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Proposed Registration Decision

PRD2011-25

# Ametoctradin

*(publié aussi en français)*

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# Overview

## Proposed Registration Decision for Ametoctradin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Initium Fungicide Technical, Zampro Fungicide and BAS 650 00 F Fungicide, containing the technical grade active ingredient ametoctradin, for use on brassica leafy vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, hops, grapes and potatoes to control or suppress various diseases including downy mildew, late blight, and phytophthora blight.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of ametoctradin, Zampro Fungicide and BAS 650 00 F Fungicide.

## 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 acceptable<sup>1</sup> 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 value<sup>2</sup> 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 (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra)

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

<sup>2</sup> "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 ametoctradin, the PMRA will consider all comments received from the public in response to this consultation document<sup>3</sup>. The PMRA will then publish a Registration Decision<sup>4</sup> on ametoctradin, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

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

## **What Is Ametoctradin?**

Ametoctradin is a novel fungicidal compound present as the lone active ingredient in BAS 650 00 F Fungicide and as one of two components, along with dimethomorph, in the combination product Zampro Fungicide. Ametoctradin is a non-systemic and preventative compound used for foliar applications to manage plant diseases caused by water moulds. It acts on pathogen cells by interfering with their normal respiration process. BAS 650 00 F Fungicide and Zampro Fungicide are used on brassica leafy vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, hops, grapes and potatoes to control or suppress various diseases including downy mildew, late blight, and phytophthora blight.

## **Health Considerations**

### **Can Approved Uses of Ametoctradin Affect Human Health?**

**Products containing ametoctradin are unlikely to affect your health when used according to label directions.**

Potential exposure to ametoctradin may occur through the diet (food and water), when handling and applying the product or when entering treated sites. 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 (e.g., children and nursing mothers). 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.

In laboratory animals, the active ingredient ametoctradin was of low acute toxicity by the oral, dermal and inhalation routes. Ametoctradin was minimally irritating to the skin and the eyes and did not cause allergic skin reactions.

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

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*

The end-use product, Zampro Fungicide, was of low acute toxicity via the dermal and inhalation routes. It was non-irritating to the eye and slightly irritating to the skin. Zampro Fungicide did not cause an allergic skin reaction. Zampro Fungicide was of moderate acute toxicity via the oral route; consequently the hazard signal words “WARNING-POISON” are required on the label.

The end-use product, BAS 650 00 F Fungicide, was of low acute toxicity by the oral, dermal and inhalation routes. It was non-irritating to the eye and slightly irritating to the skin and did not cause an allergic skin reaction.

The active ingredient ametoctradin did not cause cancer in animals and did not damage genetic material. There was no indication that ametoctradin caused damage to the nervous system or immune system. Ametoctradin did not cause birth defects in animals and there was no effect on the ability to reproduce. There was no indication of target organ toxicity. When ametoctradin was given to pregnant or nursing animals, no effects on the developing fetus or juvenile animal were observed.

The risk assessment ensures that the level of human exposure is well below the lowest dose at which no effects occurred in animal tests.

## **Residues in Water and Food**

### **Dietary risks from food and water are not of concern.**

Aggregate dietary intake estimates (food plus water) revealed that the general population and children one to two years old, the subpopulation which would ingest the most ametoctradin relative to body weight, are expected to be exposed to less than 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from ametoctradin is not of concern for all population sub-groups. Ametoctradin is not carcinogenic; therefore, a cancer dietary exposure assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of ametoctradin is not likely to cause acute health effects in the general population (including infants and children). An acute reference dose was not established, therefore, an acute dietary intake estimate is not required.

*The Food and Drugs Act (FDA)* 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 FDA 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 ametoctradin on potatoes, dry bulb onions, green onions, head lettuce, leaf lettuce, spinach, celery, broccoli, cabbage, mustard greens, tomatoes, peppers, cucumber, cantaloupe, squash, grapes and hops were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this consultation document.



## **Occupational Risks From Handling BAS 650 00 F Fungicide or Zampro Fungicide**

**Occupational risks are not of concern when BAS 650 00 F Fungicide or Zampro Fungicide are used according to the label directions, which include protective measures.**

Farmers and custom applicators who mix, load or apply BAS 650 00 F Fungicide or Zampro Fungicide, as well as field workers re-entering freshly treated fields, can come in direct contact with ametoctradin residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying BAS 650 00 F Fungicide or Zampro Fungicide must wear long pants, long-sleeved shirt and socks and shoes. During mixing, loading, clean-up and repair activities, workers must also wear chemical resistant gloves. For aerial application, the field crew and the mixer/loaders must wear chemical resistant gloves, coveralls and goggles or face shield during mixing/loading, clean-up and repair. The label also requires that workers do not enter treated fields for 12 hours after application for BAS 650 00 F Fungicide; restricted entry intervals for Zampro Fungicide (a co-formulation with dimethomorph) range from 12 hours to 20 days, depending on the crop and activity. The uses of the co-formulation are currently supported on the Canadian dimethomorph end-use product label. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, it was determined that the risks to these individuals are not a concern.

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

## **Environmental Considerations**

### **What Happens When Ametoctradin Is Introduced Into the Environment?**

When ametoctradin is applied as a preventative fungicide in field and vineyard crops, some of it finds its way into soil and water. Ametoctradin is only sparingly soluble in water and will quickly partition to sediments. However, ametoctradin is rapidly broken down by microbial activity in soil and water; thus, it is not expected to persist in the environment. Two of its four major transformation products (M650F03 and M650F04) will be present in soil and aquatic systems for a longer period of time. Laboratory studies indicate that ametoctradin is not mobile in soil, however its transformation products may be. In field studies conducted in Europe and North America, ametoctradin and its major transformation products M650F01, M650F02 and M650F03 were not detected at depth in the soil profile, indicating a minimal potential for groundwater contamination. However, the transformation product M650F04 was detected at depth and may therefore reach groundwater. In North American field studies, ametoctradin and three of the four major transformation products were not found in significant amounts at the beginning of the next growing season, however significant amounts of M650F04 can carry over. Although the transformation product M650F04 is persistent and may reach groundwater, it is unlikely to cause a risk to human health or the environment based on its toxicological profile. Ametoctradin is not volatile and is, therefore, not expected to be subject to long range transport in the atmosphere.

Ametoctradin can be applied by field sprayer, airblast sprayer or aerial application. There is a potential that non-target terrestrial and aquatic habitats may be exposed to the chemical as a result of spray drift or runoff. Ametoctradin presents a negligible risk to terrestrial organisms, including plants, beneficial insects (bees and other beneficial arthropods), birds and small mammals, at the proposed use rates. Ametoctradin is not expected to pose a risk to aquatic invertebrates, amphibians or freshwater fish. Ametoctradin exposure can present a risk to freshwater algae and marine fish. In order to minimize the potential for exposure resulting from off-field drift, no-spray buffer zones will be required between the treated area and downwind aquatic habitats. No environmental risk was identified from exposure to ametoctradin's major transformation products.

## **Value Considerations**

### **What Is the Value of BAS 650 00 F Fungicide and Zampro Fungicide?**

**BAS 650 00 F Fungicide and Zampro Fungicide are preventative fungicides effective in the control or suppression of many important plant diseases caused by water moulds.**

BAS 650 00 F Fungicide and Zampro Fungicide provide effective solutions to manage commercially important diseases such as downy mildew on brassica leafy vegetables, bulb vegetables, cucurbit vegetables, leafy vegetables, grapes, and hops, late blight on potatoes and fruiting vegetables, and phytophthora blight on cucurbit vegetables and fruiting vegetables. Ametoctradin provides users with a new fungicidal mode of action with no documented cross-resistance with other fungicidal active ingredients used in controlling water mould diseases. In addition, because ametoctradin is combined with dimethomorph in Zampro Fungicide, a single application of this product provides a dual mode of action, thereby reducing the probability of disease resistance development. Moreover, some of the diseases shown to be sensitive to BAS 650 00 F Fungicide and Zampro Fungicide, such as phytophthora blight, have very limited options for their control in terms of currently registered products.

## **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 650 00 F Fungicide and Zampro Fungicide to address the potential risks identified in this assessment are as follows.

### **Key Risk-Reduction Measures**

#### **Human Health**

As there is a concern with users coming into direct contact with ametoctradin on the skin or through inhalation of spray mists, anyone mixing, loading and applying BAS 650 00 F Fungicide or Zampro Fungicide must wear long pants, a long-sleeved shirt and socks and shoes. During

mixing, loading, clean-up and repair activities, workers must also wear chemical resistant gloves. For aerial application, the field crew and the mixer/loaders must wear chemical resistant gloves, coveralls and goggles or face shield during mixing/loading, clean-up and repair. In addition, standard label statements to protect against drift during application are required.

## **Environment**

To protect sensitive aquatic species from the use of ametoctradin, mitigation measures are required on the label. These include adding precautionary statements to the label regarding environmental hazards and the directions for use, as well as no-spray buffer zones of up to 10 m for freshwater habitats and 1 m for marine habitats to mitigate potential exposures via spray drift.

## **Next Steps**

Before making a final registration decision on ametoctradin, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA 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). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

## **Other Information**

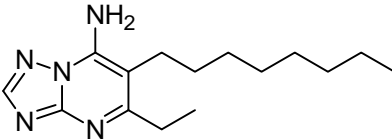
When the PMRA makes its registration decision, it will publish a Registration Decision on ametoctradin (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application,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

# Science Evaluation

## Ametoctradin

### 1.0 The Active Ingredient, Its Properties and Uses

#### 1.1 Identity of the Active Ingredient

Active substance	Ametoctradin
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine
2. Chemical Abstracts Service (CAS)	5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine
CAS number	865318-97-4
Molecular formula	C <sub>15</sub> H <sub>25</sub> N <sub>5</sub>
Molecular weight	275.4
Structural formula	
Purity of the active ingredient	99.2 % nominal

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

### Technical Product— Intium Fungicide Technical

Property	Result																		
Colour and physical state	white crystalline solid																		
Odour	odourless																		
Melting range	197.7 – 198.7																		
Boiling point or range	decomposes prior to boiling																		
Density	1.12 g/cm <sup>3</sup>																		
Vapour pressure at 20°C	2.1 x10 <sup>-10</sup> Pa																		
Ultraviolet (UV)-visible spectrum	<p>Methanol pure, pH 7.6:  <math>\lambda = 221 \text{ nm}</math>      <math>\epsilon = 1.66 \times 10^4 \text{ M}^{-1} \text{ cm}^{-1}</math>  <math>\lambda = 295 \text{ nm}</math>      <math>\epsilon = 1.31 \times 10^4 \text{ M}^{-1} \text{ cm}^{-1}</math></p> <p>Methanol : Water = 1 : 99, pH 7.2:  <math>\lambda = 217 \text{ nm}</math>      <math>\epsilon = 2.65 \times 10^4 \text{ M}^{-1} \text{ cm}^{-1}</math>  <math>\lambda = 294 \text{ nm}</math>      <math>\epsilon = 9.86 \times 10^3 \text{ M}^{-1} \text{ cm}^{-1}</math></p> <p>Methanol : HCl : Water = 1 : 10 : 89, pH 1.0:  <math>\lambda = 218 \text{ nm}</math>      <math>\epsilon = 2.96 \times 10^4 \text{ M}^{-1} \text{ cm}^{-1}</math>  <math>\lambda = 295 \text{ nm}</math>      <math>\epsilon = 1.43 \times 10^4 \text{ M}^{-1} \text{ cm}^{-1}</math></p> <p>Methanol : NaOH : Water = 1 : 10 : 89, pH 12.5:  <math>\lambda = 224 \text{ nm}</math>      <math>\epsilon = 1.21 \times 10^4 \text{ M}^{-1} \text{ cm}^{-1}</math>  <math>\lambda = 295 \text{ nm}</math>      <math>\epsilon = 9.98 \times 10^3 \text{ M}^{-1} \text{ cm}^{-1}</math></p>																		
Solubility in water at 20°C	0.14 mg/L																		
Solubility in organic solvents at 20°C (g/100 mL)	<table> <thead> <tr> <th>Solvent</th> <th>Solubility</th> </tr> </thead> <tbody> <tr> <td>n-Heptane</td> <td>&lt;0.001</td> </tr> <tr> <td>Toluene</td> <td>0.01</td> </tr> <tr> <td>Acetonitrile</td> <td>0.05</td> </tr> <tr> <td>Ethyl acetate</td> <td>0.08</td> </tr> <tr> <td>Acetone</td> <td>0.19</td> </tr> <tr> <td>Dichloromethane</td> <td>0.30</td> </tr> <tr> <td>Methanol</td> <td>0.72</td> </tr> <tr> <td>Dimethyl sulfoxide</td> <td>1.07</td> </tr> </tbody> </table>	Solvent	Solubility	n-Heptane	<0.001	Toluene	0.01	Acetonitrile	0.05	Ethyl acetate	0.08	Acetone	0.19	Dichloromethane	0.30	Methanol	0.72	Dimethyl sulfoxide	1.07
Solvent	Solubility																		
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Dichloromethane	0.30																		
Methanol	0.72																		
Dimethyl sulfoxide	1.07																		
n-Octanol-water partition coefficient (K <sub>ow</sub> )	<table> <thead> <tr> <th>pH</th> <th>log K<sub>ow</sub></th> </tr> </thead> <tbody> <tr> <td>4</td> <td>4.24</td> </tr> <tr> <td>7</td> <td>4.40</td> </tr> <tr> <td>9</td> <td>4.18</td> </tr> </tbody> </table>	pH	log K <sub>ow</sub>	4	4.24	7	4.40	9	4.18										
pH	log K <sub>ow</sub>																		
4	4.24																		
7	4.40																		
9	4.18																		
Dissociation constant (pK <sub>a</sub> )	2.78 (calculated)																		
Stability (temperature, metal)	stable in the presence of metal and metal ions at normal and elevated temperatures																		

## End-Use Product— Zampro Fungicide

Property	Result
Colour	white
Odour	faint aromatic
Physical state	liquid suspension
Formulation type	suspension concentrate (SC)
Guarantee	Ametoctradin 300 g/L Dimethomorph 225 g/L
Container material and description	HDPE jugs
Density	1.11 g/mL
pH of 1% dispersion in water	7.1
Oxidizing or reducing action	Not an oxidizing agent, a weak reducing agent
Storage stability	Stable at ambient temperature for two years
Corrosion characteristics	No corrosion observed to storage container
Explodability	The product is not explosive

## End-Use Product— BAS 650 00 F Fungicide

Property	Result
Colour	off-white
Odour	faint aromatic
Physical state	liquid suspension
Formulation type	suspension concentrate
Guarantee	Ametoctradin 200 g/L
Container material and description	HDPE jugs
Density	1.04 g/mL
pH of 1% dispersion in water	8.4
Oxidizing or reducing action	Not an oxidizing agent, a weak reducing agent
Storage stability	Stable at ambient temperature for two years
Corrosion characteristics	No corrosion observed to storage container
Explodability	The product is not explosive

### 1.3 Directions for Use

Ametoctradin, contained in BAS 650 00 F Fungicide and Zampro Fungicide, is used for the control or suppression of foliar diseases including downy mildew on brassica leafy vegetables, bulb vegetables, cucurbit vegetables, some leafy vegetables, grapes, and hops, late blight on potatoes and fruiting vegetables, and phytophthora blight on cucurbit vegetables and fruiting vegetables. The products are applied as preventative foliar treatments at rates ranging from 0.8 to 1.0 L/ha for Zampro Fungicide and 1.2 to 1.5 L/ha for BAS 650 00 F Fungicide. For both products, the application rate range of ametoctradin is 240 to 300 g/ha.

### 1.4 Mode of Action

Ametoctradin inhibits mitochondrial functioning in water mould cells, thereby disrupting the normal respiration process in target pathogens. The uptake of ametoctradin is limited to the waxy layers of the leaf surface. It has very good preventative properties and shows no cross-resistance to other important Oomycete fungicides. Ametoctradin is not intended for curative use.

Therefore, products containing this active ingredient should be applied preventatively to ensure maximum efficacy.

## **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 the impurities in Intium Fungicide Technical have been validated and assessed to be acceptable for the determinations.

### **2.2 Method for Formulation Analysis**

The methods provided for the analysis of the active ingredient(s) in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

### **2.3 Methods for Residue Analysis**

For environmental media, high-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

In plant and animal commodities, HPLC-MS/MS methods were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective limits of quantitation of the methods. Acceptable recoveries (70-120%) were obtained in plant and animal matrices. The proposed enforcement methods were successfully validated in several plant and animal matrices by an independent laboratory. Adequate extraction efficiencies were demonstrated using radiolabelled samples of several crop matrices and goat tissues analyzed with the respective enforcement methods.

## **3.0 Impact on Human and Animal Health**

### **3.1 Toxicology Summary**

A detailed review of the toxicological database for ametoctradin was conducted. The database is complete for the purpose of this application. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to ametoctradin.

Following oral administration of radiolabelled ametoctradin in rats, it was rapidly absorbed with saturation occurring at the highest dose. Feces accounted for three fold higher levels of recovered radioactivity compared to urine. The amount of radiolabel in exhaled air was

negligible. The majority of the radiolabel ( $\geq 85\%$ ) was eliminated from the body within 48 hours. There was no evidence of bioaccumulation. There was no difference in absorption/excretion between the sexes. Absorbed ametoctradin was rapidly and widely distributed. The peak level in each organ was reached within 1-2 hours. Dose and gender did not have an effect on distribution. The highest tissue levels appeared in the liver, kidneys, thyroid and pancreas, as well as adipose tissue (low dose males), uterus (low dose females) and adrenals, bone marrow and carcass (all at the high dose). Bile cannulation revealed higher biliary excretion in males.

Following a single oral dose of ametoctradin, the majority of the administered dose was excreted unchanged in feces. The most frequently observed metabolite was M650F06 (8-13% of administered dose in bile and feces), however, as many as four other metabolites reached 1-4% of the administered dose. Ametoctradin is metabolized by terminal oxidation of the octyl side chain to the respective carboxylic acid followed by degradation of the carboxylic side chain comparable. In addition, conjugates of the oxidized metabolites with taurine or with glucuronic acid have been identified.

The active ingredient ametoctradin was of low acute toxicity by the oral, dermal and inhalation routes in rats. Ametoctradin was minimally irritating to the skin and the eyes of rabbits and was not a dermal sensitizer in guinea pigs (Maximization method) or mice (Local Lymph Node Assay [LLNA]).

The end-use product, Zampro Fungicide, was of moderate acute toxicity via the oral route and low toxicity via the dermal and inhalation routes in rats. It was non-irritating to the eye and slightly irritating to the skin of rabbits. Zampo Fungicide was not a dermal sensitizer in mice (LLNA).

The end-use product, BAS 650 00 F Fungicide, was of low acute toxicity by the oral, dermal and inhalation routes in rats. It was non-irritating to the eye and slightly irritating to the skin of rabbits and was not a dermal sensitizer in guinea pigs (Maximization method) or mice (LLNA).

Overall, ametoctradin showed very low mammalian toxicity. Most of the studies were tested at or near the limit dose. There was no indication of target organ toxicity or sex/species sensitivity. There was also no indication of increased toxicity with increased duration of exposure in any tested species.

Repeated oral dosing in rats, mice and dogs with high doses of ametoctradin did not result in any adverse effects. Short-term repeated dermal dosing in rats produced no evidence of dermal or systemic toxicity. There was no evidence of carcinogenic potential in the mouse or rat. Neurotoxicity and immunotoxicity testing did not reveal any adverse effects. The 2-generation reproductive toxicity study did not reveal any systemic or reproductive effects in the parental rats or in the offspring. No maternal or developmental toxicity was noted in either developmental toxicity study.

When ametoctradin was tested in a battery of *in vitro* and *in vivo* genotoxicity assays, the results were negative.



Select toxicity studies were submitted for three metabolites; M650 F02 is a soil metabolite, and M650 F03 and M650 F04 are plant metabolites. M650 F03 and M650 F04 were tested in 90-day dietary rat studies. No adverse effects were observed at any dose level. Various batteries of genotoxicity studies were performed on the three metabolites, all of which were negative.

Results of the toxicology studies conducted on laboratory animals with ametoctradin and its associated end-use products are summarized in Appendix I, Tables 2 and 3. The toxicology endpoints for use in the human health risk assessment are summarized in Appendix I, Table 4.

## **Incident Reports**

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. As of September 28th 2011, the PMRA had received no incident reports for products containing ametoctradin.

### **3.1.1 PCPA 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* (PCPA) 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 as it pertains to the toxicity to infants and children, extensive data were available for ametoctradin. The database contains the full complement of required studies, including developmental toxicity studies in rats and rabbits, and a reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, no evidence of sensitivity of the young was observed in the 2-generation reproductive toxicity study. No adverse toxicological effects were observed in either the parents or the offspring. In the developmental toxicity studies in rats and rabbits, no adverse toxicological effects were observed. Consequently the 10-fold factor required under the *Pest Control Products Act* was reduced to 1-fold.

### **3.2 Determination of Acute Reference Dose**

An acute reference dose was not established as there were no acute endpoints of concern.

### **3.3 Determination of Acceptable Daily Intake**

To estimate dietary risk of repeat exposure, the one year dog study with a no observed adverse effect level (NOAEL) of 848 mg/kg bw/day was selected for risk assessment. No lowest observed adverse effect level (LOAEL) was observed in this study as there were no treatment related effects at any dose tested. This study was chosen for the endpoint selection for ametoctradin as this was the lowest NOAEL in the database. Standard uncertainty factors of 10-

fold for interspecies extrapolation and 10-fold for intraspecies variability have been applied. As discussed in the PCPA Hazard Characterization section, the PCPA factor is 1-fold. The composite assessment factor (CAF) is 100-fold.

The acceptable daily intake (ADI) is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{848 \text{ mg/kg bw/day}}{100} = 8.48 \text{ mg/kg bw/day of ametoctradin.}$$

## **Cancer Assessment**

There was no evidence of carcinogenicity and therefore, no cancer risk assessment was necessary.

## **3.4 Occupational and Residential Risk Assessment**

### **3.4.1 Toxicological Endpoints**

#### **Short- and Intermediate-term Dermal**

There was no systemic or dermal toxicity at any dose tested in the 21-day dermal study. There were no toxicological concerns identified in oral toxicity studies that, by virtue of the study design, assessed endpoints that were not examined in the short-term dermal study. Therefore, a quantitative approach for dermal risk assessment was not required.

#### **Short- and Intermediate-term Inhalation**

There was no inhalation study submitted or required. For short- and intermediate-term exposure via the inhalation route, the NOAEL of 912 mg/kg bw/day from the 90-day dog oral study was selected. This study was chosen for the endpoint selection for ametoctradin as this was the lowest NOAEL in short-term studies, and was considered appropriate for short- and intermediate- term exposure durations.

The target Margin of Exposure (MOE) for this scenario is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

#### **3.4.1.1 Dermal Absorption**

Chemical specific dermal absorption data were submitted for ametoctradin. In the *in vivo* study, groups of male rats (four per time point per dose) received a dermal application of 2000, 133.3 or 13.3  $\mu\text{g}/\text{cm}^2$  ametoctradin (the SC formulation mixed with  $^{14}\text{C}$ - ametoctradin) on 10  $\text{cm}^2$  of preclipped skin, with a dosing volume 10  $\mu\text{L}/\text{cm}^2$ . After the 8-hour exposure, the semi-occlusive covers were removed and the skin was washed, followed by a post-exposure period of 0, 24 or 168 hours under protective cover and another wash before sacrifice. Mean recoveries of

radioactivity across the dose groups ranged from 95.1% to 114.0% of the applied radioactivity, with the vast majority of radioactivity recovered from the skin wash. The final dermal absorption values included both the absorbed dose (found in the urine, feces, cage wash, blood cells, plasma and carcass) as well as the absorbable dose (application site and surrounding skin). The total absorption after 8 hours of exposure and 168 hours of collection was 0.76%, 1.93% and 6.37% of the applied dose at 2000, 133.3 and 13.3  $\mu\text{g}/\text{cm}^2$ , respectively.

In the *in vitro* dermal penetration study in the rat and human skin membranes, preparations of human and rat split thickness skin, with an area of 1  $\text{cm}^2$ , were treated with the undiluted formulation concentration of BAS 651 00 F Fungicide and the 1:1250 aqueous dilution under semi-occlusive conditions. After a 24 hour exposure, the skin preparations were thoroughly washed. The test substance was fully recovered (97-105% of the dose) for the high and low concentrations in both rat and human skin preparations. The *in vitro* absorption rates of the test substance in rat and human skin preparation, as determined from the combined radioactivity in the receptor fluid samples from 0-24 hours, the receptor fluid at the end of the exposure, the receptor chamber wash, the skin preparation and the *stratum corneum* (i.e. tape strips), were 0.97% and 0.51% of the dose for rat and human skin, respectively, for the undiluted formulation, and 4.9% and 2.8% of the dose, respectively, for the spray dilution.

The submitted studies did not qualify for the draft NAFTA triple-pack approach, as they utilized different exposure durations (8 hours for the *in vivo* study and 24 hours for the *in vitro* study). Therefore, the dermal absorption value of 6.37%, based on the results from the low dose group (13.3  $\mu\text{g}/\text{cm}^2$ ) in the *in vivo* rat study after 168 hours of collection, was considered appropriate for ametoctradin. However, since no dermal endpoint was determined for ametoctradin due to low toxicity, a quantitative dermal risk assessment was not required.

### **3.4.2 Occupational Exposure and Risk**

#### **3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment**

Individuals have potential for exposure to BAS 650 00 F Fungicide and Zampro Fungicide during mixing, loading and application. As chemical specific data for assessing human exposures were not submitted, inhalation exposure estimates for workers were estimated using the Pesticide Handlers Exposure Database (PHED), version 1.1. PHED is a compilation of generic mixer/loader and applicator passive dosimetry data which facilitates the generation of scenario-specific exposure estimates. Dermal exposure was not assessed, as there is no dermal endpoint for ametoctradin. Exposure estimates are outlined in Table 3.4.1.

**Table 3.4.1. PHED Unit Exposure Estimates for Workers Mixing, Loading and Applying BAS 650 00 F Fungicide and Zampro Fungicide Using Proposed Personal Protective Equipment (PPE)**

Scenario	Exposure (in µg/kg a.i. handled)
	Inhalation Exposure
A. Liquid, open mixing and loading	1.6
B. Groundboom application, open cab	0.96
C. Airblast application, open cab	5.8
D. Aerial application	0.07
E. M/L/A with low pressure handwand	45.2
F. M/L/A with backpack sprayer	62.1
<u>A + B</u> : M/L/A with groundboom, combined total exposure	2.56
<u>A + C</u> : M/L/A with airblast, combined total exposure	7.4

Exposure estimates were derived for mixer/loaders and applicators applying BAS 650 00 F Fungicide and Zampro Fungicide to all proposed crops using groundboom, airblast, aerial and handheld application equipment. Handlers are assumed to have potential short- to intermediate-term inhalation exposure to ametoctradin. 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 70 kg adult body weight. Exposure estimates were compared to the NOAEL of 912 mg/kg bw/day to obtain the MOE; the target MOE is 100. The risk assessment results are summarized in Table 3.4.2. All uses exceed the target MOE and are considered acceptable based on the label directions and PPE.

**Table 3.4.2. Ametoctradin Daily Dose Estimates and MOEs for Workers Mixing, Loading and Applying BAS 650 00 F Fungicide and Zampro Fungicide**

Scenario	Inhalation Exposure (µg/kg a.i. handled)	ATPD (ha) <sup>1</sup>	Maximum Application Rate (kg a.i./ha)	Daily Dose (mg/kg bw/day) <sup>2</sup>	NOAEL (mg/kg bw/day)	MOE <sup>3</sup>
M/L/A (Groundboom)	2.56	360	0.3	0.00395	912	230900
M/L/A (Airblast)	7.4	20	0.3	0.00063	912	1437800
M/L/A (Low pressure handwand)	45.2	1	0.3	0.00019	912	4708000
M/L/A (Backpack)	62.1	1	0.3	0.00027	912	3426700
Mixing/loading (Aerial)	1.6	400	0.3	0.00274	912	332500
Application (Aerial)	0.07	400	0.3	0.00012	912	7600000

<sup>1</sup>ATPD default values are 20 ha/day for airblast applications, 360 ha/day for custom groundboom applications, 400 ha/day for aerial applications and 1 ha/day for greenhouse applications

<sup>2</sup>Daily dose = [Inhalation exposure (µg/kg a.i. handled) x ATPD (ha) x Application rate (kg a.i./ha)]/(70 kg bw x 1000 µg/mg)

<sup>3</sup>MOE = NOAEL (912 mg/kg bw/day)/Daily dose (mg/kg bw/day)

### 3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with BAS 650 00 F Fungicide and Zampro Fungicide to perform cultural activities such as hand harvesting, irrigation, scouting, hand thinning, and hand weeding. Given the nature of activities performed, the duration of exposure is considered short- to intermediate-term and the primary route of exposure for workers that enter treated crops would be dermal, through contact with residues on leaves.

A quantitative post-application risk assessment was not performed for ametoctradin, as exposure is considered to be primarily via the dermal route and PMRA does not require a dermal endpoint for this active ingredient.

### 3.4.3 Residential Exposure and Risk Assessment

There are no domestic class products, therefore, a residential handler assessment was not required.

