g a.i./ha (no toxicity observed in any crop species); ER25 > 157 g a.i./ha, or >1,500 mL formulation/ha	No classification	2789297
	21-d Vegetative vigour	BAS 750 02 F (EP - 403.5 g a.i./L; corresponds to Cevya and Maxtima) + adjuvant	NOAER ≥ 527 g a.i./ha (no toxicity observed in any crop species); ER25 > 527 g a.i./ha, or >1,500 mL formulation/ha	No classification	2789190

^a Atkins et al.(1981) for bees and USEPA classification for others, where applicable

Table 22 Screening Level Risk Assessment of Mefentrifluconazole for Non-target Terrestrial Species Other Than Birds and Mammals

Organism	Exposure	Endpoint Value	EEC	RQ	Level of Concern ¹
TGAI – Mefentrifluconazole (<i>In-field: Maxtima, turf, ground; off-field: Cevya, orchard, airblast</i>)					
Earthworm	Acute - TGAI	LC50/2: > 500 mg a.i./kg soil dw	1.31 mg a.i./kg soil (turf)	<0.003	Not exceeded
	Chronic reproduction - TGAI	NOEC (reproduction): 8 mg a.i./kg soil dw	1.31 mg a.i./kg soil (turf)	0.16	Not exceeded
Collembola	Chronic – TGAI	NOEC: ≥ 400 mg a.i./kg soil dw	1.31 mg a.i./kg soil (turf)	<0.003	Not exceeded
Predatory soil mite, <i>Hypoaspis aculeifer</i> [soil dwelling]	Laboratory (artificial soil) - TGAI	NOEC: ≥ 1,000 mg a.i./kg soil dw, and EC50: > 1,000 mg a.i./kg soil dw	In-field: 1.31 mg a.i./kg soil (turf)	<0.001	Not exceeded
			Off-field: 0.15 mg a.i./kg soil (orchard)	<0.0002	Not exceeded
EP: Lenvyor (100 g mefentrifluconazole/L) (<i>peas and beans, aerial</i>)					
Earthworm	Acute - Lenvyor	LC50/2: 35.2 mg a.i./kg soil dw	0.195 mg a.i./kg soil	0.005	Not exceeded
	Chronic reproduction – Lenvyor	NOEC: ≥ 8.1 mg a.i./kg soil dw	0.195 mg a.i./kg soil	<0.02	Not exceeded
Collembola	Chronic - Lenvyor	NOEC: ≥ 24.3 mg a.i./kg soil dw	0.195 mg a.i./kg soil	<0.01	Not exceeded
Predatory mite, <i>Typhlodromus pyri</i> [foliar dwelling]	Contact (glass plates) - Lenvyor	LR50: 76.9 g a.i./ha	In-field: 175 g a.i./ha	2.3	*LOC = 2 Exceeded
			Off-field: 40.3 g a.i./ha	0.52	*LOC = 2 Not exceeded
Predatory soil mite, <i>Hypoaspis aculeifer</i> [soil dwelling]	Laboratory (artificial soil) - Lenvyor	LC50: > 27.2 mg a.i./kg soil dw	In-field: 0.195 mg a.i./kg soil	<0.007	Not exceeded
			Off-field: 0.045 mg a.i./kg soil	<0.002	Not exceeded
Parasitic wasp, <i>Aphidius rhopalosiphi</i> [foliar dwelling]	Contact (glass plates) - Lenvyor	LR50: 9.44 g a.i./ha	In-field: 175 g a.i./ha	19	*LOC = 2 Exceeded
			Off-field: 40.3 g a.i./ha	4.3	*LOC = 2 Exceeded
EP: Cevya, Maxtima (400 g mefentrifluconazole/L) (<i>Cevya: orchard, air blast / Maxtima: turf, ground</i>)					
Earthworm	Acute – Cevya, Maxtima	LC50/2: > 174.5 mg a.i./kg soil dw	0.20 mg a.i./kg soil (orchard)	<0.001	Not exceeded
			1.31 mg a.i./kg soil (turf)	<0.008	Not exceeded
Collembola ²	Chronic - Lenvyor	NOEC: ≥ 24.3 mg a.i./kg soil dw	1.31 mg a.i./kg soil (Maxtima turf use)	<0.05	Not exceeded
Predatory mite, <i>Typhlodromus pyri</i> [foliar dwelling]	Contact (glass plates) – Cevya, Maxtima	LR50: > 450 g a.i./ha	In-field: 299 g a.i./ha (orchard)	<0.66	Not exceeded
			In-field: 1,523 g a.i./ha (turf)	<3.4	*LOC = 2 May be exceeded
			Off-field: 221 g a.i./ha (orchard)	<0.49	*LOC = 2 Not exceeded
			Off-field: 91.4 g a.i./ha (turf)	<0.20	Not exceeded
Parasitic wasp, <i>Aphidius rhopalosiphi</i>	Contact (glass plates) - Cevya, Maxtima	LR50: > 450 g a.i./ha	In-field: 299 g a.i./ha (orchard)	<0.66	Not exceeded
			In-field: 1,523 g a.i./ha	<3.4	*LOC = 2

Organism	Exposure	Endpoint Value	EEC	RQ	Level of Concern ¹
[foliar dwelling]			(turf)		May be exceeded
			Off-field: 221 g a.i./ha (orchard)	<0.49	*LOC = 2 Not exceeded
			Off-field: 91.4 g a.i./ha (turf)	<0.20	Not exceeded
EP: BAS 752 RC (coformulation – mefentrifluconazole and fluxapyroxad) (potato, aerial)					
Earthworm	Acute - BAS 752 RC	LC50/2: > 85.1 mg a.i./kg soil dw	0.132 mg a.i./kg soil	<0.002	Not exceeded
Predatory mite, <i>Typhlodromus pyri</i> [foliar dwelling]	Contact (glass plates) - BAS 752 RC	LR50: > 332 g a.i./ha (> 1.70 L formulation/ha)	In-field: 167 g a.i./ha (0.835 L formulation/ha)	<0.50	*LOC = 2 Not exceeded
			Off-field: 38.4 g a.i./ha (0.192 L formulation/ha)	<0.12	*LOC = 2 Not exceeded
Parasitic wasp, <i>Aphidius rhopalosiphi</i> [foliar dwelling]	Contact (glass plates) - BAS 752 RC	LR50: > 332 g a.i./ha (> 1.70 L formulation/ha)	In-field: 167 g a.i./ha (0.835 L formulation/ha)	<0.50	*LOC = 2 Not exceeded
			Off-field: 38.4 g a.i./ha (0.192 L formulation/ha)	<0.12	*LOC = 2 Not exceeded
EP: Belyan (coformulation – mefentrifluconazole, pyraclostrobin, fluxapyroxad) (potato, aerial)					
Earthworm	Acute – Belyan	LC50/2: 46.5 mg a.i./kg soil dw	0.132 mg a.i./kg soil	<0.003	Not exceeded
Terrestrial plants					
Terrestrial vascular plants	Seedling emergence - Lenvyor	ER25: > 157 g a.i./ha	In-field: 438 g a.i./ha (cum. app. rate soil)	<2.8	May be exceeded
			Off-field: 101 g a.i./ha (cum. app. rate soil)	<0.64	Not exceeded
	Seedling emergence – Cevya, Maxtima (+adjuvant)	ER25: > 527 g a.i./ha	In-field: 446 g a.i./ha (cum. app. rate soil – orchard)	<0.85	Not exceeded
			In-field: 2,950 g a.i./ha (turf)	<5.6	May be exceeded
			Off-field: 330 g a.i./ha (cum. app. rate soil - orchard)	<0.63	Not exceeded
			Off-field: 177 g a.i./ha (turf)	<0.34	Not exceeded
	Vegetative vigour - Lenvyor	ER25: > 157 g a.i./ha	In-field: 175 g a.i./ha (cum. app. rate leaf)	<1.1	May be exceeded
			Off-field: 40.3 g a.i./ha (cum. app. rate leaf)	<0.26	Not exceeded
	Vegetative vigour - Cevya, Maxtima (+adjuvant)	ER25: > 527 g a.i./ha	In-field: 299 g a.i./ha (cum. app. rate leaf – orchard)	<0.57	Not exceeded
			In-field: 1,523 g a.i./ha (cum. app. rate leaf - turf)	<2.9	May be exceeded
			Off-field: 221 g a.i./ha (cum. app. rate leaf - orchard)	<0.42	Not exceeded

¹ Level of concern = 1 for most species and 2 for glass plate studies using the standard beneficial arthropod test species, *Typhlodromus pyri* and *Aphidius rhopalosiphi*
² No collembolan study was submitted for the Maxtima EP. Risk was assessed using the Lenvyor collembolan study.

Table 23 Screening Level Risk Assessment of Mefentrifluconazole for Pollinators for Foliar Applications

Organism	Exposure	Endpoint Value	EEC ¹	RQ	Level of Concern ²
Acute Oral, Adults					
Honey bee, <i>Apis mellifera</i>	TGAI	LD50: > 100 µg a.i./bee	1 kg a.i./ha × 29 µg a.i./bee per kg/ha = 29 µg a.i./bee	<0.29	Not exceeded
	Lenvyor	LD50: 52 µg a.i./bee	0.15 kg a.i./ha × 29 µg a.i./bee per kg/ha = 4.35 µg a.i./bee	0.08	Not exceeded
	Cevya, Maxtima	LD50: > 100 µg a.i./bee	1 kg a.i./ha × 29 µg a.i./bee per kg/ha = 29 µg a.i./bee	<0.29	Not exceeded
	BAS 752 RC	LD50: > 98.7 µg a.i./bee	0.075 kg a.i./ha × 29 µg a.i./bee per kg/ha = 2.18 µg a.i./bee	<0.02	Not exceeded
	Belyan	LD50: > 87.0 µg a.i./bee	0.075 kg a.i./ha × 29 µg a.i./bee per kg/ha = 2.18 µg a.i./bee	<0.03	Not exceeded
Bumble bee, <i>Bombus terrestris</i>	TGAI	LD50: > 195.4 µg a.i./bee	1 kg a.i./ha × 29 µg a.i./bee per kg/ha = 29 µg a.i./bee	<0.15	Not exceeded
Acute Contact, Adults					
Honey bee, <i>Apis mellifera</i>	TGAI	LD50: > 100 µg a.i./bee	1 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 2.4 µg a.i./bee	<0.02	Not exceeded
	Lenvyor	LD50: 30 µg a.i./bee	0.15 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 0.36 µg a.i./bee	0.01	Not exceeded
	Cevya, Maxtima	LD50: > 100 µg a.i./bee	1 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 2.4 µg a.i./bee	<0.02	Not exceeded
	BAS 752 RC	LD50: > 98.7 µg a.i./bee	0.075 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 0.18 µg a.i./bee	<0.002	Not exceeded
	Belyan	LD50: > 81.1 µg a.i./bee	0.075 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 0.18 µg a.i./bee	<0.002	Not exceeded
Bumble bee, <i>Bombus terrestris</i>	TGAI	LD50: > 200 µg a.i./bee	1 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 2.4 µg a.i./bee	<0.012	Not exceeded
Chronic Oral, Adults					
Honey bee, <i>Apis mellifera</i>	Chronic oral, adults - TGAI	NOAED: ≥ 110.5 µg a.i./bee/day	1 kg a.i./ha × 29 µg a.i./bee per kg/ha = 29 µg a.i./bee	0.26	Not exceeded
Larvae Studies					
Honey bee, <i>Apis mellifera</i>	Acute oral, larvae - TGAI	LD50: 43.9 µg a.i./larva	1 kg a.i./ha × 12 µg a.i./larva per kg/ha = 12 µg a.i./larva	0.27	Not exceeded
	Chronic oral, larvae - TGAI	NOAED: 6.4 µg a.i./larva/day	1 kg a.i./ha × 12 µg a.i./larva per kg/ha = 12 µg a.i./larva Turf rate (Label proposed for golf)	1.9	Exceeded

Organism	Exposure	Endpoint Value	EEC ¹	RQ	Level of Concern ²
			course use only)		
			0.15 kg a.i./ha × 12 µg a.i./larva per kg/ha = 1.8 µg a.i./larva (orchard/beet rate)	0.28	Not exceeded
¹ Foliar EEC = maximum single application rate (kg a.i./ha) × adjustment factor (29 µg a.i./bee per kg a.i./ha for adult oral, 2.4 µg a.i./bee per kg a.i./ha for adult contact, or 12 µg a.i./larva per kg/ha for larvae)					
² Level of concern = 0.4 for acute risk to pollinators and 1.0 for chronic risk to pollinators.					

Table 24 Screening Level Risk Assessment of Mefentrifluconazole for Pollinators for Seed Treatment Application (Relenya EP)

Organism	Exposure	Endpoint Value	EEC ¹	RQ	Level of Concern ²
Acute Oral, Adults					
Honey bee, <i>Apis mellifera</i>	TGAI	LC50: > 100 µg a.i./bee	1 µg a.i./g × 0.292 g/day = 0.29 µg a.i./bee	<0.003	Not exceeded
	Relenya / Cevya, Maxtima	LC50: > 100 µg a.i./bee ³	1 µg a.i./g × 0.292 g/day = 0.29 µg a.i./bee	<0.003	Not exceeded
Bumble bee, <i>Bombus terrestris</i>	TGAI	LC50: > 195.4 µg a.i./bee	1 µg a.i./g × 0.292 g/day = 0.29 µg a.i./bee	<0.001	Not exceeded
Chronic Oral, Adults					
Honey bee, <i>Apis mellifera</i>	Chronic oral, adults	NOAEL: ≥110.5 µg a.i./bee/day	1 µg a.i./g × 0.292 g/day = 0.29 µg a.i./bee	0.003	Not exceeded
Acute and Chronic Oral, Larvae					
Honey bee, <i>Apis mellifera</i>	Acute oral, larvae	LD50: 43.9 µg a.i./larva	1 µg a.i./g × 0.124 g/day = 0.124 µg a.i./larva	0.003	Not exceeded
	Chronic oral, larvae	NOAEL: 6.4 µg a.i./larva/day	1 µg a.i./g × 0.124 g/day = 0.124 µg a.i./larva	0.02	Not exceeded
¹ Seed treatment EEC = 1 µg a.i./g food (pollen and nectar; default value for seed treatments) × consumption rate (0.292 g food/day for adults or 0.124 g food/day for larvae)					
² Level of concern = 0.4 for acute risk to pollinators and 1.0 for chronic risk to pollinators.					
³ Relenya Seed Treatment EP has the same guarantee of active ingredient as Cevya and Maxtima EPs of 400 g a.i./L. As such, the honey bee endpoint for the EP containing 403.5 g a.i./L is also used for the seed treatment risk assessment.					

Table 25 Screening Level Risk Assessment of Mefentrifluconazole for Birds and Mammals for Foliar Applications (turf, maximum in-field)

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	Maximum EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)				
Acute	>23.6	Insectivore	123.9	<5.3
Reproduction	24.8	Insectivore	123.9	5.0
Medium Sized Bird (0.1 kg)				
Acute	>23.6	Insectivore	96.7	<4.1
Reproduction	24.8	Insectivore	96.7	3.9
Large Sized Bird (1 kg)				
Acute	>23.6	Herbivore (short grass)	62.5	<2.7
Reproduction	24.8	Herbivore (short grass)	62.5	2.5
Small Mammal (0.015 kg)				
Acute	>200	Insectivore	71.3	<0.36
Reproduction	72.0	Insectivore	71.3	0.99
Medium Sized Mammal (0.035 kg)				
Acute	>200	Herbivore (short grass)	138.3	<0.69
Reproduction	72.0	Herbivore (short grass)	138.3	1.9
Large Sized Mammal (1 kg)				
Acute	>200	Herbivore (short grass)	73.9	<0.37
Reproduction	72.0	Herbivore (short grass)	73.9	1.0

Table 26 Screening Level Risk Assessment of Mefentrifluconazole for Birds and Mammals for Foliar Applications (orchard, maximum in-field)

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	Maximum EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)				
Acute	>23.6	Insectivore	24.4	<1.0
Reproduction	24.8	Insectivore	24.4	0.98
Medium Sized Bird (0.1 kg)				
Acute	>23.6	Insectivore	19.0	<0.81
Reproduction	24.8	Insectivore	19.0	0.77
Large Sized Bird (1 kg)				
Acute	>23.6	Herbivore (short grass)	12.3	<0.52
Reproduction	24.8	Herbivore (short grass)	12.3	0.50
Small Mammal (0.015 kg)				
Acute	>200	Insectivore	14.0	<0.07
Reproduction	72.0	Insectivore	14.0	0.19
Medium Sized Mammal (0.035 kg)				
Acute	>200	Herbivore (short grass)	27.2	<0.14
Reproduction	72.0	Herbivore (short grass)	27.2	0.38

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	Maximum EDE (mg a.i./kg bw)	RQ
Large Sized Mammal (1 kg)				
Acute	>200	Herbivore (short grass)	14.5	<0.07
Reproduction	72.0	Herbivore (short grass)	14.5	0.20

Table 27 Screening Level Risk Assessment of Mefentrifluconazole for Birds and Mammals for Seed Treatment (peas, maximum rate of 20 g a.i./100 kg seed)

	Toxicity (mg a.i./kg bw/d)	EDE (mg a.i./kg bw/d)	RQ
Small Bird (0.02 kg)			
Acute	>23.6	50.8	<2.2
Reproduction	24.8	50.8	2.0
Medium Bird (0.10 kg)			
Acute	>23.6	39.9	<1.7
Reproduction	24.8	39.9	1.6
Large Bird (1.00 kg)			
Acute	>23.6	11.6	<0.5
Reproduction	24.8	11.6	0.5
Small Mammals (0.015 kg)			
Acute	>200	29.0	<0.1
Reproduction	72.0	29.0	0.4
Medium Mammals (0.035 kg)			
Acute	>200	25.0	<0.1
Reproduction	72.0	25.0	0.3
Large Mammals (1.00 kg)			
Acute	>200	13.7	<0.1
Reproduction	72.0	13.7	0.2

Table 28 Screening Level Risk Assessment of Mefentrifluconazole for Mammals for Foliar Applications (turf) – Maximum and Mean Residues, On- and Off-field

			Maximum Nomogram Residues				Mean Nomogram Residues			
			In-field		Off-field		In-field		Off-field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ
Medium Sized Mammal (0.035 kg)										
Acute	>200	Insectivore	62.5	<0.31	3.75	<0.02	43.2	<0.22	2.59	<0.01
	>200	Granivore (grain and seeds)	9.67	<0.05	0.58	<0.003	4.61	<0.02	0.28	<0.001
	>200	Frugivore (fruit)	19.3	<0.10	1.16	<0.006	9.22	<0.05	0.55	<0.003
	>200	Herbivore (short grass)	138	<0.69	8.30	<0.042	49.1	<0.25	2.95	<0.01
	>200	Herbivore (long grass)	84.4	<0.42	5.06	<0.03	27.6	<0.14	1.65	<0.008
	>200	Herbivore (forage crops)	128	<0.64	7.67	<0.04	42.3	<0.21	2.54	<0.01
Repro- duction	72.0	Insectivore	62.5	0.87	3.75	0.05	43.2	0.60	2.59	0.04
	72.0	Granivore (grain and seeds)	9.67	0.13	0.58	0.008	4.61	0.06	0.28	0.004
	72.0	Frugivore (fruit)	19.3	0.27	1.16	0.02	9.22	0.13	0.55	0.008
	72.0	Herbivore (short grass)	138	1.9	8.30	0.12	49.1	0.68	2.95	0.04
	72.0	Herbivore (long grass)	84.4	1.2	5.06	0.07	27.6	0.38	1.65	0.02
	72.0	Herbivore (Broadleaf plants)	128	1.8	7.67	0.11	42.3	0.59	2.54	0.04
Large Sized Mammal (1 kg)										
Acute	>200	Insectivore	33.4	<0.17	2.00	<0.01	23.1	<0.12	1.38	<0.007
	>200	Granivore (grain and seeds)	5.17	<0.03	0.31	<0.002	2.46	<0.01	0.15	<0.0007
	>200	Frugivore (fruit)	10.3	<0.05	0.62	<0.003	4.93	<0.02	0.30	<0.002
	>200	Herbivore (short grass)	73.9	<0.37	4.43	<0.02	26.2	<0.13	1.57	<0.008
	>200	Herbivore (long grass)	45.1	<0.23	2.71	<0.01	14.7	<0.07	0.88	<0.004

			Maximum Nomogram Residues				Mean Nomogram Residues			
			In-field		Off-field		In-field		Off-field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ
	>200	Herbivore (Broadleaf plants)	68.4	<0.34	4.10	<0.02	22.6	<0.11	1.36	<0.007
Repro- duction	72.0	Insectivore	33.4	0.46	2.00	0.03	23.1	0.32	1.38	0.02
	72.0	Granivore (grain and seeds)	5.17	0.07	0.31	0.004	2.46	0.03	0.15	0.002
	72.0	Frugivore (fruit)	10.3	0.14	0.62	0.008	4.93	0.069	0.30	0.004
	72.0	Herbivore (short grass)	73.9	1.0	4.43	0.06	26.2	0.36	1.57	0.02
	72.0	Herbivore (long grass)	45.1	0.63	2.71	0.04	14.7	0.2046	0.88	0.01
	72.0	Herbivore (Broadleaf plants)	68.4	0.95	4.10	0.06	22.6	0.3138	1.36	0.02

Table 29 Risk Assessment of Mefentrifluconazole for Birds for Foliar Applications (turf) – Maximum and Mean Residues, On- and Off-field

			Maximum Nomogram Residues				Mean Nomogram Residues			
			In-field		Off Field		In-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ
Small Bird (0.02 kg)										
Acute	>23.6	Insectivore	123.9	<5.3	7.44	<0.3	85.6	<3.63	5.13	<0.22
	>23.6	Granivore (grain and seeds)	19.2	<0.8	1.15	<0.0	9.15	<0.39	0.55	<0.02
	>23.6	Frugivore (fruit)	38.4	<1.6	2.30	<0.1	18.3	<0.78	1.10	<0.05
Dietary	>76.0	Insectivore	123.9	<1.6	7.44	<0.1	85.6	<1.13	5.13	<0.07
	>76.0	Granivore (grain and seeds)	19.2	<0.3	1.15	<0.0	9.15	<0.12	0.55	<0.01
	>76.0	Frugivore (fruit)	38.4	<0.5	2.30	<0.0	18.3	<0.24	1.10	<0.01

			Maximum Nomogram Residues				Mean Nomogram Residues			
			In-field		Off Field		In-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ
Reproduction	24.8	Insectivore	123.9	5.0	7.44	0.3	85.6	3.45	5.13	0.21
	24.8	Granivore (grain and seeds)	19.2	0.8	1.15	0.0	9.15	0.37	0.55	0.02
	24.8	Frugivore (fruit)	38.4	1.5	2.30	0.1	18.3	0.74	1.10	0.04
Medium Sized Bird (0.1 kg)										
Acute	>23.6	Insectivore	96.7	<4.1	5.80	<0.2	66.8	<2.83	4.01	<0.17
	>23.6	Granivore (grain and seeds)	15.0	<0.6	0.90	<0.0	7.14	<0.30	0.43	<0.02
	>23.6	Frugivore (fruit)	29.9	<1.3	1.80	<0.1	14.3	<0.60	0.86	<0.04
Dietary	>76.0	Insectivore	96.7	<1.3	5.80	<0.1	66.8	<0.88	4.01	<0.05
	>76.0	Granivore (grain and seeds)	15.0	<0.2	0.90	<0.0	7.14	<0.09	0.43	<0.01
	>76.0	Frugivore (fruit)	29.9	<0.4	1.80	<0.0	14.3	<0.19	0.86	<0.01
Reproduction	24.8	Insectivore	96.7	3.9	5.80	0.2	66.8	2.69	4.01	0.16
	24.8	Granivore (grain and seeds)	15.0	0.6	0.90	0.0	7.14	0.29	0.43	0.02
	24.8	Frugivore (fruit)	29.9	1.2	1.80	0.1	14.3	0.58	0.86	0.03
Large Sized Bird (1 kg)										
Acute	>23.6	Insectivore	28.2	<1.2	1.69	<0.1	19.5	<0.83	1.17	<0.05
	>23.6	Granivore (grain and seeds)	4.37	<0.2	0.26	<0.0	19.5	<0.83	0.13	<0.01
	>23.6	Frugivore (fruit)	8.74	<0.4	0.52	<0.0	4.17	<0.18	0.25	<0.01
	>23.6	Herbivore (short grass)	62.5	<2.6	3.75	<0.2	22.2	<0.94	1.33	<0.06
	>23.6	Herbivore (long grass)	38.2	<1.6	2.29	<0.1	12.5	<0.53	0.75	<0.03
	>23.6	Herbivore (Broadleaf plants)	57.8	<2.4	3.47	<0.1	19.1	<0.81	1.15	<0.05
Dietary	>76.0	Insectivore	28.2	<0.4	1.69	<0.0	19.5	<0.26	1.17	<0.02
	>76.0	Granivore (grain and seeds)	4.37	<0.1	0.26	<0.0	19.5	<0.26	0.13	<0.00
	>76.0	Frugivore (fruit)	8.74	<0.1	0.52	<0.0	4.17	<0.05	0.25	<0.00
	>76.0	Herbivore (short grass)	62.5	<0.8	3.75	<0.0	22.2	<0.29	1.33	<0.02
	>76.0	Herbivore (long grass)	38.2	<0.5	2.29	<0.0	12.5	<0.16	0.75	<0.01
	>76.0	Herbivore (Broadleaf plants)	57.8	<0.8	3.47	<0.0	19.1	<0.25	1.15	<0.02

			Maximum Nomogram Residues				Mean Nomogram Residues			
			In-field		Off Field		In-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ
Reproduction	24.8	Insectivore	28.2	1.1	1.69	0.1	19.5	0.79	1.17	0.05
	24.8	Granivore (grain and seeds)	4.37	0.2	0.26	0.0	19.5	0.79	0.13	0.01
	24.8	Frugivore (fruit)	8.74	0.4	0.52	0.0	4.17	0.17	0.25	0.01
	24.8	Herbivore (short grass)	62.5	2.5	3.75	0.2	22.2	0.89	1.33	0.05
	24.8	Herbivore (long grass)	38.2	1.5	2.29	0.1	12.5	0.50	0.75	0.03
	24.8	Herbivore (Broadleaf plants)	57.8	2.3	3.47	0.1	19.1	0.77	1.15	0.05

Table 30 Risk Assessment of Mefentrifluconazole for Small Birds for Foliar Applications (Orchard) – Maximum and Mean Residues, On- and Off-field

			Maximum Nomogram Residues				Mean Nomogram Residues			
			In-field		Off Field		In-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ
Small Bird (0.02 kg)										
Acute	>23.6	Insectivore	24.4	<1.0	18.02	<0.8	16.8	<0.71	12.4	<0.53
	>23.6	Granivore (grain and seeds)	3.77	<0.2	2.79	<0.1	1.80	<0.08	1.33	<0.06
	>23.6	Frugivore (fruit)	7.54	<0.3	5.58	<0.2	3.60	<0.15	2.66	<0.11
Dietary	>76.0	Insectivore	24.4	<0.3	18.0	<0.2	16.8	<0.22	12.4	<0.16
	>76.0	Granivore (grain and seeds)	3.77	<0.0	2.79	<0.0	1.80	<0.02	1.33	<0.02
	>76.0	Frugivore (fruit)	7.54	<0.1	5.58	<0.1	3.60	<0.05	2.66	<0.04

			Maximum Nomogram Residues				Mean Nomogram Residues			
			In-field		Off Field		In-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ	EDE (mg a.i./kg bw/d)	RQ
Reproduction	24.8	Insectivore	24.4	1.0	18.0	0.7	16.8	0.68	12.4	0.50
	24.8	Granivore (grain and seeds)	3.77	0.2	2.79	0.1	1.80	0.07	1.33	0.05
	24.8	Frugivore (fruit)	7.54	0.3	5.58	0.2	3.60	0.14	2.66	0.11

Table 31 Risk to Birds from Mefentrifluconazole Seed Treatment Exposure – Using Acute Oral LD50 of 816 mg a.i./kg bw and LOAEL of 47.3 mg a.i./kg bw/day

	Toxicity (mg a.i./kg bw/d)	EDE (mg a.i./kg bw/d)	RQ
Small bird (0.02 kg)			
Acute	81.6	50.8	0.6
Reproduction	47.3	50.8	1.1
Medium bird (0.10 kg)			
Acute	81.6	39.9	0.5
Reproduction	47.3	39.9	0.8
Large bird (1.00 kg)			
Acute	81.6	11.6	0.1
Reproduction	47.3	11.6	0.2

Table 32 Further Characterization of Risk to Birds from Mefentrifluconazole Seed Treatment Exposure – Using Acute Oral LD50 of 816 mg a.i./kg bw and LOAEL of 47.3 mg a.i./kg bw/day

Toxicity (mg a.i./kg bw/d)		EDE (mg a.i./kg bw/d)	RQ	Number of Seeds Needed to Reach Endpoint		Area Required (m2)			
						No Drilling of seeds During Planting		Precision Drilling Used for Planting of Seeds	
				min	max	min	max	min	max
Small bird (0.02 kg)									
Acute	81.6	50.8	0.6	24.5	65.3	0.16	1.70	31.1	340
Dietary	>76.0	50.8	<0.7	22.8	60.8	0.14	1.58	28.9	317
Reproduction	47.3	50.8	1.1	14.2	37.8	0.09	0.99	18.0	197
Medium bird (0.10 kg)									
Acute	81.6	39.9	0.5	122	326	0.78	8.50	155	1700
Dietary	>76.0	39.9	<0.5	114	304	0.72	7.92	145	1583
Reproduction	47.3	39.9	0.8	71.0	189	0.45	4.93	90.0	985
Large bird (1.00 kg)									
Acute	81.6	11.6	0.1	1224	3264	7.77	85.0	1553	17000
Dietary	>76.0	11.6	<0.2	1140	3040	7.23	79.2	1447	15833
Reproduction	47.3	11.6	0.2	710	1892	4.50	49.3	900	9854

Table 33 Further Characterization of the Risk of the End-use Products Lenvyor and Belyan to Non-target Predatory and Parasitic Arthropods Using Results from Extended Laboratory Studies