#### 3.4.3.1 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to non-crop sites where public access is often restricted, and only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools

and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

### **3.5 Food Residues Exposure Assessment**

#### **3.5.1 Residues in Plant and Animal Foodstuffs**

The residue definition for risk assessment and enforcement in plant products is ametoctradin, and in animal commodities is ametoctradin and the metabolite M650F06. The HPLC-MS/MS data gathering/enforcement analytical methods are valid for the quantification of ametoctradin residues in crop matrices, and the HPLC-MS/MS enforcement analytical method is valid for the quantification of the residues of ametoctradin and metabolite M650F06 in livestock matrices. The residues of ametoctradin are stable in wheat, lettuce, potato and grape for up to 24 months, and in tomatoes for up to 16 months, when stored in a freezer at -20°C. Ametoctradin residues concentrated in the processed commodity raisins (3.7x). Quantifiable residues are not expected to occur in livestock matrices with the current use pattern. Supervised residue trials conducted throughout the United States and Canada using end-use products containing ametoctradin in or on potatoes, dry bulb onions, green onions, head lettuce, leaf lettuce, spinach, celery, broccoli, cabbage, mustard greens, tomatoes, peppers, cucumber, cantaloupe, squash, grapes and hops are sufficient to support the proposed maximum residue limits.

#### **3.5.2 Dietary Risk Assessment**

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.0), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

##### **3.5.2.1 Chronic Dietary Exposure Results and Characterization**

The following criteria were applied to the basic chronic analysis: 100% crop treated, default processing factors, residues of ametoctradin in crops at maximum residue limit (MRL) values, and residues of ametoctradin and the metabolite M650F06 in animal commodities based on limit of quantitation (LOQ) values. The basic chronic dietary exposure from all supported ametoctradin food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 1% of the ADI. Aggregate exposure from food and water is considered acceptable. The PMRA estimates that chronic dietary exposure to ametoctradin from food and water is 0.3% (0.024584 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 0.5% (0.043041 mg/kg bw/day) of the ADI.

##### **3.5.2.2 Acute Dietary Exposure Results and Characterization**

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified. An acute dietary exposure analysis was not required.

### 3.5.3 Aggregate Exposure and Risk

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

### 3.5.4 Maximum Residue Limits

**Table 3.5.1 Proposed Maximum Residue Limits (MRLs)**

<b>Commodity</b>	<b>Recommended MRL (ppm)</b>
Crop Subgroup 1C – Tuberos and Corm Vegetables Subgroup	0.05
Crop Subgroup 3-07A – Bulb Onion Subgroup	1.5
Crop Subgroup 3-07B – Green Onion Subgroup	20
Crop Group 4 – Leafy Vegetables (except Brassica Vegetables) Group, except spinach	40
Spinach	50
Crop SubGroup 5A – Head and Stem Brassica Subgroup	9
Crop SubGroup 5B – Leafy Brassica Greens Subgroup	50
Crop Group 8-09 – Fruiting Vegetable Group	1.5
Crop Group 9 – Cucurbit Vegetables Group	3.0
Crop Group 13-07F – Small Fruit Vine Climbing Subgroup, except Fuzzy Kiwifruit	4.0
Raisins	8.0
Hops	10
Fat , meat and meatbyproducts of cattle, goats, hogs, horses, poultry and sheep; eggs, milk	0.02

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 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 methodology, field trial data, and the chronic dietary risk estimates are summarized in Appendix I, Tables 1, 5 and 6.

## 4.0 Impact on the Environment

### 4.1 Fate and Behaviour in the Environment

Based on its physical-chemical properties, ametoctradin is only sparingly soluble in water, is not likely to volatilize from moist soil or water surfaces under field conditions, has a limited potential to photodegrade in the environment, and has the potential to bioaccumulate in aquatic

organisms (Appendix I, Table 7). Physical/chemical properties of ametoctradin's identified transformation products are summarized in Appendix I, Table 8. Environmental fate data for ametoctradin and its four major transformation products (M650F01, M650F02, M650F03 and M650F04) are summarized in Appendix 1, Table 9. A summary of the major transformation products, their maximum formation rate (as a percentage of applied radiation in the study) and time of maximum occurrence in each of the studies are in Appendix I, Table 10.

Once ametoctradin enters the terrestrial environment, it is expected to readily adsorb to soil. Laboratory studies on adsorption/desorption indicate that ametoctradin is not mobile, but that its transformation products may be. Ametoctradin is non-persistent in aerobic soil, where it undergoes microbial biotransformation. The transformation products M650F01 and M650F02 are transient, but M650F03 is slightly to moderately persistent and M650F04 is slightly persistent to persistent based on laboratory biotransformation studies. Under anaerobic (flooded) soil conditions, ametoctradin and its transformation products are persistent. Photolysis is not expected to contribute to the degradation of ametoctradin on soil. In terrestrial field studies conducted with ametoctradin and M650F03 and M650F04, ametoctradin and M650F03 were found to dissipate quickly with no significant carry over to the following growing season and no evidence of leaching in the soil column. The transformation product M650F04, however, can carry over to the following season in significant quantities and was detected at depths of up to 80 to 90 cm in the soil, indicating that it has the potential to leach.

Ametoctradin can enter the aquatic environment through spray drift, overland runoff or through the movement of soil particles to which ametoctradin is bound. Once in the water, ametoctradin is not expected to hydrolyse. In a water/sediment system, ametoctradin will rapidly partition to sediments due to its hydrophobic nature and high soil adsorption capacity, where it will undergo microbial degradation. Ametoctradin is non-persistent in both aerobic and anaerobic water/sediment systems. Phototransformation is not expected to be an important route of degradation for ametoctradin or M650F03 in aquatic systems.

## **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 (i.e. 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 (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. Screening level EECs for ametoctradin on plant surfaces and in soil are in Appendix I, Table 11, and in Appendix I, Table 12, for concentrations in vegetation and insect food sources for birds and mammals. Screening level EECs for ametoctradin in water are in Appendix I, Table 13, and in Appendix I, Table 14, for major transformation products. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value ( $RQ = \text{exposure}/\text{toxicity}$ ), and the risk quotient is then compared to the level of concern (LOC = 1). 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. Refined EECs for ametoctradin spray drift input to water are in Appendix I, Table 15, and for ametoctradin runoff input to water are in Appendix I, Tables 16 – 18.

#### 4.2.1 Risks to Terrestrial Organisms

A risk assessment of ametoctradin, its two end-use products Zampro Fungicide and BAS 650 00 F Fungicide, and the transformation products M650F03 and M650F04 was undertaken for terrestrial organisms based on available toxicity data for each of the compounds to earthworms (acute and chronic exposure), bees (acute oral and dermal exposure), non-target beneficial arthropods (acute contact and field studies), soil-dwelling arthropods (chronic exposure), birds (acute oral, dietary and chronic), mammals (acute oral, dietary and chronic) and terrestrial plants (effects on seedling emergence and vegetative vigour).

A summary of terrestrial toxicity data for ametoctradin is presented in Appendix I, Table 19, and the accompanying screening level risk assessment is in Appendix I, Table 20.

**Earthworms:** Ametoctradin, its two end-use products and the transformation products M650F01, M650F03 and M650F04 were not acutely toxic to earthworms. Earthworm survival and reproduction were also not adversely affected by chronic exposure to the two end-use products or M650F03 or M650F04. Risk was determined based on EECs for the highest use rate scenario of Zampro Fungicide application on grapes. The LOC was not exceeded for earthworms (Appendix I, Table 20).

**Bees (pollinators):** Acute oral and contact exposure to ametoctradin and its two end-use products did not result in significant mortality or sublethal effects in honey bees. The resulting RQs for both acute contact and oral exposure routes were all below the LOC, indicating ametoctradin is not expected to pose a risk to pollinators (Appendix I, Table 20).

**Beneficial arthropods:** The toxicity of Zampro Fungicide and BAS 650 00 F Fungicide was determined for acute laboratory and field exposure to the parasitic wasp (*Aphidius rhopalosiphi*)

and predaceous mite (*Typhlodromus pyri*), and for acute laboratory exposure to the green lacewing (*Chrysoperlea carnea*). Zampro Fungicide was not toxic to any of the arthropods on either an acute or chronic field exposure basis. BAS 650 00 F Fungicide was acutely toxic to the parasitic wasp on glass plate exposure, but not under refined exposure to dry residues on leaves, nor under field exposure. No risks to arthropods living within treated crops were determined for the highest application rates for Zampro Fungicide (Appendix I, Table 20). Therefore, Zampro Fungicide and BAS 650 00 F Fungicide are not expected to pose a risk to beneficial arthropods living within or adjacent to treated fields.

**Soil-dwelling arthropods:** The chronic toxicity of BAS 650 00 F Fungicide and Zampro Fungicide, as well as the soil transformation products M650F03 and M650F04 were assessed for springtails (*Folsomia candida*) and soil mites (*Hypoaspis aculeifer*). No adverse effects were observed in springtails following exposure to either end-use product. No adverse effects from either M650F03 or M650F04 were seen in soil mites, however, survival and reproduction in springtails were significantly reduced following chronic exposure to M650F03 (Appendix I, Table 19). Risk was determined for the highest application rates for Zampro Fungicide. Expected environmental concentrations for M650F03 and M650F04 were based on a conservative assumption of 100% conversion of parent EECs, adjusting for the molecular weight ratio of transformation product to parent. Exposure to ametoctradin and major transformation products from the application of either BAS 650 00 F Fungicide or Zampro Fungicide is not expected to pose a risk to soil-dwelling arthropods (Appendix I, Table 20).

**Birds:** From acute oral exposure, ametoctradin was practically non-toxic to bobwhite quail (*Coturnix virginianus*), mallard duck (*Anas platyrhynchos*) and zebra finch (*Taeniopygia guttata*), with no treatment-related mortalities or clinical effects occurring in any species. Zampro Fungicide was also non-toxic on an acute oral basis to bobwhite quail. During short-term dietary exposure to bobwhite quail and mallard duck, no treatment-related mortality occurred, however, mallard ducks experienced a significant decrease in body weight at the highest concentration tested. During 21-week dietary exposure studies, no treatment-related adverse effects on reproductive parameters or on the parental generations were observed for either bobwhite quail or mallard ducks (Appendix I, Table 19). No unacceptable risk for acute mortality or reproductive effects from ametoctradin exposure is expected for small, medium or large birds (Appendix I, Table 21). Likewise, birds of all size classes are not expected to be at acute risk from Zampro Fungicide exposure (Appendix I, Table 21).

**Mammals:** The laboratory toxicity of ametoctradin, BAS 650 00 F Fungicide, Zampro Fungicide and the transformation products M650F03 and M650F04 to rats was used to determine risk to small terrestrial mammals. Ametoctradin and BAS 650 00 F Fungicide were not acutely toxic to rats (Appendix I, Table 19). However, mortality was observed for acute oral exposure to Zampro Fungicide. Subchronic dietary exposure (90 days) of ametoctradin and its transformation products M650F03 and M650F04 did not result in any toxicologically relevant effects up to 15,000 mg/kg diet. Ametoctradin is also not a reproductive toxicant in rats, as there was no evidence of a treatment related effect on reproduction or development (Appendix I, Table 19). A screening level risk assessment for three size classes of small mammals, based on a conservative assumption of vegetation and insect food sources, did not identify a concern for acute mortality or reproductive risks for ametoctradin exposure in field crops or vineyards (Appendix I, Table

21). Acute exposure of BAS 650 00 F Fungicide resulted in RQs > 1 (Appendix I, Table 21). However, as the maximum RQ was < 3 based on a study where no mortality was seen up to 2000 mg EP/kg bw, the PMRA considers this end-use product to pose a negligible risk to mammals. The screening level risk for acute Zampro Fungicide exposure to maximum possible residues resulted in RQs up to 8.4 (Appendix I, Table 21), while refined RQs based on average expected residues were ≤ 2.8 on-field and ≤ 1.6 off-field (Appendix I, Tables 22 and 23). The fact that the risk quotients only slightly exceeded the level of concern when considering mean residues and that the risk quotients were based on the lower boundary of the range of concentrations that resulted in a 50% mortality response in the test group suggests a low probability for acute mortality to occur in the field. Therefore, the PMRA considers Zampro Fungicide to pose a negligible risk to small mammals foraging in or around treated vineyards.

**Non-target plants:** The toxicity of BAS 650 00 F Fungicide and Zampro Fungicide to non-target plants was determined through vegetative vigour and seedling emergence assays using standard crop species. No significant adverse effects (i.e., > 25% effect) were observed in any plant species in either the vegetative vigour or seedling emergence assays with either BAS 650 00 F Fungicide or Zampro Fungicide (Appendix I, Table 19). The EC<sub>25</sub> is therefore > 2.8 L/ha (> 570 g a.i./ha) for BAS 650 00 F Fungicide and > 5.0 L/ha (> 1500 g a.i./ha, as ametoctradin) for Zampro Fungicide. The screening level risk assessment for BAS 650 00 F Fungicide determined RQs of < 1.4 for seedling emergence and vegetative vigour (Appendix I, Table 20). It is uncertain whether the LOC has been exceeded for this end-use product as the RQs are based on endpoints above the limit of the test concentration and at rates below the expected environmental concentrations for the Canadian use pattern. The risk to plants from exposure to Zampro Fungicide, however, is not above the LOC based on exposure to ametoctradin in the formulation at rates above the maximum EEC (Appendix I, Table 20). Therefore, ametoctradin is not expected to pose a risk to non-target terrestrial plants at the proposed Canadian use rate.

#### 4.2.2 Risks to Aquatic Organisms

Aquatic organisms can be exposed to ametoctradin as a result of spray drift and over-land runoff. To assess the potential for adverse effects, screening level EECs in the aquatic environment, based on a direct application to water following application to grapes, were used as the exposure estimates. A risk assessment of ametoctradin, its two end-use products Zampro Fungicide and BAS 650 00 F Fungicide, and the transformation products M650F01, M650F02, M650F03 and M650F04 was undertaken for freshwater and marine aquatic organisms based on available toxicity data for each of the compounds to algae (acute), aquatic plants (acute), invertebrates (acute and chronic), fish (acute and chronic) and amphibians (using fish as surrogate data). It should be noted that due to the low solubility of ametoctradin, effects endpoints for some aquatic toxicity studies are reported as greater than the highest concentration tested. In most cases no effects were evident at functional solubility limits. A summary of aquatic toxicity data for ametoctradin and the two end use products are presented in Appendix I, Table 24. For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC<sub>50</sub> or LC<sub>50</sub> are used in modifying the toxicity values for aquatic plants and invertebrates, and fish species, respectively when calculating RQs. No uncertainty factors are applied to chronic no observed effect concentration (NOEC) endpoints. For groups where the LOC is exceeded (i.e., RQ ≥ 1), a refined Tier 1 assessment is conducted to determine risk resulting from spray drift and runoff separately. The

calculated risk quotients are summarized in Appendix I, Table 25 (screening level), Table 26 (Tier 1 – spray drift only) and Table 27 (Tier 1 – runoff only). For the majority of aquatic toxicity studies, the sparingly soluble nature of ametoctradin limited the interpretation of aquatic risk. Because effects for some organisms were non-existent or limited within functional solubility limits, reported endpoints (expressed as > the highest test concentrations) were sometimes above the highest achievable solubility of the TGAI in the test solution. For the purposes of the assessments the highest concentrations tested were used as conservative effects endpoints resulting at times in apparent RQs exceeding the LOC.

**Freshwater algae and plants:** Of the three algal and one plant species tested, ametoctradin was only toxic to diatoms (*Navicula pelliculosa*) within the range of achievable solubility of the technical grade active ingredient. Screening level risk to diatoms exceeded the LOC (RQ > 1; Appendix I, Table 25), as did refined risk from spray drift from airblast and aerial sprayers (Appendix I, Table 26), indicating a potential risk from ametoctradin exposure to freshwater algae. Diatoms are not expected to be at risk from ametoctradin runoff inputs (Appendix I, Table 27). For the freshwater plant duckweed, the most sensitive measureable endpoint, based on yield, did not exceed the LOC (Appendix I, Table 25).

**Freshwater invertebrates:** Acute exposure of *Daphnia* to ametoctradin, its two end-use products and four major transformation products did not result in significant mortality. However, chronic exposure to ametoctradin resulted in reduced reproduction, and chronic exposure to M650F03 resulted in significant reductions in parental growth, survival, and reduced fecundity in *Daphnia* (Appendix I, Table 24). Chronic exposure of the freshwater midge, *Chironomus riparius*, to BAS 650 00 F Fungicide in a 28-day static spiked sediment study resulted in a significant reduction in emergence rate (Appendix I, Table 24).

Exposure of ametoctradin up to its functional solubility limit, its two end-use products or four major transformation products, did not exceed the LOC for acute or chronic exposure to *D. magna* (Appendix I, Table 25). A screening level risk assessment was not done for chronic exposure of BAS 650 00 F Fungicide to the freshwater midge because the exposure route in the toxicity study was from spiked sediment and not from overlying water. Rather, a Tier 1 risk assessment, based on pore water EECs from runoff inputs, found no risk to sediment-dwelling invertebrates (Appendix I, Table 27).

**Freshwater fish and amphibians:** The toxicity of ametoctradin to fish was assessed for acute exposure considering toxicity studies from four species (rainbow trout, common carp, bluegill sunfish, fathead minnow) and one species for chronic exposure (fathead minnow). Ametoctradin was not acutely toxic to freshwater fish up to its functional limit of solubility in test systems for either the technical grade active ingredient or the BAS 650 00 F Fungicide formulation (i.e., an LC50 was not reached). An LC50 was reached for Zampro Fungicide, a co-formulation with dimethomorph which is known to have some toxicity for fish (Appendix I, Table 24); however, the LC50 was approximately forty times higher than the limit of solubility for the technical grade active ingredient in neutral pH waters.

The transformation products M650F03 and M650F04 were also not acutely toxic to rainbow trout. Chronic exposure to ametoctradin resulted in reduced survival of fathead minnows (Appendix I, Table 24).

Although an acute risk quotient potentially above the LOC was identified for fish (Appendix I, Table 25), the PMRA does not expect a risk to freshwater fish from acute exposure to BAS 650 00 F Fungicide and Zampro Fungicide because: 1) for the technical grade active ingredient the acute endpoint of concern (50% mortality) was not observed up to the limits of solubility for any species tested (10% mortality was seen at the highest dose in rainbow trout only), 2) assessment using acute fish toxicity data for the two formulated end-use products (which allow for a greater solubility of ametoctradin in water) did not exceed the LOC for fish (Appendix I, Table 25), and 3) the half-life of ametoctradin in water/sediment systems is 2 days or less (Appendix I, Table 9). Chronic exposure of ametoctradin to the fathead minnow did not exceed the LOC for fish. The transformation products M650F03 and M650F04 are also not an acute risk to fish (Appendix I, Table 25).

For the screening level assessment, the risk to amphibians was characterized by comparing EECs in 15 cm water depth with fish toxicity endpoints as surrogates for aquatic life-stages of amphibians. Acute risks were assessed for exposure to ametoctradin, the end-use products BAS 650 00 F Fungicide and Zampro Fungicide (as ametoctradin), and the transformation products M650F03 and M650F04; chronic risk was assessed for ametoctradin.

An acute risk quotient potentially above the LOC was identified for amphibians based on the limited solubility of the ametoctradin technical grade active ingredient (Appendix I, Table 25). Considering that the assessment for amphibians to the two end-use products (which allow for a greater solubility of ametoctradin in water) did not exceed the LOC for amphibians (Appendix I, Table 25), the PMRA does not expect a risk to amphibians from acute exposure to BAS 650 00 F Fungicide and Zampro Fungicide. The transformation products M650F03 and M650F04 are also not expected to pose an acute risk to amphibians.

A chronic risk from ametoctradin exposure to amphibians was identified at the screening level (Appendix I, Table 25) and under refined Tier 1 estimates for exposure via spray drift (RQs up to 3.3 for airblast sprayers) (Appendix I, Table 26). Considering the risk is based on effects from a 33-day laboratory study with continuous dosing (flow-through) design, and the expected half-life of ametoctradin in aquatic systems is less than 2 days, amphibians are not expected to be at chronic risk from ametoctradin spray drift.

**Marine species:** Ametoctradin was not acutely toxic up to its functional limit of solubility to the saltwater diatom (*Skeletonema costatum*), Eastern oyster (*Crassostrea virginica*), mysid (*Americamysis bahia*), or the sheepshead minnow (*Cyprinidon variegates*) (all LC50 values above highest achievable test concentration) (Appendix I, Table 24). In an acute 10-day spiked sediment study, BAS 650 00 F Fungicide was also not toxic to the amphipod *Leptocheirus plumulosus*.

Acute exposure to ametoctradin did not exceed the LOC for marine algae or invertebrates (Appendix I, Table 25). However, based on its limited solubility in salt water, the PMRA's LOC may be exceeded for acute ametoctradin exposure to marine fish, as refined risk quotients based on inputs from spray drift were potentially above the PMRA's LOC (Appendix I, Table 26). In the absence of confirmatory data with end-use product formulations, the PMRA cannot rule out

the possibility of risk to marine fish. Therefore, mitigative measures for spray drift will be required for marine habitats.

A screening level risk assessment was not done for acute exposure of BAS 650 00 F Fungicide for *L. plumulosus* as the exposure route in that toxicity study was from spiked sediment and not overlying water. A Tier I risk assessment based on measured pore water endpoints and EECs found no risk to sediment-dwelling marine invertebrates from runoff sources (Appendix I, Table 27).

## **5.0 Value**

### **5.1 Effectiveness Against Pests**

#### **5.1.1 Acceptable Efficacy Claims**

Demonstrations of BAS 650 00 F Fungicide and Zampro Fungicide efficacy against labelled pests were provided in a total of 59 and 71 trials, respectively.

##### **5.1.1.1 Brassica Leafy Vegetables**

###### *Downy mildew*

A total of six trials were considered in the value assessment of Zampro Fungicide efficacy claims for brassica leafy vegetables. Downy mildew control levels reached nearly 100% under moderate to high disease pressure. For BAS 650 00 F Fungicide, five trials were considered in the value assessment of BAS 650 00 F Fungicide efficacy claims for brassica leafy vegetables. The highest level of efficacy observed was a reduction of downy mildew severity of 79% on cabbage under moderate disease pressure.

##### **5.1.1.2 Bulb Vegetables**

###### *Downy mildew*

A total of six trials were considered in the value assessment of Zampro Fungicide efficacy claims for bulb vegetables. Under high disease pressure, 94% reductions in downy mildew were attained. Both components of the pre-mix product individually showed significant effect against downy mildew on onions among the trials reviewed. Ten trials were considered in the value assessment of BAS 650 00 F Fungicide efficacy claims for bulb vegetables. Downy mildew incidence was reduced by as much as 89% under high disease pressure. Yield benefits were also observed from BAS 650 00 F Fungicide applications with increases of almost 20%.

##### **5.1.1.3 Cucurbit Vegetables**

###### *Downy mildew*

Five field trials were presented in support of the value assessment of Zampro Fungicide efficacy claims for cucurbit vegetables. Under high disease pressure, reductions in downy mildew

severity reached 91% and 92% for the low and high rates of Zampro Fungicide, respectively. Both components of the pre-mix product showed significant activity against downy mildew in cucurbits. Up to 86% reductions of disease severity in cucumbers was obtained with ametoctradin alone.

Two field trials, one on cucumbers and one on cantaloupes, were presented in support of the BAS 650 00 F Fungicide efficacy claims against downy mildew for cucurbit vegetables. Downy mildew incidence was reduced by as much as 91% in cantaloupes when BAS 650 00 F Fungicide was applied at the recommended rate under moderately high disease pressure.

#### *Phytophthora blight*

A total of five trials were considered in the value assessment of Zampro Fungicide efficacy claims for bulb vegetables. Observed levels of disease control were as high as 100% under moderate to high disease pressure. Although direct evidence is not available to demonstrate the efficacy of both components individually, the claim has value in instances where downy mildew and phytophthora blight may be targeted by a single application of Zampro Fungicide.

No trials were available to directly demonstrate the efficacy of BAS 650 00 F Fungicide against phytophthora blight in cucurbits. However, in examining trials used in support of the same claim on the Zampro Fungicide label, applications of this product, which is a combination of ametoctradin and dimethomorph, generally result in higher levels of disease control compared to applications of dimethomorph alone. Therefore, this claim was supported in consideration of indirect evidence and of the fact that there are currently very few options available for the management of this disease.

#### **5.1.1.4 Fruiting Vegetables**

##### *Phytophthora blight*

Three trials were provided to demonstrate good efficacy on the part of Zampro Fungicide in reducing levels of phytophthora blight disease in fruiting vegetables. Under moderate to high disease pressure, disease was reduced by up to 62% following Zampro Fungicide applications. The level of disease reduction was comparable to the only currently registered standard, which had also been tested in the trials. In addition to the observed reductions in disease levels stemming from Zampro Fungicide applications, there was a significant increase in total and marketable yield associated with the treatment.

No trials were available to directly demonstrate the efficacy of BAS 650 00 F Fungicide against phytophthora blight in fruiting vegetables. However, this claim on the BAS 650 00 F Fungicide is supported for fruiting vegetables for the same reason as it was supported for the cucurbit crop group. The causal agents in both crop groups are identical and disease development is favoured under similar conditions. In addition, the labelled use patterns in both cases are also identical.

### *Late blight*

Four field trials and three greenhouse trials testing Zampro Fungicide on tomatoes were reviewed in support of the claim against late blight on fruiting vegetables. The maximum control levels observed in trials with high disease pressure ranged from 81-100%. Evidence of efficacy for both active ingredients in Zampro Fungicide was also provided by these trials.

A single trial on tomato along with five trials on potatoes testing BAS 650 00 F Fungicide were reviewed in support of the late blight claim for fruiting vegetables. Potatoes were deemed to be similar enough in terms of susceptibility and development to tomato plants and other members of the fruiting vegetable crop group to be considered relevant for support of this claim. Under high disease pressure, disease severity was reduced by up to 55% in the tomato trial and by an average of 84% in the potato trials following applications of BAS 650 00 F Fungicide.

Based on a common susceptibility of crops within the fruiting vegetables and their similarity in structure and production practices, the claim can be extended to the entire group based on the tomato and potato data for both products.

#### **5.1.1.5 Grapes**

##### *Downy mildew*

A total of eleven trials were considered in the value assessment of the Zampro Fungicide efficacy claim for downy mildew on grapes. Reductions in the severity of downy mildew often reached 100% in both leaves and fruits. For BAS 650 00 F Fungicide efficacy claims, two trials were considered in the value assessment of against downy mildew in grapes. Disease severity was reduced by up to 99% and 100% in the trials under moderate to high disease pressure.

#### **5.1.1.6 Hops**

##### *Downy mildew*

Six field trials were presented in support of the value assessment of Zampro Fungicide efficacy claim against downy mildew in hops. Under moderate to high disease pressure, downy mildew control was consistently high and reached up to 99%. Both components of the pre-mix product showed significant activity against downy mildew in hops. A single trial was submitted with direct evidence demonstrating the efficacy of BAS 650 00 F Fungicide against downy mildew on hops where applications of the product resulted in increases of 63 and 247% in healthy leaves and strobiles, respectively, relative to untreated control plants. This result was obtained under moderate disease pressure.



### **5.1.1.7 Lettuce, celtsuce, endive, radicchio, and upland cress**

#### *Downy mildew*

Seven field trials were considered in support of the Zampro Fungicide claim against downy mildew in lettuce and other leafy vegetables. The trials were conducted on various types of lettuce including head and leaf lettuce, Chinese leaf lettuce and romaine lettuce. The highest level of disease control observed for Zampro Fungicide treatments was 96% under high disease pressure. A total of three trials were submitted to support this claim on BAS 650 00 F Fungicide. Although levels of disease control resulting from ametoctradin alone were variable in the submitted trials, there was adequate evidence to support a claim of downy mildew suppression on lettuce and other leafy vegetables. Support was based on a maximum reduction level of 79% from applications of BAS 650 00 F Fungicide along with the superior performance of combined applications of dimethomorph and ametoctradin (i.e. Zampro Fungicide) compared to dimethomorph alone in the trials submitted for support of the Zampro Fungicide claim.

### **5.1.1.8 Potatoes**

#### *Late blight and tuber blight*

Thirteen field trials were submitted and reviewed in support of efficacy claims for Zampro Fungicide against late blight. Applications of the recommended rates of Zampro Fungicide provided consistently significant reductions in disease severity and incidence assessed on upper leaves and whole plants under high disease pressure. Disease control was observed to reach 99% in a number of instances.

Among the submitted trials, assessments made in at least three trials were also supportive of the claim against tuber blight, a disease caused by the same pathogen as late blight. Reductions in the number of blighted tubers reached up to 91%. Excellent control of late blight was also demonstrated when BAS 650 00 F Fungicide was applied alone. Under very high disease pressure, as determined by foliar assessments, control of disease severity surpassed 90%. Yield benefits were also apparent where, for example, a 95% drop in lost yield was obtained following repeated applications of BAS 650 00 F Fungicide.

## **5.2 Phytotoxicity**

There are some concerns of possible phytotoxicity with the combined use of Zampro Fungicide with certain adjuvants on brassica leafy vegetables. Some level of phytotoxicity was observed in a few of the trials submitted. As a result, a statement is added to the Zampro Fungicide and BAS 650 00 F Fungicide labels disallowing the addition of non-ionic surfactants on brassica leafy vegetables. There are no concerns for crop tolerance when BAS 650 00 F Fungicide or Zampro Fungicide are used on the proposed crops and when label directions are followed.

### **5.3 Economics**

Registration of ametoctradin fungicides in the proposed labelled crops provides additional tools to vegetable and grape growers for control of economically important diseases. Growers in Canada will have access to a fungicide available to their U.S.A. and European counterparts. This allows Canadian growers to remain competitive in global markets.

### **5.4 Sustainability**

#### **5.4.1 Survey of Alternatives**

The chemical and other non-conventional/biological fungicidal active ingredients listed in Appendix I, Table 29, are found in products that are registered for control or suppression of diseases indicated on the Zampro Fungicide and BAS 650 00 F Fungicide labels. These registered alternatives are labelled for use on either an entire crop group or limited to certain crops within a listed crop group.

#### **5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management**

Cultural practices such as planting tolerant or resistant cultivars, crop rotations, cropping patterns, crop husbandry, and hygiene are important means to prevent disease development in crops. Zampro Fungicide and BAS 650 00 F Fungicide would not interfere with these preventative measures when used as recommended.