Organism	Exposure	Endpoint value	EEC	RQ	Level of Concern ¹
EP: Lenvyor (100 g mefentrifluconazole/L) (peas and beans, aerial)					
Predatory mite, <i>Typhlodromus pyri</i> [foliar dwelling]	Extended laboratory (excised leaves) - Lenvyor	LR50: > 300 g a.i./ha	In-field: 175 g a.i./ha	<0.58	Not exceeded
			Off-field: 40.3 g a.i./ha	<0.13	Not exceeded
		NOER (mortality): 75 g a.i./ha	In-field: 175 g a.i./ha	2.3	Exceeded
			Off-field: 40.3 g a.i./ha	<0.54	Not exceeded
Parasitic wasp, <i>Aphidius rhopalosiphi</i> [foliar dwelling]	Extended laboratory (plants) - Lenvyor	LR50: > 300 g a.i./ha	In-field: 175 g a.i./ha	<0.58	Not exceeded
			Off-field: 40.3 g a.i./ha	<0.13	Not exceeded
		NOER: ≥ 300 g a.i./ha	In-field: 175 g a.i./ha	<0.58	Not exceeded
			Off-field: 40.3 g a.i./ha	<0.13	Not exceeded
Predatory insect green lacewing, <i>Chrysoperla carnea</i> [foliar dwelling]	Extended laboratory (excised leaves) - Lenvyor	LR50: > 300 g a.i./ha	In-field: 175 g a.i./ha	<0.58	Not exceeded
			Off-field: 40.3 g a.i./ha	<0.13	Not exceeded
		NOER: ≥ 300 g a.i./ha	In-field: 175 g a.i./ha	<0.58	Not exceeded
			Off-field: 40.3 g a.i./ha	<0.13	Not exceeded
EP: Belyan (coformulation – mefentrifluconazole, pyraclostrobin, fluxapyroxad) (potato, aerial)					
Predatory mite, <i>Typhlodromus pyri</i> [foliar dwelling]	Extended laboratory (excised leaves) - Belyan	LR50: > 456 g a.i./ha (> 3.39 L formulation/ha)	In-field: 167 g a.i./ha (1.25 L formulation/ha)	<0.37	Not exceeded
			Off-field: 38.4 g a.i./ha (0.288 L formulation/ha)	<0.08	Not exceeded
		NOER (mortality, reproduction): ≥ 456 g a.i./ha (≥ 3.39 L formulation/ha)	In-field: 167 g a.i./ha (1.25 L formulation/ha)	<0.37	Not exceeded
			Off-field: 38.4 g a.i./ha (0.288 L formulation/ha)	<0.08	Not exceeded
Parasitic wasp, <i>Aphidius rhopalosiphi</i> [foliar dwelling]	Extended laboratory (plants) - Belyan	LR50: 251 g a.i./ha (1,862 mL formulation/ha)	In-field: 167 g a.i./ha (1.25 L formulation/ha)	0.67	Not exceeded
			Off-field: 38.4 g a.i./ha (0.288 L formulation/ha)	0.15	Not exceeded
		NOER (mortality): 76 g a.i./ha (2.26 L formulation/ha)	In-field: 167 g a.i./ha (1.25 L formulation/ha)	2.2	Exceeded
			Off-field: 38.4 g a.i./ha (0.288 L formulation/ha)	0.51	Not exceeded

Table 34 Toxicity of Mefentrifluconazole to Non-target Aquatic Organisms

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
Freshwater Species					
<i>Daphnia magna</i>	48-h Acute Static	BAS 750 F (TGAI)	EC50 = 0.946 mg a.i./L	Highly toxic	2789751
	48-h Acute Static	M750F002 (TP)	EC50 > 98.6 mg TP/L	Cannot classify, but at most Slightly toxic	2789767
	48-h Acute Static	M750F003 (TP)	EC50 > 103 mg TP/L	Practically non- toxic	2789765
	48-h Acute Static	M750F005 (TP)	EC50 > 8.53 mg TP/L	Cannot classify, but at most Moderately toxic	2789753
	48-h Acute Static	M750F006 (TP)	EC50 = 4.36 mg TP/L	Moderately toxic	2789755
	48-h Acute Static	M750F007 (TP)	EC50 > 9.91 mg TP/L	Cannot classify, but at most Moderately toxic	2789759
	48-h Acute Static	M750F008 (TP)	EC50 > 7.79 mg TP/L	Cannot classify, but at most Moderately toxic	2789757
	48-h Acute Static	M750F036 (TP)	EC50 > 85.6 mg TP/L	Cannot classify, but at most Slightly toxic	2789761
	48-h Acute Static	M750F037 (TP)	EC50 > 109 mg TP/L	Practically non- toxic	2789763
	48-h Acute	BAS 750 01 F (EP - 98.9 g a.i./L; corresponds to	EC50 = 0.1641 mg a.i./L, or 1.648 mg formulation/L	a.i.: Highly toxic	2789271

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
	Static	Lenvyor)		EP: Moderately toxic	
	48-h Acute	BAS 750 BS F (blank formulation of Lenvyor)	EC50 = 3.1 mg blank formulation/L	Moderately toxic	2789273
	Static				
	48-h Acute	BAS 750 02 F (EP - 403.5 g a.i./L – corresponds to Cevya and Maxtima)	EC50 = 1.09 mg a.i./L, or 3.09 mg formulation/L	a.i. and EP: Moderately toxic	2789177
	Static				
	48-h Acute	BAS 753 02 F (EP coformulation – corresponds to Belyan)	EC50 = 0.0115 mg a.i./L, or 0.104 mg formulation/L	a.i.: Very highly toxic EP: Highly toxic	2789086
	21-d Chronic	BAS 750 F (TGAI)	NOAEC: 0.00913 mg a.i./L; LOAEC (number of live offspring per parent and successful birth rate): 0.0183 mg a.i./L	No classification	2789769
	Semi static				
<i>Daphnia pulex</i>	21-d Chronic	BAS 750 F (TGAI)	NOAEC: 0.0276 mg a.i./L; LOAEC (number of live offspring and successful birth rate): 0.0406 µg a.i./L	No classification	2789771
	Semi static				
<i>Daphnia longispina</i>	21-d Chronic	BAS 750 F (TGAI)	NOAEC: 0.0343 mg a.i./L; LOAEC (length, no. of live offspring/parent, and successful birth rate): 0.0513 mg a.i./L	No classification	2789773
	Semi-static				
Amphipod, <i>Hyaella azteca</i>	10-d Acute	BAS 750 F (TGAI)	LC50 > 0.19 mg a.i./L (overlying water); >1.7 mg a.i./L (pore water)	Cannot classify, but at most Highly toxic	2789803
	Applied to sediment				
	Static renewal				
Midge, <i>Chironomus dilutus</i>	10-d Acute	BAS 750 F (TGAI)	LC50 > 0.17 mg a.i./L (overlying water); > 1.4 mg a.i./L (pore water)	Cannot classify, but at most Highly toxic	2789801
	Applied to sediment				
	Static renewal				

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
	63-d Chronic Applied to sediment Static renewal	BAS 750 F (TGAI)	NOAEC: 0.0049 mg a.i./L (overlying water); 0.088 mg a.i./L (pore water); LOAEC (emergence): 0.0083 mg a.i./L (overlying water); 0.152 mg a.i./L (pore water)	No classification	2789809
Midge, <i>Chironomus riparius</i>	28-d Chronic Applied to sediment Static	BAS 750 F (TGAI)	NOAEC: 0.00108 mg a.i./L (overlying water); 0.0015 mg a.i./L (pore water); LOAEC (emergence): 0.00229 mg a.i./L (overlying water); 0.0021 mg a.i./L (pore water)	No classification	2789807
Rainbow trout, <i>Oncorhynchus mykiss</i>	96-h Acute Flow through	BAS 750 F (TGAI)	LC50 = 0.536 mg a.i./L	Highly toxic	2789727
	96-h Acute Static	M750F006 (TP)	LC50 = 5.94 mg TP/L	Moderately toxic	2789739
	96-h Acute Static	M750F007 (TP)	LC50 > 7.03 mg TP/L	Cannot classify, but at most Moderately toxic	2789737
	96-h Acute Static	BAS 750 01 F (EP - 98.9 g a.i./L; corresponds to Lenvyor)	LC50 = 0.0455 mg a.i./L, or 0.457 mg formulation/L	a.i.: Very highly toxic EP: Highly toxic	2789265
	96-h Acute Static	BAS 750 BS F (blank formulation of Lenvyor)	LC50 = 1.4 mg blank formulation/L	Moderately toxic	2789269
	96-h Acute Static	BAS 750 02 F (EP – 403.5 g a.i./L; corresponds to Cevya and Maxtima)	LC50 = 0.477 mg a.i./L, or 1.35 mg formulation/L	a.i.: Highly toxic EP: Moderately toxic	2789175
	96-h Acute Static	BAS 753 02 F (EP coformulation – corresponds to Belyan)	LC50 = 0.00536 mg a.i./L, or 0.054 mg formulation/L	a.i. and EP: Very highly toxic	2789083

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
Zebrafish, <i>Danio rerio</i>	96-h Acute	BAS 750 F (TGAI)	LC50 = 0.823 mg a.i./L	Highly toxic	2789733
	Static				
	68/69-d Chronic (sexual development)	BAS 750 F (TGAI)	NOEC: ≥ 0.045 mg a.i./L; LOEC: > 0.045 mg a.i./L	No classification	2789741
	Flow through				
	36-d Chronic (early life stage)	BAS 750 F (TGAI)	NOAEC: 0.027 mg a.i./L; LOAEC (length): 0.063 mg a.i./L	No classification	2789743
Fathead minnow, <i>Pimephales promelas</i>	Flow through				
	Chronic (full life cycle)	BAS 750 F (TGAI)	NOAEC: 0.0222 mg a.i./L; LOAEC (F1 survival): 0.0455 mg a.i./L	No classification	2789747
	Flow through				
	96-h Acute	BAS 750 F (TGAI)	LC50 = 0.65 mg a.i./L	Highly toxic	2789735
	Static				
Carp, <i>Cyprinus carpio</i>	96-h Acute	BAS 750 01 F (EP- 98.9 g a.i./L; corresponds to Lenvyor)	LC50 > 0.152 mg a.i./L, or > 1.53 mg formulation/L	Cannot classify, but at most Highly toxic	2789267
	Static				
Freshwater green alga, <i>Pseudokirchneriella subcapitata</i>	96-h Acute	BAS 750 F (TGAI)	LC50 = 1.13 mg a.i./L	Moderately toxic	2789731
	Flow through				
	96-h Acute	BAS 750 F (TGAI)	EC50 (area under the curve - biomass) = 1.08 mg a.i./L	No classification	2789777
	Static				
	96-h Acute	M750F002 (TP)	EC50 (yield, growth rate, and area under the curve) > 101.4 mg TP/L	No classification	2789799
	Static				
	72-h Acute	M750F003 (TP)	EC50 (yield, growth rate, and area under the curve) > 103 mg TP/L	No classification	2789797

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
	Static				
	72-h Acute	M750F005 (TP)	EC50 (yield, growth rate, and area under the curve) > 8.521 mg TP/L	No classification	2789785
	Static				
	72-h Acute	M750F006 (TP)	EC50 (yield) = 0.174 mg TP/L	No classification	2789783
	Static				
	72-h Acute	M750F007 (TP)	EC50 (yield, growth rate) > 9.14 mg TP/L	No classification	2789781
	Static				
	96-h Acute	M750F008 (TP)	EC50 (area under the curve - biomass) = 2.00 mg TP/L	No classification	2789779
	Static				
	96-h Acute	M750F036 (TP)	EC50 (yield, growth rate, and area under the curve) > 95.89 mg TP/L	No classification	2789793
	Static				
	96-h Acute	M750F037 (TP)	EC50 (area under the curve – biomass) = 98.4 mg TP/L	No classification	2789795
	Static				
	96-h Acute	BAS 750 01 F (EP - 98.9 g a.i./L; corresponds to Lenvyor)	EC50 (yield, growth rate, and area under the curve) = 0.28 mg a.i./L, or 2.8 mg formulation/L	No classification	2789275
	Static				
	72-h Acute	BAS 750 02 F (EP– 403.5 g a.i./L; corresponds to Cevya and Maxtima)	EC50 (yield) = 1.10 mg a.i./L, or 3.14 mg formulation/L	No classification	2789179
	Static				
	72-h Acute	BAS 753 02 F (EP coformulation – corresponds to Belyan)	EC50 (yield, growth rate, and area under the curve/biomass) > 0.235 mg a.i./L, or > 2.27 mg formulation/L	No classification	2789087
	Static				
Freshwater cyanobacterium / blue-green alga, <i>Anabaena flos-aquae</i>	96-h Acute	BAS 750 F (TGAI)	EC50 (yield, growth rate, and area under the curve/biomass) > 3.09 mg a.i./L	No classification	2789787
	Static				

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ^a	PMRA#
Freshwater diatom, <i>Navicula pelliculosa</i>	96-h Acute Static	BAS 750 F (TGAI)	EC50 (yield) = 0.765 mg a.i./L	No classification	2789789
Vascular plant, duckweed <i>Lemna gibba</i>	7-d Dissolved Static	BAS 750 F (TGAI)	EC50 > 1.874 mg a.i./L	No classification	2789812
Marine species					
Mysid shrimp (crustacean)	96-h Acute Flow through	BAS 750 F (TGAI)	LC50 = 1.30 mg a.i./L	Moderately toxic	2789719
	28-d Chronic Flow through	BAS 750 F (TGAI)	NOAEC \geq 0.0132 mg a.i./L; LOAEC: >0.0132 mg a.i./L	No classification	2789775
<i>Leptocheirus plumulosus</i> (crustacean)	10-d Acute Applied to sediment Static	BAS 750 F (TGAI)	LC50 > 0.30 mg a.i./L (overlying water); > 0.83 mg a.i./L (pore water)	Cannot classify, but at most Highly toxic	2789805
Eastern oyster (mollusk)	96-h Acute Flow through	BAS 750 F (TGAI)	EC50 = 0.908 mg a.i./L	Highly toxic	2789721
Sheepshead minnow	96-h Acute Semi static	BAS 750 F (TGAI)	LC50 = 0.756 mg a.i./L	Highly toxic	2789729
	35-d Chronic (early life stage) Flow through	BAS 750 F (TGAI)	NOAEC: \geq 0.147 mg a.i./L; LOAEC: > 0.147 mg a.i./L	No classification	2789745
Marine diatom, <i>Skeletonema costatum</i>	96-h Acute Static	BAS 750 F (TGAI)	EC50 (yield) = 0.393 mg a.i./L	No classification	2789791

^a USEPA classification, where applicable.