Determining when conditions are favourable for disease development is a fundamental tool for the effectiveness of any Integrated Pest Management (IPM) strategy. The use of degree day models and decision making tools make it possible to apply control tools, such as fungicides, only when required and at a time conducive to achieving maximum effectiveness. Field scouting and forecasting techniques provide information to the grower on when to start and when to adjust timings of applications. Scouting the fields for signs of diseases is an important tool for predicting outbreaks. Proper identification of diseases is crucial to successful control. Zampro Fungicide and BAS 650 00 F Fungicide, used as recommended, would not interfere with crop scouting or other observational measures used to identify diseases. Zampro Fungicide and BAS 650 00 F Fungicide should only be applied when environmental conditions favour disease development or the appropriate model indicates that preventative applications need to be applied.

### **5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance**

Isolates of grape downy mildew have been found outside of North America that are resistant to all fungicides within the same mode of action group as dimethomorph (group 40 - carboxylic acid amides). The degree of sensitivity to dimethomorph varies among populations.

Ametoctradin is a new mode of action fungicide. No resistance has been documented to this new fungicide. Based on studies indicating that the inheritance of resistance to group 40 fungicides appears to be recessive, the risk of resistance development to this group of fungicides is rated as low to moderate and can be managed by appropriate product use.

### **5.4.4 Contribution to Risk Reduction and Sustainability**

The use of Zampro Fungicide and BAS 650 00 F Fungicide fits well into an IPM program and are recommended for preventative use. Zampro Fungicide is systemic and an anti-sporulant resulting in periods of extended disease control when compared to protectant fungicides. The risk of oomycete diseases becoming tolerant to Zampro Fungicide is low to moderate, since it is comprised of two fungicides with different modes of action and overlapping spectra of controlled diseases. Furthermore, Zampro Fungicide is only recommended for use in rotation with other mode of action fungicides that are also effective against the target pathogens. Recommendations are made to consult with local advisory system recommendations to determine the best time for spray initiation, thus, preventing unnecessary application of the product.

## **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, i.e., persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, ametoctradin and its major transformation products M650F01, M650F02, M650F03 and M650F04 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:

Ametoctradin does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Appendix I, Table 28, for comparison with Track 1 criteria.

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

Ametoctradin does not form any major transformation products that meet all Track 1 criteria. See Appendix I, Table 28, for comparison with Track 1 criteria.

## **6.2 Formulants and Contaminants of Health or Environmental Concern**

During the review process, contaminants in the technical are compared against the list in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, 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:

Technical grade active ingredient, ametoctradin, and the end-use products, BAS 650 00 F Fungicide and Zampro Fungicide, do not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

The potential presence of impurities known to have, or suspected to have, health and/or environmental implications are also assessed in accordance with DIR98-04.

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

## **7.0 Summary**

### **7.1 Human Health and Safety**

The toxicology database submitted for ametoctradin is adequate to define the majority of toxic effects that may result from exposure to ametoctradin. Ametoctradin showed very low mammalian toxicity. Most of the studies were tested at or near the limit dose. There was no evidence of carcinogenicity in rats or mice after longer-term dosing. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies. Ametoctradin is not neurotoxic. In short-term and chronic studies on laboratory animals, there was no indication of target organ toxicity. The risk assessment ensures that the level of human exposure is well below the lowest dose at which no effects occurred in animal tests.

Mixers, loaders, applicators and workers entering treated fields are not expected to be exposed to levels of ametoctradin that will result in unacceptable risk when BAS 650 00 F Fungicide and Zampro Fungicide are used according to label directions. The personal protective equipment on the product label is adequate to protect workers. Risk to workers re-entering treated areas is not of concern provided that specified restricted entry intervals are observed.

The nature of the residue in plants and animals is adequately understood. The residue definition is ametoctradin in plant products, and is ametoctradin and the metabolite M650F06 in animal matrices. The proposed use of ametoctradin on tuberous and corm vegetables, bulb vegetables, leafy vegetables, Brassica vegetables, fruiting vegetables, cucurbit vegetables, grapes and hops does not constitute an unacceptable chronic dietary risk (food and drinking water) to any

segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend MRLs to protect human health. The PMRA recommends that the following MRLs be specified for residues of ametoctradin.

<b>Commodity</b>	<b>Recommended MRL (ppm)</b>
Crop Subgroup 1C – Tuberos and Corm Vegetables Subgroup	0.05
Crop Subgroup 3-07A – Bulb Onion Subgroup	1.5
Crop Subgroup 3-07B – Green Onion Subgroup	20
Crop Group 4 – Leafy Vegetables (except Brassica Vegetables) Group, except spinach	40
Spinach	50
Crop SubGroup 5A – Head and Stem Brassica Subgroup	9
Crop SubGroup 5B – Leafy Brassica Greens Subgroup	50
Crop Group 8-09 – Fruiting Vegetable Group	1.5
Crop Group 9 – Cucurbit Vegetables Group	3.0
Crop Group 13-07F – Small Fruit Vine Climbing Subgroup, except Fuzzy Kiwifruit	4.0
Raisins	8.0
Hops	10
Fat , meat and meatbyproducts of cattle, goats, hogs, horses, poultry and sheep; eggs, milk	0.02

## 7.2 Environmental Risk

Ametoctradin is non-persistent in soil and aquatic systems, is not mobile in the environment and is not expected to volatilize to the atmosphere. The transformation product M650F04 is persistent and may reach groundwater and surface water, however, it is unlikely to cause a risk to human health or the environment based on its toxicological profile. Ametoctradin presents a negligible risk to terrestrial organisms at the proposed use rates. Ametoctradin is not expected to pose a risk to aquatic invertebrates, amphibians or freshwater fish. Ametoctradin exposure can present a risk to freshwater algae and marine fish. In order to minimize the potential for spray drift exposure, no-spray buffer zones between the treated area and downwind aquatic areas will be required. The width of these spray buffer zones will be specified on the product label. No environmental risk was identified from exposure to ametoctradin’s major transformation products.

## 7.3 Value

The data submitted to register BAS 650 00 F Fungicide and Zampro Fungicide were sufficient in supporting the value of the products’ uses for control or suppression of water mould diseases on brassica leafy vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, grapes, hops, potatoes and certain leafy vegetables.

## **7.4 Unsupported Uses**

All uses were supported either as proposed or with amendments (see Appendix 1, Tables 30 and 31).

## **8.0 Proposed Regulatory Decision**

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Intium Fungicide Technical, Zampro Fungicide and BAS 650 00 F Fungicide, containing the technical grade active ingredient ametoctradin, for use on brassica leafy vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, hops, grapes and potatoes to control or suppress various diseases including downy mildew, late blight, and phytophthora blight.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.



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## List of Abbreviations

$\lambda$	wavelength
%	percent
°C	degree(s) Celsius
$\mu\text{g}$	microgram(s)
$\mu\text{L}$	microliter(s)
a.i.	active ingredient
ADI	acceptable daily intake
AR	applied radioactivity
ASAE	American Society of Agricultural Engineers
atm	atmosphere
ATPD	area treated per day
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
bw	body weight
BW	generic body weight
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CBI	confidential business information
cm	centimetre(s)
cm <sup>2</sup>	centimetre(s) squared
cm <sup>3</sup>	centimetre(s) cubed
d	day(s)
DACO	data code
DALA	day(s) after last application
DAT	day(s) after treatment
DFOP	double first-order in parallel
DFOS	double first-order in series
DNA	deoxyribonucleic acid
DT50	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT90	dissipation time 90% (the dose required to observe a 90% decline in concentration)
dw	dry weight
EC25	effective concentration on 25% of the population
EC50	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental exposure concentration
ELS	early life stage
EP	end-use product
ErC50	effective concentration on 50% of the population (effects on biomass)
ESI	electrospray ionization
EyC50	effective concentration on 50% of the population (effects on yield)
FDA	Food and Drugs Act
FIR	food ingestion rate



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FOMC	first-order multi compartment
fw	fresh weight
g	gram(s)
GAP	good agricultural practice
GS	growth stage
h	hour(s)
ha	hectare(s)
HAFT	highest average field trial
HCl	hydrogen chloride
HDPE	high density polyethylene
HPLC	high performance liquid chromatography
ID	identification
IORE	indeterminate order rate equation
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
KFOC	Freundlich organic carbon partition coefficient
kg	kilogram(s)
Kow	n-octanol-water partition coefficient
kPa	kilogram(s) Pascal
L	litre(s)
LC50	lethal concentration 50%
LD50	lethal dose 50%
LLNA	Local Lymph Node Assay
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR50	lethal rate 50%
m	metre(s)
m <sup>3</sup>	metre(s) cubed
M	mole(s)
MAS	maximum average score
max.	maximum
MB	Manitoba
mg	milligram(s)
min.	minimum
mL	millilitre(s)
m/l/a	mixer/loader/applicator
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
n	number of samples
N/A	not applicable
NAFTA	North American Free Trade Agreement
NaOH	sodium hydroxide
nm	nanometre(s)
NOAEL	no observed adverse effect level

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NOEC	no observed effect concentration
NOER	no observed effect rate
NZW	New Zealand white
OECD	Organization for Economic Co-operation and Development
ON	Ontario
Pa	Pascal
PBI	plantback interval
PCPA	Pest Control Products Act
PEI	Prince Edward Island
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
RQ	risk quotient
SC	suspension concentrate
SD	South Dakota
SFO	single first-order
Std. Dev.	standard deviation
STMdR	supervised trial median residues
STMR	supervised trial mean residues
t <sub>1/2</sub>	half-life
TGAI	technical grade active ingredient
T <sub>max</sub>	time to maximum concentration
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
U.S.A.	United States of America
US EPA	United States Environmental Protection Agency
UV	ultraviolet



## Appendix I Tables and Figures

**Table 1 Residue Analysis**

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Soil / Sediment	L0091	Ametoctradin	HPLC-MS/MS	0.01 mg/kg	1871082
		M650F01			1871076
		M650F02			
		M650F03			
Water	574/0	Ametoctradin	HPLC-MS/MS	0.05 µg/kg	1871085 2040808
	L0113	M650F01	HPLC-MS/MS	0.05 µg/kg	1871086 2040808
		M650F02			
		M650F03			
M650F04					
Plant	Method L0117 Enforcement method	Ametoctradin	HPLC-MS/MS	0.01 ppm: Wheat grain, potato, lettuce, orange, sunflower seed	1871607
	Method L0078	Ametoctradin	HPLC-MS/MS	0.01 ppm: Wheat grain, potato, lettuce, orange, sunflower seed	1871601
Animal	Method L0104 Enforcement method	Ametoctradin , M650F01 and M650F06	HPLC-MS/MS	0.01 ppm: Muscle, fat, liver, kidney, eggs, milk	1871604

**Table 2 Toxicity Profile of End-use Products Containing Ametoctradin  
(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 (Zampro Fungicide)
Oral (Acute toxic class method)  Wistar rats  PMRA# 1871682	<b>Moderate toxicity</b>  500 mg/kg bw < Female LD50 < 2000 mg/kg bw
Dermal  Wistar rats  PMRA# 1871684	<b>Low toxicity</b>  LD50 > 5000 mg/kg bw
Inhalation (nose/head only- exposure)  Wistar rats  PMRA# 1871686	<b>Low toxicity</b>  LC50 > 5.5 mg/L

<b>Study Type/Animal/PMRA #</b>	<b>Study Results (Zampro Fungicide)</b>
Skin Irritation NZW rabbits PMRA# 1871688	<b>Slightly irritating</b> MAS (24, 48 and 72 h) = 0.333/8
Eye Irritation NZW rabbits PMRA# 1871690	<b>Non-irritating</b> MAS (24, 48 and 72 h) = 0/110
Skin Sensitization (Local Lymph Node Assay) CBA Mice PMRA# 1871692	<b>Not a skin sensitizer</b>
<b>Study Type/Animal/PMRA #</b>	<b>Study Results (BAS 650 00 F Fungicide)</b>
Acute Oral Toxicity Wistar Rat PMRA# 1871863	<b>Low Toxicity</b> Female LD50 > 2000 mg/kg bw
Acute Dermal Toxicity Wistar Rat PMRA# 1871867	<b>Low Toxicity</b> LD50 > 5000 mg/kg bw
Acute Inhalation Toxicity Wistar Rat PMRA# 1871791	<b>Low Toxicity</b> LC50 > 5.1 mg/L
Eye Irritation NZW Rabbit PMRA# 1871871	<b>Non-Irritating</b> MAS (24, 48 and 72 h) = 0/110
Skin Irritation NZW Rabbit PMRA# 1871869	<b>Slightly Irritating</b> MAS (24, 48 and 72 h) = 0.78/8
Skin Sensitization (LLNA) CBA Mouse PMRA# 1871875	<b>Not a Skin Sensitizer</b>

<b>Study Type/Animal/PMRA #</b>	<b>Study Results (Zampro Fungicide)</b>
Skin Sensitization (Buehler Method)  Dunkin Hartley Guinea Pig  PMRA# 1871877	Not a Skin Sensitizer

**Table 3 Toxicity Profile of Technical Ametoctradin**  
(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)

<b>Study Type/Animal/PMRA #</b>	<b>Study Results</b>
Acute Oral Toxicity  Wistar Rat  PMRA# 1871101	Low Toxicity  Female LD50 > 2000 mg/kg bw
Acute Dermal Toxicity  Wistar Rat  PMRA# 1871104	<b>Low Toxicity</b>  LD50 > 2000 mg/kg bw
Acute Inhalation Toxicity  Wistar Rat  PMRA# 1871106	<b>Low Toxicity</b>  LC50 > 5.5 mg/L
Eye Irritation  NZW Rabbit  PMRA# 1871114	<b>Minimally Irritating</b>  MAS (24, 48 and 72 h) = 0.22/110
Dermal Irritation  NZW Rabbit  PMRA# 1871109	Minimally Irritating  MAS (24, 48 and 72 h) = 0.22/8
Skin Sensitization (LLNA)  CBA Mouse  PMRA# 1871117	<b>Not a Skin Sensitizer</b>
Skin Sensitization (Maximization Method)  Dunkin-Hartley Guinea Pig  PMRA# 1871118	<b>Not a Skin Sensitizer</b>  Challenge: 2/20 (grade 1) at 24 h, 0/20 at 48 h

Study Type/Animal/PMRA #	Study Results
Metabolism/Toxicokinetics (single oral)  PMRA# 1871092 PMRA# 1871093 PMRA# 1871094 PMRA# 1871097	<p><b>Absorption:</b> Ametoctradin was rapidly absorbed with a Tmax of 1-2 hours with saturation at the high dose. There were no gender-related differences.</p> <p><b>Distribution:</b> Absorbed ametoctradin was rapidly and widely distributed. The peak level in each organ appeared within 1-2 hours. Dose and gender did not have an effect. The highest tissue levels appeared in the liver, kidneys, thyroid, pancreas, as well as adipose tissue (low dose males), uterus (low dose females), adrenal glands, bone marrow and carcass (all at high dose). Bile cannulation revealed higher bile excretion in males (23 and 12% for males and females, respectively at 50 mg/kg bw and 11 and 3% at 500 mg/kg bw).</p> <p><b>Metabolism:</b> Ametoctradin is metabolized by terminal oxidation of the octyl side chain to the respective carboxylic acid followed by degradation of the carboxylic side chain comparable. In addition, conjugates of the oxidized metabolites with taurine or with glucuronic acid have been identified. In addition, conjugates of the oxidized metabolites with taurine or with glucuronic acid have been identified. The most frequently observed metabolite was M650F06 (8-13% of administered dose in bile and feces), however, as many four other metabolites reached 1-4% of the administered dose.</p> <p><b>Excretion:</b> Feces (<math>\geq 73\%</math> of the dose) and urine (<math>\leq 22\%</math> of the dose) were the major routes of excretion. The amount of radiolabelled exhaled air was negligible. The majority of the administered dose (<math>\geq 85\%</math>) was eliminated from the body within 48 hours post dosing in a gender independent excretion pattern. There was no evidence of bioaccumulation.</p>
28-d Dermal Toxicity  Wistar Rat  PMRA# 1871134	NOAEL = 1000 mg/kg bw/day  LOAEL not established. No treatment- related effects at any dose.
90-d Oral Toxicity (diet)  C57BL/6NCrl Mice  PMRA# 1871121	NOAEL = 1119 mg/kg bw/day  LOAEL not established. No treatment- related effects at any dose.
90-d Oral Toxicity (diet)  Wistar Rat  PMRA# 1871122	NOAEL = 1083 mg/kg bw/day  LOAEL not established. No treatment- related effects at any dose.
12 Month Oral Toxicity (diet)  Beagle  PMRA# 1871130	NOAEL = 848 mg/kg bw/day  LOAEL not established. No treatment- related effects at any dose.
18 Month Oral Toxicity (diet)  C578BL/ 6 J Rj Mice  PMRA# 1871158	NOAEL = 1543 mg/kg bw/day  LOAEL not established. No treatment- related effects at any dose.  <b>No evidence of carcinogenicity</b>

Study Type/Animal/PMRA #	Study Results
24 Month Oral Toxicity (diet) Wistar Rat PMRA# 1871152	NOAEL = 871 mg/kg bw/day LOAEL not established. No treatment- related effects at any dose. <b>No evidence of carcinogenicity</b>
2-Generation Reproductive Toxicity (diet) Wistar Rat PMRA# 1871165	Parental, Reproductive and Offspring toxicity NOAEL = 1000 (actual intake 939) mg/kg bw/day LOAEL not established. No treatment- related effects at any dose. <b>No evidence of sensitivity of the young.</b>
Developmental Toxicity (gavage) Himalayan Rabbit PMRA# 1871173	Maternal and Developmental Toxicity NOAEL = 1000 mg/kg bw/day LOAEL not established. No treatment- related effects at any dose.
Developmental Toxicity (gavage) Wistar Rat PMRA# 1871169	Maternal and Developmental Toxicity NOAEL = 1000 mg/kg bw/day LOAEL not established. No treatment- related effects at any dose.
<i>In Vitro</i> Bacterial Assay for Gene Mutation (Ames test) PMRA#1871139	Negative
<i>In Vitro</i> Chromosomal Aberration PMRA #1871142	Negative
<i>In Vitro</i> Mammalian Clastogenicity PMRA# 1871144	Negative
<i>In Vivo</i> Micronucleus Test in Rats PMRA# 1871147	Negative
<i>In Vivo</i> Micronucleus Test in Mice PMRA# 1871148	Negative
In Vivo Unscheduled DNA Synthesis PMRA# 1871150	Negative
Acute Neurotoxicity (gavage) Wistar rats PMRA 1757638	NOAEL = 2000 mg/kg bw LOAEL not established. No treatment- related effects at any dose.



Study Type/Animal/PMRA #	Study Results
Short-term Neurotoxicity (diet)  Wistar rats  PMRA 1871184	NOAEL = 921 mg/kg bw/day  LOAEL not established. No treatment- related effects at any dose.
Immunotoxicity (lymphocyte subpopulation analysis, NK cell activity and T-cell response) (diet)  C57BL/6 J Rj mice  PMRA# 1871099	NOAEL = 1956 mg/kg bw/day  LOAEL not established. No treatment- related effects at any dose.
<b>M650 F02 (metabolite)</b>	
<i>In Vitro</i> Bacterial Assay for Gene Mutation (Ames test)  PMRA# 1871204	Negative
In Vivo Micronucleus test in mice  PMRA# 1871198	Negative
<b>M650 F03 (metabolite)</b>	
<i>In Vitro</i> Bacterial Assay for Gene Mutation (Ames test)  PMRA# 1871205	Negative
<i>In Vitro</i> Mammalian Clastogenicity  PMRA# 1871203	Negative
<i>In Vitro</i> Chromosomal Aberration PMRA# 1871210	Negative
<i>In Vivo</i> Micronucleus Test in Mice  PMRA# 1871196	Negative
90-day oral toxicity (diet)  Wistar Rat  PMRA# 1871218	NOAEL = 943 mg/kg bw/day  LOAEL not established. No treatment- related effects at any dose.
<b>M650 F04 (metabolite)</b>	
<i>In Vitro</i> Bacterial Assay for Gene Mutation (Ames test)  PMRA# 1871204	Negative
<i>In vitro</i> gene mutation in mammalian cells  PMRA# 1871202	Negative
<i>In Vitro</i> Chromosomal Aberration  PMRA #1871207	Negative

Study Type/Animal/PMRA #	Study Results
90-day oral toxicity (diet) Wistar Rat PMRA# 1871221	NOAEL = 1034 mg/kg bw/day LOAEL not established. No treatment- related effects at any dose.

**Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Ametoctradin**

Exposure Scenario	Study	Point of Departure and Endpoint	CAF1 or Target MOE
Acute dietary	Not required.		
Repeated dietary	One year dog toxicity	NOAEL = 848 mg/kg bw/day (highest dose tested) No treatment related effects.	100
	ADI = 8.48 mg/kg bw/day		
Short and intermediate –term dermal	A quantitative risk assessment was not conducted.		
Short and intermediate-term inhalation <sup>2</sup>	90-day dog toxicity	NOAEL = 912 mg/kg bw/day (highest dose tested) No treatment related effects.	100
Cancer	Not required.		

- 1 CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational and residential assessments
- 2 Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

**Table 5 Integrated Food Residue Chemistry Summary**

NATURE OF THE RESIDUE IN LETTUCE		PMRA# 1871227
<b>Radiolabel Position</b>	2,7- <sup>14</sup> C-BAS 650F	
<b>Test Site</b>	Under natural climatic conditions without the influence of rain, in individual pots.	
<b>Treatment</b>	Foliar treatment	
<b>Rate</b>	3 x 223 g a.i./ha; total rate of 669 g a.i./ha	
<b>End-use product</b>	Suspension concentrate (SC) formulation	
<b>Preharvest interval</b>	7 days	
<b>Matrix</b>	<b>PHI (days)</b>	2,7- <sup>14</sup> C-BAS 650F
		<b>TRR (ppm)</b>
Leaves	7	8.486
<b>Metabolites Identified</b>	<b>Major Metabolites (&gt;10% TRR)</b>	<b>Minor Metabolites (&lt;10% TRR)</b>
Lettuce leaves	Ametoctradin	None
<p>The extractability of the radioactive residues with methanol and water was very high, 99.3% of the TRRs could be extracted. Most of the radioactive residues (98.9% of the TRRs) were extracted with methanol, and only a minor portion (0.4% of the TRRs) was extracted with water. Because of the high extractability, the post extraction residues (0.7% of the TRRs) were not further characterized.</p> <p>In the combined methanol extract of lettuce leaves, ametoctradin was the only component, accounting for 8.39 ppm (98.9% of the TRRs). The identification was performed by HPLC as well as HPLC-ESI-MS/MS analyses.</p>		

NATURE OF THE RESIDUE IN TOMATO		PMRA# 1871228
<b>Radiolabel Position</b>	2,7- <sup>14</sup> C-BAS 650F	
<b>Test Site</b>	In individual pots in greenhouse.	
<b>Treatment</b>	Foliar treatment	
<b>Rate</b>	3 x 300 g a.i./ha; total rate of 900 g a.i./ha	
<b>End-use product</b>	SC formulation	
<b>Preharvest interval</b>	1 day	
<b>Matrix</b>	<b>PHI (days)</b>	2,7- <sup>14</sup> C-BAS 650F
		<b>TRR (ppm)</b>
Leaves	1	9.159
Fruits	1	0.360
<b>Metabolites Identified</b>	<b>Major Metabolites (&gt;10% TRR)</b>	<b>Minor Metabolites (&lt;10% TRR)</b>
Tomato leaves	Ametoctradin	None
Tomato fruits	Ametoctradin	None
<p>The extractability of the radioactive residues with methanol and water was very high for tomato leaves and tomato fruits (99.4% and 99.3% of the TRRs, respectively). Most of the radioactive residues of both tomato matrices were extracted with methanol, while only minor portions were extracted with water (&lt;1.0% of the TRRs). From tomato leaves, a portion of 98.6% of the TRRs was extracted with methanol, and additional 0.8% of the TRRs were extracted with water. In the case of tomato fruits, 99.1% of the TRRs were extracted with methanol and 0.2% of the TRRs were extracted with water. The residual radioactive residues after solvent extraction (0.6% of the TRRs in tomato leaves and 0.7% of the TRRs in ripe tomato fruits) were not further characterized.</p> <p>In the combined methanol extracts of tomato leaves and tomato fruits, ametoctradin was the only component detected, accounting for 9.04 ppm (98.6% of the TRRs) and 0.36 ppm (99.1% of the TRRs), respectively. The identification was performed by HPLC analyses and co-chromatography investigations.</p>		
NATURE OF THE RESIDUE IN POTATO		PMRA# 1871231
<b>Radiolabel Position</b>	2,7- <sup>14</sup> C-BAS 650F	
<b>Test Site</b>	Under natural climatic conditions without the influence of rain, in individual pails.	
<b>Treatment</b>	Foliar treatment	
<b>Rate</b>	3 x 441 g a.i./ha; total rate of 1.322 kg a.i./ha	
<b>End-use product</b>	SC formulation	
<b>Preharvest interval</b>	7 days	
<b>Matrix</b>	<b>PHI (days)</b>	2,7- <sup>14</sup> C-BAS 650F
		<b>TRR (ppm)</b>
Immature leaves	-14 (right after 2 <sup>nd</sup> application)	21.355
Immature tubers		0.026
Potato leaves	7	48.390
Potato tubers		0.048
<b>Metabolites Identified</b>	<b>Major Metabolites (&gt;10% TRR)</b>	<b>Minor Metabolites (&lt;10% TRR)</b>
Immature leaves	Ametoctradin	M650F01 and /or M650F04, M650F03, M650F18
Immature tubers	Ametoctradin, M650F03	None
Potato leaves	Ametoctradin	M650F01 and M650F04, M650F03, M650F13 & M650F14, M650F18, M650F28
Potato tubers	M650F03, M650F04	Ametoctradin

The total radioactive residues in potato immature leaves (growth stage 43/44) sampled 14 days prior to the last treatment (immediately after the 2<sup>nd</sup> application) accounted for 22.117 ppm. In potato mature leaves at growth stage 93 (7 DAT), the radioactive residues were 44.741 ppm. In potato tubers, the residue levels were significantly lower, accounting for 0.025 ppm (growth stage 43/44) and 0.041 ppm (growth stage 93). The extractability of the radioactive residues with methanol and water was very high for potato leaves at both growth stages 43/44 and 93 (99.0 and 99.1% of the TRRs, respectively), and high for potato tubers at growth stage 43/44 as well as at GS 93 (92.4 and 88.7% of the TRRs, respectively), and bound residues were very low.

In potato **leaves** at GS 43/44 and GS 93, about 95% (21.028 ppm) and 85% (37.992 ppm) of the TRRs were identified as ametoctradin, respectively, indicating negligible or very little metabolism occurring in the foliage of the plant. A number of minor components, i. e., M650F01, M650F03, M650F04; M650F13 (or isomer), M650F14 (or isomer), M650F18 (or isomer) and M650F28 (or isomer) as well as unidentified polar and medium polar derivatives of ametoctradin were detected in potato leaves, but no single component present exceeded 2% of the TRRs.

In potato immature **tubers** at GS 43/44, sampled 14 days prior to the last treatment (immediately after the 2<sup>nd</sup> application), 67.3% of the TRRs (0.017 ppm) was detected as ametoctradin in potato tubers. Metabolite M650F03 (13.1% of the TRRs or 0.003 ppm) and trace amounts of unknown polar derivatives (two components each <7.5% of the TRRs or 0.002 ppm) accompanied ametoctradin. In comparison, at 7 days after the last treatment, M650F03 (39.5% of the TRRs or 0.016 ppm) became the major component in potato tubers at GS 93 together with M650F04 (27.3% of the TRRs or 0.011 ppm), and only very small amounts of ametoctradin were detectable (3.6% of the TRRs or 0.001 ppm).

Since low levels of metabolites M650F03 and M650F04 were found in tubers and not in directed leaves and fruits, it is assumed that these metabolites are taken up from the soil. The results obtained for potato tubers were explained as follows:

- Metabolites M650F03 and M650F04 are well-known from soil degradation studies,
- Until the first sampling, a little metabolism of ametoctradin occurred in the soil resulting in minor amounts of M650F03, which along with a part of ametoctradin translocated to the tubers.
- Until the last sampling, ametoctradin was almost completely converted (because of the additional time for metabolism to occur) to M650F03 and M650F04. The latter metabolites were the major components present in the soil for uptake into the tubers.

**The metabolism of ametoctradin in three diverse crops (lettuce, tomato and potato) are similar. No metabolic pathway is proposed since ametoctradin was the only residue found in treated leaves and fruits. As metabolites M650F03 and M650F04 (observed in potato tubers only) are of no toxicological concern, the residue definition in plants is ametoctradin.**

CONFINED ACCUMULATION IN ROTATIONAL CROPS –		PMRA# 1871740	
Lettuce, radish, wheat			
Radiolabel Position		2,7- <sup>14</sup> C-BAS 650F	
Test site		The crops were grown in plastic containers under natural climatic conditions without the influence of rain in a glass roofed vegetation hall, in phytotrons or in the glass house depending on the climatic conditions outside.	
Formulation used for trial		SC formulation	
Application rate and timing		Soil was treated at 1440 g a.i./ha and aged for 30, 120 and 365 days.	
Metabolites Identified		Major Metabolites	Minor Metabolites
Matrix	PBI (days)	(>10% TRR)	(<10% TRR)
Lettuce (immature)	30	M650F03	M650F04, M650F29/30, M650F32, M650F33, M650F37/38, M650F39
Lettuce (mature)	30	Ametoctradin, M650F03	M650F04, M650F29/30, M650F32, M650F33, M650F37/38, M650F39
Radish tops	30	M650F03	M650F04, M650F29/30, M650F32,

			M650F39
Radish roots	30	M650F03	M650F04
Wheat straw	30	M650F03, M650F04	Ametoctradin, M650F29/30, M650F32, M650F33, M650F37/38, M650F39
Wheat chaff	30	M650F03, M650F04	M650F29/30, M650F32, M650F33, M650F37/38, M650F39
Wheat grain	30	M650F03, M650F04	M650F29/30, M650F33
Lettuce (immature)	120	M650F03, M650F04	M650F29/30, M650F32, M650F33, M650F37/38, M650F39
Lettuce (mature)	120	M650F04	M650F03, M650F29/30, M650F32, M650F33, M650F37/38, M650F39
Radish tops	120	M650F03	M650F04, M650F29/30, M650F39
Radish roots	120	M650F03, M650F04	--
Wheat forage	120	M650F03, M650F04	Ametoctradin, M650F29/30, M650F32, M650F37/38, M650F39
Wheat straw	120	M650F03, M650F04	Ametoctradin, M650F29/30, M650F32, M650F33, M650F37/38, M650F39
Wheat chaff	120	M650F04	M650F03, M650F29/30, M650F32, M650F37/38, M650F39
Wheat grain	120	M650F04	M650F03, M650F29/30, M650F37/38
Lettuce (immature)	365	M650F04	M650F03, M650F32, M650F37/38, M650F39
Lettuce (mature)	365	M650F04	M650F03, M650F29/30, M650F32, M650F37/38, M650F39
Radish tops	365	M650F03	M650F04, M650F29/30, M650F37/38, M650F39
Radish roots	365	M650F03, M650F04	M650F32, M650F33, M650F37/38, M650F39
Wheat forage	365	M650F03, M650F04	M650F29/30, M650F37/38, M650F39
Wheat straw	365	M650F03, M650F04	M650F29/30, M650F32, M650F37/38, M650F39
Wheat chaff	365	M650F04	M650F03, M650F29/30, M650F32, M650F33, M650F37/38, M650F39
Wheat grain	365	M650F04	M650F03

In rotational crop matrices (lettuce, radish and wheat) investigated, no or only traces of ametoctradin were detected. The main metabolites detected in all crops and matrices were M650F03 and M650F04, which are known from soil degradation studies. It is most likely that the major transformation steps occurred in the soil before translocation to the plants.

The proposed metabolic pathway of ametoctradin in rotational crops involves a terminal oxidation of the octyl side chain of the parent molecule to the respective carboxylic acid, followed by a shortening of the carboxylic side chain (loss of 3 x C<sub>2</sub>-unit analogous to the  $\beta$ -oxidation of fatty acids) to produce metabolite M650F03. Subsequent conjugation of M650F03 with glucose led to the formation of metabolite M650F29, while decarboxylation formed metabolite M650F39. Further transformation of the latter metabolite via oxidation (analogous to the  $\omega$ -oxidation of fatty acids) generated metabolites M650F32, M650F33 and M650F04, respectively. Metabolite M650F04 could also be formed via an  $\alpha$ -oxidation of the carboxylic side chain of M650F03. Hydroxylation of the ethyl side chain of M650F04 followed by an intramolecular esterification produced metabolites M650F37 and M650F38, respectively, while conjugation of M650F04 with glucose formed metabolite M650F30.

NATURE OF THE RESIDUE IN LAYING HEN		PMRA# 1871234, 1871237
Nine laying hens were dosed orally with 2,7- <sup>14</sup> C-BAS 650F at 0.81 mg/kg bw/day (corresponding to 11.5 ppm in feed) by gavage once daily for 10 days. The hens were euthanized 23 hours after administration of the final dose.		
Radiolabel Position	2,7- <sup>14</sup> C-BAS 650F	
Matrices	% of Administered Dose	
Excreta	91.31%	
Muscle	0.06% (0.026 ppm)	
Fat	0.00% (0.014 ppm)	
Liver	0.03% (0.112 ppm)	
Eggs	0.09% (0.040 ppm)	
Metabolites identified	Major Metabolites (>10% TRR)	Minor Metabolites (<10% TRR)
Muscle	None	M650F01, M650F06
Fat	Ametoctradin, M650F01	None
Liver	None	M650F01, M650F06
Eggs	Ametoctradin	None
NATURE OF THE RESIDUE IN LACTATING GOAT		PMRA # 1871242, 1871244
Two lactating goats were dosed orally with 2,7- <sup>14</sup> C-BAS 650F at 0.49-0.51 mg/kg bw/day (corresponding to 12 ppm in feed) by gavage once daily for 10 days. The goats were euthanized ~23 hours after administration of the final dose.		
Radiolabel Position	2,7- <sup>14</sup> C-BAS 650F	
Matrices	% of Administered Dose	
Urine and feces	60.32 – 83.88%	
Muscle	0.02% (0.010 ppm)	
Fat	0.00% (0.016 ppm)	
Kidney	0.00% (0.036 ppm)	
Liver	0.03% (0.100 ppm)	
Milk	0.15% (0.097 ppm)	
Metabolites identified	Major Metabolites (>10% TRR)	Minor Metabolites (<10% TRR)
Muscle	None	None
Fat	M650F01, M650F06	M650F09
Kidney	M650F01, M650F06	M650F09
Liver	M650F01, M650F06	None
Milk	M650F01, M650F06	M650F09
Proposed Metabolism in Livestock		
<p>Ametoctradin was found only in eggs and fat of poultry. Metabolites M 650F01, M650F06 and M650F09 were found in other tissues of animal origin at various levels. The metabolic pathways in goat, hen and rat are similar. Ametoctradin is in large part metabolized by oxidation of the aliphatic side chain to the respective terminal carboxylic acid and subsequent stepwise oxidative cleavage of the side chain (loss of C2-units) analogous to the <math>\beta</math>-oxidation of fatty acids.</p>		
<p><b>The metabolism of ametoctradin in animals is adequately documented. The residue definition in animals is ametoctradin and metabolite M650F06.</b></p>		
FREEZER STORAGE STABILITY		PMRA# 1871617
Ametoctradin residues were shown to be stable at -20°C for up to 24 months in wheat grain, lettuce, potato and grape, and for up to 16 months in tomato.		

CROP FIELD TRIALS - Potato							PMRA# 187177			
Twenty-one trials were conducted on potato in NAFTA Growing Regions 1, 2, 3, 5, 7A, 9, 10, 11, 12 and 14 at a total rate of 0.88-1.2 kg a.i./ha/season (~1X GAP).										
Residue decline samples were harvested at 0, 1, 4, 7 and 10 days after last application (DALA). No discernible trend could be observed since all treated potato samples showed very low residues ( $\leq 0.01$ -0.02 ppm).										
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Ametoctradin Residue Levels (ppm)							
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.	
Potato	884-1195	4	42	<0.01	0.05	0.04	0.01	0.01	0.01	
CROP FIELD TRIALS - Bulb vegetables							PMRA# 1871722			
Thirteen trials were established on dry bulb onions (ten trials) and green onions (three trials), the representative crops of Crop Group 3. Trials were conducted in NAFTA Growing Regions 1, 5, 6, 8, 10, 11 and 12 at a total trial rate of 0.89-0.98 kg a.i./ha/season (1X GAP).										
Residue decline samples were harvested at 0, 1-2, 3, 7 and 10 DALA. Mean residues in treated samples decreased from 0.28 ppm at 0 DALA to 0.12 ppm at 10 DALA in dry bulb onions, and from 5.50 ppm at 0 DALA to 2.55 ppm at 10 DALA in green onions.										
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Ametoctradin Residue Levels (ppm)							
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.	
Dry bulb onion	891-977	0	20	0.06	0.85	0.84	0.21	0.28	0.22	
Green onion	899-931	0	6	3.05	11.13	9.11	4.04	5.50	3.10	
CROP FIELD TRIALS - Leafy vegetables							PMRA# 1871713			
Thirty-four trials were established on leaf lettuce (nine trials), head lettuce (eight trials), spinach (eight trials) and celery (nine trials), the representative crops of Crop Group 4. Trials were conducted in NAFTA Growing Regions 1, 1A, 2, 3, 5, 6, 9, 10 and 12 at a total rate of 0.89-0.94 kg a.i./ha/season (1X GAP).										
Residue decline samples were harvested at 0, 1, 3-4, 7 and 10 DALA. Mean residues in treated samples decreased from 10.01 ppm at 0 DALA to 3.04 ppm at 10 DALA in leaf lettuce, from 4.13 ppm at 0 DALA to 1.60 ppm at 10 DALA in head lettuce, from 16.02 ppm at 0 DALA to 5.05 ppm at 10 DALA in spinach, and from 5.42 ppm at 0 DALA to 1.70 ppm at 10 DALA in celery.										
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Ametoctradin Residue Levels (ppm)							
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.	
Leaf lettuce	896-924	0	18	2.73	19.51	17.86	8.93	10.01	5.67	
Head lettuce	895-916	0	16	2.45	6.63	6.17	3.84	4.13	1.39	
Spinach	890-939	0	16	4.99	34.06	34.02	14.11	16.02	8.34	
Celery	896-922	0	18	1.78	11.18	10.68	4.90	5.42	2.45	
CROP FIELD TRIALS - Brassica vegetables							PMRA# 1871726			
Twenty-seven trials were established on broccoli (ten trials), cabbage (ten trials), and mustard greens (seven trials), the representative crops of Crop Group 5. Trials were conducted in NAFTA Growing Regions 1, 2, 3, 5, 5A, 6, 8, 10 and 12 at a total rate of 0.88-0.96 kg a.i./ha/season (1X GAP).										
Residue decline samples were harvested at 0, 1, 3, 7 and 10 DALA. Mean residues in treated samples decreased from 1.73 ppm at 0 DALA to 0.60 ppm at 10 DALA in broccoli, from 2.10 ppm at 0 DALA to 1.30 ppm at 10 DALA in cabbage, and from 16.62 ppm at 0 DALA to 6.25 ppm at 10 DALA in mustard greens.										
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Ametoctradin Residue Levels (ppm)							
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.	
Broccoli	891-962	0	20	<0.01	3.22	3.03	1.64	1.73	0.90	

Cabbage	889-907	0	20	0.25	7.07	6.19	1.62	2.10	1.68
Mustard greens	882-902	0	14	5.15	29.22	27.81	14.85	16.62	7.45
<b>CROP FIELD TRIALS - Fruiting vegetables</b>						<b>PMRA# 1871724</b>			
Thirty trials were established on tomatoes (twenty trials, including two on cherry tomato varieties), bell peppers (seven trials), and non-bell peppers (three trials), the representative crops of Crop Group 8. Trials were conducted in NAFTA Growing Regions 1, 2, 3, 5, 5A, 6 and 8 at a total rate of 0.88-0.93 kg a.i./ha/season (1X GAP).									
Residue decline samples were harvested at 4, 10 and 14 DALA. Mean residues in treated samples decreased from 0.23 ppm at 4 DALA to 0.16 ppm at 14 DALA in tomato, from 0.23 ppm at 4 DALA to 0.97 ppm at 14 DALA in bell peppers, and from 0.42 ppm at 4 DALA to 0.23 ppm at 14 DALA in non-bell peppers.									
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Ametoctradin Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Tomato	880-930	4	40	0.03	0.83	0.71	0.18	0.23	0.19
Pepper (bell)	883-933	4	14	0.04	0.98	0.84	0.14	0.23	0.28
Pepper (non-bell)	881-928	4	6	0.12	0.79	0.69	0.43	0.42	0.27
<b>CROP FIELD TRIALS – Cucurbit vegetables</b>						<b>PMRA# 1871728</b>			
Twenty-six trials were established on cucumbers (eight trials), cantaloupe (eight trials), summer squash (five trials) and winter squash (five trials), the representative crops of Crop Group 9. Trials were conducted in NAFTA Growing Regions 1, 2, 3, 5, 6, 10 and 12 at a total rate of 0.89-0.93 kg a.i./ha/season (1X GAP).									
Residue decline samples were harvested at 0, 1, 3, 7 and 10 DALA. Mean residues in treated samples decreased from 0.12 ppm at 0 DALA to 0.03 ppm at 10 DALA in cucumber, from 0.76 ppm at 0 DALA to 0.34 ppm at 10 DALA in cantaloupe, from 0.53 ppm at 0 DALA to 0.15 ppm at 10 DALA in summer squash, and from 0.43 ppm at 0 DALA to 0.24 ppm at 10 DALA in winter squash.									
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Ametoctradin Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Cucumber	885-918	0	15	0.04	0.32	0.24	0.11	0.12	0.07
Cantaloupe	896-930	0	16	0.08	1.73	1.71	0.65	0.76	0.50
Summer squash	885-918	0	10	0.07	1.16	1.12	0.37	0.53	0.41
Winter squash	885-907	0	10	0.04	1.25	1.23	0.34	0.43	0.45
<b>CROP FIELD TRIALS - Grapes</b>						<b>PMRA# 1871715</b>			
Thirteen trials were conducted on grapes in NAFTA Growing Regions 1, 5, 10, 11 and 12 at a total rate of 1.18-1.24 kg a.i./ha/ season (1X GAP).									
Residue decline samples were harvested at 0, 7, 14-15, 26-28 and 35 days after last application (DALA). Mean residues in treated grape samples decreased from 1.13 ppm at 0 DALA to 0.85 ppm at 35 DALA.									
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Ametoctradin Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Grape	1180-1240 (dilute spray)	14-15	13	0.19	1.60	1.60	0.91	0.91	0.42
Grape	1180-1220 (concentrated spray)	14-15	13	0.10	2.17	2.17	0.49	0.70	0.62
<b>CROP FIELD TRIALS - Hops</b>						<b>PMRA# 1871719</b>			
Three trials were conducted on hops in NAFTA Growing Regions 11 and 12 at a total rate of 0.90-0.95 kg a.i./ha/ season (1X GAP).									
Residue decline samples were harvested at 0, 3, 7, 10 and 14 DALA. Mean residues in treated hop samples decreased from 3.47 ppm at 0 DALA to 2.15 ppm at 14 DALA.									



Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Ametoctradin Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Hops	898-914 (dilute spray)	7	3	0.96	2.38	2.38	1.65	1.66	0.71
Hops	907-947 (concentrated spray)	7	3	0.82	4.63	4.63	2.42	2.62	1.91
<b>RESIDUE DATA IN ROTATIONAL CROPS</b>						<b>PMRA# 1871742</b>			
Six trials (two each for radish, lettuce and winter wheat) were conducted during the 2008-2009 growing seasons in NAFTA Growing Regions 2 and 10.									
Commodity	Total Application Rate (g a.i./ha)	PBI (days)	Ametoctradin Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Wheat forage	900	30-120	4	<0.01	<0.01	<0.01	<0.01	<0.01	--
Wheat hay	900	30-120	4	<0.01	<0.01	<0.01	<0.01	<0.01	--
Wheat grain	900	30-120	4	<0.01	<0.01	<0.01	<0.01	<0.01	--
Wheat straw	900	30-120	4	<0.01	<0.01	<0.01	<0.01	<0.01	--
Radish tops	900	30-120	4	<0.01	<0.01	<0.01	<0.01	<0.01	--
Radish root	900	30-120	4	<0.01	<0.01	<0.01	<0.01	<0.01	--
Lettuce leaves	900	30-120	4	<0.01	<0.01	<0.01	<0.01	<0.01	--
<b>PROCESSED FOOD AND FEED - Grape</b>						<b>PMRA# 1871735</b>			
<b>Test Site</b>	Four trials in Germany								
<b>Treatment</b>	Broadcast foliar application								
<b>Rate</b>	Four applications at 1.04-1.19 kg a.i./ha/application for a total rate of 4.19-4.72 kg a.i./ha/season								
<b>End-use product</b>	SC formulation								
<b>Preharvest interval</b>	20 days								
<b>Processed Commodity</b>	<b>Processing Factor</b>								
Wet pomace	3.5x								
Juice	0.35x								
Wine	<0.1x								
Raisins	3.7x								
<b>PROCESSED FOOD AND FEED - Potato</b>						<b>PMRA# 1871730</b>			
<b>Test Site</b>	Four trials in Germany								
<b>Treatment</b>	Broadcast foliar application								
<b>Rate</b>	Six applications at 720 g a.i./ha/application for a total rate of 4.32 kg a.i./ha/season								
<b>End-use product</b>	SC formulation								
<b>Preharvest interval</b>	7 days								
<b>Processed Commodity</b>	<b>Processing Factor</b>								
Chips	Ametoctradin residues were <0.01 ppm in potato tuber and all processed commodities. No processing factors could be derived for ametoctradin in potato processed fractions.								
Flakes									
Microwave-boiled potatoes									
Peel									
Peeled potato									
Fried potato									
Cooked potato									

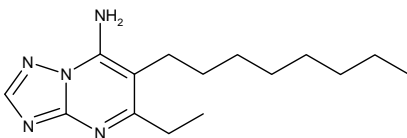
<b>PROCESSED FOOD AND FEED - Tomato</b>		<b>PMRA# 1871733</b>
<b>Test Site</b>	Four trials in Germany	
<b>Treatment</b>	Broadcast foliar application	
<b>Rate</b>	Three applications at 900 g a.i./ha/application for a total rate of 2.7 kg a.i./ha/season	
<b>End-use product</b>	SC formulation	
<b>Preharvest interval</b>	1 day	
<b>Processed Commodity</b>	<b>Processing Factor</b>	
Canned tomatoes	0.02x	
Paste	0.41x	
Peeled tomatoes	0.02x	
Puree	0.83x	
Tomato peel	5.8x	
Washed tomatoes	0.25x	
Wet pomace	1.27x	
<b>LIVESTOCK FEEDING – Dairy cattle</b>		<b>PMRA# 2020589</b>
<p>A cow feeding study was conducted at feeding levels of 3, 8 and 30 ppm. The results showed that all residues of ametoctradin at all feeding levels were <math>\leq</math>LOQ (<math>\leq</math>0.01 ppm) in milk, muscle and fat. Quantifiable residues of metabolite M650F06 were seen in liver (0.041 ppm) and kidney (0.018 ppm) only at the highest feeding level of 30 ppm.</p> <p>Potato culls is the only animal feed item for which there is a proposed use of ametoctradin. Maximum residues in potato tubers were 0.05 ppm in the field trials (1x GAP) and were <math>\leq</math>0.01 ppm in potato tubers and all processed commodities in the processing studies (~5x GAP). Considering that no significant residues are expected in livestock feed from the proposed use of ametoctradin, there is no expectation of quantifiable residues in animal commodities.</p>		

**Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment**

<b>PLANT STUDIES</b>	
<b>RESIDUE DEFINITION FOR ENFORCEMENT</b> Primary crops Rotational crops	Ametoctradin Ametoctradin
<b>RESIDUE DEFINITION FOR RISK ASSESSMENT</b> Primary crops Rotational crops	Ametoctradin Ametoctradin
<b>METABOLIC PROFILE IN DIVERSE CROPS</b>	Similar
<b>ANIMAL STUDIES</b>	
<b>ANIMALS</b>	<b>Ruminant and poultry</b>
<b>RESIDUE DEFINITION FOR ENFORCEMENT</b>	Ametoctradin and M650F06
<b>RESIDUE DEFINITION FOR RISK ASSESSMENT</b>	Ametoctradin and M650F06
<b>METABOLIC PROFILE IN ANIMALS</b> (goat, hen, rat)	Similar
<b>FAT SOLUBLE RESIDUE</b>	No
<b>DIETARY RISK FROM FOOD AND WATER</b>	

	POPULATION	ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)	
		Food Only	Food and Water
		<b>Basic chronic non-cancer dietary risk</b>  <b>ADI = 8.5 mg/kg bw/day</b>  <b>Estimated chronic drinking water concentration = 0.63 µg a.i./L</b>	<b>All infants &lt; 1 year</b>
<b>Children 1–2 years</b>	0.5		0.5
<b>Children 3 to 5 years</b>	0.4		0.4
<b>Children 6–12 years</b>	0.3		0.3
<b>Youth 13–19 years</b>	0.2		0.2
<b>Adults 20–49 years</b>	0.3		0.3
<b>Adults 50+ years</b>	0.3		0.3
<b>Females 13 to 49 years</b>	0.3		0.3
<b>Total population</b>	0.3		0.3

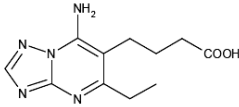
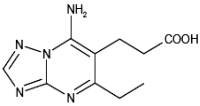
**Table 7 Physical and Chemical Properties of the Active Ingredient Ametoctradin Relevant to the Environment**

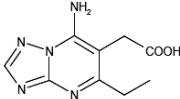
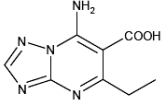
Property	Result	Comment
Active Substance	BAS 650 F Technical; ametoctradin, Initium Technical fungicide	
Function	Fungicide	
Chemical name:		
International Union of Pure and Applied Chemistry (IUPAC)	5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7 amine	
Chemical Abstract Services (CAS)	[1,2,4]triazolo-[1,5-a]pyrimidin-7-amine, 5-ethyl-6-octyl	
CAS Number:	865318-97-4	
Molecular Formula	C <sub>15</sub> H <sub>25</sub> N <sub>5</sub>	
Molecular Weight	275.4 g/mol	
Structural Formula		
Isomers	None.	
Physical state	Solid	
Density	1.12 g/cm <sup>3</sup>	
pH	pH of pure water: 5.6 pH of CIPAC water D: 6.3 pH at 0.13 mg/L in pure water: 5.9 pH at 0.13 mg/L in CIPAC water D: 6.2 pH at 1.0 % in pure water: 5.8 pH at 1.0 % in CIPAC water D: 6.4	No significant change in pH after accelerated storage at 54 °C for 14 days.

Property	Result	Comment
Vapour pressure at 20°C	$2.1 \times 10^{-10}$ Pa	Relatively non-volatile under field conditions (Kennedy and Talbert, 1977).
Henry's law constant at 20°C	$H = 4.13 \times 10^{-10}$ kPa*m <sup>3</sup> *mol <sup>-1</sup> (= $4.08 \times 10^{-12}$ atm*m <sup>3</sup> *mol <sup>-1</sup> ); $1/H = 6.0 \times 10^9$	Not likely to volatilize from water or moist soil (US EPA 1975).
Ultraviolet (UV) / visible spectrum	<u><math>\lambda_{\max}</math> (nm): Not provided.</u> UV molecular extinction $\epsilon$ [l mol <sup>-1</sup> cm <sup>-1</sup> ]:  Methanol pure, pH 7.6: 16611 at 221 nm 13113 at 295 nm  Methanol : Water = 1 : 99, pH 7.2: 26485 at 217 nm 9861 at 294 nm  Methanol : HCl : Water = 1 : 10 : 89, pH 1.0: 29557 at 218 nm 14288 at 295 nm  Methanol : NaOH : Water = 1 : 10 : 89, pH 12.5: 12107 at 224 nm 9977 at 295 nm	Limited potential to photodegrade in the visible range (maximum absorption spectra at 221 – 295 nm in methanol: water).
Solubility (mg/L) in water at 20°C	Neutral/near neutral deionized water: 0.14 Aqueous buffers pH 4: 0.23 pH 7: 0.15 pH 9: 0.20	Sparingly soluble in water.
Solubility (g/L) in organic solvents at 20°C	Solvent solubility in [g/100 ml] solution solvent Methanol 0.71 0.72 Toluene 0.01 0.01 n-Heptane <0.001 <0.001 Ethylacetate 0.08 0.08 Dichloromethane 0.31 0.30 Acetone 0.18 0.19 Acetonitrile 0.05 0.05 Dimethyl sulfoxide 1.08 1.07	Solubility generally increases with increasing organic solvent polarity.
n-Octanol/water partition coefficient (log K <sub>ow</sub> )	neutral: 4.40 buffered pH 4: 4.24 buffered pH 9: 4.18	Potential for bioaccumulation.

Property	Result	Comment
Dissociation constant (pK <sub>a</sub> )	2.78	The low aqueous solubility of ametoctradin precluded the direct determination of a pK <sub>a</sub> value; rather it was estimated using ACD/Labs modelling software which uses a database of molecular fragments with known pK <sub>a</sub> values and the Hammett equation with proprietary modifications to estimate pK <sub>a</sub> values. Ametoctradin in aqueous solution will be 50% protonated when the pH of the solution is equal to the pK <sub>a</sub> . From the estimated pK <sub>a</sub> of the nitrogen in the 2 position of the triazole ring, this will be a pH of 2.78. Ametoctradin will be essentially unionized in a range from pH 4 to pH 10.
Stability (temperature, metal)	BAS 650 F is stable in the presence of metal and metal ions at normal and elevated temperature (54°C).	
Storage stability	Chemical stability: a.i. content initially: 100% a.i. content after acc. storage at 54°C for 14 days in a sealed glass container: 99%	No significant degradation of a.i. was observed after accelerated storage. Thus, the substance is considered to be chemically stable.

**Table 8 Physical and Chemical Properties of Major Environmental Transformation Products for Ametoctradin**

Compound code	Chemical name (IUPAC)	Molecular weight	Structure	Physico-chemical properties
M650F01	4-(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)butanoic acid	249.3		Water solubility (pure water at 20°C): 3.8 (± 0.1) g/L  pH of saturated solution with hydro-chloride: 2.5  Log K <sub>ow</sub> : 0.69 at acidic conditions  pK <sub>a</sub> : 4.3 when titrated with 0.002 M NaOH
M650F02	3-(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)propanoic acid	235.3		Water solubility (pure water at 20°C): 79 (± 2) g/L  pH of saturated solution with hydro-chloride: 0.5  Log K <sub>ow</sub> : 0.33 at acidic conditions and 1.0 at neutral conditions  pK <sub>a</sub> : 4.0 when titrated with 0.01 M NaOH

Compound code	Chemical name (IUPAC)	Molecular weight	Structure	Physico-chemical properties
M650F03	(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)acetic acid	221.2		Water solubility (pure water at 20°C): 2.9 (± 0.2) g/L  pH of saturated solution with hydro-chloride: 2.0  Log K <sub>ow</sub> : 0.16 at acidic conditions  pKa: 3.8 when titrated with 0.002 M NaOH
M650F04	7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidine-6-carboxylic acid	207.2		Water solubility (pure water at 20°C): 0.35 (± 0.01) g/L  pH of saturated solution: 3.5  Log K <sub>ow</sub> : 0.87 at acidic conditions  pKa: 4.0 when titrated with 0.002 M NaOH

**Table 9 Fate and Behaviour of Ametoctradin and its Transformation Products in the Terrestrial and Aquatic Environment**

Study	Test substance	Study conditions	Value <sup>a,b</sup>	Comments	Reference
<b>Abiotic transformation</b>					
Hydrolysis	Ametoctradin	50°C, pH 4, 5, 7, 9	DT <sub>50</sub> > 1 year (estimated)	Stable	1871502
Phototransformation on soil	Ametoctradin	22°C, sandy loam	Could not be determined	Not a route of transformation	1871265
Phototransformation on water	Ametoctradin	22°C, pH 7	DT <sub>50</sub> = 76.8 d (environmental)	Not an important route of transformation	1871055
	M650F03	22°C, pH 7, 8	DT <sub>50</sub> = 11.6 – 35.6 d	Not an important route of transformation	1871296
<b>Biotransformation</b>					
Biotransformation in aerobic soil	BAS 650 F	Bruch West (sandy loam), 20°C, 360 d	DT <sub>50</sub> = 1.3 d, DT <sub>90</sub> = 7.3 d (DFOP) Representative t <sub>1/2</sub> = 2.2 d (DFOP DT <sub>90</sub> x 0.301)	Non-persistent	1871250
		LUFA 5M (sandy loam), 20°C, 120 d	DT <sub>50</sub> = 1.5 d, DT <sub>90</sub> = 8.4 d (DFOP) Representative t <sub>1/2</sub> = 2.5 d (DFOP DT <sub>90</sub> x 0.301)	Non-persistent	1871268

Study	Test substance	Study conditions	Value <sup>a,b</sup>	Comments	Reference
		LUFA 2.2 (loamy sand), 20°C, 120 d	DT <sub>50</sub> = 1.8 d, DT <sub>90</sub> = 7.6 d (DFOP) Representative t <sub>1/2</sub> = 2.3 d (DFOP DT <sub>90</sub> x 0.301)	Non-persistent	
		Li 10 (loamy sand), 20°C, 120 d	DT <sub>50</sub> = 3.2 d, DT <sub>90</sub> = 12.8 d (DFOP) Representative t <sub>1/2</sub> = 3.9 d (DFOP DT <sub>90</sub> x 0.301)	Non-persistent	
		Li 10 (loamy sand), 10°C, 120 d	DT <sub>50</sub> = 6.4 d, DT <sub>90</sub> = 24.9 d (DFOP) Representative t <sub>1/2</sub> = 7.5 d (DFOP DT <sub>90</sub> x 0.301)	Non-persistent	
		Idaho (sandy loam), 25°C, 365 d	DT <sub>50</sub> = 9.6 d, DT <sub>90</sub> = 192 d (DFOP) Representative t <sub>1/2</sub> = 57.8 d (DFOP DT <sub>90</sub> x 0.301)	Non-persistent	1871248
		Illinois (loam), 25°C, 365 d	DT <sub>50</sub> = 6.9 d, DT <sub>90</sub> = 22.9 d (SFO)	Non-persistent	
		New Jersey (loam), 25°C, 365 d	DT <sub>50</sub> = 7.1 d, DT <sub>90</sub> = 23.5 d (SFO)	Non-persistent	
		Wisconsin (loamy sand), 25°C, 365 d	DT <sub>50</sub> = 16.7 d, DT <sub>90</sub> = 267 d (DFOP) Representative t <sub>1/2</sub> = 80.4 d (DFOP DT <sub>90</sub> x 0.301)	Slightly persistent	
	M650F03	LUFA 3A (loam), 20°C, 120 d	DT <sub>50</sub> = 75.1 d, DT <sub>90</sub> = 249 d (SFO)	Moderately persistent	1871284
		LUFA 2.2 (loamy sand), 20°C, 120 d	DT <sub>50</sub> = 43.5 d, DT <sub>90</sub> = 144 d (SFO)	Slightly persistent	
		LUFA 2.3 (sandy loam), 20°C, 120 d	DT <sub>50</sub> = 28.8 d, DT <sub>90</sub> = 95.7 d (SFO)	Slightly persistent	
		Wisconsin (sand), 20°C, 120 d	DT <sub>50</sub> = 35.0 d, DT <sub>90</sub> = 116 d (SFO)	Slightly persistent	
	M650F04	LUFA 3A (loam), 20°C, 120 d	DT <sub>50</sub> = 28.0 d, DT <sub>90</sub> = 139 d (DFOP) Representative t <sub>1/2</sub> = 41.9 d (DFOP DT <sub>90</sub> x 0.301)	Slightly persistent	1871286
		LUFA 2.3 (sandy loam), 20°C, 120 d	DT <sub>50</sub> = 106 d, DT <sub>90</sub> = 351 d (SFO)	Moderately persistent	
		Birkenheide (loamy sand), 20°C, 120 d	DT <sub>50</sub> = 289 d, DT <sub>90</sub> = 1020 d (DFOP) Representative t <sub>1/2</sub> = 307 d (DFOP DT <sub>90</sub> x 0.301)	Persistent	