Table 35 Screening Level Risk Assessment of Mefentrifluconazole for Aquatic Organisms

Organism	Exposure	Endpoint Value	EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
Freshwater Species					
Invertebrates					
TGAI - Mefentrifluconazole					
Daphnia magna	Acute	LC50/2: 0.473 mg a.i./L	0.364	0.77	Not exceeded
	Chronic	NOEC (reproduction): 0.00913 mg a.i./L	0.364	40	Exceeded
Daphnia pulex	Chronic	NOAEC (reproduction): 0.0276 mg a.i./L	0.364	13	Exceeded
Daphnia longispina	Chronic	NOAEC (reproduction and parental size): 0.0343 mg a.i./L	0.364	11	Exceeded
Amphipod, Hyalella azteca	Acute (applied to sediment)	LC50/2: > 0.095 mg a.i./L (overlying water);	0.364	<3.6	May be exceeded
		LC50/2: > 0.85 mg a.i./L (pore water)	0.364	<0.43	Not exceeded
Midge, Chironomus dilutus	Acute (applied to sediment)	LC50/2: > 0.09 mg a.i./L (overlying water)	0.364	<4.0	May be exceeded
		LC50/2: > 0.7 mg a.i./L (pore water)	0.364	<0.52	Not exceeded
	Chronic (applied to sediment)	NOAEC (emergence): 0.0049 mg a.i./L (overlying water)	0.364	74	Exceeded
		NOAEC (emergence): 0.088 mg a.i./L (pore water)	0.364	4.1	Exceeded
Midge, Chironomus riparius	Chronic (applied to sediment)	NOAEC (emergence): 0.00108 mg a.i./L (overlying water)	0.364	340	Exceeded
		NOAEC (emergence): 0.0015 mg a.i./L (pore water)	0.364	243	Exceeded
Transformation Products					
Daphnia magna	Acute – M750F002	LC50/2: > 49.3 mg TP/L	0.224	<0.005	Not exceeded
	Acute - M750F003	LC50/2: > 51.5 mg TP/L	0.263	<0.006	Not exceeded
	Acute - M750F005	LC50/2: > 4.27 mg TP/L	0.347	<0.081	Not exceeded

Organism	Exposure	Endpoint Value	EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
	Acute - M750F006	LC50/2: 2.18 mg TP/L	0.325	0.15	Not exceeded
	Acute - M750F007	LC50/2: > 4.96 mg TP/L	0.308	<0.062	Not exceeded
	Acute - M750F008	LC50/2: > 3.90 mg TP/L	0.325	<0.083	Not exceeded
	Acute - M750F036	LC50/2: > 42.8 mg TP/L	0.230	<0.006	Not exceeded
	Acute - M750F037	LC50/2: > 54.5 mg TP/L	0.114	<0.002	Not exceeded
End-use Products					
<i>Daphnia magna</i>	Acute - Lenvyor	LC50/2: 0.082 mg a.i./L	0.0536	0.65	Not exceeded
	Acute – Cevya, Maxtima	LC50/2: 0.545 mg a.i./L	0.364	0.68	Not exceeded
	Acute - Belyan	LC50/2: 0.00575 mg a.i./L	0.0366	6.4	Exceeded
Fish and Amphibians					
TGAI - Mefentrifluconazole					
Rainbow trout, <i>Oncorhynchus mykiss</i> [cold water species]	Acute	LC50/10: 0.0536 mg a.i./L	0.364	6.8	Exceeded
Zebrafish, <i>Danio rerio</i> [warm water species]	Acute	LC50/10: 0.0823 mg a.i./L	0.364	4.4	Exceeded
	Chronic (sexual development)	NOEC: \geq 0.045 mg a.i./L	0.364	<8.1	May be exceeded
	Chronic (early life stage)	NOAEC (length): 0.027 mg a.i./L	0.364	13	Exceeded
	Chronic (full life cycle)	NOAEC (F1 survival): 0.0222 mg a.i./L	0.364	16	Exceeded
Fathead minnow, <i>Pimephales promelas</i> [warm water species]	Acute	LC50/10: 0.065 mg a.i./L	0.364	5.6	Exceeded
Carp, <i>Cyprinus carpio</i> [warm water species]	Acute	LC50/10: 0.113 mg a.i./L	0.364	3.2	Exceeded
Amphibians (using fish data as surrogate)	Acute	LC50/10: 0.0536 mg a.i./L	1.94 (for 15cm deep water body) ²	36	Exceeded
	Chronic (sexual development)	NOEC: \geq 0.045 mg a.i./L	1.94 (for 15 cm deep water body) ²	<43	May be exceeded
	Chronic (early life	NOAEC (length): 0.027 mg a.i./L	1.94 (for 15 cm deep water body) ²	72	Exceeded

Organism	Exposure	Endpoint Value	EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
	stage)				
	Chronic (full life cycle)	NOAEC (F1 survival): 0.0222 mg a.i./L	1.94 (for 15 cm deep water body) ²	87	Exceeded
Transformation Products					
Rainbow trout, <i>Oncorhynchus mykiss</i>	Acute - M750F006	LC50/10: 0.594 mg TP/L	0.325	0.55	Not exceeded
	Acute - M750F007	LC50/10: > 0.703 mg TP/L	0.308	<0.44	Not exceeded
Amphibians (using fish data as surrogate)	Acute - M750F006	LC50/10: 0.594 mg TP/L	1.734 (for 15 cm deep water body) ²	2.9	Exceeded
	Acute - M750F007	LC50/10: > 0.703 mg TP/L	1.645 (for 15 cm deep water body) ²	<2.3	May be exceeded
End-use Products					
Rainbow trout, <i>Oncorhynchus mykiss</i>	Acute - Lenvyor	LC50/10: 0.00455 mg a.i./L	0.0536	12	Exceeded
	Acute – Cevya, Maxtima	LC50/10: 0.0477 mg a.i./L	0.364	7.6	Exceeded
	Acute - Belyan	LC50/10: 0.000536 mg a.i./L	0.0366	68	Exceeded
Fathead minnow, <i>Pimephales promelas</i>	Acute - Lenvyor	LC50/10: > 0.0152 mg a.i./L	0.0536	<3.5	May be exceeded
Amphibians (using fish data as surrogate)	Acute - Lenvyor	LC50/10: 0.00455 mg a.i./L	0.286 (for 15 cm deep water body)	63	Exceeded
	Acute – Cevya, Maxtima	LC50/10: 0.0477 mg a.i./L	1.94 (for 15 cm deep water body) ²	41	Exceeded
	Acute - Belyan	LC50/10: 0.000536 mg a.i./L	0.195 (for 15 cm deep water body)	364	Exceeded
Algae and Vascular Plants					
TGAI - Mefentrifluconazole					
Green alga, <i>Pseudokirchneriella subcapitata</i>	Acute	EC50/2: 0.54 mg a.i./L	0.364	0.67	Not exceeded
Blue-green alga, <i>Anabaena flos-aquae</i>	Acute	EC50/2: >1.55 mg a.i./L	0.364	<0.23	Not exceeded
Diatom, <i>Navicula pelliculosa</i>	Acute	EC50/2: 0.383 mg a.i./L	0.364	0.95	Not exceeded
Transformation Products					
Green alga, <i>Pseudokirchneriella subcapitata</i>	Acute - M750F002	EC50/2: > 50.7 mg TP/L	0.224	<0.004	Not exceeded
	Acute - M750F003	EC50/2: > 51.5 mg TP/L	0.263	<0.005	Not exceeded
	Acute - M750F005	EC50/2: > 4.26 mg TP/L	0.347	<0.08	Not exceeded
	Acute - M750F006	EC50/2: 0.087 mg TP/L	0.325	3.7	Exceeded

Organism	Exposure	Endpoint Value	EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
	Acute - M750F007	EC50/2: > 4.57 mg TP/L	0.308	<0.07	Not exceeded
	Acute - M750F008	EC50/2: 1.00 mg TP/L	0.325	0.33	Not exceeded
	Acute - M750F036	EC50/2: > 47.9 mg TP/L	0.230	<0.005	Not exceeded
	Acute - M750F037	EC50/2: 49.2 mg TP/L	0.114	0.002	Not exceeded
End-use Products					
Green alga, <i>Pseudokirchneriella subcapitata</i>	Acute - Lenvyor	EC50/2: 0.14 mg a.i./L	0.0536	0.38	Not exceeded
	Acute - Cevya, Maxtima	EC50/2: 0.55 mg a.i./L	0.364	0.66	Not exceeded
	Acute - Belyan	EC50/2: > 0.118 mg a.i./L	0.0366	<0.31	Not exceeded
Vascular Plants					
TGAI – Mefentrifluconazole					
Vascular plant, duckweed <i>Lemna gibba</i>	Dissolved	EC50/2: > 0.937 mg a.i./L	0.364	<0.34	Not exceeded
Marine Species					
TGAI - Mefentrifluconazole					
Mysid shrimp (crustacean)	Acute	LC50/2: 0.65 mg a.i./L	0.364	0.56	Not exceeded
	Chronic	NOAEC: ≥ 0.0132 mg a.i./L	0.364	<28	May be exceeded
<i>Leptocheirus plumulosus</i> (crustacean)	Acute	LC50/2: > 0.15 mg a.i./L (overlying water)	0.364	<2.4	May be exceeded
		LC50/2: > 0.415 mg a.i./L (pore water)	0.364	<0.88	Not exceeded
Eastern oyster (mollusk)	Acute	EC50/2: 0.454 mg a.i./L	0.364	0.8	Not exceeded
Sheepshead minnow	Acute	LC50/10: 0.378 mg a.i./L	0.364	0.96	Not exceeded
	Chronic (early life stage)	NOAEC: ≥ 0.147 mg a.i./L	0.364	≤ 2.5	May be exceeded
Marine diatom, <i>Skeletonema costatum</i>	Acute	EC50/2: 0.197 mg a.i./L	0.364	1.8	Exceeded
¹ EEC is for 80-cm deep water body, except for amphibians where an EEC for a 15-cm deep water body is used. ² The water solubility of mefentrifluconazole is 0.81 mg/L. This EEC value exceeds the limit of solubility for mefentrifluconazole.					

Table 36 Refined Risk Assessment for Non-target Aquatic Organisms Exposed to Spray Drift of Mefentrifluconazole

Organism	Exposure	Endpoint Value	Refined EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
Freshwater Species					
Invertebrates					
TGAI - Mefentrifluconazole					
<i>Daphnia magna</i>	Chronic	NOEC (reproduction): 0.00913 mg a.i./L	0.0410	4.5	Exceeded
<i>Daphnia pulex</i>	Chronic	NOAEC (reproduction): 0.0276 mg a.i./L	0.0410	1.5	Exceeded
<i>Daphnia longispina</i>	Chronic	NOAEC: 0.0343 mg a.i./L	0.0410	1.2	Exceeded
End-use Products					
<i>Daphnia magna</i>	Acute - Belyan	LC50/2: 0.00575 mg a.i./L	0.00843	1.5	Exceeded
Fish and Amphibians					
TGAI - Mefentrifluconazole					
Rainbow trout, <i>Oncorhynchus mykiss</i>	Acute	LC50/10: 0.0536 mg a.i./L	0.0410	0.76	Not exceeded
Zebrafish, <i>Danio rerio</i>	Acute	LC50/10: 0.0823 mg a.i./L	0.0410	0.50	Not exceeded
	Chronic (sexual development)	NOEC: ≥ 0.045 mg a.i./L	0.0410	<0.91	Not exceeded
	Chronic (early life stage)	NOAEC (length): 0.027 mg a.i./L	0.0410	1.5	Exceeded
	Chronic (full life cycle)	NOAEC (F1 survival): 0.0222 mg a.i./L	0.0410	1.8	Exceeded
Fathead minnow, <i>Pimephales promelas</i>	Acute	LC50/10: 0.065 mg a.i./L	0.0410	0.63	Not exceeded
Carp, <i>Cyprinus carpio</i>	Acute	LC50/10: 0.113 mg a.i./L	0.0410	0.36	Not exceeded
Amphibians (using fish data as surrogate)	Acute	LC50/10: 0.0536 mg a.i./L	0.219 (for 15 cm deep water body)	4.1	Exceeded
	Chronic (sexual development)	NOEC: ≥ 0.045 mg a.i./L	0.219 (for 15 cm deep water body)	<4.9	May be exceeded
	Chronic (early life stage)	NOAEC (length): 0.027 mg a.i./L	0.219 (for 15 cm deep water body)	8.1	Exceeded
	Chronic (full life cycle)	NOAEC (F1 survival): 0.0222	0.219 (for 15 cm deep	9.9	Exceeded

Organism	Exposure	Endpoint Value	Refined EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
		mg a.i./L	water body)		
Transformation Products					
Amphibians (using fish data as surrogate)	Acute - M750F006	LC50/10: 0.594 mg TP/L	0.196 (for 15 cm deep water body)	0.33	Not exceeded
	Acute - M750F007	LC50/10: > 0.703 mg TP/L	0.186 (for 15 cm deep water body)	<0.26	Not exceeded
End-use Products					
Rainbow trout, <i>Oncorhynchus mykiss</i>	Acute - Lenvyor	LC50/10: 0.00455 mg a.i./L	0.0123	2.7	Exceeded
	Acute – Cevya, Maxtima	LC50/10: 0.0477 mg a.i./L	0.0410	0.86	Not exceeded
	Acute - Belyan	LC50/10: 0.000536 mg a.i./L	0.00843	16	Exceeded
Fathead minnow, <i>Pimephales promelas</i>	Acute - Lenvyor	LC50/10: > 0.0152 mg a.i./L	0.0123	<0.81	Not exceeded
Amphibians (using fish data as surrogate)	Acute - Lenvyor	LC50/10: 0.00455 mg a.i./L	0.0657 (for 15 cm deep water body)	14	Exceeded
	Acute – Cevya, Maxtima	LC50/10: 0.0477 mg a.i./L	0.219 (for 15 cm deep water body)	4.6	Exceeded
	Acute - Belyan	LC50/10: 0.000536 mg a.i./L	0.0449 (for 15 cm deep water body)	84	Exceeded
Algae and Vascular Plants					
Transformation Products					
Green alga, <i>Pseudokirchneriella subcapitata</i>	Acute - M750F006	EC50/2: 0.0087 mg TP/L	0.0367	0.42	Not exceeded
Marine Species					
TGAI - Mefentrifluconazole					
Mysid shrimp (crustacean)	Chronic	NOAEC: ≥ 0.0132 mg a.i./L	0.0410	3.1	Exceeded
<i>Leptocheirus plumulosus</i> (crustacean)	Acute	LC50/2: > 0.15 mg a.i./L (overlying water)	0.0410	<0.27	Not exceeded
Sheepshead minnow	Chronic (early life stage)	NOAEC: ≥ 0.147 mg a.i./L	0.0410	0.28	Not exceeded
Marine diatom, <i>Skeletonema costatum</i>	Acute	EC50/2: 0.197 mg a.i./L	0.0410	0.21	Not exceeded
¹ EEC is for 80 cm deep water body, except for amphibians where an EEC for a 15 cm deep water body is used.					

Table 37 EECs (in µg a.i./L) of the Combined Residue of Mefentrifluconazole and M750F006 for the Ecological Risk Assessment of Mefentrifluconazole

Use	Water Depth	Water Column					Pore Water	
		Peak	24 hour	96 hour	21 day	Yearly	Peak	21 day
All agricultural crops	80 cm	11	11	10	9.0	8.3	8.4	8.4
	15 cm	29	23	17	14	13	--	--
Turf only	80 cm	30	28	26	23	20	21	21
	15 cm	87	66	44	34	31	--	--

Table 38 Refined Risk Assessment for Non-target Aquatic Organisms Exposed to Run-off of Mefentrifluconazole

Organism	Exposure	Endpoint Value	Refined EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
Freshwater species					
Invertebrates					
TGAI - Mefentrifluconazole					
<i>Daphnia magna</i>	Chronic	NOEC (reproduction): 0.00913 mg a.i./L	0.023	2.5	Exceeded
<i>Daphnia pulex</i>	Chronic	NOAEC (reproduction): 0.0276 mg a.i./L	0.023	0.83	Not exceeded
<i>Daphnia longispina</i>	Chronic	NOAEC: 0.0343 mg a.i./L	0.023	0.67	Not exceeded
Amphipod, <i>Hyalella azteca</i>	Acute	LC50/2: > 0.095 mg a.i./L (overlying water)	0.026 (overlying water)	<0.27	Not exceeded
		LC50/2: 0.85 mg a.i./L (pore water)	0.021 (pore water)	<0.024	Not exceeded
Midge, <i>Chironomus dilutus</i>	Acute	LC50/2: > 0.09 mg a.i./L (overlying water)	0.026 (overlying water)	<0.29 <0.23	Not exceeded
		LC50/2: > 0.7 mg a.i./L (pore water)	0.021 (pore water)	<0.03	Not exceeded
	Chronic	NOAEC: 0.0049 mg a.i./L (overlying water)	0.023 (overlying water)	4.7	Exceeded
		NOAEC: 0.088 mg a.i./L (pore water)	0.021 (pore water)	0.24	Not exceeded

Organism	Exposure	Endpoint Value	Refined EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
Midge, <i>Chironomus riparius</i>	Chronic	NOAEC: 0.00108 mg a.i./L (overlying water)	0.023 (overlying water)	21	Exceeded
		NOAEC: 0.0015 mg a.i./L (pore water)	0.021 (pore water)	14	Exceeded
Fish and Amphibians					
TGAI - Mefentrifluconazole					
Rainbow trout, <i>Oncorhynchus mykiss</i>	Acute	LC50/10: 0.0536 mg a.i./L	0.026	0.49	Not exceeded
Zebrafish, <i>Danio rerio</i>	Acute	LC50/10: 0.0823 mg a.i./L	0.026	0.32	Not exceeded
	Chronic (sexual development)	NOEC: ≥ 0.045 mg a.i./L	0.023	0.51	Not exceeded
	Chronic (early life stage)	NOAEC (length): 0.027 mg a.i./L	0.023	0.85	Not exceeded
	Chronic (full life cycle)	NOAEC (F1 survival): 0.0222 mg a.i./L	0.023	1.0	Exceeded
Fathead minnow, <i>Pimephales promelas</i>	Acute	LC50/10: 0.065 mg a.i./L	0.026	0.4	Not exceeded
Carp, <i>Cyprinus carpio</i>	Acute	LC50/10: 0.113 mg a.i./L	0.026	0.23	Not exceeded
Amphibians (using fish data as surrogate)	Acute	LC50/10: 0.0536 mg a.i./L	0.044	0.82	Not exceeded
	Chronic (sexual development)	NOEC: ≥ 0.045 mg a.i./L	0.034	0.76	Not exceeded
	Chronic (early life stage)	NOAEC (length): 0.027 mg a.i./L	0.034	1.3	Exceeded
	Chronic (full life cycle)	NOAEC (F1 survival): 0.0222 mg a.i./L	0.034	1.5	Exceeded
Transformation Products					
Amphibians (using fish data as surrogate)	Acute - M750F006	LC50/10: 0.594 mg TP/L	0.044	0.07	Not exceeded
	Acute -	LC50/10: >	0.044	<0.06	Not exceeded

Organism	Exposure	Endpoint Value	Refined EEC – 80 cm (mg/L) ¹	RQ	Level of Concern
	M750F007	0.703 mg TP/L			
Algae and Vascular Plants					
Transformation Products					
Green alga, <i>Pseudokirchneriella subcapitata</i>	Acute - M750F006	EC50/2: 0.087 mg TP/L	0.026	0.30	Not exceeded
Marine Species					
TGAI - Mefentrifluconazole					
Mysid shrimp (crustacean)	Chronic	NOAEC: ≥ 0.0132 mg a.i./L	0.023	<1.7	Exceeded
<i>Leptocheirus plumulosus</i> (crustacean)	Acute	LC50/2: > 0.15 mg a.i./L (overlying water)	0.026	<0.17	Not exceeded
Sheepshead minnow	Chronic (early life stage)	NOAEC: ≥ 0.147 mg a.i./L	0.023	0.16	Not exceeded
Marine diatom, <i>Skeletonema costatum</i>	Acute	EC50/2: 0.197 mg a.i./L	0.026	0.13	Not exceeded
¹ EEC is for 80 cm deep water body, except for amphibians where an EEC for a 15 cm deep water body is used.					

Table 39 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value		Active Ingredient Endpoints	Transformation Products Endpoints
CEPA toxic or CEPA toxic equivalent ¹	Yes		Yes	Yes
Predominantly anthropogenic ²	Yes		Yes	Yes
Persistence ³ :	Soil	Half-life ≥ 182 days	Yes: Half-lives of 355 to 626 days	Yes: Half-lives of 356 to 1,210 days based on combined residues
	Water	Half-life ≥ 182 days	Yes: total system half-lives of 192 to 350 days	Yes: Half-lives of 126 and 303 days based on combined residues
	Sediment	Half-life ≥ 365 days	No: total system half-lives of 192 to 350 days	No: total system half-lives of 126 and 303 days based on combined residues

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value		Active Ingredient Endpoints	Transformation Products Endpoints
	Air	Half-life \geq 2 days or evidence of long range transport	No: AOPWIN (v1.92) predicted half-life of 1.7 days	No: based on AOPWIN predictions for M750F002, M750F003, M750F005, M750F006, M750F007, M750F008, and M750F036 Yes: based on AOPWIN predictions for M750F001 and M750F037
Bioaccumulation ⁴	Log K _{ow} \geq 5		No: 3.4	No: -1.28 to 3.44 based on EPI Suite predictions
	BCF \geq 5000		No: 350 L/kg (normalised to 5% lipid content)	Not available
	BAF \geq 5000		Not available	Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet all TSMP Track 1 criteria.	No, does not meet all TSMP Track 1 criteria.

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).

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.

³ If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air), then the criterion for persistence is considered to be met.

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}).

Table 40 Supported Use Claims

Supported Use Claims for Lenvyor
1. Control of blackleg (<i>Leptosphaeria maculans</i>) on canola, rapeseed (<i>Brassica</i> spp., <i>Brassica napus</i>), mustard (<i>Brassica</i> spp., <i>Brassica juncea</i>) including oilseed/condiment mustard at 0.5 – 1.0 L product/ha when applied initially at the 2 to 6-leaf stage on a 10 – 14 day interval, and with a maximum of 3 L/ha per year.
2. Control of pasmo (<i>Septoria linicola</i>) on flax at 0.5 – 1.0 L product/ha when applied at 20 – 50% flowering stage on a 10 – 14 day interval, and with a maximum of 3 L/ha per year.
3. Control of the following diseases on corn (field, pop, sweet, and seed) at 0.75 – 1.0 L product/ha when applied preventatively on a 10 – 14 day interval, and with a maximum of 3 L/ha (for field, pop and seed corn) or 4 L/ha (for sweet corn) per year. <ul style="list-style-type: none"> 1) Common rust (<i>Puccinia sorghi</i>) 2) Gray leaf spot (<i>Cercospora zeae-maydis</i>) 3) Northern leaf blight (<i>Setosphaeria turcica</i>) 4) Eye spot (<i>Aureobasidium zeae</i>)

4. Control or suppression of the following diseases on Crop Subgroup 6C (dried shelled peas and beans, except soybeans) when applied preventatively on a 10 – 14 day interval, and with a maximum of 4.5 L/ha per year. <ol style="list-style-type: none"> 1) Control of mycosphaerella blight (<i>Mycosphaerella pinodes</i>) and ascochyta blight (<i>Ascochyta pisi</i> and <i>A. rabiei</i>) at 0.75 – 1.0 L product/ha 2) Control of powdery mildew (<i>Erysiphe pisi</i>) at 0.75 L product/ha 3) Control of rust (<i>Uromyces appendiculatus</i>) at 0.75 L product/ha (on dry bean only) 4) Suppression of anthracnose (<i>Colletotrichum truncatum</i>) at 0.75 – 1.0 L product/ha
5. Control of the following diseases on soybean at 0.75 – 1.0 L product/ha when applied preventatively on a 10 – 14 day interval, and with a maximum of 3 L/ha per year. <ol style="list-style-type: none"> 1) Frog eye leaf spot (<i>Cercospora sojae</i>) 2) Septoria brown spot (<i>Septoria glycines</i>) 3) Cercospora leaf blight & purple seed stain (PSS) (<i>Cercospora kikuchii</i>)
6. Suppression of early leaf spot (<i>Cercospora arachidicola</i>) on peanut at 1.0 L product/ha (100 g a.i./ha) when applied preventatively on a 10 – 14 day interval, and with a maximum of 4 L/ha per year.
7. Control of cercospora leaf spot (<i>Cercospora beticola</i>) on sugar beet at 0.75 – 1.5 L product/ha when applied preventatively on a 14 day interval, and with a maximum of 3 L/ha per year.
8. Control of early blight (<i>Alternaria solani</i>) on potato at 0.75 – 1.0 L product/ha when applied preventatively on a 7 – 14 day interval, and with a maximum of 4.5 L/ha per year.
9. Control of the following diseases on wheat (spring, winter and durum) at 0.5 – 1.0 L product/ha when applied preventatively on a 10 – 14 day interval, and with a maximum of 3 L/ha per year. <ol style="list-style-type: none"> 1) Septoria leaf blotch (<i>Septoria tritici</i> or <i>Septoria nodorum</i>) 2) Stripe rust (<i>Puccinia striiformis</i>) 3) Leaf rust (<i>Puccinia recondita</i>)
10. Aerial application on all labelled crops, except peanut.
Supported Use Claims for Cevya
1. Suppression of early leaf spot (<i>Cercospora arachidicola</i>) on peanut at 0.25 L product/ha when applied preventatively on a 10 – 14 day interval, and with a maximum of 1 L/ha per year.
2. Control or suppression of the following diseases on Crop Group 11-09 (pome fruit) at 0.25 – 0.375 L product/ha when applied preventatively on a 7 – 10 day interval, and with a maximum of 1.125 L/ha per year. <ol style="list-style-type: none"> 1) Control of apple scab (<i>Venturia inaequalis</i>) 2) Suppression of powdery mildew (<i>Podosphaera leucotricha</i>)
3. Control of early blight (<i>Alternaria solani</i>) on potato at 0.19 – 0.25 L product/ha when applied preventatively on a 7 – 14 day interval, and with a maximum of 1.125 L/ha per year.
4. Control of powdery mildew (<i>Erysiphe necator</i>) on grape at 0.19 – 0.25 L product/ha when applied preventatively on a 14 day interval, and with a maximum of 1.125 L/ha per year.
5. Suppression of the following diseases on Crop Group 12-09 (stone fruit) at 0.25 – 0.375 L

product/ha when applied preventatively on a 7 – 14 day interval, and with a maximum of 1.125 L/ha per year.
<ul style="list-style-type: none"> 1) Brown rot blossom blight (<i>Monilinia fructicola</i>, <i>M. laxa</i>) 2) Powdery mildew (<i>Podosphaera clandestine</i>, <i>P. pannosa</i>)
6. Control of cercospora leaf spot (<i>Cercospora beticola</i>) on sugar beet at 0.19 – 0.375 L product/ha when applied preventatively on a 14 day interval, and with a maximum of 0.75 L/ha per year.
7. Suppression of the following diseases on tree nuts at 0.25 – 0.375 L product/ha when applied preventatively on a 7 – 14 day interval, and with a maximum of 1.125 L/ha per year.
<ul style="list-style-type: none"> 1) Brown rot blossom blight (<i>Monilinia fructicola</i>, <i>M. laxa</i>) 2) Alternaria leaf spot (<i>Alternaria alternata</i>)
8. Aerial application on potato and sugar beet.
Supported Use Claims for Maxtima
1. Control of anthracnose (<i>Colletotrichum cereale</i>) on turf at 6.25 mL product/100 m ² , with a 14-day re-application interval. No more than 7.5 L/ha may be applied annually.
2. Control of brown patch (<i>Rhizoctonia solani</i>) on turf at 25 mL product/100 m ² , with a 14-day re-application interval. No more than 7.5 L/ha may be applied annually.
3. Control of dollar spot (<i>Sclerotinia homoeocarpa</i>) on turf at 6.25 mL product/100 m ² , with a 14-21 day re-application interval. No more than 7.5 L/ha may be applied annually.
4. Control of gray snow mould / typhula blight (<i>Typhula incarnata</i> , <i>T. ishkariensis</i>) on turf at 12.5 – 25 mL product/100 m ² , with a single application in late fall just prior to snow cover. Use the higher rate for areas with a history of severe disease pressure.
5. Suppression of microdochium patch (fusarium patch) and pink snow mould (<i>Microdochium nivale</i>) on turf at 12.5 – 25 mL product/100 m ² , with a single application in late fall just prior to snow cover. Use the higher rate for areas with a history of severe disease pressure.
6. Control of take-all patch (<i>Gaeumannomyces graminis</i>) on turf at 12.5 mL product/100 m ² , with a 28-day re-application interval. No more than 7.5 L/ha may be applied annually.
Supported Use Claims for Relenya
1. Control of seed rot / pre-emergence damping-off, post emergence damping-off and seedling blight caused by soil-borne <i>Fusarium</i> spp. and <i>Rhizoctonia solani</i> on corn (field corn, popcorn, sweet corn, seed corn) at 12.5 – 25 mL product/100 kg seed. The high rate is for use when planting into cold, wet soils, or if disease pressure is expected to be high.
2. Control of seed rot and seedling blight caused by soil-borne <i>Fusarium</i> spp. and control of seed rot / pre-emergence damping-off, post emergence damping-off and seedling blight caused by soil-borne <i>Rhizoctonia solani</i> on Crop Subgroup 6C (dried shelled peas and beans) at 12.5 – 50 mL product/100 kg seed. The high rate is for use when planting into cold, wet soils, or if disease pressure is expected to be high.
3. Control of seed rot / pre-emergence damping-off, post emergence damping-off and seedling blight caused by soil-borne <i>Fusarium</i> spp. and <i>Rhizoctonia solani</i> on soybean at 12.5 – 50 mL product/100 kg seed. The high rate is for use when planting into cold, wet soils, or if disease pressure is expected to be high.

4. Control of seed rot / pre-emergence damping-off, post emergence damping-off and seedling blight caused by soil-borne <i>Fusarium</i> spp. and dwarf bunt caused by <i>Tilletia controversa</i> on wheat (spring wheat, winter wheat, durum wheat and triticale) at 12.5 – 25 mL product/100 kg seed. The high rate is for use when planting into cold, wet soils, or if disease pressure is expected to be high.
5. Control of seed rot / pre-emergence damping-off caused by soil-borne <i>Fusarium</i> spp. on canola and rapeseed at 12.5 – 50 mL product/100 kg seed. The high rate is for use when planting into cold, wet soils, or if disease pressure is expected to be high.
Supported Use Claims for BAS 752 RC
1. Control of blackleg (<i>Leptosphaeria maculans</i>) on canola/rapeseed at 0.375 L product/ha when applied initially at the 2 to 6-leaf stage on a 10 – 14 day interval, and with a maximum of 0.75 L/ha per year.
2. Control or suppression of the following diseases on flax at 0.375 L product/ha when applied initially at 20 – 50% flowering stage on a 10 – 14 day interval with a maximum of 0.75 L/ha per year. <ul style="list-style-type: none"> 1) Control of pasmo (<i>Septoria linicola</i>) 2) Suppression of white mold (<i>Sclerotinia sclerotiorum</i>)
3. Control or suppression of the following diseases on dry pea, lentil, chickpea and fababean at 0.375 L product/ha when applied preventatively on a 10 – 14 day interval, and with a maximum of 0.75 L/ha per year. <ul style="list-style-type: none"> 1) Control of mycosphaerella blight (<i>Mycosphaerella pinodes</i>) 2) Control of ascochyta blight (<i>Ascochyta</i> spp.) 3) Control of powdery mildew (<i>Erysiphe</i> spp.) 4) Suppression of anthracnose (<i>Colletotrichum truncatum</i>) 5) Suppression of white mold (<i>Sclerotinia sclerotiorum</i>)
4. Control of early blight (<i>Alternaria solani</i>) on potato at 0.375 L product/ha when applied preventatively on a 7 – 14 day interval, and with a maximum of 1.5 L/ha per year.
5. Aerial application on all labelled crops.
Supported Use Claims for Belyan
1. Control of blackleg (<i>Leptosphaeria maculans</i>) on canola, rapeseed, mustard and oriental mustard (oilseed/condiment mustard) at 0.45 – 0.56 L product/ha when applied initially at the 2 to 6-leaf stage on a 10 – 14 day interval, and with a maximum of 1.12 L/ha per year.
2. Control of pasmo (<i>Septoria linicola</i>) on flax at 0.45 – 0.56 L product/ha when applied initially at 20 – 50% flowering stage on a 10 – 14 day interval, and with a maximum of 1.12 L/ha per year.
3. Control or suppression of the following diseases on Crop Subgroup 6C (dried shelled peas and beans, except soybean) at 0.56 L product/ha when applied preventatively on a 10 – 14 day interval, and with a maximum of 1.12 L/ha per year. <ul style="list-style-type: none"> 1) Control of mycosphaerella blight (<i>Mycosphaerella pinodes</i>) 2) Control of ascochyta blight (<i>Ascochyta</i> spp.) 3) Control of rust (<i>Uromyces appendiculatus</i>) (on dry bean only) 4) Control of powdery mildew (<i>Erysiphe</i> spp.) 5) Control of anthracnose (<i>Colletotrichum</i> spp.)