Study	Test substance	Study conditions	Value <sup>a,b</sup>	Comments	Reference	
		Wisconsin (sand), 20°C, 120 d	DT <sub>50</sub> = 132 d, DT <sub>90</sub> = 439 d (SFO)	Persistent		
Biotransformation in anaerobic soil	Ametoctradin	Bruch West (sandy loam), 20°C, 360 d	DT <sub>50</sub> = 182 d, DT <sub>90</sub> = 606 d (SFO)	Persistent	1871262	
Biotransformation in aerobic water/sediment	Ametoctradin	Berghäuser Altrhein, 20°C	Water:  DT <sub>50</sub> = 0.69 d, DT <sub>90</sub> = 2.3 d (SFO)		1871328	
			Sediment:  DT <sub>50</sub> = 2.1 d, DT <sub>90</sub> = 21.8 d (DFOP)			
			Representative t <sub>1/2</sub> = 6.6 d (DFOP DT <sub>90</sub> x 0.301)			
			Total system:  DT <sub>50</sub> = 1.7 d, DT <sub>90</sub> = 5.7 d (SFO)	Non-persistent		
		Ranschgraben, 20°C	Water:  DT <sub>50</sub> = 0.89 d, DT <sub>90</sub> = 2.9 d (SFO)			1871326
			Sediment:  DT <sub>50</sub> = 2.1 d, DT <sub>90</sub> = 7.8 d (DFOP)			
			Representative t <sub>1/2</sub> = 2.4 d (DFOP DT <sub>90</sub> x 0.301)			
			Total system:  DT <sub>50</sub> = 1.5 d, DT <sub>90</sub> = 5.0 d (SFO)	Non-persistent		
Biotransformation in anaerobic water/sediment	Ametoctradin	White Lake, SD (sand sediment), 25°C	Water:  DT <sub>50</sub> = 106 d, DT <sub>90</sub> = 10.3 d (IORE)		1871326	
			Representative t <sub>1/2</sub> = 3.1 d (IORE DT <sub>90</sub> x 0.301)			
			Sediment:  DT <sub>50</sub> = 13.8 d, DT <sub>90</sub> = 227 d (IORE)			
			Representative t <sub>1/2</sub> = 68.4 d (IORE DT <sub>90</sub> x 0.301)			
			Total system:  DT <sub>50</sub> = 7.4 d, DT <sub>90</sub> = 60.1 d (DFOP)	Non-persistent		
			Representative t <sub>1/2</sub> = 18.1 d (DFOP DT <sub>90</sub> x 0.301)			



Study	Test substance	Study conditions	Value <sup>a,b</sup>	Comments	Reference
<b>Mobility</b>					
Adsorption	Ametoctradin	Schifferstadt (loamy sand)	K <sub>FOC</sub> = 6620 L/kg	Immobile	1871292
		LUFA 2.2 (loamy sand)	K <sub>FOC</sub> = 3560 L/kg	Slight	
		New Jersey (loam)	K <sub>FOC</sub> = 4060 L/kg	Slight	
		1680 (loamy sand)	K <sub>FOC</sub> = 4320 L/kg	Slight	
		LUFA 3A (loam)	K <sub>FOC</sub> = 2250 L/kg	Slight	
		Studernheim (sandy loam)	K <sub>FOC</sub> = 1580 L/kg	Low	
		California (sandy loam)	K <sub>FOC</sub> = 4060 L/kg	Slight	
	M650F01	Schifferstadt (loamy sand)	K <sub>FOC</sub> = 193 L/kg	Moderate	1871316
		LUFA 2.2 (loamy sand)	K <sub>FOC</sub> = 62 L/kg	High	
		New Jersey (loam)	K <sub>FOC</sub> = 162 L/kg	Moderate	
		1680 (loamy sand)	K <sub>FOC</sub> = 68 L/kg	High	
		LUFA 3A (loam)	K <sub>FOC</sub> = 28 L/kg	Very high	
		Studernheim (sandy loam)	K <sub>FOC</sub> = 22 L/kg	Very high	
		California (sandy loam)	K <sub>FOC</sub> = 78 L/kg	High	
	M650F02	Schifferstadt (loamy sand)	K <sub>FOC</sub> = 31 L/kg	Very high	1871318
		LUFA 2.2 (loamy sand)	K <sub>FOC</sub> = 34 L/kg	Very high	
		New Jersey (loam)	K <sub>FOC</sub> = 89 L/kg	High	
		1680 (loamy sand)	K <sub>FOC</sub> = 33 L/kg	Very high	
		LUFA 3A (loam)	K <sub>FOC</sub> = 16 L/kg	Very high	
		Studernheim (sandy loam)	K <sub>FOC</sub> = 14 L/kg	Very high	
		California (sandy loam)	K <sub>FOC</sub> = 36 L/kg	Very high	
	M650F03	Münster (sandy loam)	K <sub>FOC</sub> = 63 L/kg	High	1871300
		LUFA 2.2 (loamy sand)	K <sub>FOC</sub> = 51 L/kg	High	
		New Jersey (loam)	K <sub>FOC</sub> = 59 L/kg	High	
		1680 (loamy sand)	K <sub>FOC</sub> = 15 L/kg	Very high	
		LUFA 3A (loam)	K <sub>FOC</sub> = 11 L/kg	Very high	
		Studernheim (sandy loam)	K <sub>FOC</sub> = 12 L/kg	Very high	
		California (sandy loam)	K <sub>FOC</sub> = 31 L/kg	Very high	
Schifferstadt (sand)		K <sub>FOC</sub> = 199 L/kg	Moderate	1871315	
LUFA 2.1 (sand)		K <sub>FOC</sub> = 25 L/kg	Very high		
Große Erde (loamy sand)		K <sub>FOC</sub> = 11 L/kg	Very high		
LUFA 2.3 (sandy loam)		K <sub>FOC</sub> = 33 L/kg	Very high		

Study	Test substance	Study conditions	Value <sup>a,b</sup>	Comments	Reference
	M650F04	La Gironda (silty clay loam)	$K_{FOC} = 13 \text{ L/kg}$	Very high	1871302
		Münster (sandy loam)	$K_{FOC} = 47 \text{ L/kg}$	Very high	
		LUFA 2.2 (loamy sand)	$K_{FOC} = 40 \text{ L/kg}$	Very high	
		New Jersey (loam)	$K_{FOC} = 44 \text{ L/kg}$	Very high	
		1680 (loamy sand)	$K_{FOC} = 11 \text{ L/kg}$	Very high	
		LUFA 3A (loam)	$K_{FOC} = 8 \text{ L/kg}$	Very high	
		Studernheim (sandy loam)	$K_{FOC} = 8 \text{ L/kg}$	Very high	
		California (sandy loam)	$K_{FOC} = 17 \text{ L/kg}$	Very high	1871312
		Schifferstadt (sand)	$K_{FOC} = 118 \text{ L/kg}$	High	
		LUFA 2.1 (sand)	$K_{FOC} = 11 \text{ L/kg}$	Very high	
		Große Erde (loamy sand)	$K_{FOC} = 9 \text{ L/kg}$	Very high	
		LUFA 2.3 (sandy loam)	$K_{FOC} = 23 \text{ L/kg}$	Very high	
		La Gironda (silty clay loam)	$K_{FOC} = 8 \text{ L/kg}$	Very high	
<b>Field studies</b>					
Field dissipation	Ametoctradin	Ontario	$DT_{50} = 4.2 \text{ d}, DT_{90} = 13.8 \text{ d (SFO)}$	Non-persistent	1871908
		Illinois	$DT_{50} = 1.1 \text{ d}, DT_{90} = 3.7 \text{ d (SFO)}$	Non-persistent	
		Florida	$DT_{50} = 5.0 \text{ d}, DT_{90} = 16.5 \text{ d (SFO)}$	Non-persistent	
		California	$DT_{50} = 1.5 \text{ d}, DT_{90} = 12.9 \text{ d (DFOS)}$	Non-persistent	1871900
		Washington	$DT_{50} = 0.4 \text{ d}, DT_{90} = 3.2 \text{ d (FOMC)}$	Non-persistent	
	M650F03	Denmark (sand)	$DT_{50} = 19.8 \text{ d}, DT_{90} = 65.8 \text{ d (SFO)}$	Slightly persistent	1871879
		UK (sandy loam)	$DT_{50} = 6.9 \text{ d}, DT_{90} = 48.8 \text{ d (FOMC)}$	Non-persistent	
		Germany (loamy sand)	$DT_{50} = 16.4 \text{ d}, DT_{90} = 54.5 \text{ d (SFO)}$	Slightly persistent	
		Italy (silt loam)	$DT_{50} = 16.6 \text{ d}, DT_{90} = 419.8 \text{ d (DFOP)}$	Slightly persistent	
		Spain (sand)	$DT_{50} = 14.0 \text{ d}, DT_{90} = 250.3 \text{ d (DFOP)}$	Non-persistent	
	M650F04	Denmark (sand)	$DT_{50} = 48.6 \text{ d}, DT_{90} = 161.6 \text{ d (SFO)}$	Moderately persistent	1871882
		UK (sandy loam)	$DT_{50} = 25.1 \text{ d}, DT_{90} = > 656 \text{ d}^c \text{ (DFOP)}$	Slightly persistent	
		Germany (loamy sand)	$DT_{50} = 82.9 \text{ d}, DT_{90} = 275.5 \text{ d (DFOP)}$	Moderately persistent	

Study	Test substance	Study conditions	Value <sup>a,b</sup>	Comments	Reference
		Italy (silt loam)	DT <sub>50</sub> = 186.5 d, DT <sub>90</sub> = > 638 d <sup>c</sup> (DFOP)	Persistent	
		Spain (sand)	DT <sub>50</sub> = 48.5 d, DT <sub>90</sub> = > 720 d <sup>c</sup> (DFOP)	Moderately persistent	

a Kinetics models: DFOP = Double first-order in parallel; SFO = single first-order; FOMC = first-order multi compartment; DFOS = double first-order in series; IORE = indeterminate order rate equation.

b Representative t<sub>1/2</sub> = DT<sub>90</sub> / 3.32. Used by the PMRA for laboratory biotransformation studies to approximate a pseudo first-order t<sub>1/2</sub> from non-linear two compartment regression models.

c DT<sub>90</sub> estimate was greater than 2x the length of the sampling period

**Table 10 Summary of Maximum Formation of Major Transformation Products (%AR) in Ametoctradin Laboratory Studies at the Observed Day After Treatment (DAT)**

Study conditions	Study duration [days]	Temp. [°C]	Max. Form. M650F01 (%AR), [DAT]	Max. Form. M650F02 (%AR), [DAT]	Max. Form. M650F03 (%AR), [DAT]	Max. Form. M650F04 (%AR), [DAT]	Reference	
<b>Hydrolysis</b>	7	50	Not Detected (stable to hydrolysis)				1871502	
<b>Phototransformation on soil</b> Bruch West (sandy loam)	15	22	6.1 [11]	4.5 [15]	1.3 [11]	Not detected	1871265	
<b>Phototransformation in water</b>	15	22	3 Unknown peaks (maximum of 11.7% AR)				1871055	
<b>Aerobic Soil</b>								
Bruch West (sandy loam)	360	20	31.2 [2]	13.0 [3]	57.0 [10]	25.2 [119]	1871250	
LUFA 5M (sandy loam)	120	20	26.3 [2]	11.0 [3]	40.8 [15]	55.7 [120]	1871268	
LUFA 2.2 (loamy sand)	120	20	36.0 [3]	5.5 [10]	39.7 [15]	30.7 [120]		
Li 10 (loamy sand)	120	20	53.9 [10]	3.6 [6]	50.9 [30]	30.4 [120]		
Li 10 (loamy sand)	120	10	66.5 [15]	3.7 [15]	57.9 [93]	12.7 [120]		
Idaho (sandy loam)	365	25	25.3 [14]	5.2 [14]	51.9 [30]	27.8 [227]	1871248	
Illinois (loam)	365	25	34.6 [14]	4.6 [14]	26.1 [14]	31.1 [120]		
New Jersey (loam)	365	25	36.5 [14]	7.2 [14]	32.3 [30]	22.9 [91]		
Wisconsin (loamy sand)	365	25	42.8 [30]	3.7 [59]	19.9 [59]	28.1 [227]		
<b>Anaerobic Soil*</b>								
Bruch West (sandy loam)	118	20	33.7 [3]	9.8 [3]	6.3 [3]	-	1871262	
<b>Aerobic Water/sediment</b>								
Berghäuser Altrhein	Water	100	20	13.3 [4]	9.1 [7]	47.8 [7]	12.8 [59]	1871328
	Sediment			1.5 [14]	3.2 [14]	20.8 [59]	6.1 [81]	
Ranschgraben	Water	100	20	21.3 [2]	10.2 [4]	53.6 [14]	14.4 [81]	
	Sediment			1.6 [2]	2.7 [30]	18.5 [30]	4.9 [100]	
<b>Anaerobic Water/sediment*</b>								
White Lake, SD	Water	365	25	37.6 [7]	3.1 [30]	76.2 [272]	4.9 [365]	1871326
	Sediment			-	-	13.2 [272]	0.9 [181]	

AR = Applied radioactivity, DAT = Days after treatment

\* The maximum amounts of transformation products formed during the aerobic/anaerobic transition period.

**Table 11 Screening Level EECs for Ametoctradin in Soil and on Plants Based on Direct Application**

Parameter	Crop	
	Potatoes	Grapes
Application rate (g a.i./ha)	300	300
No. of applications	3	4
Interval between applications (days)	5	7
Soil half-life (days) <sup>a</sup>	16.7	16.7
Foliar half-life (days) <sup>b</sup>	10	10
Soil bulk density (g/cm <sup>3</sup> )	1.5	1.5
Soil depth (cm)	15	15
<b>Cumulative application rate to plants (g a.i./ha)</b>	<b>662</b>	<b>668</b>
<b>Cumulative application rate to soil (g a.i./ha)</b>	<b>741.9</b>	<b>817.7</b>
<b>EEC<sub>soil</sub> (mg a.i./kg soil dw)</b>	<b>0.330</b>	<b>0.363</b>

<sup>a</sup>Based on longest DT50 from aerobic soil studies (Wisconsin sandy loam).

<sup>b</sup>Default foliar half-life for estimating cumulative application to plants.

**Table 12 Screening Level EECs for Ametoctradin in Vegetation and Insects After a Direct Application at the Cumulative Application Rate of 668 g a.i./ha (application to grapes)**

Food item	EEC (mg a.i./kg fw) <sup>a</sup>		Fresh / dry weight ratios	EEC (mg a.i./kg dw)	
	Maximum Residues	Mean Residues		Maximum Residues	Mean Residues
Short range grass	143	50	3.3 <sup>b</sup>	472	166
Leaves and leafy crops	81	26	11 <sup>b</sup>	889	291
Long grass	65	21	4.4 <sup>b</sup>	288	93
Forage crops	81	26	5.4 <sup>b</sup>	436	143
Small insects	35	19	3.8 <sup>c</sup>	132	73
Pods with seeds	8.7	4.1	3.9 <sup>c</sup>	34	16
Large insects	8.7	4.1	3.8 <sup>c</sup>	33	16
Grain and seeds	8.7	4.1	3.8 <sup>c</sup>	33	16
Fruit	8.7	4.1	7.6 <sup>c</sup>	66	31

<sup>a</sup>Based on correlations reported in Hoerger and Kenaga (1972) and Kenaga (1973) and modified by Fletcher (1994)

<sup>b</sup>Fresh / dry weight ratios from Harris (1975)

<sup>c</sup>Fresh / dry weight ratios from Spector (1956)

**Table 13 Screening Level EECs for Ametoctradin in Water**

Use Scenario	EEC (mg a.i./L)	
	Non-permanent / shallow water bodies (15 cm)	Permanent water bodies (80 cm)
Grapes (4 x 300 g a.i./ha)	0.213	0.0399
Potatoes (3 x 300 g a.i./ha)	0.230	0.0432

**Table 14 Screening Level EECs for Ametoctradin Transformation Products in Water**

Transformation Product	Molecular weight ratio to ametoctradin	EEC (mg a.i./L)	
		Non-permanent / shallow water bodies (15 cm)	Permanent water bodies (80 cm)
M650F01	249.3/275.4 = 0.905	0.208	0.0391
M650F02	235.3/275.4 = 0.854	0.196	0.0369
M650F03	221.2/275.4 = 0.803	0.185	0.0347
M650F04	207.2/275.4 = 0.752	0.173	0.0325

**Table 15 Refined Tier I Aquatic EECs for Ametoctradin Based on Spray Drift Input Only**

Crop	Sprayer Type	% Drift at 1 m downwind <sup>a</sup>	EEC (mg a.i./L)	
			Non-permanent/ shallow water bodies (15 cm)	Permanent water bodies (80 cm deep)
Grapes (4 x 300 g a.i./ha)	Airblast (early season application)	74	0.158	0.0295
	Airblast (late season application)	59	0.126	0.0235
Potatoes (3 x 300 g a.i./ha)	Field sprayer	6 <sup>b</sup>	0.0138	0.00259
	Aerial	23 <sup>b</sup>	0.0529	0.00994

<sup>a</sup>Based on spray drift models of Wolf and Caldwell (2001) for field sprayers, Ganzelmeier et al. (1995) for airblast sprayers and AgDISP for aerial application.

<sup>b</sup>Based on an ASAE Medium spray quality.

**Table 16 Level 1 Aquatic Ecoscenario Modelling EECs (mg a.i./L) for Ametoctradin in a Water Body 0.15 m Deep, Excluding Spray Drift, Overlying Water**

Region	EEC (mg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
<b>Prairies, 3 x 0.3 kg a.i./ha, at 5-day intervals</b>						
MB-Potato	0.023	0.0035	0.0013	0.00075	0.00056	0.00019
<b>Atlantic, 3 x 0.3 kg a.i./ha, at 5-day intervals</b>						
PEI-Potato	0.053	0.0085	0.0027	0.0014	0.0011	0.00042
<b>Ontario, 4 x 0.3 kg a.i./ha, at 7-day intervals</b>						
ON-Grapes	0.012	0.0017	0.00048	0.00027	0.00023	0.000093

**Table 17 Level 1 Aquatic Ecoscenario Modelling EECs (mg a.i./L) for Ametoctradin in a Water Body 0.8 m Deep, Excluding Spray Drift, Overlying Water**

Region	EEC (mg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
<b>Prairies, 3 x 0.3 kg a.i./ha, at 5-day intervals</b>						
MB-Potato	0.0043	0.0015	0.00062	0.00036	0.00027	0.000094
<b>Atlantic, 3 x 0.3 kg a.i./ha, at 5-day intervals</b>						
PEI-Potato	0.010	0.0034	0.0012	0.00066	0.00054	0.00021
<b>Ontario, 4 x 0.3 kg a.i./ha, at 7-day intervals</b>						
ON-Grapes	0.0022	0.00071	0.00021	0.00013	0.00012	0.000047

**Table 18 Level 1 Aquatic Ecoscenario Modelling EECs (mg a.i./L) for Ametoctradin in a Water Body 0.8 m Deep, Excluding Spray Drift, Benthic Layer**

Region	EEC (mg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
<b>Prairies, 3 x 0.3 kg a.i./ha, at 5-day intervals</b>						
MB-Potato	0.00043	0.00042	0.00037	0.00026	0.00021	0.000078
<b>Atlantic, 3 x 0.3 kg a.i./ha, at 5-day intervals</b>						
PEI-Potato	0.00055	0.00054	0.00046	0.00034	0.00030	0.00014
<b>Ontario, 4 x 0.3 kg a.i./ha, at 7-day intervals</b>						
ON-Grapes	0.00012	0.00012	0.00010	0.000086	0.000076	0.000034

**Table 19 Toxicity of Ametoctradin, Zampro Fungicide, BAS 650 00 F Fungicide and Major Transformation Products to Non-Target Terrestrial Species**

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference
<i>Invertebrates</i>					
Earthworm ( <i>Eisenia fetida</i> )	Acute 14-d	Ametoctradin	LC <sub>50</sub> >1000 mg a.i./kg soil dw	N/A	1871554
		BAS 650 00 F Fungicide	LC <sub>50</sub> >1000 mg EP/kg soil dw or >182 mg ametoctradin/kg soil dw	N/A	1871831
		Zampro Fungicide	LC <sub>50</sub> >1000 mg EP/kg soil dw or >268 mg ametoctradin /kg soil dw or >204.8 mg dimethomorph/kg soil dw	N/A	1871647
		M650F01	LC <sub>50</sub> >817 mg/kg soil dw	N/A	1871557
		M650F03	LC <sub>50</sub> >1000 mg/kg soil dw	N/A	1871553
		M650F04	LC <sub>50</sub> >1000 mg/kg soil dw	N/A	1871555
	56-d Chronic (28-d exposure)	BAS 650 00 F Fungicide	NOEC = 107.4 mg EP/kg soil dw or 20.9 mg ametoctradin /kg soil dw NOEC at highest test concentration	N/A	1871835
		Zampro Fungicide	NOEC = 76 mg EP/kg soil dw or 20.4 mg ametoctradin /kg soil	N/A	1871649

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference
			dw or 15.5 mg dimethomorph/kg soil dw NOEC at highest test concentration		
		M650F03	NOEC = 83.5 mg/kg soil dw NOEC at highest test concentration	N/A	1871560
		M650F04	NOEC = 95.8 mg/kg soil dw NOEC at highest test concentration	N/A	1871561
Honey bee ( <i>Apis mellifera</i> )	Acute contact and oral 48-h	Ametoctradin	Oral LD <sub>50</sub> >111.5 µg a.i./bee Contact LD <sub>50</sub> >100 µg a.i./bee	Relatively non-toxic	1871508
		BAS 650 00 F Fungicide	Oral LD <sub>50</sub> >568.9 µg EP/bee or >109.3 µg ametoctradin /bee  Contact LD <sub>50</sub> >520.5 µg EP/bee or >100.0 µg ametoctradin /bee	Relatively non-toxic	1871813
		Zampro Fungicide	Oral LD <sub>50</sub> >248.2 µg EP/bee or >67.6 µg ametoctradin /bee or >49.6 µg dimethomorph/bee  Contact LD <sub>50</sub> >211.81 µg EP/bee or >57.7 µg ametoctradin/bee or >42.3 µg dimethomorph/bee	Relatively non-toxic	1871637
Parasitic arthropod	Acute contact 48-h (laboratory-treated glass plates)	BAS 650 00 F Fungicide	LR <sub>50</sub> 1.22 L EP/ha or = 234 g ametoctradin/ha	N/A	1871820
Parasitic wasp ( <i>Aphidius rhopalosiphi</i> )		Zampro Fungicide	LR <sub>50</sub> >3.2 L EP/ha or >970 g ametoctradin/ha or >718 g dimethomorph/ha	N/A	1871641
	48-h exposure, 11-d observation (dry residues on barley seedlings)	BAS 650 00 F Fungicide	LR <sub>50</sub> >9.6 L EP/ha or >1962 g ametoctradin/ha	N/A	1871825
		Zampro Fungicide	LR <sub>50</sub> >2.4 L EP/ha or >717 g ametoctradin/ha or >547 g dimethomorph/ha	N/A	1871645
Predatory arthropod	Acute contact 7-d (laboratory-treated glass plates)	BAS 650 00 F Fungicide	LR <sub>50</sub> >9.6 L EP/ha or >1843 g ametoctradin/ha	N/A	1871817
Predaceous mite ( <i>Typhlodromus pyri</i> )		Zampro Fungicide	LR <sub>50</sub> >3.2 L EP/ha or >970 g ametoctradin/ha or >718 g dimethomorph/ha	N/A	1871643
	Field study (Germany): 4 applications, 68-d period, May-June	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 2.4 L EP/ha or 491 g ametoctradin/ha	N/A	1871520
	Field study (France): 4 applications, 63-d period, April-June	BAS 650 00 F Fungicide	Slight/transient effects at 4 applications of 2.28 L EP/ha or 468 g ametoctradin/ha	N/A	1871540
	Field study (France): 4 applications, 66-d period, May-June	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 2.4 L EP/ha or 491 g ametoctradin/ha	N/A	1871528
	Field study (Germany): 4 applications, 62-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 2.4 L EP/ha or 491 g ametoctradin/ha	N/A	1871515
	Field study (France): 4 applications, 61-day period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 2.4 L EP/ha or 491 g ametoctradin/ha	N/A	1871536
	Field study (France): 4 applications, 60-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 2.4 L EP/ha or 491 g ametoctradin/ha	N/A	1871525
Green lacewing ( <i>Chrysoperlea carnea</i> )	Contact, up to 15-d observation (laboratory- treated glass plates)	BAS 650 00 F Fungicide	LR <sub>50</sub> >3.6 L EP/ha or >735.8 g ametoctradin/ha	N/A	1871823
	Acute contact 7-d	Zampro Fungicide	LR <sub>50</sub> >3.2 L EP/ha or >956 g ametoctradin/ha or >729 g dimethomorph/ha	N/A	1871639
Springtail ( <i>Folsomia candida</i> )	28-d Chronic	BAS 650 00 F Fungicide	NOEC = 1000 mg EP/kg soil dw or 194.8 mg ametoctradin/kg soil dw NOEC at highest test concentration	N/A	1871838
		Zampro Fungicide	NOEC = 1000 mg EP/kg soil dw or 268.0 mg ametoctradin/kg soil dw	N/A	1871651

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference
			or 204.8 mg dimethomorph/kg soil dw NOEC at highest test concentration		
		M650F03	LOEC = 100 mg/kg soil dw NOEC = 50 mg/kg soil dw Endpoint based on survival and reproduction	N/A	1871549
		M650F04	NOEC = 95.8 mg/kg soil dw NOEC at highest test concentration	N/A	1871548
Soil mites ( <i>Hypoaspis aculeifer</i> )	14-d Reproduction	M650F03	NOEC = 100 mg/kg soil dw NOEC at highest test concentration	N/A	1871545
		M650F04	NOEC = 95.8 mg/kg soil dw NOEC at highest test concentration	N/A	1871544
<b>Birds</b>					
Bobwhite quail ( <i>Colinus virginianus</i> )	Acute Oral - single dose, 14-d observation	Ametoctradin	LD <sub>50</sub> >2000 mg a.i./kg bw/d	Practically non-toxic	1871330
		Zampro Fungicide	LD <sub>50</sub> >2000 mg EP/kg bw/d or >545.0 mg ametoctradin/kg bw/d or >403.8 mg dimethomorph/kg bw/d	Practically non-toxic	1871629
	Dietary 5-d exposure, 3-d postexposure	Ametoctradin	LC <sub>50</sub> >5000 mg a.i./kg diet or >758 mg a.i./kg bw/d NOEC = 5000 mg a.i./kg diet or = 758 mg a.i./kg bw/d	Practically non-toxic	1871340
	Reproduction 1-generation, 22-week dietary	Ametoctradin	NOEC = 1400 mg a.i./kg diet or = 115.2 mg a.i./kg bw/d NOEC at highest test dose	N/A	1871344
Mallard duck ( <i>Anas platyrhynchos</i> )	Acute Oral - single dose, 14-d observation	Ametoctradin	LD <sub>50</sub> >2000 mg a.i./kg bw/d	Practically non-toxic	1871334
	Dietary 5-d exposure, 3-d postexposure	Ametoctradin	LC <sub>50</sub> >5000 mg a.i./kg diet or >1549 mg a.i./kg bw/d NOEC = 2000 mg a.i./kg diet or = 671 mg a.i./kg bw/d	Practically non-toxic	1871341
	Reproduction 1-generation, 21-week dietary	Ametoctradin	NOEC = 1400 mg a.i./kg diet or = 187.8 mg a.i./kg bw/d NOEC at highest test dose	N/A	1871348
Zebra finch ( <i>Taeniopygia guttata</i> )	Acute Oral - single dose, 14-d observation	Ametoctradin	LD <sub>50</sub> >2000 mg a.i./kg bw/d	Practically non-toxic	1871337
<b>Mammals</b>					
Rat Strain: Wistar/HanRec:WIST (SPF)	Acute oral	Ametoctradin	LD <sub>50</sub> > 2000 mg a.i./kg bw	Practically non-toxic	
		BAS 650 00 F Fungicide	LD <sub>50</sub> > 2000 mg EP/kg bw, or > 383.2 mg ametoctradin/kg bw	Practically non-toxic	
		Zampro Fungicide	LD <sub>50</sub> > 500 mg EP/kg bw, but < 2000 mg EP/kg bw or > 134.7 mg ametoctradin /kg bw, but < 538.6 mg ametoctradin/kg bw, or >101 mg dimethomorph/kg bw, but <404 mg dimethomorph/kg bw	Slightly toxic	
	Subchronic (90-d) dietary	Ametoctradin	NOAEL = 15000 mg a.i./kg diet, or = 1083 mg a.i./kg bw/day (males) NOAEL at highest test dose	Practically non-toxic	
		M650F03	NOAEL = 15000 mg/kg diet, or = 943 mg/kg bw/day (males) NOAEL at highest test dose	Practically non-toxic	
		M650F04	NOAEL = 15000 mg/kg diet, or = 1034 mg/kg bw/day (males) NOAEL at highest test dose	Practically non-toxic	
	2-Generation reproduction toxicity	Ametoctradin	NOAEL = 939 mg a.i./kg bw/day NOAEL at highest test dose	N/A	
Parental and development toxicity	Ametoctradin	NOAEL = 1000 mg a.i./kg bw/day NOAEL at highest test dose	N/A		
<b>Vascular plants</b>					
Sunflower ( <i>Helianthus annuus</i> ), oilseed rape ( <i>Brassica napus</i> ), sugar	Vegetative vigour (21-d observation)	BAS 650 00 F Fungicide	NOER = 2.8 L EP/ha or 570 g ametoctradin/ha Limit test at single application rate.	N/A	1871395



Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference
beet ( <i>Beta vulgaris</i> ), soybean ( <i>Glycine max</i> ), pea ( <i>Pisum sativum</i> ), tomato ( <i>Lycopersicon esculentum</i> ), onion ( <i>Allium cepa</i> ), oat ( <i>Avena sativa</i> ), barley ( <i>Hordeum vulgare</i> ), corn ( <i>Zea mays</i> )	Seedling emergence (21-d observation)	BAS 650 00 F Fungicide	NOER = 2.8 L EP/ha or 570 g ametoctradin/ha Limit test at single application rate.	N/A	1871401
Oilseed rape ( <i>Brassica napus</i> ), carrot ( <i>Daucus carota</i> ), soybean ( <i>Glycine max</i> ), cabbage ( <i>Brassica oleracea</i> ), tomato ( <i>Lycopersicon esculentum</i> ), lettuce ( <i>Lactuca sativa</i> ), ryegrass ( <i>Lolium perenne</i> ), wheat ( <i>Triticum aestivum</i> ), onion ( <i>Allium cepa</i> ), corn ( <i>Zea mays</i> )	Vegetative vigour (21-d observation)	Zampro Fungicide	NOER = 5.0 L EP/ha or 1500 g ametoctradin/ha or 1100 g dimethomorph/ha NOER at highest test rate.	N/A	1871657
	Seedling emergence (21-d observation)	Zampro Fungicide	NOER = 5.0 L EP/ha or 1500 g ametoctradin/ha or 1100 g dimethomorph/ha NOER at highest test rate.	N/A	1871659

a US EPA classification, where applicable

**Table 20 Screening Level Risk Assessment on Non-Target Terrestrial Species**

Organism	Exposure	Test Substance	Endpoint Value	EEC	RQ	LOC Exceeded?
<b>Invertebrates</b>						
Earthworm ( <i>Eisenia fetida</i> )	Acute 14-d	Ametoctradin	1/2 LC <sub>50</sub> >500 mg a.i./kg soil dw	0.363 mg a.i./kg soil dw	<0.01	No
		BAS 650 00 F Fungicide	1/2 LC <sub>50</sub> >91 mg a.i./kg soil dw	0.363 mg a.i./kg soil dw	<0.01	No
		Zampro Fungicide	1/2 LC <sub>50</sub> >134 mg ametoctradin/kg soil dw	0.363 mg a.i./kg soil dw	<0.01	No
		M650F01	1/2 LC <sub>50</sub> >409 mg/kg soil dw	0.329 mg a.i./kg soil dw <sup>a</sup>	<0.01	No
		M650F03	1/2 LC <sub>50</sub> >500 mg/kg soil dw	0.292 mg a.i./kg soil dw <sup>b</sup>	<0.01	No
		M650F04	1/2 LC <sub>50</sub> >500 mg/kg soil dw	0.273 mg a.i./kg soil dw <sup>c</sup>	<0.01	No
	56-d Chronic (28-d exposure)	BAS 650 00 F Fungicide	NOEC ≥ 20.9 mg a.i./kg soil dw	0.363 mg a.i./kg soil dw	≤0.02	No
		Zampro Fungicide	NOEC ≥ 20.4 mg ametoctradin/kg soil dw	0.363 mg a.i./kg soil dw	≤0.02	No
		M650F03	NOEC ≥ 83.5 mg/kg soil dw	0.292 mg a.i./kg soil dw <sup>b</sup>	<0.01	No
		M650F04	NOEC ≥ 95.8 mg/kg soil dw	0.273 mg a.i./kg soil dw <sup>c</sup>	<0.01	No
Honey bee ( <i>Apis mellifera</i> )	48-h Oral LD <sub>50</sub>	Ametoctradin	129.4 kg a.i./ha <sup>d</sup>	0.668 kg a.i./ha	0.01	No
		BAS 650 00 F Fungicide	122.4 kg a.i./ha <sup>d</sup>	0.668 kg a.i./ha	0.01	No
		Zampro Fungicide	75.7 kg a.i./ha <sup>d</sup>	0.668 kg a.i./ha	0.01	No
	48-h Contact LD <sub>50</sub>	Ametoctradin	112 kg a.i./ha <sup>d</sup>	0.668 kg a.i./ha	0.01	No
		BAS 650 00 F Fungicide	112 kg a.i./ha <sup>d</sup>	0.668 kg a.i./ha	0.01	No
		Zampro Fungicide	64.6 kg a.i./ha <sup>d</sup>	0.668 kg a.i./ha	0.01	No
Parasitic wasp ( <i>Aphidius rhopalosiphii</i> )	Acute contact 48-h (laboratory-treated glass plates)	BAS 650 00 F Fungicide	LR <sub>50</sub> = 234 g a.i./ha	668 g a.i./ha	<b>2.85</b>	<b>Yes</b>
		Zampro Fungicide	LR <sub>50</sub> >970 g a.i./ha (ametoctradin)	668 g a.i./ha	<0.69	No
	48-h exposure, 11-d observation	BAS 650 00 F Fungicide	LR <sub>50</sub> >1962 g a.i./ha	668 g a.i./ha	<0.34	No

Organism	Exposure	Test Substance	Endpoint Value	EEC	RQ	LOC Exceeded?
	(dry residues on barley seedlings)	Zampro Fungicide	LR <sub>50</sub> >717 g a.i./ha (ametotradin)	668 g a.i./ha	<0.93	No
Predaceous mite ( <i>Typhlodromus pyri</i> )	Acute contact 7-d (laboratory-treated glass plates)	BAS 650 00 F Fungicide	LR <sub>50</sub> >1843 g a.i./ha	668 g a.i./ha	<0.36	No
		Zampro Fungicide	LR <sub>50</sub> >970 g a.i./ha (ametotradin)	668 g a.i./ha	<0.69	No
	Field study (Germany): 4 applications, 68-d period, May-June	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 2.4 L EP/ha or 491 g a.i./ha (NOEC = 838 g a.i./ha) <sup>c</sup>	668 g a.i./ha	0.80	No
	Field study (France): 4 applications, 63-d period, April-June	BAS 650 00 F Fungicide	Slight/transient effects at 4 applications of 468 g a.i./ha (NOEC = 799 g a.i./ha) <sup>f</sup>	668 g a.i./ha	0.84	No
	Field study (France): 4 applications, 66-d period, May-June	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha) <sup>c</sup>	668 g a.i./ha	0.80	No
	Field study (Germany): 4 applications, 62-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha) <sup>c</sup>	668 g a.i./ha	0.80	No
	Field study (France): 4 applications, 61-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha) <sup>c</sup>	668 g a.i./ha	0.80	No
	Field study (France): 4 applications, 60-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha) <sup>c</sup>	668 g a.i./ha	0.80	No
Green lacewing ( <i>Chrysoperlea carnea</i> )	Contact, up to 15-d observation (laboratory-treated glass plates)	BAS 650 00 F Fungicide	LR <sub>50</sub> >735.8 g a.i./ha	668 g a.i./ha	<0.91	No
	Acute contact 7-d	Zampro Fungicide	LR <sub>50</sub> >956 g a.i./ha (ametotradin)	668 g a.i./ha	<0.70	No
Springtail ( <i>Folsomia candida</i> )	28-d Chronic	BAS 650 00 F Fungicide	NOEC ≥ 194.8 mg a.i./kg soil dw	0.363 8 mg a.i./kg soil dw	< 0.01	No
		Zampro Fungicide	NOEC ≥ 268.0 mg a.i./kg soil dw (ametotradin)	0.363 8 mg a.i./kg soil dw	< 0.01	No
		M650F03	NOEC = 50 mg/kg soil dw	0.292 8 mg a.i./kg soil dw <sup>b</sup>	0.01	No
		M650F04	NOEC ≥ 95.8 mg/kg soil dw	0.273 8 mg a.i./kg soil dw <sup>c</sup>	< 0.01	No
Soil mites ( <i>Hypoaspis aculeifer</i> )	14-d Reproduction	M650F03	NOEC ≥ 100 mg/kg soil dw	0.292 8 mg a.i./kg soil dw <sup>b</sup>	< 0.01	No
		M650F04	NOEC ≥ 95.8 mg/kg soil dw	0.2738 mg a.i./kg soil dw <sup>c</sup>	< 0.01	No
<b>Vascular Plants</b>						
Sunflower (Helianthus annuus), oilseed rape (Brassica napus), sugar beet (Beta vulgaris), soybean (Glycine max), pea (Pisum sativum), tomato	Vegetative vigour (21-d observation)	BAS 650 00 F Fungicide	EC <sub>25</sub> > 570 g a.i./ha (ametotradin)	817.7 g a.i./ha	< 1.43	Yes <sup>g</sup>
	Seedling emergence (21-d observation)	BAS 650 00 F Fungicide	EC <sub>25</sub> > 570 g a.i./ha (ametotradin)	817.7 g a.i./ha	< 1.43	Yes <sup>g</sup>

Organism	Exposure	Test Substance	Endpoint Value	EEC	RQ	LOC Exceeded?
(Lycopersicon esculentum), onion (Allium cepa), oat (Avena sativa), barley (Hordeum vulgare), corn (Zea mays)						
Oilseed rape (Brassica napus), carrot (Daucus carota), soybean (Glycine max), cabbage (Brassica oleracea), tomato (Lycopersicon esculentum), lettuce (Lactuca sativa), ryegrass (Lolium perenne), wheat (Triticum aestivum), onion (Allium cepa), corn (Zea mays)	Vegetative vigour (21-d observation)	Zampro Fungicide	EC <sub>25</sub> > 1500 g a.i./ha (ametoctradin)	817.7 g a.i./ha	< 0.55	No
	Seedling emergence (21-d observation)	Zampro Fungicide	EC <sub>25</sub> > 1500 g a.i./ha (ametoctradin)	817.7 g a.i./ha	< 0.55	No
Organism	Exposure	Test Substance	Endpoint Value	EEC	RQ	LOC Exceeded?
<b>Invertebrates</b>						
Earthworm (Eisenia fetida)	Acute 14-d	Ametoctradin	1/2 LC50 >500 mg a.i./kg soil dw	0.363 mg a.i./kg soil dw	<0.01	No
		BAS 650 00 F Fungicide	1/2 LC50 >91 mg a.i./kg soil dw	0.363 mg a.i./kg soil dw	<0.01	No
		Zampro Fungicide	1/2 LC50 >134 mg ametoctradin/kg soil dw	0.363 mg a.i./kg soil dw	<0.01	No
		M650F01	1/2 LC50 >409 mg/kg soil dw	0.329 mg a.i./kg soil dwa	<0.01	No
		M650F03	1/2 LC50 >500 mg/kg soil dw	0.292 mg a.i./kg soil dwb	<0.01	No
		M650F04	1/2 LC50 >500 mg/kg soil dw	0.273 mg a.i./kg soil dwc	<0.01	No
	56-d Chronic (28-d exposure)	BAS 650 00 F Fungicide	NOEC ≥ 20.9 mg a.i./kg soil dw	0.363 mg a.i./kg soil dw	≤0.02	No
		Zampro Fungicide	NOEC ≥ 20.4 mg ametoctradin/kg soil dw	0.363 mg a.i./kg soil dw	≤0.02	No
		M650F03	NOEC ≥ 83.5 mg/kg soil dw	0.292 mg a.i./kg soil dwb	<0.01	No
		M650F04	NOEC ≥ 95.8 mg/kg soil dw	0.273 mg a.i./kg soil dwc	<0.01	No
Honey bee (Apis mellifera)	48-h Oral LD50	Ametoctradin	129.4 kg a.i./had	0.668 kg a.i./ha	0.01	No
		BAS 650 00 F Fungicide	122.4 kg a.i./had	0.668 kg a.i./ha	0.01	No
		Zampro Fungicide	75.7 kg a.i./had	0.668 kg a.i./ha	0.01	No

Organism	Exposure	Test Substance	Endpoint Value	EEC	RQ	LOC Exceeded?
	48-h Contact LD50	Ametoctradin	112 kg a.i./ha	0.668 kg a.i./ha	0.01	No
		BAS 650 00 F Fungicide	112 kg a.i./ha	0.668 kg a.i./ha	0.01	No
		Zampro Fungicide	64.6 kg a.i./ha	0.668 kg a.i./ha	0.01	No
Parasitic wasp (Aphidius rhopalosiphi)	Acute contact 48-h (laboratory-treated glass plates)	BAS 650 00 F Fungicide	LR50 = 234 g a.i./ha	668 g a.i./ha	2.85	Yes
		Zampro Fungicide	LR50 >970 g a.i./ha (ametoctradin)	668 g a.i./ha	<0.69	No
	48-h exposure, 11-d observation (dry residues on barley seedlings)	BAS 650 00 F Fungicide	LR50 >1962 g a.i./ha	668 g a.i./ha	<0.34	No
		Zampro Fungicide	LR50 >717 g a.i./ha (ametoctradin)	668 g a.i./ha	<0.93	No
Predaceous mite (Typhlodromus pyri)	Acute contact 7-d (laboratory-treated glass plates)	BAS 650 00 F Fungicide	LR50 >1843 g a.i./ha	668 g a.i./ha	<0.36	No
		Zampro Fungicide	LR50 >970 g a.i./ha (ametoctradin)	668 g a.i./ha	<0.69	No
	Field study (Germany): 4 applications, 68-d period, May-June	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 2.4 L EP/ha or 491 g a.i./ha (NOEC = 838 g a.i./ha)e	668 g a.i./ha	0.80	No
	Field study (France): 4 applications, 63-d period, April-June	BAS 650 00 F Fungicide	Slight/transient effects at 4 applications of 468 g a.i./ha (NOEC = 799 g a.i./ha)f	668 g a.i./ha	0.84	No
	Field study (France): 4 applications, 66-d period, May-June	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha)e	668 g a.i./ha	0.80	No
	Field study (Germany): 4 applications, 62-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha)e	668 g a.i./ha	0.80	No
	Field study (France): 4 applications, 61-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha)e	668 g a.i./ha	0.80	No
	Field study (France): 4 applications, 61-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha)e	668 g a.i./ha	0.80	No
	Field study (France): 4 applications, 61-d period, June-July	BAS 650 00 F Fungicide	No adverse effects at 4 applications of 491 g a.i./ha (NOEC = 838 g a.i./ha)e	668 g a.i./ha	0.80	No

Organism	Exposure	Test Substance	Endpoint Value	EEC	RQ	LOC Exceeded?
	applications, 60-d period, June-July		applications of 491 g a.i./ha (NOEC = 838 g a.i./ha)e			
Green lacewing (Chrysoperlea carnea)	Contact, up to 15-d observation (laboratory-treated glass plates)	BAS 650 00 F Fungicide	LR50 >735.8 g a.i./ha	668 g a.i./ha	<0.91	No
	Acute contact 7-d	Zampro Fungicide	LR50 >956 g a.i./ha (ametoctradin)	668 g a.i./ha	<0.70	No
Springtail (Folsomia candida)	28-d Chronic	BAS 650 00 F Fungicide	NOEC ≥ 194.8 mg a.i./kg soil dw	0.363 8 mg a.i./kg soil dw	< 0.01	No
		Zampro Fungicide	NOEC ≥ 268.0 mg a.i./kg soil dw (ametoctradin)	0.363 8 mg a.i./kg soil dw	< 0.01	No
		M650F03	NOEC = 50 mg/kg soil dw	0.292 8 mg a.i./kg soil dw b	0.01	No
		M650F04	NOEC ≥ 95.8 mg/kg soil dw	0.273 8 mg a.i./kg soil dw c	< 0.01	No
Soil mites (Hypoaspis aculeifer)	14-d Reproduction	M650F03	NOEC ≥ 100 mg/kg soil dw	0.292 8 mg a.i./kg soil dw b	< 0.01	No
		M650F04	NOEC ≥ 95.8 mg/kg soil dw	0.2738 mg a.i./kg soil dw c	< 0.01	No
<b>Vascular Plants</b>						
Sunflower (Helianthus annuus), oilseed rape (Brassica napus), sugar beet (Beta vulgaris), soybean (Glycine max), pea (Pisum sativum), tomato (Lycopersicon esculentum), onion (Allium cepa), oat (Avena sativa), barley (Hordeum vulgare), corn (Zea mays)	Vegetative vigour (21-d observation)	BAS 650 00 F Fungicide	EC25 > 570 g a.i./ha (ametoctradin)	817.7 g a.i./ha	< 1.43	Yesg
	Seedling emergence (21-d observation)	BAS 650 00 F Fungicide	EC25 > 570 g a.i./ha (ametoctradin)	817.7 g a.i./ha	< 1.43	Yesg
Oilseed rape (Brassica napus), carrot (Daucus carota),	Vegetative vigour (21-d observation)	Zampro Fungicide	EC25 > 1500 g a.i./ha (ametoctradin)	817.7 g a.i./ha	< 0.55	No
	Seedling	Zampro	EC25 > 1500 g	817.7 g a.i./ha	< 0.55	No

Organism	Exposure	Test Substance	Endpoint Value	EEC	RQ	LOC Exceeded?
soybean (Glycine max), cabbage (Brassica oleracea), tomato (Lycopersicon esculentum), lettuce (Lactuca sativa), ryegrass (Lolium perenne), wheat (Triticum aestivum), onion (Allium cepa), corn (Zea mays)	emergence (21-d observation)	Fungicide	a.i./ha (ametoctradin)			

aEEC for M650F01 = 0.363 mg a.i./kg soil dw \* (249.3 g/mol M650F01 / 275.4 g/mol ametoctradin).

bEEC for M650F03 = 0.363 mg a.i./kg soil dw \* (221.2 g/mol M650F03 / 275.4 g/mol ametoctradin).

cEEC for M650F01 = 0.363 mg a.i./kg soil dw \* (207.2 g/mol M650F04 / 275.4 g/mol ametoctradin).

dEndpoint derived according to Atkins (1981), whereby LD50 µg/bee x 1.12 = LD50 kg/ha.

eNOEC estimated from 4 applications of 491 g a.i./ha at a 12-d interval and a default foliar half-life of 10 days.

fNOEC estimated from 4 applications of 468 g a.i./ha at a 12-d interval and a default foliar half-life of 10 days.

g There is uncertainty as to whether the LOC was exceeded as the endpoint was above the highest tested concentration and the resulting RQ therefore represents an upper boundary of potential risk.

**Table 21 Screening Level Risk Assessment on Birds and Small Mammals**

Exposure	Test Substance	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE <sup>a</sup> (mg a.i./kg bw/d)	RQ	LOC Exceeded?
<b>Birds</b>						
<b>Small Bird (0.02 kg)</b>						
Acute	Ametoctradin	200.00	Insectivore (small insects)	33.66	0.17	No
	Zampro Fungicide	54.50 <sup>b</sup>	Insectivore (small insects)	33.66	0.62	No
Reproduction	Ametoctradin	115.20	Insectivore (small insects)	33.66	0.29	No
<b>Medium Sized Bird (0.1 kg)</b>						
Acute	Ametoctradin	200.00	Insectivore (small insects)	26.27	0.13	No
	Zampro Fungicide	54.50 <sup>b</sup>	Insectivore (small insects)	26.27	0.48	No
Reproduction	Ametoctradin	115.20	Insectivore (small insects)	26.27	0.23	No
<b>Large Sized Bird (1 kg)</b>						
Acute	Ametoctradin	200.00	Herbivore (short grass)	27.41	0.14	No
	Zampro Fungicide	54.50 <sup>b</sup>	Herbivore (short grass)	27.41	0.50	No
Reproduction	Ametoctradin	115.20	Herbivore (short grass)	27.41	0.24	No
<b>Mammals</b>						
<b>Mammals Foraging in Field Crops</b>						
<b>Small Mammal (0.015 kg)</b>						
Acute	Ametoctradin	200.00	Insectivore (small insects)	19.19	0.10	No
	BAS 650 00 F Fungicide	38.32	Insectivore (small insects)	19.19	<0.50	No
	Zampro Fungicide	13.47 <sup>b</sup>	Insectivore (small insects)	19.19	<b>1.42</b>	<b>Yes</b>
Reproduction	Ametoctradin	939.00	Insectivore (small)	19.19	0.02	No

Exposure	Test Substance	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE <sup>a</sup> (mg a.i./kg bw/d)	RQ	LOC Exceeded?
			insects)			
<b>Medium Sized Mammal (0.035 kg)</b>						
Acute	Ametoctradin	200.00	Herbivore (short grass)	60.11	0.30	No
	BAS 650 00 F Fungicide	38.32	Herbivore (short grass)	60.11	<1.57	Yes <sup>c</sup>
	Zampro Fungicide	13.47 <sup>b</sup>	Herbivore (short grass)	60.11	4.46	Yes
	Ametoctradin	200.00	Herbivore (leafy foliage)	113.29	0.57	No
	BAS 650 00 F Fungicide	38.32	Herbivore (leafy foliage)	113.29	<2.96	Yes <sup>c</sup>
	Zampro Fungicide	13.47 <sup>b</sup>	Herbivore (leafy foliage)	113.29	8.41	Yes
Reproduction	Ametoctradin	939.00	Herbivore (short grass)	60.11	0.06	No
	Ametoctradin	939.00	Herbivore (leafy foliage)	113.29	0.12	No
<b>Large Sized Mammal (1 kg)</b>						
Acute	Ametoctradin	200.00	Herbivore (short grass)	32.12	0.16	No
	BAS 650 00 F Fungicide	38.32	Herbivore (short grass)	32.12	0.84	No
	Zampro Fungicide	13.47 <sup>b</sup>	Herbivore (short grass)	32.12	2.38	Yes
	Ametoctradin	200.00	Herbivore (leafy foliage)	60.53	0.30	No
	BAS 650 00 F Fungicide	38.32	Herbivore (leafy foliage)	60.53	<1.58	Yes <sup>c</sup>
	Zampro Fungicide	13.47 <sup>b</sup>	Herbivore (leafy foliage)	60.53	4.49	Yes
Reproduction	Ametoctradin	939.00	Herbivore (short grass)	32.12	0.03	No
	Ametoctradin	939.00	Herbivore (leafy foliage)	60.53	0.06	No
<b>Mammals Foraging in Vineyard Crops</b>						
<b>Small Mammal (0.015 kg)</b>						
Acute	Ametoctradin	200.00	Insectivore (small insects)	19.36	0.10	No
	BAS 650 00 F Fungicide	38.32	Insectivore (small insects)	19.36	<0.51	No
	Zampro Fungicide	13.47 <sup>b</sup>	Insectivore (small insects)	19.36	1.44	Yes
Reproduction	Ametoctradin	939.00	Insectivore (small insects)	19.36	0.02	No
<b>Medium Sized Mammal (0.035 kg)</b>						
Acute	Ametoctradin	200.00	Herbivore (short grass)	60.65	0.30	No
	BAS 650 00 F Fungicide	38.32	Herbivore (short grass)	60.65	<1.58	Yes <sup>c</sup>
	Zampro Fungicide	13.47 <sup>b</sup>	Herbivore (short grass)	60.65	4.50	Yes
Reproduction	Ametoctradin	939.00	Herbivore (short grass)	60.65	0.06	No

Exposure	Test Substance	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE <sup>a</sup> (mg a.i./kg bw/d)	RQ	LOC Exceeded?
<b>Large Sized Mammal (1 kg)</b>						
Acute	Ametoctradin	200.00	Herbivore (short grass)	32.41	0.16	No
	BAS 650 00 F Fungicide	38.32	Herbivore (short grass)	32.41	<0.85	No
	Zampro Fungicide	13.47 <sup>b</sup>	Herbivore (short grass)	32.41	<b>2.41</b>	<b>Yes</b>
Reproduction	Ametoctradin	939.00	Herbivore (short grass)	32.41	0.03	No

a EDE = Estimated daily exposure; is calculated using the following formula: (FIR/BW) x EEC, where:

FIR: Food Ingestion Rate (Nagy, 1987). For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = 0.235(BW in g) 0.822

BW: Generic Body Weight

EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.

<sup>b</sup>Based on ametoctradin content in formulation.

<sup>c</sup>Based on the available data, the LD50 was above the highest tested concentration and the resulting RQ therefore represents a conservative upper boundary of potential risk.

**Table 22 Refined Risk Assessment for Small Mammals Feeding in Field Crops Treated With Zampro Fungicide**

			Maximum nomogram residues						Mean nomogram residues					
			On-field			Off Field			On-field			Off Field		
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?
<b>Small Mammal (0.015 kg)</b>														
Acute	13.47	Insectivore (small insects)	19.19	<b>1.42</b>	<b>Yes</b>	1.15	0.086	No	10.70	0.79	No	0.64	0.048	No
	13.47	Granivore (grain and seeds)	4.80	0.36	No	0.29	0.021	No	2.29	0.17	No	0.14	0.010	No
	13.47	Frugivore (fruit)	9.59	0.71	No	0.58	0.043	No	4.58	0.34	No	0.27	0.020	No
<b>Medium Sized Mammal (0.035 kg)</b>														
Acute	13.47	Insectivore (small insects)	16.82	<b>1.25</b>	<b>Yes</b>	1.01	0.075	No	9.38	0.70	No	0.56	0.042	No
	13.47	Insectivore (large insects)	4.20	0.31	No	0.25	0.019	No	2.01	0.15	No	0.12	0.0089	No
	13.47	Granivore (grain and seeds)	4.20	0.31	No	0.25	0.019	No	2.01	0.15	No	0.12	0.0089	No
	13.47	Frugivore (fruit)	8.41	0.62	No	0.50	0.038	No	4.01	0.30	No	0.24	0.018	No
	13.47	Herbivore (short grass)	60.11	<b>4.46</b>	<b>Yes</b>	3.61	0.27	No	21.35	<b>1.58</b>	<b>Yes</b>	1.28	0.095	No
	13.47	Herbivore (long grass)	36.70	<b>2.72</b>	<b>Yes</b>	2.20	0.16	No	11.98	0.89	No	0.72	0.053	No
	13.47	Herbivore (forage crops)	55.61	<b>4.13</b>	<b>Yes</b>	3.34	0.25	No	18.38	<b>1.36</b>	<b>Yes</b>	1.10	0.082	No
	13.47	Herbivore (leafy foliage)	113.29	<b>8.41</b>	<b>Yes</b>	n/a	n/a	n/a	37.45	<b>2.78</b>	<b>Yes</b>	n/a	n/a	n/a



			Maximum nomogram residues						Mean nomogram residues					
			On-field			Off Field			On-field			Off Field		
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?
<b>Large Sized Mammal (1 kg)</b>														
Acute	13.47	Insectivore (small insects)	8.99	0.67	No	0.54	0.0400	No	5.01	0.37	No	0.30	0.022	No
	13.47	Insectivore (large insects)	2.25	0.17	No	0.13	0.0100	No	1.07	0.080	No	0.06	0.0048	No
	13.47	Granivore (grain and seeds)	2.25	0.17	No	0.13	0.0100	No	1.07	0.080	No	0.06	0.0048	No
	13.47	Frugivore (fruit)	4.49	0.34	No	0.27	0.0200	No	2.14	0.16	No	0.13	0.0095	No
	13.47	Herbivore (short grass)	32.12	<b>2.38</b>	<b>Yes</b>	1.93	0.14	No	11.41	0.85	No	0.68	0.051	No
	13.47	Herbivore (long grass)	19.61	<b>1.46</b>	<b>Yes</b>	1.18	0.087	No	6.40	0.48	No	0.38	0.029	No
	13.47	Herbivore (forage crops)	29.72	<b>2.21</b>	<b>Yes</b>	1.78	0.13	No	9.82	0.73	No	0.59	0.044	No
	13.47	Herbivore (leafy foliage)	60.53	<b>4.49</b>	<b>Yes</b>	n/a	n/a	n/a	20.01	<b>1.49</b>	<b>Yes</b>	n/a	n/a	n/a

**Table 23 Refined Risk Assessment for Small Mammals Feeding in Vineyard Crops Treated with Zampro Fungicide**

			Maximum nomogram residues						Mean nomogram residues					
			On-field			Off Field			On-field			Off Field		
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?
<b>Small Mammal (0.015 kg)</b>														
Acute	13.47	Insectivore (small insects)	19.36	<b>1.44</b>	<b>Yes</b>	14.33	<b>1.06</b>	<b>Yes</b>	10.70	0.79	No	7.92	0.59	No
	13.47	Granivore (grain and seeds)	4.84	0.36	No	3.58	0.27	No	2.29	0.17	No	1.69	0.13	No
	13.47	Frugivore (fruit)	9.68	0.72	No	7.16	0.53	No	4.58	0.34	No	3.39	0.25	No
<b>Medium Sized Mammal (0.035 kg)</b>														
Acute	13.47	Insectivore (small insects)	16.97	<b>1.26</b>	<b>Yes</b>	12.56	0.93	No	9.38	0.70	No	6.94	0.52	No
	13.47	Insectivore (large insects)	4.24	0.31	No	3.14	0.23	No	2.01	0.15	No	1.48	0.11	No
	13.47	Granivore (grain and seeds)	4.24	0.31	No	3.14	0.23	No	2.01	0.15	No	1.48	0.11	No
	13.47	Frugivore (fruit)	8.49	0.63	No	6.28	0.47	No	4.01	0.30	No	2.97	0.22	No
	13.47	Herbivore (short grass)	60.65	<b>4.50</b>	<b>Yes</b>	44.88	<b>3.33</b>	<b>Yes</b>	21.35	<b>1.58</b>	<b>Yes</b>	15.80	<b>1.17</b>	<b>Yes</b>
	13.47	Herbivore	37.03	<b>2.75</b>	<b>Yes</b>	27.41	<b>2.03</b>	<b>Yes</b>	11.98	0.89	No	8.87	0.66	No