6) Control of Asian soybean rust (<i>Phakopsora pachyrhizi</i>)
7) Suppression of downy mildew (<i>Peronospora viciae</i> f. sp. <i>pisi</i>)
4. Control of the following diseases on soybean at 0.56 L product/ha when applied preventatively on a 10 – 14 day interval, and with a maximum of 1.12 L/ha per year. <ol style="list-style-type: none"> 1) Frog eye leaf spot (<i>Cercospora sojina</i>) 2) Septoria brown spot (<i>Septoria glycines</i>) 3) Asian soybean rust (<i>Phakopsora pachyrhizi</i>) 4) Cercospora leaf blight & purple seed stain (PSS) (<i>Cercospora kikuchii</i>)
5. Control of early blight (<i>Alternaria solani</i>) on potato at 0.56 L product/ha when applied preventatively on a 7 – 14 day interval, and with a maximum of 2.24 L/ha per year.
6. Control of the following diseases on wheat (spring, winter and durum) at 0.56 L product/ha when applied preventatively on a 10 – 14 day interval, and with a maximum of 1.12 L/ha per year. <ol style="list-style-type: none"> 1) Septoria leaf blotch (<i>Septoria tritici</i> or <i>Septoria nodorum</i>) 2) Stripe rust (<i>Puccinia striiformis</i>) 3) Leaf rust (<i>Puccinia recondita</i>) 4) Tan spot (<i>Pyrenophora tritici-repentis</i>) 5) Spot blotch (<i>Cochliobolus sativus</i>) 6) Powdery mildew (<i>Erysiphe graminis</i> f. sp. <i>tritici</i>)
7. Aerial application on all labelled crops.

Appendix II Supplemental Maximum Residue Limit Information— International Situation and Trade Implications

Mefentrifluconazole is a new active ingredient which is concurrently being registered in Canada and the United States. The MRLs proposed for mefentrifluconazole 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.

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

Currently, there are no Codex MRLs¹⁰ listed for mefentrifluconazole in or on any commodity on the Codex Alimentarius [Pesticide Residues in Food](#) website.

Table 1 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Meat of cattle, goats, horses and sheep	0.02	0.03	Not Established
Fat of hogs	0.01	0.015	Not Established
Fat of poultry	0.01	0.015	Not Established
Meat byproducts of hogs	0.01	0.03	Not Established
Milk	0.02	0.03	Not Established
Milk fat	0.1	0.80	Not Established

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

¹⁰ 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

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2789501	2017, Product identity and composition of BAS 750 F - ISO name, provisionally approved: Mefentrifluconazole, DACO: 1.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, IIA 1.3, IIA 1.4, IIA 1.5.1, IIA 1.5.2, IIA 1.6, IIA 1.7, IIA 1.8.1, IIA 1.8.2, IIA 1.9.1.1, IIA 1.9.2, IIA 1.9.3 CBI
2817548	2013, Analytical method APL0669/01 - Determination of the active ingredient Reg.No.5834378 in Reg.No. 5834378 TGAI, DACO: 2.13.1, 4.2.1 CBI
2817549	2013, Validation of the analytical method APL0669/01: Determination of the active ingredient Reg.No. 5834378 in Reg.No. 5834378 TGAI, DACO: 2.13.1, 4.2.1 CBI
2817550	2013, Analytical method APL0680/01: Determination of the impurity [CBI removed] in Reg.No. 5834378 TGAI, DACO: 2.13.1, 4.2.3 CBI
2817551	2013, Validation of the analytical method APL0680/01: Determination of the impurity [CBI removed] in Reg.No. 5834378 TGAI, DACO: 2.13.1, 4.2.3 CBI
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2817559	2016, Validation of the analytical method APL0705/01 - Determination of [CBI removed] in BAS 750 F TGAI and formulation by [CBI removed] (Including amendment no. 1), DACO: 2.13.1, 4.2.3 CBI
2817556	2014, Analytical method APL0706/01 - Determination of the impurity [CBI removed] in Reg.No. 5834378 TGAI by [CBI removed], DACO: 2.13.1, 4.2.3 CBI
2817555	2015, Validation of the analytical method APL0706/01: Determination of the impurity [CBI removed] in Reg.No. 5834378 TGAI by [CBI removed], DACO: 2.13.1, 4.2.3 CBI
2817557	2015, Analytical method APL0711/01 - Determination of the impurities [CBI removed] in Reg.No. 5834378 TGAI by [CBI removed], DACO: 2.13.1, 4.2.3 CBI
2817558	2015, Validation of the analytical method APL0711/01: Determination of the impurities[CBI removed] in Reg.No. 5834378 TGAI by [CBI removed], DACO: 2.13.1, 4.2.3 CBI
2789497	2016, BAS 750 F: Analysis of five representative batches, DACO: 2.13.3, IIA 1.11.1 CBI

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- 2788332 BASF, 2017, Tier III Chapter 2 Identity Physical, chemical and Technical properties of the product, Analytical Method, DACO: 12.7, Document M
- 2789208 2017, Analytical method AFR0093/02: Determination of Mefentrifluconazole, Fluxapyroxad and/or Pyraclostrobin content fungicidal suspension concentrate (SC) formulations and their TGAI by reverse phase HPLC, DACO: 3.4.1, IIIA 5.2.1
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- 2789559 2017, Method of analysis of BAS 750 F and its relevant metabolites in water with limit of determination (LOD) calculation (L0359/01), DACO: 8.2.2.3,IIA 4.5
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2.0 Human and Animal Health

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- 2789213 2015, BAS 750 02 F: Acute inhalation toxicity in rats, DACO: 4.6.3,IIIA 7.1.3
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- 2789215 2015, BAS 750 02 F: Primary eye irritation in rabbits, DACO: 4.6.4,IIIA 7.1.5
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- 2789573 2013, BAS 750 F - Acute oral toxicity study in rats (Including analytical report), DACO: 4.2.1,IIA 5.2.1
- 2789574 2013, BAS 750 F - Acute dermal toxicity study in rats (Including analytical report), DACO: 4.2.2,IIA 5.2.2
- 2789575 2014, BAS 750 F - Acute inhalation toxicity study in Wistar rats - 4-hour dust exposure (head-nose only), DACO: 4.2.3,IIA 5.2.3
- 2789576 2013, BAS 750 F - Acute dermal irritation / corrosion in rabbits, DACO: 4.2.5,IIA 5.2.4
- 2789577 2013, BAS 750 F - Acute eye irritation in rabbits, DACO: 4.2.4,IIA 5.2.5

2789578	2014, BAS 750 F - Test for skin sensitization using the guinea pig maximization test (GPMT) (Including analytical report), DACO: 4.2.6,IIA 5.2.6
2789567	2014, 14C-BAS 750 F - Study on plasma kinetics in C57BL/6 J Rj mice, DACO: 4.5.9,IIA 5.1.1
2789568	2016, 14C-BAS 750 F (triazole-3(5)-C14) - Study on the biokinetics in rats, DACO: 4.5.9,IIA 5.1.1
2789569	2016, Excretion and metabolism of 14C-BAS 750 F (Reg.No. 5834378) after oral administration in rats, DACO: 4.5.9,IIA 5.1.1
2789570	2015, 14C-BAS 750 F (14C-Chlorophenyl and Trifluoromethylring-U-14C labels): Study on kinetics and excretion in Wistar rats after single and repeated oral administration, DACO: 4.5.9,IIA 5.1.1
2841412	2016, Comparative in-vitro-metabolism with 14C-BAS 750 F, DACO: 4.2.9,4.3.8,4.4.5,4.5.8,4.8,IIA 5.10
2789579	2014, BAS 750 F - Repeated-dose 28-day toxicity study in C57BL/6 Rj mice - Administration via the diet, DACO: 4.3.3,IIA 5.3.1
2789580	2015, BAS 750 F - Repeated-dose 28-day oral toxicity study in beagle dogs - Oral administration (capsule), DACO: 4.3.3,IIA 5.3.1
2789581	2015, BAS 750 F - Repeated dose 28-day toxicity study in Wistar rats - Administration via the diet (Including amendment no. 1), DACO: 4.3.3,IIA 5.3.1
2789582	2015, 90-day oral dietary toxicity study with BAS 750 F in C57BL/6JRj mice (Including analytical report and amendment), DACO: 4.3.1,IIA 5.3.2
2789583	2015, BAS 750 F - Repeated dose 90-day oral toxicity study in Wistar rats - Administration via the diet, DACO: 4.3.1,IIA 5.3.2
2789584	2015, BAS 750 F - Repeated-dose 90-day oral toxicity study in beagle dogs - Oral administration (capsule), DACO: 4.3.2,IIA 5.3.3
2789585	2016, BAS 750 F - Repeated-dose 12-month toxicity study in Beagle dogs - Oral administration (capsule), DACO: 4.3.2,IIA 5.3.4
2789586	2016, BAS 750 F: Waiver for conditionally required repeat-dose inhalation toxicity study in rats, DACO: 4.3.7,IIA 5.3.5
2789587	2015, BAS 750 F - Repeated dose 28-day dermal toxicity study in Wistar rats, DACO: 4.3.5,IIA 5.3.7
2789588	2014, BAS 750 F - Salmonella typhimurium / Escherichia coli reverse mutation assay (Including analytical report), DACO: 4.5.4,IIA 5.4.1
2789589	2015, BAS 750 F - Salmonella typhimurium / Escherichia coli - Reverse mutation assay, DACO: 4.5.4,IIA 5.4.1
2789590	2015, BAS 750 F: In vitro cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells, DACO: 4.5.6,IIA 5.4.2
2789591	2014, BAS 750 F - In vitro micronucleus assay in V79 cells (Cytokinesis Block Method), DACO: 4.5.5,IIA 5.4.3
2789592	2015, BAS 750 F: Micronucleus test in human lymphocytes in vitro, DACO: 4.5.5,IIA 5.4.3
2789593	2015, BAS 750 F: In vitro cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells, DACO: 4.5.5,IIA 5.4.3
2789594	2014, BAS 750 F - Micronucleus test in bone marrow cells of the mouse, DACO: 4.5.7,IIA 5.4.4

2854736	2017, BAS 750 F - Acute oral neurotoxicity study in Wistar rats - Administration by gavage (Including amendment no. 1), DACO: 4.5.12,IIA 5.7.1
2789595	2016, BAS 750 F - Combined chronic toxicity/carcinogenicity study in Wistar rats - Administration via the diet up to 24 months (Including historical control data), DACO: 4.4.2,4.4.4,IIA 5.5.2
2789596	2015, 18-month carcinogenicity study with BAS 750 F in male and female C57BL/6JRJ mice (Including historical control data and analytical report), DACO: 4.4.3,IIA 5.5.3
2789597	2015, BAS 750 F - Two-generation reproduction toxicity study in Wistar rats - Administration via the diet, DACO: 4.5.1,IIA 5.6.1
2789598	2015, BAS 750 F - Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage), DACO: 4.8,IIA 5.6.2
2789599	2015, BAS 750 F - Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage) Including amendment No 1., DACO: 4.8,IIA 5.6.2
2789600	2015, BAS 750 F - Acute oral neurotoxicity study in Wistar rats - Administration by gavage, DACO: 4.5.12,IIA 5.7.1
2789601	2016, BAS 750 F: Waiver for 90-day neurotoxicity study, DACO: 4.5.13,IIA 5.7.4
2789602	2015, Reg.No. 6011210: Micronucleus test in human lymphocytes in vitro, DACO: 4.8,IIA 5.8
2789603	2015, Toxicological analysis of BAS 750 F and a metabolite using Derek Nexus, DACO: 4.8,IIA 5.8
2789604	2015, Toxicological analysis of Reg.No. 148502 (M750F037, a metabolite of BAS 750 F) using Derek Nexus, DACO: 4.8,IIA 5.8
2789605	2015, Toxicological analysis of Reg.No. 5863469 (M750F006, a metabolite of BAS 750 F) using Derek Nexus, DACO: 4.8,IIA 5.8
2789606	2015, Toxicological analysis of Reg.No. 6031465 (M750F002, a metabolite of BAS 750 F) using Derek Nexus, DACO: 4.8,IIA 5.8
2789607	2015, Reg.No. 6011210 - In vitro gene mutation test in L5178Y mouse lymphoma cells (TK+/- Locus assay, microwell version), DACO: 4.8,IIA 5.8
2789608	2015, Reg.No. 6011210 - Acute oral toxicity study in rats (Including concentration control analysis and homogeneity control analysis), DACO: 4.8,IIA 5.8
2789609	2015, Reg.No. 6011210 - Salmonella typhimurium / Escherichia coli - Reverse mutation assay (Including analytical report), DACO: 4.8,IIA 5.8
2789610	2016, Reg.No. 5863469 (metabolite of BAS 750 F) - Salmonella typhimurium / Escherichia coli - Reverse mutation assay, DACO: 4.8,IIA 5.8
2789611	2016, Reg.No. 6031465 (metabolite of BAS 750 F) - Salmonella typhimurium / Escherichia coli - Reverse mutation assay, DACO: 4.8,IIA 5.8
2789612	2016, Reg.No. 148502 (metabolite of BAS 750 F) - Salmonella typhimurium / Escherichia coli - Reverse mutation assay, DACO: 4.8,IIA 5.8
2789613	2016, Reg.No. 6031465 (metabolite of BAS 750 F) - Acute oral toxicity study in rats, DACO: 4.8,IIA 5.8
2789614	2016, Reg.No. 148502 (metabolite of BAS 750 F) - Acute oral toxicity study in rats, DACO: 4.8,IIA 5.8
2789615	2016, Reg.No. 6055268 (metabolite of BAS 750 F) - Salmonella typhimurium/Escherichia coli - Reverse mutation assay, DACO: 4.8,IIA 5.8

- 2789616 2016, Reg.No. 6055268 (metabolite of BAS 750 F) - Acute oral toxicity study in rats, DACO: 4.8,IIA 5.8
- 2789617 2016, Reg.No. 6011210: Repeated-dose 28-day toxicity study in C57BL/6 J Rj mice - Administration via the diet (Including analytical report), DACO: 4.8,IIA 5.8
- 2789618 2016, Reg.No. 5863469 (metabolite of BAS 750 F) - Acute oral toxicity study in rats (Including amendment no. 1), DACO: 4.8,IIA 5.8
- 2789397 2017, The Magnitude of Residues of BAS 750 F in Citrus Crop Group 10, DACO: 7.4.1,7.4.2
- 2789398 2017, Evaluation of Processed Food/Feed (PF) residues of BAS 750 F in Oranges, DACO: 7.4.5
- 2789541 2015, Independent Method Validation (ILV) of the QuEChERS Method for the Determination of BAS 750 F in 5 Plant Matrices, using LC/MS/MS (BASF Method No. L0295/01), DACO: 77.2.3A
- 2789542 2015, Independent Method Validation (ILV) of a Method for the Determination of BAS 750 F in Various Foodstuffs of Animal Origin, using LC/MS/MS (BASF Method No. L0272/01), DACO: 7.2.3A
- 2789543 2015, Independent Method Validation (ILV) of BASF method No. L0309/01 for the Determination of the BAS 750 F Diol Metabolite in Various Foodstuffs of Animal Origin, using GC/MS, DACO: 77.2.3A
- 2789544 2016, Validation of Method 1511/01: Method for the Determination of BAS 750 F (Reg. No. 5834378) in Plant Matrices by LC-MS/MS, DACO: 7.2.1, 7.2.2
- 2789545 2017, Validation of Method D1704/01: Multi-Residue Method Using Modified AOAC Official Method 2007.01 for the Determination of Residues of BAS 750 F (Reg. No. 5834378) in Animal Matrices using LC-MS/MS, DACO: 7.2.17.2.2
- 2789546 2016, Investigation of the extractability of BAS 750 F and M750F022 in samples from 14C animal metabolism studies, DACO:7.2.3B
- 2789547 2017, Investigation of the extractability of BAS 750 F in samples from 14C plant metabolism studies, DACO: 77.2.3B
- 2789548 2016, Validation of the BASF Analytical Method L0309/01: for the determination of M750F022 (Reg.No. 6011210) in animal matrices, DACO: 7.2.1
- 2789549 2015, Validation of the BASF Analytical Method L0272/01 for BAS 750 F in Animal Matrices, DACO: 7.2.1, 7.2.2
- 2789550 2015, Validation of the Multi-Residue Method QuEChERS, BASF Method Number L0295/01, for the Determination of BAS 750 F in Different Matrices of Plant Origin, DACO: 77.2.2
- 2789552 2015, Investigation of the extractability of BAS 750 F in samples from 14C plant metabolism studies, DACO: 77.2.3B
- 2789621 2015, Storage stability of Reg. No. 6011210 in animal matrices, DACO: 7.3
- 2789622 2015, Storage stability of BAS 750 F in animal matrices, DACO: 7.3
- 2789623 2016, Storage Stability of BAS 750 F in plant matrices, DACO: 7.3
- 2789628 2015, Metabolism of 14C-BAS 750 F in soybean, DACO: 6.3
- 2789629 2015, Metabolism of 14C LS 5834378 in wheat, DACO: 6.3
- 2789630 2015, Metabolism of 14C-BAS 750 F in grape, DACO: 6.3
- 2789631 2015, The Metabolism of [14C]-Reg. No 5834378 (BAS 750 F) in Laying Hens, DACO: 6.2

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- 2789632 2015, The Metabolism of [14C]-Reg. No. 5834378 (BAS 750 F) in Lactating Goats, DACO: 6.2
- 2789633 2016, Magnitude of the Residues of BAS 750 F in Tree Nut Raw Agricultural Commodities, DACO: 7.4.1,7.4.2
- 2789634 2016, Magnitude of the Residues of BAS 750 F in Cereal Grains Following Applications of BAS 750 01 F, DACO: 7.4.1,7.4.2
- 2789635 2016, Magnitude of the Residues of BAS 750 F in Sweet Corn Following Applications of BAS 750 01 F, DACO: 7.4.1,7.4.2
- 2789636 2016, Magnitude of the Residue of BAS 750 F in Legumes (Crop Groups 6 and 7) Following Applications of BAS 750 01 F, DACO: 7.4.1,7.4.2
- 2789637 2016, Magnitude of the Residue of BAS 750 F in Soybean Following Applications of BAS 750 01 F, DACO: 7.4.1,7.4.2
- 2789638 2016, Magnitude of the Residue of BAS 750 F in PomeFruits (Crop Group 11), DACO: 7.4.1,7.4.2
- 2789639 2016, Magnitude of the Residue of BAS 750 F in Stone Fruits (Crop Group 12), DACO: 7.4.1,7.4.2
- 2789640 2016, Magnitude and Decline of the Residues of BAS 750 F in Peanut Following Applications of BAS 750 01 F, DACO: 7.4.1,7.4.2
- 2789641 2016, Magnitude of the Residue of BAS 750 F in Potatoes Following Treatment with BAS 750 01 F, DACO: 7.4.1,7.4.2
- 2789642 2016, Magnitude of the Residues of BAS 750 F in/on Grapes, DACO: 7.4.1,7.4.2
- 2789643 2016, Magnitude of the Residues of BAS 750 F in Sugar beet Following Applications of BAS 750 01 F, DACO: 7.4.1,7.4.2
- 2789644 2016, Magnitude of residues of BAS 750 F in Canola Following Applications of BAS 750 01 F, DACO: 7.4.1,7.4.2
- 2789645 2016, Determination of the fatty conjugates metabolites of M750F022 (Reg. No. 6011210) in animal matrices, DACO: 7.2,7.5
- 2789646 2015, Magnitude of Residues in Tissues and Eggs of Laying Hens Following Multiple Oral Administrations of BAS 750 F, DACO: 7.5
- 2789647 2015, Magnitude of Residues in Milk and Tissues of Dairy Cows Following Multiple Oral Administrations of BAS 750 F, DACO: 7.5
- 2789648 2014, BAS 750 F: Hydrolysis at 90° C, 100° C and 120° C, DACO: 7.4.5
- 2789649 2015, Determination of residues of BAS 750 F (Reg. No. 5834378) in barley and its processed products after two applications of BAS 750 01 F in Germany, 2014, DACO: 7.4.5
- 2789650 2015, Determination of residues of BAS 750 F (Reg.No. 5834378) in wheat and its processed products after two applications of BAS 750 01 F in Germany, 2014, DACO: 7.4.5
- 2789651 2016, Determination of residues of BAS 750 F (Reg. No. 5834378) in grapes and their processed products after two applications of BAS 750 01 F in Germany, 2014, DACO: 7.4.5
- 2789652 2016, Determination of residues of BAS 750 F (Reg. No. 5834378) in sugar beets and their processed products after two applications of BAS 750 01 F in Germany, 2015, DACO: 7.4.5
- 2789653 2016, Magnitude of the Residue of BAS 750 F in Soybean Processed Commodities Following Applications of BAS 750 01 F, DACO: 7.4.5
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- 2789654 2016, Magnitude of the Residue of BAS 750 F in Potato Processed Fractions Following Treatment with BAS 750 01 F, DACO: 7.4.5
- 2789655 2016, Magnitude of the Residues of BAS 750 F in Corn Processed Fractions, DACO: 7.4.5
- 2789656 2017, Evaluation of Processed Food/Feed (PF) Residues of BAS 750 F in Apple, Final Report, DACO: 7.4.5
- 2789657 2017, Evaluation of Processed Food/Feed (PF) Residues of BAS 750 F in Plum, Final Report, DACO: 7.4.5
- 2789658 2015, Confined rotational crop study with 14C LS 5834378, DACO: 7.4.3
- 2789660 2016, Magnitude of the Residue of BAS 750 F in/on Lettuce, Radish and Wheat as Rotational Crops following Applications of BAS 750 01 F, DACO: 7.4.4

3.0 Environment

- 2788336 2017, BAS 752 01 F: An Acute Oral Toxicity Study with the Northern Bobwhite, DACO: 9.6.4,IIIA 10.1.6
- 2788337 2017, BAS 752 01 F: An Acute Oral Toxicity Study with the Northern Bobwhite, DACO: 9.6.4,IIIA 10.1.6
- 2788338 2016, Acute toxicity of BAS 752 01 F to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
- 2788339 2016, Acute toxicity of BAS 752 01 F to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
- 2788340 2016, A rate-response laboratory test to determine the effect of BAS 752 01 F on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), DACO: 9.2.8,IIIA 10.5.1
- 2788341 2016, A rate-response laboratory test to determine the effect of BAS 752 01 F on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), DACO: 9.2.8,IIIA 10.5.1
- 2788342 2016, A rate-response laboratory test to determine the effects of BAS 752 01 F on the parasitic wasp *Aphidius rhopalosiphii* (Hymenoptera, Braconidae), DACO: 9.2.8,IIIA 10.5.1
- 2788343 2016, A rate-response laboratory test to determine the effects of BAS 752 01 F on the parasitic wasp *Aphidius rhopalosiphii* (Hymenoptera, Braconidae), DACO: 9.2.8,IIIA 10.5.1
- 2788344 2016, BAS 752 01 F - Acute toxicity to the earthworm *Eisenia fetida* (Annelida, Lumbricidae) in artificial soil with 10% peat, DACO: 9.2.8,IIIA 10.6.2
- 2788345 2016, BAS 752 01 F - Acute toxicity to the earthworm *Eisenia fetida* (Annelida, Lumbricidae) in artificial soil with 10% peat, DACO: 9.2.8,IIIA 10.6.2
- 2789080 2016, BAS 753 02 F: An acute oral toxicity study with the northern bobwhite, DACO: 9.6.4,IIIA 10.1.6
- 2789081 2016, BAS 753 02 F: An acute oral toxicity study with the northern bobwhite, DACO: 9.6.4,IIIA 10.1.6
- 2789082 2016, BAS 753 02 F: Toxicity to the rainbow trout *Oncorhynchus mykiss* under laboratory conditions (acute toxicity test ? static), DACO: 9.5.4,IIIA 10.2.1.1

- 2789083 2016, BAS 753 02 F: Toxicity to the rainbow trout *Oncorhynchus mykiss* under laboratory conditions (acute toxicity test ? static), DACO: 9.5.4,IIIA 10.2.1.1
- 2789084 2016, Acute toxicity of BAS 753 02 F to *Daphnia magna* Straus in a 48 hour static test, DACO: 9.3.2,IIIA 10.2.2.2
- 2789085 2016, Effect of BAS 753 02 F on the growth of the green alga *Pseudokirchneriella subcapitata*, DACO: 9.3.2,IIIA 10.2.2.2
- 2789086 2016, Acute toxicity of BAS 753 02 F to *Daphnia magna* Straus in a 48 hour static test, DACO: 9.3.2,IIIA 10.2.2.2
- 2789087 2016, Effect of BAS 753 02 F on the growth of the green alga *Pseudokirchneriella subcapitata*, DACO: 9.3.2,IIIA 10.2.2.2
- 2789088 2016, BAS 753 02 F: Effects (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
- 2789089 2016, BAS 753 02 F: Effects (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
- 2789090 2016, A rate-response extended laboratory test to determine the effects of BAS 753 02 F on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), DACO: 9.2.8,IIIA 10.5.1
- 2789091 2016, A rate-response extended laboratory test to determine the effects of BAS 753 02 F on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae), DACO: 9.2.8,IIIA 10.5.1
- 2789092 2016, A rate-response extended laboratory test to determine the effects of BAS 753 02 F on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), DACO: 9.2.8,IIIA 10.5.1
- 2789094 2016, A rate-response extended laboratory test to determine the effects of BAS 753 02 F on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae), DACO: 9.2.8,IIIA 10.5.1
- 2789097 2016, Acute toxicity of BAS 753 02 F to the earthworm *Eisenia andrei* in artificial soil with 10 % peat, DACO: 9.2.8,IIIA 10.6.2
- 2789099 2016, Acute toxicity of BAS 753 02 F to the earthworm *Eisenia andrei* in artificial soil with 10 % peat, DACO: 9.2.8,IIIA 10.6.2
- 2789173 2015, Northern bobwhite (*Colinus virginianus*) acute oral toxicity test (LD50) with BAS 750 02 F, DACO: 9.6.4,IIIA 10.1.6
- 2789174 2015, Northern bobwhite (*Colinus virginianus*) acute oral toxicity test (LD50) with BAS 750 02 F, DACO: 9.6.4,IIIA 10.1.6
- 2789175 2016, BAS 750 02 F - Rainbow trout, acute toxicity test, DACO: 9.5.4,IIIA 10.2.2.1
- 2789176 2016, BAS 750 02 F - Rainbow trout, acute toxicity test, DACO: 9.5.4,IIIA 10.2.2.1
- 2789177 2016, Acute toxicity of BAS 750 02 F to *Daphnia magna* STRAUS in a 48 hour static test, DACO: 9.3.2,IIIA 10.2.2.2
- 2789178 2016, Acute toxicity of BAS 750 02 F to *Daphnia magna* STRAUS in a 48 hour static test, DACO: 9.3.2,IIIA 10.2.2.2
- 2789179 2016, Effect of BAS 750 02 F on the Growth of the Green Alga *Pseudokirchneriella subcapitata*., DACO: 9.8.2,9.8.3,IIIA 10.2.2.3
- 2789180 2016, Effect of BAS 750 02 F on the Growth of the Green Alga *Pseudokirchneriella subcapitata*., DACO: 9.8.2,9.8.3,IIIA 10.2.2.3

- 2789182 2016, Acute toxicity of BAS 750 02 F to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
- 2789183 2016, Acute toxicity of BAS 750 02 F to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
- 2789184 2016, Effects of BAS 750 02 F on the predatory mite *Typhlodromus pyri* SCHEUTEN in a laboratory test, DACO: 9.2.8,IIIA 10.5.1
- 2789185 2016, Effects of BAS 750 02 F on the parasitic wasp *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) in a laboratory test, DACO: 9.2.8,IIIA 10.5.1
- 2789186 2016, Effects of BAS 750 02 F on the predatory mite *Typhlodromus pyri* SCHEUTEN in a laboratory test, DACO: 9.2.8,IIIA 10.5.1
- 2789187 2016, Effects of BAS 750 02 F on the parasitic wasp *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) in a laboratory test, DACO: 9.2.8,IIIA 10.5.1
- 2789188 2015, Acute toxicity of BAS 750 02 F to the earthworm *Eisenia fetida* in artificial soil with 10% peat, DACO: 9.2.8,IIIA 10.6.2
- 2789189 2015, Acute toxicity of BAS 750 02 F to the earthworm *Eisenia fetida* in artificial soil with 10% peat, DACO: 9.2.8,IIIA 10.6.2
- 2789190 2016, BAS 750 02 F + BAS 9226 0 S: A test to determine the effects on non-target plants, DACO: 9.8.6,IIIA 10.8.1.2
- 2789191 2016, BAS 750 02 F + BAS 9226 0 S: A test to determine the effects on non-target plants, DACO: 9.8.6,IIIA 10.8.1.2
- 2789192 2016, BAS 750 02 F + BAS 9226 0S: A test to determine the effects on non-target plants (Including amendment no. 1), DACO: 9.8.6,IIIA 10.8.1.3
- 2789193 2016, BAS 750 02 F + BAS 9226 0S: A test to determine the effects on non-target plants (Including amendment no. 1), DACO: 9.8.6,IIIA 10.8.1.3
- 2789264 2014, BAS 750 01 F - Rainbow trout, acute toxicity test, DACO: 9.5.4,IIIA 10.2.1.1
- 2789265 2014, BAS 750 01 F - Rainbow trout, acute toxicity test, DACO: 9.5.4,IIIA 10.2.1.1
- 2789266 2016, BAS 750 01 F - Acute toxicity study in the fathead minnow (*Pimephales promelas*), DACO: 9.5.4,IIIA 10.2.2.1
- 2789267 2016, BAS 750 01 F - Acute toxicity study in the fathead minnow (*Pimephales promelas*), DACO: 9.5.4,IIIA 10.2.2.1
- 2789268 2015, BAS 750 BS F (blank formulation of BAS 750 01 F) - Rainbow trout, acute toxicity test, DACO: 9.5.4,IIIA 10.2.2.1
- 2789269 2015, BAS 750 BS F (blank formulation of BAS 750 01 F) - Rainbow trout, acute toxicity test, DACO: 9.5.4,IIIA 10.2.2.1
- 2789270 2015, BAS 750 01 F - *Daphnia magna* acute immobilization test, DACO: 9.3.2,IIIA 10.2.2.2
- 2789271 2015, BAS 750 01 F - *Daphnia magna* acute immobilization test, DACO: 9.3.2,IIIA 10.2.2.2
- 2789272 2015, BAS 750 BS F (blank formulation of BAS 750 01 F) - *Daphnia magna*, acute immobilization test, DACO: 9.3.2,IIIA 10.2.2.2
- 2789273 2015, BAS 750 BS F (blank formulation of BAS 750 01 F) - *Daphnia magna*, acute immobilization test, DACO: 9.3.2,IIIA 10.2.2.2
- 2789274 2015, BAS 750 01 F - *Pseudokirchneriella subcapitata* SAG 61.81 - Growth inhibition test, DACO: 9.8.2,9.8.3,IIIA 10.2.2.3