			Maximum nomogram residues						Mean nomogram residues					
			On-field			Off Field			On-field			Off Field		
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?	EDE (mg a.i./kg bw/d)	RQ	LOC Exceeded?
		(long grass)												
	13.47	Herbivore (forage crops)	56.12	<b>4.17</b>	<b>Yes</b>	41.53	<b>3.08</b>	<b>Yes</b>	18.38	<b>1.36</b>	<b>Yes</b>	13.60	<b>1.01</b>	<b>Yes</b>
<b>Large Sized Mammal (1 kg)</b>														
Acute	13.47	Insectivore (small insects)	9.07	0.67	No	6.71	0.50	No	5.01	0.37	No	3.71	0.28	No
	13.47	Insectivore (large insects)	2.27	0.17	No	1.68	0.12	No	1.07	0.08	No	0.79	0.06	No
	13.47	Granivore (grain and seeds)	2.27	0.17	No	1.68	0.12	No	1.07	0.08	No	0.79	0.06	No
	13.47	Frugivore (fruit)	4.53	0.34	No	3.36	0.25	No	2.14	0.16	No	1.59	0.12	No
	13.47	Herbivore (short grass)	32.41	<b>2.41</b>	<b>Yes</b>	23.98	<b>1.78</b>	<b>Yes</b>	11.41	0.85	No	8.44	0.63	No
	13.47	Herbivore (long grass)	19.79	<b>1.47</b>	<b>Yes</b>	14.64	<b>1.09</b>	<b>Yes</b>	6.40	0.48	No	4.74	0.35	No
	13.47	Herbivore (forage crops)	29.99	<b>2.23</b>	<b>Yes</b>	22.19	<b>1.65</b>	<b>Yes</b>	9.82	0.73	No	7.27	0.54	No

**Table 24 Summary of Toxicity of Ametoctradin, Zampro Fungicide, BAS 650 00 F Fungicide and Major Transformation Products to Aquatic Life**

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference
<b>Freshwater Species</b>					
<b>Algae</b>					
Green algae: ( <i>Pseudokirchneriella subcapitata</i> )	Acute 96-h static	Ametoctradin	E <sub>50</sub> and E <sub>100</sub> >0.118 mg a.i./L	N/A	1871479
	Acute 72-h static	BAS 650 00 F Fungicide	E <sub>50</sub> and E <sub>100</sub> >100 mg EP/L, or >18.4 mg ametoctradin/L	N/A	1871810
		Zampro Fungicide	E <sub>50</sub> = 74.2 mg EP/L or = 20.2 mg ametoctradin/L, or = 15.0 mg dimethomorph/L  E <sub>100</sub> = 72.6 mg EP/L or = 19.8 mg ametoctradin/L, or = 14.7 mg dimethomorph/L	N/A	1871635
		M650F03	E <sub>50</sub> and E <sub>100</sub> >82.6 mg/L	N/A	1871493
		M650F04	E <sub>50</sub> and E <sub>100</sub> >95.8 mg/L	N/A	1871486
Blue-green algae ( <i>Anabaena flos-aquae</i> )	Acute 96-h static	Ametoctradin	E <sub>50</sub> and E <sub>100</sub> >0.0679 mg a.i./L	N/A	1871483
Diatom	Acute 96-h static	Ametoctradin	E <sub>50</sub> >0.0203 mg a.i./L	N/A	1871482

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference
<i>(Navicula pelliculosa)</i>			E <sub>7</sub> C <sub>50</sub> = 0.0078 mg a.i./L		
<b>Plants</b>					
Duckweed <i>(Lemna gibba)</i>	Acute 48-h semi-static	Ametoctradin	E <sub>7</sub> C <sub>50</sub> > 0.211 mg a.i./L E <sub>7</sub> C <sub>50</sub> = 0.132 mg a.i./L	N/A	1871506
<b>Invertebrates</b>					
<i>Daphnia magna</i>	Acute 48-h static	Ametoctradin	EC <sub>50</sub> > 0.155 mg a.i./L	Not toxic up to functional solubility limit <sup>b</sup>	1871447
		BAS 650 00 F Fungicide	EC <sub>50</sub> > 105.2 mg EP/L or > 19.4 mg ametoctradin/L	Practically non-toxic	1871798
		Zampro Fungicide	EC <sub>50</sub> > 77.9 mg EP/L or > 21.2 mg ametoctradin/L, or > 15.7 mg dimethomorph/L	Practically non-toxic <sup>c</sup>	1871633
		M650F01	EC <sub>50</sub> > 100 mg/L	Practically non-toxic	1871445
		M650F02	EC <sub>50</sub> > 75.8 mg/L	Practically non-toxic <sup>c</sup>	1871464
		M650F03	EC <sub>50</sub> > 82.6 mg/L	Practically non-toxic <sup>c</sup>	1871460
		M650F04	EC <sub>50</sub> > 95.8 mg/L	Practically non-toxic <sup>c</sup>	1871457
	Chronic 21-d semi-static	Ametoctradin	LOEC = 0.088 mg a.i./L NOEC = 0.044 mg a.i./L Endpoints based on average offspring per living female.	N/A	1871466
		M650F03	LOEC = 83.5 mg/L NOEC = 41.8 mg/L Endpoints based on parental growth and survival, reduced fecundity.	N/A	1871472
	Midge <i>(Chironomus riparius)</i>	Chronic 28-d static, spiked sediment	BAS 650 00 F Fungicide	NOEC = 221.6 mg ametoctradin/kg dw sed NOEC = 0.242 mg ametoctradin/L (pore water) NOEC = 0.0064 mg ametoctradin/L (overlying water) Endpoints based on emergence rate.	N/A
<b>Fish</b>					
Rainbow trout <i>(Oncorhynchus mykiss)</i>	Acute 96-h flow-through	Ametoctradin	LC <sub>50</sub> > 0.0646 mg a.i./L	Not toxic up to functional solubility limit <sup>b</sup>	1871415
	Acute 96-h static	BAS 650 00 F Fungicide	LC <sub>50</sub> > 103 mg EP/L or > 19.0 mg ametoctradin/L	Practically non-toxic	1871807
		Zampro Fungicide	LC <sub>50</sub> = 23.2 mg EP/L or = 6.32 mg ametoctradin/L, or = 4.68 mg dimethomorph/L	Slightly toxic	1871631
		M650F03	LC <sub>50</sub> > 82.6 mg/L	Practically non-toxic <sup>c</sup>	1871427
		M650F04	LC <sub>50</sub> > 95.8 mg/L	Practically non-toxic <sup>c</sup>	1871432
Common carp <i>(Cyprinus carpio)</i>	Acute 96-h flow-through	Ametoctradin	LC <sub>50</sub> > 0.110 mg a.i./L	Not toxic up to functional solubility limit <sup>b</sup>	1871422
Bluegill sunfish <i>(Lepomis macrochirus)</i>	Acute 96-h flow-through	Ametoctradin	LC <sub>50</sub> > 0.129 mg a.i./L	Not toxic up to functional solubility limit <sup>b</sup>	1871417
Fathead minnow	Acute 96-h flow-	Ametoctradin	LC <sub>50</sub> > 0.123 mg a.i./L	Not toxic up to	1871424

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity <sup>a</sup>	Reference
<i>(Pimephales promelas)</i>	through			functional solubility limit <sup>b</sup>	
	Chronic (ELS) 33-d flow-through	Ametoctradin	LOEC = 0.124 mg a.i./L NOEC = 0.0480 mg a.i./L Endpoints based on survival	N/A	1871435
<b>Marine Species</b>					
<b>Algae</b>					
Saltwater diatom ( <i>Skeletonema costatum</i> )	Acute 96-h static	Ametoctradin	E <sub>r</sub> C <sub>50</sub> and E <sub>y</sub> C <sub>50</sub> >0.108 mg a.i./L	Not toxic up to functional solubility limit <sup>b</sup>	1871493
<b>Invertebrates</b>					
Mollusk Eastern oyster ( <i>Crassostrea virginica</i> )	Acute 96-h flow-through	Ametoctradin	EC <sub>50</sub> >0.097 mg a.i./L	Not toxic up to functional solubility limit <sup>b</sup>	1871387
Crustacean mysid ( <i>Americamysis bahia</i> )	Acute 96-h flow-through	Ametoctradin	LC <sub>50</sub> >0.094 mg a.i./L	Not toxic up to functional solubility limit <sup>b</sup>	1871385
Amphipod ( <i>Leptocheirus plumulosus</i> )	Acute 10-d static, spiked sediment	BAS 650 00 F Fungicide	EC <sub>50</sub> >70 mg ametoctradin/kg dw sed EC <sub>50</sub> >0.500 mg ametoctradin/L (pore water) EC <sub>50</sub> >0.046 mg ametoctradin/L (overlying water)	N/A	1871497
<b>Fish</b>					
Sheepshead minnow ( <i>Cyprinodon variegates</i> )	Acute 96-h flow-through	Ametoctradin	LC <sub>50</sub> >0.110 mg a.i./L	Not toxic up to functional solubility limit <sup>b</sup>	1871390

aUS EPA classification for aquatic organisms, where applicable.

bToxicity endpoint is higher than maximum achievable test concentration; therefore ametoctradin considered not to be toxic up to its functional solubility limit within the test system.

cToxicity endpoint was higher than 100 mg/L based on nominal application rates; therefore PMRA considers the end-use product to be practically non-toxic according US EPA classification criteria.

**Table 25 Screening Level Risk Assessment for Aquatic Organisms**

Organism	Exposure	Test Substance	Endpoint Value	EEC (mg/L)	RQ	LOC Exceeded?
<b>Freshwater Species</b>						
<b>Algae</b>						
Green algae: ( <i>Pseudokirchneriella subcapitata</i> )	Acute 96-h static	Ametoctradin	1/2 E <sub>r</sub> C <sub>50</sub> or E <sub>y</sub> C <sub>50</sub> >0.059 mg a.i./L	0.0432	<0.73	No
	Acute 72-h static	BAS 650 00 F Fungicide	1/2 E <sub>r</sub> C <sub>50</sub> or E <sub>y</sub> C <sub>50</sub> >9.2 mg a.i./L	0.0432	<0.01	No
		Zampro Fungicide	1/2 E <sub>r</sub> C <sub>50</sub> = 10.1 mg a.i./L (ametoctradin)	0.0432	<0.01	No
			1/2 E <sub>y</sub> C <sub>50</sub> = 9.9 mg a.i./L (ametoctradin)	0.0432	<0.01	No
		M650F03	1/2 E <sub>r</sub> C <sub>50</sub> or E <sub>y</sub> C <sub>50</sub> >41.3 mg/L	0.0347	<0.01	No
M650F04	1/2 E <sub>r</sub> C <sub>50</sub> or E <sub>y</sub> C <sub>50</sub> >47.9 mg/L	0.0325	<0.01	No		
Blue-green algae ( <i>Anabaena flos-aquae</i> )	Acute 96-h static	Ametoctradin	1/2 E <sub>r</sub> C <sub>50</sub> or E <sub>y</sub> C <sub>50</sub> >0.0340 mg a.i./L	0.0432	<1.27	Yes <sup>a</sup>
Diatom ( <i>Navicula pelliculosa</i> )	Acute 96-h static	Ametoctradin	1/2 E <sub>r</sub> C <sub>50</sub> >0.0102 mg a.i./L	0.0432	<4.26	Yes <sup>a</sup>
			1/2 E <sub>y</sub> C <sub>50</sub> = 0.0039 mg a.i./L	0.0432	11.08	Yes
<b>Plants</b>						
Duckweed ( <i>Lemna gibba</i> )	Acute 48-h semi-static	Ametoctradin	1/2 E <sub>r</sub> C <sub>50</sub> >0.106 mg a.i./L	0.0432	<0.41	No

			1/2 E <sub>y</sub> C <sub>50</sub> = 0.066 mg a.i./L	0.0432	0.65	No
<b>Invertebrates</b>						
<i>Daphnia magna</i>	Acute 48-h static	Ametoctradin	1/2 EC <sub>50</sub> >0.0775 mg a.i./L	0.0432	<0.56	No
		BAS 650 00 F Fungicide	1/2 EC <sub>50</sub> >9.7 mg a.i./L	0.0432	<0.01	No
		Zampro Fungicide	1/2 EC <sub>50</sub> >10.6 mg a.i./L (ametoctradin)	0.0432	<0.01	No
		M650F01	1/2 EC <sub>50</sub> >50 mg/L	0.0391	<0.01	No
		M650F02	1/2 EC <sub>50</sub> >37.9 mg/L	0.0369	<0.01	No
		M650F03	1/2 EC <sub>50</sub> >41.3 mg/L	0.0347	<0.01	No
	Chronic 21-d semi-static	Ametoctradin	NOEC = 0.044 mg a.i./L	0.0432	0.98	No
		M650F03	NOEC = 41.8 mg/L	0.0347	<0.01	No
<b>Fish</b>						
Rainbow trout ( <i>Oncorhynchus mykiss</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.00646 mg a.i./L	0.0432	<b>&lt;6.69</b>	<b>Yes<sup>a</sup></b>
	Acute 96-h static	BAS 650 00 F Fungicide	1/10 LC <sub>50</sub> >1.90 mg a.i./L	0.0432	<0.02	No
		Zampro Fungicide	1/10 LC <sub>50</sub> = 0.632 mg a.i./L (ametoctradin)	0.0432	0.07	No
		M650F03	1/10 LC <sub>50</sub> >8.26 mg/L	0.0347	<0.01	No
		M650F04	1/10 LC <sub>50</sub> >9.58 mg/L	0.0325	<0.01	No
Common carp ( <i>Cyprinus carpio</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.011 mg a.i./L	0.0432	<b>&lt;3.93</b>	<b>Yes<sup>a</sup></b>
Bluegill sunfish ( <i>Lepomis macrochirus</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.0129 mg a.i./L	0.0432	<b>&lt;3.35</b>	<b>Yes<sup>a</sup></b>
Fathead minnow ( <i>Pimephales promelas</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.0123 mg a.i./L	0.0432	<b>&lt;3.51</b>	<b>Yes<sup>a</sup></b>
	Chronic (ELS) 33-d flow-through	Ametoctradin	NOEC = 0.0480 mg a.i./L	0.0432	0.90	No
Amphibians	Acute (96-h)	Ametoctradin	1/10 LC <sub>50</sub> >0.00646 mg a.i./L	0.23	<b>&lt;35.60</b>	<b>Yes<sup>a</sup></b>
		BAS 650 00 F Fungicide	1/10 LC <sub>50</sub> >1.90 mg a.i./L	0.23	<0.12	No
		Zampro Fungicide	1/10 LC <sub>50</sub> = 0.632 mg a.i./L (ametoctradin)	0.23	0.36	No
		M650F03	1/10 LC <sub>50</sub> >8.26 mg/L	0.185	<0.02	No
		M650F04	1/10 LC <sub>50</sub> >9.58 mg/L	0.173	<0.02	No
	Chronic (Early Life Stage) 33-d	Ametoctradin	NOEC = 0.0480 mg a.i./L (fathead minnow; survival endpoint)	0.23	<b>4.79</b>	<b>Yes</b>
<b>Marine Species</b>						
<b>Algae</b>						
Saltwater diatom ( <i>Skeletonema costatum</i> )	Acute 96-h static	Ametoctradin	1/2 E <sub>r</sub> C <sub>50</sub> and E <sub>y</sub> C <sub>50</sub> >0.054 mg a.i./L	0.0432	<0.80	No
<b>Invertebrates</b>						
Mollusk Eastern oyster ( <i>Crassostrea virginica</i> )	Acute 96-h flow-through	Ametoctradin	1/2 EC <sub>50</sub> >0.0485 mg a.i./L	0.0432	<0.89	No
Crustacean mysid ( <i>Americanysis bahia</i> )	Acute 96-h flow-through	Ametoctradin	1/2 LC <sub>50</sub> >0.047 mg a.i./L	0.0432	<0.92	No
<b>Fish</b>						
Sheepshead minnow ( <i>Cyprinodon variegates</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.011 mg a.i./L	0.0432	<b>&lt;3.93</b>	<b>Yes<sup>a</sup></b>

<sup>a</sup>The LOC is potentially exceeded due to the limited solubility of the test substance and how effects endpoints are reported. Thus, the RQ represents a conservative upper boundary of potential risk, while actual risk in the environment will depend on solubility of the test substance in natural waters, which is expected to be below thresholds for effects. See text for additional explanation.

**Table 26 Refined Risk Assessment for Aquatic Organisms Based on Spray Drift Inputs Only**

Organism	Exposure	Test Substance	Endpoint Value	Field Sprayer		Airblast – Early Season		Airblast – Late Season		Aerial		LOC Exceeded ?
				EEC (mg/L)	RQ	EEC (mg/L)	RQ	EEC (mg/L)	RQ	EEC (mg/L)	RQ	
<b>Freshwater Species</b>												
<b>Algae</b>												
Blue-green algae ( <i>Anabaena flos-aquae</i> )	Acute 96-h static	Ametoctradin	1/2 E <sub>r</sub> C <sub>50</sub> or E <sub>y</sub> C <sub>50</sub> >0.0340 mg a.i./L	0.00259	<0.08	0.0295	<0.87	0.0235	<0.69	0.0094	<0.28	No
Diatom ( <i>Navicula pelliculosa</i> )	Acute 96-h static	Ametoctradin	1/2 E <sub>y</sub> C <sub>50</sub> = 0.0039 mg a.i./L	0.00259	0.66	0.0295	<b>7.56</b>	0.0235	<b>6.03</b>	0.0094	<b>2.41</b>	<b>Yes</b>
<b>Fish</b>												
Rainbow trout ( <i>Oncorhynchus mykiss</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.00646 mg a.i./L	0.00259	<0.40	0.0295	<b>&lt;4.57</b>	0.0235	<b>&lt;3.64</b>	0.0094	<b>&lt;1.46</b>	<b>Yes<sup>a</sup></b>
Common carp ( <i>Cyprinus carpio</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.011 mg a.i./L	0.00259	<0.24	0.0295	<b>&lt;2.68</b>	0.0235	<b>&lt;2.14</b>	0.0094	<0.85	<b>Yes<sup>a</sup></b>
Bluegill sunfish ( <i>Lepomis macrochirus</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.0129 mg a.i./L	0.00259	<0.20	0.0295	<b>&lt;2.29</b>	0.0235	<b>&lt;1.82</b>	0.0094	<0.73	<b>Yes<sup>a</sup></b>
Fathead minnow ( <i>Pimephales promelas</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.0123 mg a.i./L	0.00259	<0.21	0.0295	<b>&lt;2.40</b>	0.0235	<b>&lt;1.91</b>	0.0094	<0.76	<b>Yes<sup>a</sup></b>
Amphibians	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.00646 mg a.i./L	0.0138	<b>&lt;2.14</b>	0.1580	<b>&lt;24.5</b>	0.126	<b>&lt;19.5</b>	0.0529	<b>&lt;8.19</b>	<b>Yes<sup>a</sup></b>
	Chronic (Early Life Stage (33-d))	Ametoctradin	NOEC = 0.0480 mg a.i./L (fathead minnow; survival endpoint)	0.0138	0.29	0.1580	<b>3.29</b>	0.126	<b>2.63</b>	0.0529	<b>1.10</b>	<b>Yes</b>
<b>Marine Species</b>												
<b>Fish</b>												
Sheepshead minnow (Cyprinodon variegates)	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.011 mg a.i./L	0.00259	<0.24	0.0295	<b>&lt;2.68</b>	0.0235	<b>&lt;2.14</b>	0.0094	<0.85	<b>Yes<sup>a</sup></b>

<sup>a</sup>The LOC is potentially exceeded due to the limited solubility of the test substance and how effects endpoints are reported. Thus, the RQ represents a conservative upper boundary of potential risk, while actual risk in the environment will depend on solubility of the test substance in natural waters, which is expected to be below thresholds for effects. See text for additional explanation.

**Table 27 Refined Risk Assessment for Aquatic Organisms Based on Runoff Inputs Only**

Organism	Exposure	Test Substance	Endpoint Value	Use Scenario				LOC Exceeded?
				PEI Potatoes		ON Grapes		
				EEC (mg/L)	RQ	EEC (mg/L)	RQ	
<b>Freshwater Species</b>								
<b>Algae</b>								
Blue-green algae ( <i>Anabaena flos-aquae</i> )	Acute 96-h static	Ametoctradin	1/2 E <sub>r</sub> C <sub>50</sub> or E <sub>y</sub> C <sub>50</sub> >0.0340 mg a.i./L	0.0034	<0.10	0.00071	<0.02	No
Diatom ( <i>Navicula pelliculosa</i> )	Acute 96-h static	Ametoctradin	1/2 E <sub>r</sub> C <sub>50</sub> = 0.0039 mg a.i./L	0.0034	0.87	0.00071	0.18	No
<b>Invertebrates</b>								
Midge ( <i>Chironomus riparius</i> )	Chronic 28-d static, spiked sediment	BAS 650 00 F Fungicide	NOEC = 0.242 mg a.i./L (pore water)	0.00046	<0.01	0.00010	<0.01	No
<b>Fish</b>								
Rainbow trout ( <i>Oncorhynchus mykiss</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.00646 mg a.i./L	0.0034	<0.53	0.00071	<0.11	No
Common carp ( <i>Cyprinus carpio</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.011 mg a.i./L	0.0034	<0.31	0.00071	<0.06	No
Bluegill sunfish ( <i>Lepomis macrochirus</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.0129 mg a.i./L	0.0034	<0.26	0.00071	<0.06	No
Fathead minnow ( <i>Pimephales promelas</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.0123 mg a.i./L	0.0034	<0.28	0.00071	<0.06	No
Amphibians	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.00646 mg a.i./L	0.0085	<1.32	0.00170	<0.26	Yes <sup>a</sup>
	Chronic (Early Life Stage (33-d))	Ametoctradin	NOEC = 0.0480 mg a.i./L (fathead minnow)	0.0027	0.06	0.00048	0.01	No
<b>Marine Species</b>								
<b>Invertebrates</b>								
Amphipod ( <i>Leptocheirus plumulosus</i> )	Acute 10-d static, spiked sediment	BAS 650 00 F Fungicide	1/2 EC <sub>50</sub> >0.25 mg a.i./L (pore water)	0.00054	<0.01	0.00012	<0.01	No
<b>Fish</b>								
Sheepshead minnow ( <i>Cyprinodon variegates</i> )	Acute 96-h flow-through	Ametoctradin	1/10 LC <sub>50</sub> >0.011 mg a.i./L	0.0034	<0.31	0.00071	<0.06	No

<sup>a</sup>The LOC is potentially exceeded due to the limited solubility of the test substance and how effects endpoints are reported. Thus, the RQ represents a conservative upper boundary of potential risk, while actual risk in the environment will depend on solubility of the test substance in natural waters, which is expected to be below thresholds for effects. See text for additional explanation.

**Table 28 Toxic Substances Management Policy Considerations - Comparison of Ametoctradin and its Major Transformation Products to TSMP Track 1 Criteria.**

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
Toxic or toxic equivalent as defined by the <i>Canadian Environmental Protection Act</i> <sup>1</sup>	Yes		Yes. RQs for aquatic invertebrates > LOC.	No. RQs for all Transformation Products < LOC
Predominantly anthropogenic <sup>2</sup>	Yes		Yes	Yes
Persistence <sup>3</sup> :	Soil	Half-life $\geq$ 182 days	Longest DT <sub>50</sub> = 16.7 days (representative half-life [DT <sub>90</sub> / 3.32] = 80.4 days)	M650F01: Not determined. Based on laboratory studies, not expected to persist in environment. M650F02: Transient; not expected to be seen in environment. M650F03: Longest half-life = 75.1 days M650F04: Longest DT <sub>50</sub> = 289 days (representative half-life [DT <sub>90</sub> / 3.32] = 307 days)
	Water	Half-life $\geq$ 182 days	Longest half-life = 0.89 days	M650F01: Longest half-life = 3.2 days M650F02: Longest DT <sub>50</sub> = 16.3 days (representative half-life [DT <sub>90</sub> / 3.32] = 26.9 days) M650F03: : Longest DT <sub>50</sub> = 344 days (representative half-life [DT <sub>90</sub> / 3.32] = 343 days) M650F04: Could not be determined (insufficient data)
	Sediment	Half-life $\geq$ 365 days	Longest DT <sub>50</sub> = 2.1 days (representative half-life [DT <sub>90</sub> / 3.32] = 6.6 days)	M650F01 and M650F04: Could not be determined (insufficient data) M650F02: Longest DT <sub>50</sub> = 19.3 days (representative half-life [DT <sub>90</sub> / 3.32] = 41.6 days) M650F03: Longest half-life = 208 days)
	Air	Half-life $\geq$ 2 days or evidence of long range transport	Half-life or volatilization is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure ( $2.1 \times 10^{-10}$ Pa) and Henry's Law	Not available. Not expected to be volatile, based on parent compound.



TSMP Track 1 Criteria	TSMP Track 1 Criterion value	Active Ingredient Endpoints	Transformation Products Endpoints
		Constant ( $4.08 \times 10^{-12}$ atm*m <sup>3</sup> *mol <sup>-1</sup> ).	
Bioaccumulation <sup>4</sup>	Log K <sub>ow</sub> ≥ 5	4.4 (neutral pH)	Range: 0.16 to 1.0 under acidic to neutral conditions for M650F01, M650F02, M650F03, M650F04
	BCF ≥ 5000	Steady state BCF values (L/kg): 148 (total radioactive residues) 0.37 (BAS 650 F only)	Not available
	BAF ≥ 5000	Not available	Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?		No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.

<sup>1</sup>All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion may be refined if required (i.e., all other TSMP criteria are met).

<sup>2</sup>The 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.

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

<sup>4</sup>Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K<sub>ow</sub>).

**Table 29 Alternative Fungicides Registered for Diseases on Crops and Crop Groups on the Zampro Fungicide and BAS 650 00 F Fungicide Labels**

Pests	Crops	Active Ingredient	Resistance Management Group
Downy mildew	Brassica vegetables	<i>Bacillus subtilis</i> (Strain QST 713)	44
		Boscalid	7
		Chlorothalonil	M5
		Copper (different salts)	M1
		Fenamidone	11
		Fluopicolide	43
		Mandipropamid	40
		Pyraclostrobin	11
	Bulb vegetables	<i>Bacillus subtilis</i> (Strain QST 713)	44
		Boscalid	7
		Copper (different salts)	M1
		Fenamidone	11
		Fosetyl-Al	33
		Mancozeb	M3
		Mandipropamid	40
		Maneb	M3
		Metalaxyl-M and -S isomer	4
		Pyraclostrobin	11
	Cucurbit vegetables	<i>Bacillus subtilis</i> (Strain QST 713)	44
		Chlorothalonil	M5
		Copper (different salts)	M1
Cyazofamid		21	
Fenamidone		11	
Fluopicolide		43	

Pests	Crops	Active Ingredient	Resistance Management Group
		Folpet	M4
		Mancozeb	M3
		Mandipropamid	40
		Maneb	M3
		Propamocarb hydrochloride	28
		Pyraclostrobin	11
		Grape	Boscalid
	Captan		M4
	Copper (different salts)		M1
	Fluopicolide		43
	Folpet		M4
	Kresoxim-methyl		11
	Mancozeb		M3
	Mandipropamid		40
	Metalaxyl-M and -S isomer		4
	Metiram		M3
	Mono- and dipotassium phosphate		33
	Pyraclostrobin		11
	Zoxamide		22
	Hops	Copper (different salts)	M1
		Mandipropamid	40
		Metalaxyl-M and -S isomer	4
	Lettuce, celtuce, endive, radicchio, and upland cress	<i>Bacillus subtilis</i> (Strain QST 713)	44
		Fluopicolide	43
		Fosetyl-Al	33
		Mancozeb	M3
		Mandipropamid	40
		Metalaxyl-M and -S isomer	4
Propamocarb hydrochloride		28	
Late blight (tuber blight)	Potatoes	Azoxystrobin	11
		Captan	M4
		Chlorothalonil	M5
		Copper (different salts)	M1
		Cyazofamid	21
		Cymoxanil	27
		Dimethomorph	40
		Famoxodone	11
		Fluazinam	29
		Fluopicolide	43
		Mancozeb	M3
		Mandipropamid	40
		Maneb	M3
		Metalaxyl-M and -S isomer	4
		Metiram	M3
		Mono- and di-potassium salt of phosphorous acid	33
		Propamocarb hydrochloride	28
		Pyraclostrobin	11
		Zoxamide	22
		Fruiting vegetables	Captan
	Chlorothalonil		M5

Pests	Crops	Active Ingredient	Resistance Management Group
		Copper (different salts)	M1
		Cymoxanil	27
		Famoxadone	11
		Fluopicolide	43
		Mancozeb	M3
		Mandipropamid	40
		Maneb	M3
		Metiram	M3
		Propamocarb hydrochloride	28
		Pyraclostrobin	11
		Thiram	M3
		Ziram	M3
Phytophthora blight	Fruiting vegetables	Fluopicolide	43
		Mandipropamid	40
	Cucurbit vegetables	Fluopicolide	43

**Table 30 Zampro Fungicide Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported**

Proposed use claim	Supported Use
To control downy mildew on brassica leafy vegetables, apply Zampro Fungicide at a rate of 0.8-1.0 L/ha at five to seven day intervals.	Supported with an application intervals of seven days rather five to seven days
To control downy mildew on bulb vegetables, apply Zampro Fungicide at a rate of 1.0 L/ha at five to seven day intervals.	Supported as proposed
To control downy mildew on cucurbit vegetables, apply Zampro Fungicide at a rate of 0.8-1.0 L/ha at five to seven day intervals.	Supported as proposed
To control late blight on fruiting vegetables, apply Zampro Fungicide at a rate of 0.8-1.0 L/ha at five to seven day intervals.	Supported as proposed
To control downy mildew on grapes, apply Zampro Fungicide at a rate of 0.8-1.0 L/ha at seven to ten day intervals.	Supported as proposed
To control downy mildew on hops, apply Zampro Fungicide at a rate of 0.8-1.0 L/ha at ten day intervals.	Supported as proposed
To control downy mildew on leafy vegetables, apply Zampro Fungicide at a rate of 1.0 L/ha at five to seven day intervals	Supported on lettuce (head and leaf), celtuce, endive, radicchio, and upland cress
To control late blight on potatoes, apply Zampro Fungicide at a rate of 0.8-1.0 L/ha at five to seven day intervals	Supported with an application interval of five to ten days rather than five to seven days.
To control tuber blight on potatoes, apply Zampro Fungicide at a rate of 1.0 L/ha at five to seven day intervals	Supported with an application interval of five to ten days rather than five to seven days.
To control phytophthora blight on fruiting vegetables, apply Zampro Fungicide at a rate of 0.8-1.0 L/ha at five to seven day intervals	Conditionally supported for suppression at a rate of 1.0 L/ha.
To control phytophthora blight on cucurbit vegetables, apply Zampro Fungicide at a rate of 1.0 L/ha at five to seven day intervals	Conditionally supported for suppression.