- 2789275 2015, BAS 750 01 F - *Pseudokirchneriella subcapitata* SAG 61.81 - Growth inhibition test, DACO: 9.8.2,9.8.3,IIIA 10.2.2.3
- 2789276 2015, Acute toxicity of BAS 750 01 F to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
- 2789277 2015, Acute toxicity of BAS 750 01 F to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
- 2789278 2015, Effects of BAS 750 01 F on the reproduction of the collembolan *Folsomia candida*, DACO: 9.2.8,IIIA 10.5.1
- 2789279 2015, Effects of BAS 750 01 F on the reproduction of the collembolan *Folsomia candida*, DACO: 9.2.8,IIIA 10.5.1
- 2789280 2015, Effects of BAS 750 01 F on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat (Including amendment no. 1), DACO: 9.2.8,IIIA 10.5.1
- 2789281 2015, Effects of BAS 750 01 F on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat (Including amendment no. 1), DACO: 9.2.8,IIIA 10.5.1
- 2789282 2015, A rate-response laboratory test to determine the effects of BAS 750 01 F on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), DACO: 9.2.8,IIIA 10.5.1
- 2789283 2015, A rate-response laboratory test to determine the effects of BAS 750 01 F on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), DACO: 9.2.8,IIIA 10.5.1
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2789705 8.1.1
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2789706 8.1.1
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2789708
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oral administration (LD50), DACO: 9.6.2.1,9.6.2.2,9.6.2.3,IIA 8.1.1
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2789710
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(*Anas platyrhynchos*), DACO: 9.6.2.4,9.6.2.5,IIA 8.1.2
2789711
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(*Anas platyrhynchos*), DACO: 9.6.2.4,9.6.2.5,IIA 8.1.2
2789712
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2789715 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
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2789716 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
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2789717 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
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bahia, determined under flow-through test conditions, DACO:
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- 2789781 2015, Effect of Reg.No. 6003432 (M750F007, metabolite of BAS 750 F) on the growth of the green alga *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3,IIA 8.4
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- 2789783 2016, Reg.No. 5863469 (metabolite of BAS 750 F, M750F006) - *Pseudokirchneriella subcapitata* SAG 61.81 - Growth inhibition test, DACO: 9.8.2,9.8.3,IIA 8.4

- 2789784 2016, Reg.No. 5863469 (metabolite of BAS 750 F, M750F006) -
Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test, DACO:
9.8.2,9.8.3,IIA 8.4
- 2789785 2016, Reg.No. 6003433 (metabolite of BAS 750 F, M750F005) -
Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test, DACO:
9.8.2,9.8.3,IIA 8.4
- 2789786 2016, Reg.No. 6003433 (metabolite of BAS 750 F, M750F005) -
Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test, DACO:
9.8.2,9.8.3,IIA 8.4
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flos-aquae, DACO: 9.8.2,9.8.3,IIA 8.4
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flos-aquae, DACO: 9.8.2,9.8.3,IIA 8.4
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pelliculosa, DACO: 9.8.2,9.8.3,IIA 8.4
- 2789790 2015, BAS 750 F: Growth inhibition test with the freshwater diatom, Navicula
pelliculosa, DACO: 9.8.2,9.8.3,IIA 8.4
- 2789791 2015, BAS 750 F: Growth inhibition test with the marine diatom, Skeletonema
costatum, DACO: 9.8.2,9.8.3,IIA 8.4
- 2789792 2015, BAS 750 F: Growth inhibition test with the marine diatom, Skeletonema
costatum, DACO: 9.8.2,9.8.3,IIA 8.4
- 2789793 2016, Reg.No. 6055268 (metabolite of BAS 750 F, M750F036) -
Pseudokirchneriella subcapitata SAG 61.81, growth inhibition test, DACO:
9.8.2,9.8.3,IIA 8.4
- 2789794 2016, Reg.No. 6055268 (metabolite of BAS 750 F, M750F036) -
Pseudokirchneriella subcapitata SAG 61.81, growth inhibition test, DACO:
9.8.2,9.8.3,IIA 8.4
- 2789795 2016, Reg. No. 148502 (Metabolite of BAS 750 F, M750F037) -
Pseudokirchneriella subcapitata SAG 61.81, Growth inhibition Test, DACO:
9.8.2,9.8.3,IIA 8.4
- 2789796 2016, Reg. No. 148502 (Metabolite of BAS 750 F, M750F037) -
Pseudokirchneriella subcapitata SAG 61.81, Growth inhibition Test, DACO:
9.8.2,9.8.3,IIA 8.4
- 2789797 2016, Effect of Reg. No. 5924326 (M750F003, metabolite of BAS 750 F) on
the Growth of the Green Alga Pseudokirchneriella subcapitata, DACO:
9.8.2,9.8.3,IIA 8.4
- 2789798 2016, Effect of Reg. No. 5924326 (M750F003, metabolite of BAS 750 F) on
the Growth of the Green Alga Pseudokirchneriella subcapitata, DACO:
9.8.2,9.8.3,IIA 8.4
- 2789799 2016, Reg. No. 6031465 (Metabolite of BAS 750 F, M750F002) -
Pseudokirchneriella subcapitata SAG 61.81 - Growth Inhibition Test (Including
Amendment No. 1), DACO: 9.8.2,9.8.3,IIA 8.4
- 2789800 2016, Reg. No. 6031465 (Metabolite of BAS 750 F, M750F002) -
Pseudokirchneriella subcapitata SAG 61.81 - Growth Inhibition Test (Including
Amendment No. 1), DACO: 9.8.2,9.8.3,IIA 8.4

- 2015, BAS 750 F - 10-day toxicity test exposing midge (*Chironomus dilutus*) to a test substance applied to sediment under static-renewal conditions, DACO: 9.9,IIA 8.5.1
- 2015, BAS 750 F - 10-day toxicity test exposing midge (*Chironomus dilutus*) to a test substance applied to sediment under static-renewal conditions, DACO: 9.9,IIA 8.5.1
- 2015, BAS 750 F - 10-Day toxicity test exposing freshwater amphipods (*Hyalella azteca*) to a test substance applied to sediment under static-renewal conditions, DACO: 9.9,IIA 8.5.1
- 2015, BAS 750 F - 10-Day toxicity test exposing freshwater amphipods (*Hyalella azteca*) to a test substance applied to sediment under static-renewal conditions, DACO: 9.9,IIA 8.5.1
- 2015, BAS 750 F - 10-Day toxicity test exposing estuarine amphipods (*Leptocheirus plumulosus*) to a test substance applied to sediment under static conditions, DACO: 9.9,IIA 8.5.1
- 2015, BAS 750 F - 10-Day toxicity test exposing estuarine amphipods (*Leptocheirus plumulosus*) to a test substance applied to sediment under static conditions, DACO: 9.9,IIA 8.5.1
- 2015, Chronic toxicity of Reg.No. 5834378 to the non-biting midge *Chironomus riparius* - A spiked sediment study, DACO: 9.9,IIA 8.5.2
- 2015, Chronic toxicity of Reg.No. 5834378 to the non-biting midge *Chironomus riparius* - A spiked sediment study, DACO: 9.9,IIA 8.5.2
- 2016, Life-Cycle Toxicity Test Exposing Midges (*Chironomus dilutus*) to BAS 750 F Applied to Sediment under Static-Renewal Conditions Following EPA Test Methods, DACO: 9.9,IIA 8.5.2
- 2016, Life-Cycle Toxicity Test Exposing Midges (*Chironomus dilutus*) to BAS 750 F Applied to Sediment under Static-Renewal Conditions Following EPA Test Methods, DACO: 9.9,IIA 8.5.2
- 2017, Waiver request for chronic testing with BAS 750 F on the sediment dwelling species *Leptocheirus plumulosus* and *Hyalella azteca*, DACO: 9.9,IIA 8.5.2
- 2014, BAS 750 F (Reg.No. 5834378) - *Lemna gibba* CPCC 310 growth inhibition test, DACO: 9.8.5,IIA 8.6
- 2014, BAS 750 F (Reg.No. 5834378) - *Lemna gibba* CPCC 310 growth inhibition test, DACO: 9.8.5,IIA 8.6
- 2015, Acute toxicity of BAS 750 F to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.4.2,IIA 8.7.1
- 2015, Acute toxicity of BAS 750 F to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.4.2,IIA 8.7.1
- 2015, Acute toxicity of BAS 750 F to the bumblebee *Bombus terrestris* L. under laboratory conditions, DACO: 9.2.4.1,IIA 8.7.2
- 2015, Acute toxicity of BAS 750 F to the bumblebee *Bombus terrestris* L. under laboratory conditions, DACO: 9.2.4.1,IIA 8.7.2
- 2015, Acute toxicity of BAS 750 F to the bumblebee *Bombus terrestris* L. under laboratory conditions, DACO: 9.2.4.1,IIA 8.7.2

- 2016, Determination of residues of BAS 750 01 F (BAS 750 F) in nectar, pollen, and flowers of *Phacelia tanacetifolia* after one application in a semi-field residue study with honeybees (*Apis mellifera* L.) in Germany 2014, DACO: 9.2.4.1,IIA 8.7.3
- 2789819 2016, Determination of residues of BAS 750 01 F (BAS 750 F) in nectar, pollen, and flowers of *Phacelia tanacetifolia* after one application in a semi-field residue study with honeybees (*Apis mellifera* L.) in Germany 2014, DACO: 9.2.4.1,IIA 8.7.3
- 2789820 2014, Effects of BAS 750 F on the reproduction of the predatory mite *Hypoaspis aculeifer*, DACO: 9.2.6,IIA 8.8.2.1
- 2789821 2014, Effects of BAS 750 F on the reproduction of the predatory mite *Hypoaspis aculeifer*, DACO: 9.2.6,IIA 8.8.2.1
- 2789822 2013, Effects of BAS 750 F on the reproduction of the collembolan *Folsomia candida*, DACO: 9.2.7,IIA 8.8.2.5
- 2789823 2013, Effects of BAS 750 F on the reproduction of the collembolan *Folsomia candida*, DACO: 9.2.7,IIA 8.8.2.5
- 2789824 2015, Chronic toxicity of BAS 750 F (Reg.No. 5834378) to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.7,IIA 8.8.2.5
- 2789825 2015, Chronic toxicity of BAS 750 F (Reg.No. 5834378) to the honeybee *Apis mellifera* L. under laboratory conditions, DACO: 9.2.7,IIA 8.8.2.5
- 2789826 2015, Acute toxicity of BAS 750 F to honeybee larvae (*Apis mellifera* L.) under laboratory conditions (in vitro), DACO: 9.2.7,IIA 8.8.2.5
- 2789827 2015, Acute toxicity of BAS 750 F to honeybee larvae (*Apis mellifera* L.) under laboratory conditions (in vitro), DACO: 9.2.7,IIA 8.8.2.5
- 2789828 2017, Repeated exposure of honey bee (*Apis mellifera*) larvae to BAS 750 F under laboratory conditions (in vitro), DACO: 9.2.7,IIA 8.8.2.5
- 2789829 2017, Repeated exposure of honey bee (*Apis mellifera*) larvae to BAS 750 F under laboratory conditions (in vitro), DACO: 9.2.7,IIA 8.8.2.5
- 2789830 2015, Acute toxicity of BAS 750 F to the earthworm *Eisenia fetida* in artificial soil with 10% peat, DACO: 9.2.3.1,IIA 8.9.1
- 2789831 2015, Acute toxicity of BAS 750 F to the earthworm *Eisenia fetida* in artificial soil with 10% peat, DACO: 9.2.3.1,IIA 8.9.1
- 2789832 2013, Sublethal toxicity of Reg.No. 5834378 (BAS 750 F) to the earthworm *Eisenia fetida* in artificial soil, DACO: 9.2.3.1,IIA 8.9.2
- 2789833 2013, Sublethal toxicity of Reg.No. 5834378 (BAS 750 F) to the earthworm *Eisenia fetida* in artificial soil, DACO: 9.2.3.1,IIA 8.9.2
- 2789834 2018, BASF Response to EPA Ecological Study Review, DACO: 9.9
- 2884547

4.0 Value

- 2789309 2017, Value 10 appendix- flax, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789310 2017, Value 10 appendix- tree nut, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,

- IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789311 2017, Value 10 appendix- Grape, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789312 2017, Value 10 appendix- Peanut, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789313 2017, Value 10 appendix- canola, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789314 2017, Value 10 appendix- stone fruit, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789315 2017, Value 10 appendix- wheat, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789316 2017, Value 10 appendix- Pome fruit, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789317 2017, Value 10 appendix- Potatoes, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7
- 2789318 2017, Value 10 appendix- sugar beets, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIA 6.1.1,IIA 6.1.2,IIA 6.1.3,IIA 6.1.4.1,IIA 6.1.4.2,IIA 6.1.4.3,IIA 6.2.1,IIA 6.2.2,IIA 6.2.3,IIA 6.2.4,IIA 6.2.5,IIA 6.2.6,IIA 6.2.7,IIA 6.2.8,IIA 6.3,IIA 6.4.1,IIA 6.4.2,IIA 6.4.3,IIA 6.5,IIA 6.6,IIA 6.7

- 2789319 2017, Value 10 appendix- turf, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2789320 2017, Value 10 appendix- Corn, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2789321 2017, Value 10 Summary, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2789322 2017, Value 10 appendix- pulses, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2820332 2017, Value 10 Summary: response to PMRA decision request for Value, DACO: 10.2.3.4,IIIA 6.1.3
- 2820333 2017, Value 10 Powdery Mildew, DACO: 10.2.3.4,IIIA 6.1.3
- 2820335 2017, Value 10 Raw data Powdery Mildew, DACO: 10.2.3.4,IIIA 6.1.3
- 2789372 2017, RELENYA a fungicide seed treatment for use in canola, corn, Crop Subgroup 6C, soybean and wheat., DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2789380 2017, Value 10 Raw Data files - Corn, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2789381 2017, Value 10 Raw Data files Canola, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2789382 2017, Value 10 Raw Data files - pulses, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7

- 2789383 2017, Value 10 Raw Data files - wheat, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2789384 2017, Value 10 Raw Data files - soybeans, DACO: 10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7

B. Additional Information Considered

Published Information

1.0 Environment

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