**Table 31 BAS 650 00 F Fungicide Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported**

<b>Proposed use claim</b>	<b>Supported Use</b>
To control downy mildew on brassica leafy vegetables, apply BAS 650 00 F Fungicide at a rate of 1.5 L/ha at five to seven day intervals.	Supported as proposed for suppression.
To control downy mildew on bulb vegetables, apply BAS 650 00 F Fungicide at a rate of 1.5 L/ha at five to seven day intervals.	Supported as proposed
To control downy mildew on cucurbit vegetables, apply BAS 650 00 F Fungicide at a rate of 1.5 L/ha at five to seven day intervals.	Supported as proposed
To control late blight on fruiting vegetables, apply BAS 650 00 F Fungicide at a rate of 1.5 L/ha at five to seven day intervals.	Supported as proposed
To control downy mildew on grapes, apply BAS 650 00 F Fungicide at a rate of 1.2-1.5 L/ha at seven to ten day intervals.	Supported at the rate of 1.2 L/ha
To control downy mildew on hops, apply BAS 650 00 F Fungicide at a rate of 1.2-1.5 L/ha at ten day intervals.	Conditionally supported as proposed
To control downy mildew on leafy vegetables, apply BAS 650 00 F Fungicide at a rate of 1.5 L/ha at five to seven day intervals	Supported for suppression on lettuce (head and leaf), celtnuce, endive, radicchio, and upland cress
To control late blight on potatoes, apply BAS 650 00 F Fungicide at a rate of 1.2-1.5 L/ha at five to seven day intervals	Supported with an application interval of five to ten days rather than five to seven days.
To control phytophthora blight on fruiting vegetables, apply BAS 650 00 F Fungicide at a rate of 1.5 L/ha at five to seven day intervals	Conditionally supported for suppression.
To control phytophthora blight on cucurbit vegetables, apply BAS 650 00 F Fungicide at a rate of 1.5 L/ha at five to seven day intervals	Conditionally supported for suppression.



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

Ametoctradin is a new active ingredient which is concurrently being registered in the United States. The US EPA is in agreement with the specified Canadian MRLs and will be promulgating the same tolerances (40 CFR Part 180).

Currently, there are no Codex MRLs established for ametoctradin.

**Table 1 Differences Between MRLs in Canada and in Other Jurisdictions**

Commodity	Canada (ppm)	U.S.A. (ppm)	Codex* (ppm)
Crop Subgroup 1C – Tuberous and Corm Vegetables Subgroup	0.05	0.05	Not reviewed by Codex
Crop Subgroup 3-07A – Bulb Onion Subgroup	1.5	1.5	
Crop Subgroup 3-07B – Green Onion Subgroup	20	20	
Crop Group 4, except spinach – Leafy Vegetables (except Brassica Vegetables) Group, except spinach	40	40	
Spinach	50	50	
Crop SubGroup 5A – Head and Stem Brassica Subgroup	9	9	
Crop SubGroup 5B – Leafy Brassica Greens Subgroup	50	50	
Crop Group 8-09 – Fruiting Vegetables	1.5	1.5	
Crop Group 9 – Cucurbit Vegetables	3.0	3.0	
Crop Group 13-07F – Small Fruit Vine Climbing Subgroup, except Fuzzy Kiwifruit	4.0	4.0	
Raisins	8.0	8.0	
Hops	10	10	
Fat , meat and meatbyproducts of cattle, goats, hogs, horses, poultry and sheep; eggs, milk	0.02	0.02	

\* Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

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.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.



## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Chemistry

PMRA Document Number	Reference
1871011	2009, Product identity and composition of BAS 650 F, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 3.4.2, IIA 1.8.1, IIA 1.8.2, IIIA 5.2.4 CBI
1922351	2010, BAS 650 F: Manufacturing process and starting materials source [CBI removed] DACO: 2.11.1, 2.11.2, 2.11.3 CBI
1871010	2010, Analytical profile of BAS 650 F TGAI batches used in toxicological and ecotoxicological experiments (Including amendment no. 1), DACO: 2.13.3, IIA 1.11.1 CBI
1922352	2010, BAS 650 F TC: Composition of the technical grade active ingredient (TGAI), DACO: 2.12.2 CBI
1871066	2008, Analytical method AFL0759/01: Determination of Reg.No. 4993353 in BAS 650 F (TGAI) and the formulations BAS 652 00 F and BAS 653 00 F, DACO: 2.13.1, IIA 4.2.1 CBI
1871068	2008, Validation of analytical method AFL0759/01: Determination of Reg.No. 4993353 in BAS 650 F (TGAI) and the formulations BAS 652 00 F and BAS 653 00 F, DACO: 2.13.1, IIA 4.2.1 CBI
1871069	2008, Determination of the impurities in BAS 650 F TGAI (technical grade active ingredient), DACO: 2.13.4, IIA 4.2.3 CBI
1871070	2010, Validation of analytical method APL0572/01 Determination of the impurities in BAS 650 F TGAI (technical grade active ingredient) (Including amendment no. 1), DACO: 2.13.4, IIA 4.2.3
1871012	2005, Determination of the melting point / boiling point and the appearance of Reg.No. 4 993 353 PAI, DACO: 2.14.1, 2.14.13, 2.14.2, 2.14.3, 2.14.4, 2.14.5, IIA 2.1.1, IIA 2.1.2, IIA 2.1.3, IIA 2.4.1, IIA 2.4.2
1871036	2007, Physical and chemical properties of BAS 650 F (Reg.No. 4 993 353) TC - Accelerated storage stability up to 2 weeks at 54°C, DACO: 2.14.1, 2.14.14, 2.14.2, 2.14.3, 2.14.6, 2.16, IIA 2.14, IIA 2.16, IIA 2.17.1, IIA 2.2, IIA 2.4.1, IIA 2.4.2
1871034	2006, BAS 650 F - Reg.No. 4 993 353: Physical properties of the pure active ingredient, DACO: 2.14.6, 2.14.9, IIA 2.2, IIA 2.3.1
1871040	2005, Spectra (UV-VIS, NMR, IR, MS) of Reg.No. 4 993 353 PAI, DACO: 2.13.2, 2.14.12, IIA 2.5.1.1, IIA 2.5.1.2, IIA 2.5.1.3, IIA 2.5.1.4, IIA 2.5.1.5 CBI
1871042	2005, Determination of the water solubility of Reg.No. 4 993 353 PAI in deionized water and at pH4, pH7, pH9 at 20°C, DACO: 2.14.7, IIA 2.6
1871046	2005, Determination of the solubility in organic solvents at 20°C of Reg.No. 4 993 353 PAI, DACO: 2.14.8, IIA 2.7
1871048	2005, Determination of the octanol/water partition coefficient of Reg.No. 4 993 353 PAI at 20°C, DACO: 2.14.11, IIA 2.8.1, IIA 2.8.2
1871059	2006, Determination of the dissociation constant of Reg.No. 4 993 353 (BAS 650 F) in accordance with OECD-Guideline 112, DACO: 2.14.10, 8.2.3.2, IIA 2.9.5



1871017	2007, Evaluation of physical and chemical properties according to Directive 94/37/EC (67//548/EC Annex V), DACO: 2.16, IIA 2.11.1, IIA 2.11.2, IIA 2.13, IIA 2.14, IIA 2.15
1871020	2010, BAS 650 F (MP): Determination of oxidation/reduction, DACO: 2.16, IIA 2.15
1871022	2010, BAS 650 F (TGAI): Stability to normal and elevated temperature, metal and metal ions, DACO: 2.14.13, IIA 2.17.2
1871024	2010, BAS 650 F (TC/TGAI): Storage stability and corrosion characteristics in commercial type containers when stored for up to 2 weeks at 54°C, DACO: 2.14.13, IIA 2.17.2
2040810	2011, BAS 650 F (TC/TGAI): Long-term storage stability and corrosion characteristics in commercial type containers when stored at 25°C, DACO: 2.14.14, 3.5.14, 3.5.7, IIA 2.17.1, IIIA 2.13, IIIA 2.4.1
1871038	2007, Henrys law constant for BAS 650 F (Reg.No. 4 993 353), DACO: 2.16, IIA 2.3.2
1871667	2007, Physical and chemical properties of BAS 651 00 F (BAS 650 F/BAS 550 F 300/225 g/L SC) - Accelerated storage stability up to 14 days at 54°C, DACO: 3.5.10, 3.5.11, 3.7, IIIA 2.3.1, IIIA 2.5.3, IIIA 2.7.4
1871661	2009, BAS 650 F/Dimethomorph 300/225 g/L SC - chemical and physical stability of formula BAS 651 00 F when stored in HDPE packs, DACO: 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9, 8.2.2.1, 8.2.3.6, IIIA 2.1, IIIA 2.13, IIIA 2.4.2, IIIA 2.5.2, IIIA 2.6.1, IIIA 2.7.1, IIIA 2.8.2, IIIA 2.8.3.1, IIIA 2.8.3.2, IIIA 2.8.5.2, IIIA 2.8.6.1, IIIA 2.8.8.2
1871666	2009, BAS 651 00 F: Determination of oxidation/reduction, DACO: 3.5.8, IIIA 2.2.2
1871663	2007, Evaluation of physical and chemical properties according to Directive 94/37/EC (67//548/EC Annex V), DACO: 3.5.11, 3.5.12, 3.5.8, IIIA 2.2.1, IIIA 2.2.2, IIIA 2.3.2, IIIA 2.3.3
1871624	2010, BAS 651 00 F: Group A - Product identity, composition and analysis, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 3.2.1, 3.2.2, 3.3.1, IIA 1.8.1, IIA 1.8.2, IIIA 1.4.5.1 CBI
1871676	2006, Validation of analytical method AFL 0723/01 for the determination of BAS 650 F and Dimethomorph (BAS 550 F) in BAS 651 00 F, DACO: 3.4.1, IIIA 5.2.1
1871674	2006, Determination of BAS 650 F and Dimethomorph (BAS 550 F) in BAS 651 00 F, DACO: 3.4.1, IIIA 5.2.1
1871850	2007, Physical and chemical properties of BAS 650 00 F (BAS 650 F 200 g/l SC) - Accelerated storage stability up to 14 days at 54°C, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9, IIIA 2.3.2, IIIA 2.4.1, IIIA 2.4.2, IIIA 2.6.1, IIIA 2.6.2, IIIA 2.7.2
1871846	2009, BAS 650 F 200 g/L SC - chemical and physical stability of formula BAS 650 00 F when stored in HDPE packs, DACO: 3.5.14, IIIA 2.13
1871848	2009, BAS 650 00 F: Determination of oxidation/reduction, DACO: 3.5.8, IIIA 2.2.2
1871802	2010, BAS 650 00 F - Group A - Product identity, composition and analysis, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 3.2.1, 3.2.2, 3.2.3, 3.3.1, IIA 1.8.1, IIA 1.8.2, IIIA 1.4.5.1 CBI
1871854	2006, Validation of analytical method AFL 0722/01 for the determination of BAS 650 F in BAS 650 00 F, DACO: 3.4.1, IIIA 5.2.1
1871856	2006, Determination of BAS 650 F in BAS 650 00 F, DACO: 3.4.1, IIIA 5.2.1
1871082	2008, Validation of analytical method L0091 for the determination of residues of BAS 650 F and its metabolites M650F01, M650F02, MF650F03 and M650F04 in soil samples, DACO: 8.2.2.1, IIA 4.4

1871076	2009, Independent laboratory validation of BASF analytical method L0091: The determination of residues of BAS650F and its metabolites, M650F01, M650F02, M650F03, and M650F04 in soil samples, DACO: 8.2.2.1, IIA 4.4
1871085	2008, Validation of the BASF analytical method 574/0 for the determination of residues of BAS 650 F in tap and surface water samples, DACO: 8.2.2.3, IIA 4.5
2040808	2011, Independent laboratory validation of BASF analytical methods 574/0 and L0113 - Methods for determination of residues of BAS 650 F in water samples and methods for the determination of BAS 650 F metabolites M650F01, M650F02, M650F03 and M650F04 in water samples. DACO: 8.2.2.3, IIA 4.5
1871086	2008, Validation of analytical method L0113 for the determination of residues of the BAS 650 F metabolites M650F01, M650F02, M650F03 and M650F04 in water samples, DACO: 8.2.2.3, IIA 4.5

## 2.0 Human and Animal Health

PMRA Document Number	Reference
1871227	2008, Metabolism of BAS 650 F in lettuce, DACO: 6.3, IIA 6.2.1
1871228	2008, Metabolism of BAS 650 F in tomatoes, DACO: 6.3, IIA 6.2.1
1871231	2009, Metabolism of BAS 650 F in potatoes (Including amendment no. 1), DACO: 6.3, IIA 6.2.1
1871234	2007, 14C-BAS 650 F - Absorption, distribution and excretion after repeated oral administration in laying hens, DACO: 6.2, IIA 6.2.2
1871237	2008, The metabolism of 14C-BAS 650 F in laying hens, DACO: 6.2, IIA 6.2.2
1871242	2007, 14C-BAS 650 F - Absorption, distribution and excretion after repeated oral administration in lactating goats, DACO: 6.2, IIA 6.2.3
1871244	2008, Metabolism of 14C-BAS 650 F (14C-Reg. No. 4993353) in lactating goat, DACO: 6.2, IIA 6.2.3
1871601	2008, Validation of BASF method L0078/01: Method for the determination of BAS 650 F and its metabolites M650F03 and M650F04 in plant matrices, DACO: 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, IIA 4.2.5, IIA 4.2.7, IIIA 5.3.1
1871602	2008, Independent laboratory validation of BASF Method L0078 for the determination of residues of BAS 650 F and its metabolites M650F03 and M650F04 in wheat grain, potatoes, lettuce, sunflower seeds and oranges (Including amendment no. 1), DACO: 7.2.1, 7.2
1871604	2008, Validation of BASF method L0104/01: Method for the determination of BAS 650 F and its metabolites M650F01 and M650F06 in animal matrices, DACO: 7.2.1, 7.2.4, IIA 4.3
1871607	2008, Validation of BASF method L0117/01: Method for the determination of BAS 650 F in plant matrices, DACO: 7.2.1, 7.2.4, IIA 4.3
1871610	2008, Extractability of representative samples generated during plant metabolism studies, DACO: 7.2.1, 7.2.4, IIA 4.3
1871613	2008, Independent laboratory validation of BASF analytical method L0104 for the determination of BAS 650 F, M650F01 and M650F06 in bovine milk, liver, kidney, fat, and eggs by HPLC-MS/MS, DACO: 7.2.1, 7.2.4, IIA 4.3
1871617	2009, Investigation of the storage stability of BAS 650 F, M650F03 and M650F04 in plant matrices, DACO: 7.3, IIA 6.1.1
1871678	2009, Evaluation of BAS 650 F and metabolites FDA multiresidue method (MRM) testing, DACO: 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, IIIA 5.3.1
1871680	2008, Independent laboratory validation (ILV) of BASF method number L0117 for the determination of BAS 650 F in plant materials by LC-MS/MS, DACO: 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, IIIA 5.3.1
1871713	2010, Magnitude of BAS 650 F and BAS 550 F residue in leafy vegetables following

	applications of BAS 651 00 F, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1871715	2009, Magnitude of BAS 650 F and Dimethomorph residues in grapes following applications of BAS 650 00 F and Forum fungicide, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1871717	2009, The magnitude of BAS 650 F residues in potatoes following applications of BAS 650 00 F, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1871719	2009, The magnitude of BAS 650 F and Dimethomorph residues in hops following applications of Forum fungicide and BAS 650 00 F, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1871722	2010, Magnitude of BAS 650 F and BAS 550 F residue in bulb vegetables following applications of a tank mix containing BAS 650 00 F and BAS 550 11 F, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1871724	2010, Magnitude of BAS 650 F and Dimethomorph residues in fruiting vegetables following applications of a tank mix containing BAS 650 00 F and BAS 550 11 F, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1871726	2010, Magnitude of BAS 650 F and BAS 550 F residue in leafy brassica vegetables following applications of a tank mix containing BAS 650 00 F and BAS 550 11 F, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1871728	2010, The magnitude of BAS 650 F and Dimethomorph residue in cucurbits following applications of a tank mix containing BAS 650 00 F and BAS 550 11 F, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1871730	2008, Determination of residues of BAS 650 F in potatoes and their processed products after six applications of BAS 650 00 F in Germany, DACO: 7.4.5,8.4.1,IIIA 8.5.1
1871733	2008, Determination of residues of BAS 650 F in tomatoes and their processed products after three applications of BAS 650 00 F in Germany, DACO: 7.4.5,8.4.1,IIIA 8.5.1
1871735	2008, Determination of residues of BAS 650 F in grapes and their processed products after four applications of BAS 650 00 F in Germany, DACO: 7.4.5,8.4.1,IIIA 8.5.1
1871740	2008, Confined rotational crop study with 14C-BAS 650 F, DACO: 7.4.3,7.4.4,IIIA 8.6
1871742	2009, The magnitude of BAS 650 F and Dimethomorph residues in wheat, lettuce and radish planted as rotational crops following applications of BAS 651 00 F (plant back intervals of 30, 60, 90 and 120 Days), DACO: 7.4.3,7.4.4,IIIA 8.6
2020589	2011, Magnitude of residues in milk and tissues of dairy cows following multiple oral administrations of BAS 650 F including Report Amendment 1; DACO: 7.5,7.6,IIA 6.4.2
1871092	2008, 14C-BAS 650 F study on the biokinetics in rats, DACO: 4.5.9,IIA 5.1.1
1871093	2008, The metabolism of 14C-BAS 650 F (Reg.No. 4993353) in rats, DACO: 4.5.9,IIA 5.1.1
1871094	2008, 14C-BAS 650 F study on the biokinetics in rats, DACO: 4.5.9,IIA 5.1.1
1871097	2008, The metabolism of 14C-BAS 650 F (Reg.No. 4993353) in rats, DACO: 4.5.9,IIA 5.1.1
1871101	2007, BAS 650 F - Acute oral toxicity study in rats, DACO: 4.2.1,IIA 5.2.1
1871104	2007, BAS 650 F - Acute dermal toxicity study in rats, DACO: 4.2.2,IIA 5.2.2
1871106	2006, BAS 650 F - Acute inhalation toxicity study in Wistar rats - 4-hour dust exposure, DACO: 4.2.3,IIA 5.2.3
1871109	2007, BAS 650 F - Acute dermal irritation / corrosion in rabbits, DACO: 4.2.5,IIA 5.2.4
1871114	2007, BAS 650 F - Acute eye irritation in rabbits, DACO: 4.2.4,IIA 5.2.5
1871118	2009, BAS 650 F - Maximization test in guinea pigs (Including amendment no. 1), DACO: 4.2.6,IIA 5.2.6
1871121	2007, BAS 650 F: Repeated dose 90-day oral toxicity study in C57BL/6NCrl mice: Administration in the diet, DACO: 4.3.1,IIA 5.3.2
1871122	2007, BAS 650 F: Repeated dose 90-day oral toxicity in Wistar rats - Administration in the diet, DACO: 4.3.1,IIA 5.3.2
1871129	2008, BAS 650 F - Chronic toxicity study in Beagle dogs - Administration in the diet for 12 months, DACO: 4.3.2,IIA 5.3.4
1871133	2009, BAS 650 F - Repeated dose 28-day dermal toxicity study in Wistar rats (Including amendment no. 1), DACO: 4.3.5,IIA 5.3.7
1871134	2009, BAS 650 F - Repeated dose 28-day dermal toxicity study in Wistar rats (Including amendment no. 1), DACO: 4.3.5,IIA 5.3.7

1871139	2006, Salmonella typhimurium/Escherichia coli reverse mutation assay (standard plate test and preincubation test) with BAS 650 F, DACO: 4.5.4,IIA 5.4.1
1871142	2005, <i>In vitro</i> chromosome aberration test in Chinese hamster V79 cells with Reg.No. 4993353, DACO: 4.5.6,IIA 5.4.2
1871144	2007, <i>In vitro</i> gene mutation test CHO cells (HPRT locus assay) with BAS 650 F, DACO: 4.5.5,IIA 5.4.3
1871147	2008, Bone marrow chromosome analysis <i>in vivo</i> with Reg.No. 4993353 in Wistar rats - Single oral administration (Including amendment no. 1), DACO: 4.5.7,IIA 5.4.4
1871148	2005, Cytogenetic study <i>in vivo</i> with Reg.No. 4993353 in the mouse micronucleus test single oral administration, DACO: 4.5.7,IIA 5.4.4
1871150	2005, <i>In vivo</i> unscheduled DNA synthesis in rat hepatocytes with Reg.No. 4993353, DACO: 4.5.8,IIA 5.4.5
1871152	2008, BAS 650 F - Combined chronic toxicity/carcinogenicity study in Wistar rats; administration via the diet up to 24 months, DACO: 4.4.1,4.4.2,4.4.4,IIA 5.5.1,IIA 5.5.2
1871158	2008, BAS 650 F - Carcinogenicity study in C57BL/6 J Rj mice; administration via the diet over 18 months, DACO: 4.4.3,IIA 5.5.3
1871165	2008, BAS 650 F: Two-generation reproduction toxicity study in Wistar rats - Administration via the diet, DACO: 4.5.1,IIA 5.6.1
1871169	2006, BAS 650 F: Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage), DACO: 4.5.2,IIA 5.6.10
1871173	2008, Revised report: BAS 650 F: Prenatal developmental toxicity study in Himalayan rabbits - Oral administration (gavage), DACO: 4.5.3,IIA 5.6.11
1871184	2009, BAS 650 F - Repeated dose 90-day oral neurotoxicity study in Wistar rats - Administration in the diet, DACO: 4.5.13,IIA 5.7.4
1871196	2006, Cytogenetic study <i>in vivo</i> with Reg.No. 5178870 (metabolite of Reg.No. 4993353) in the mouse micronucleus test - Single oral administration (Including amendment no. 1), DACO: 4.8,IIA 5.8
1871202	2006, <i>In vitro</i> gene mutation test in CHO cells (HPRT locus assay) with Reg.No. 5211623 (metabolite of BAS 650 F), DACO: 4.8,IIA 5.8
1871204	2007, Salmonella typhimurium/Escherichia coli reverse mutation assay (standard plate test and preincubation test) with Reg.No. 5211623 (metabolite of BAS 650 F), DACO: 4.8,IIA 5.8
1871205	2006, Salmonella typhimurium/Escherichia coli reverse mutation assay (standard plate test and preincubation test) with Reg.No. 5178870 (metabolite of Reg.No. 4993353) (Including amendment no. 1), DACO: 4.8,IIA 5.8
1871207	2007, <i>In vitro</i> chromosome aberration assay in V79 cells with Reg.No. 5211623 (Metabolite of BAS 650 F), DACO: 4.8,IIA 5.8
1871218	2008, Reg.No. 5178870 (metabolite of BAS 650 F) - Repeated dose 90-day oral toxicity study in Wistar rats; Administration in the diet, DACO: 4.8,IIA 5.8
1871682	2007, BAS 651 00 F: Acute oral toxicity study in rats, DACO: 4.6.1,IIIA 7.1.1
1871684	2007, BAS 651 00 F: Acute dermal toxicity study in rats, DACO: 4.6.2,IIIA 7.1.2
1871686	2007, BAS 651 00 F - Acute inhalation toxicity study in Wistar rats 4-hour liquid aerosol exposure, DACO: 4.6.3,IIIA 7.1.3
1871688	2007, BAS 651 00 F - Acute dermal irritation/corrosion in rabbits, DACO: 4.6.5,IIIA 7.1.4
1871690	2007, BAS 651 00 F: Acute eye irritation in rabbits, DACO: 4.6.4,IIIA 7.1.5
1871691	2007, BAS 651 00 F: Acute eye irritation in rabbits, DACO: 4.6.4,IIIA 7.1.5
1871692	2007, BAS 651 00 F: Murine local lymph node assay (LLNA), DACO: 4.6.6,IIIA 7.1.6
1871863	2006, BAS 650 00 F - Acute oral toxicity study in rats, DACO: 4.6.1,IIIA 7.1.1
1871867	2006, BAS 650 00 F - Acute dermal toxicity study in rats, DACO: 4.6.2,IIIA 7.1.2
1871868	2006, BAS 650 00 F - Acute dermal irritation/corrosion in rabbits, DACO: 4.6.5,IIIA 7.1.4
1871869	2006, BAS 650 00 F - Acute dermal irritation/corrosion in rabbits, DACO: 4.6.5,IIIA 7.1.4
1871871	2006, BAS 650 00 F - Acute eye irritation in rabbits, DACO: 4.6.4,IIIA 7.1.5
1871875	2006, BAS 650 00 F - Murine local lymph node assay (LLNA), DACO: 4.6.6,IIIA 7.1.6

1871877	2009, BAS 650 00 F - BUEHLER test in guinea pigs, DACO: 4.6.6,IIIA 7.1.6
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1871671	2010, Use Site Description: BAS 650 00F and Zampro (BAS 651 00F) use in Minor Crops including Brassica Vegetables, Bulb Vegetables, Fruiting Vegetables, Grapes, Hops, Leafy Vegetables and Tuberos and Corm Vegetables. DACO: 5.11,5.2,5.6,5.7,5.9
1871697	2010, Reentry exposure and margin of safety assessments following the application of BAS 651 00F (Zampro® fungicide), a suspension concentration co-formulation containing 27.0% BAS 650 F (ametoctradin) and 20.3% dimethomorph to grapes, hops, and brassica, bulb, leafy, fruiting, and corm vegetables in Canada, DACO: 5.6, 5.7, 5.9, 5.14
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1871699	2007, Dermal absorption, Comparative dermal absorption, <i>in vitro</i> using rat and human skin, DACO: 5.8

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1871248	2010, Aerobic soil metabolism of BAS 650 F, DACO: 8.2.3.4.2,IIA 7.1.1
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1871265	2008, Soil photolysis of BAS 650 F, DACO: 8.2.3.3.1,IIA 7.1.3
1871267	2008, Rate of degradation of BAS 650 F in aerobic soil, DACO: 8.2.3.4.2,IIA 7.2.1,IIA 7.2.2
1871268	2008, Rate of degradation of BAS 650 F in aerobic soil, DACO: 8.2.3.4.2,IIA 7.2.1,IIA 7.2.2
1871282	2008, Rate of degradation in soil of M650F03 (metabolite of BAS 650F), DACO: 8.2.3.4.2,IIA 7.2.3
1871283	2008, Rate of degradation in soil of M650F04, metabolite of BAS 650 F, DACO: 8.2.3.4.2,IIA 7.2.3
1871284	2008, Rate of degradation in soil of M650F03 (metabolite of BAS 650F), DACO: 8.2.3.4.2,IIA 7.2.3
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1871295	2008, Aqueous photolysis of M650F03 (metabolite of BAS 650 F), DACO: 8.2.4.2,IIA 7.4.2
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1871311	2008, Adsorption/desorption - Study of BAS 650 F metabolite M650F04 (Reg.No. 5211623) on five soils differing in pH, DACO: 8.2.4.2,IIA 7.4.2
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1871317	2008, Determination of the adsorption / desorption behavior of M650F02 (metabolite of BAS 650 F) on soils (OECD Guideline 106), DACO: 8.2.4.2,IIA 7.4.2
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1871325	2009, BAS 650 F: Anaerobic aquatic metabolism, DACO: 8.2.3.5.5,8.2.3.5.6,IIA 7.8.2
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1871327	2008, Degradation of BAS 650 F in water/sediment systems under aerobic conditions, DACO: 8.2.3.6,IIA 7.8.3
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1942731	2006, E-fate supplemental data for: BAS 650 F: Hydrolysis at four different pH values, DACO: 8.2.3.2,IIA 2.9.1,IIA 7.5
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1942749	2008, E-fate supplemental data for: Aqueous photolysis of M650F03 (metabolite of BAS 650 F),

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1942783	2010, E-fate supplemental data for: Aerobic soil metabolism of BAS 650 F, DACO: 8.2.3.4.2,IIA 7.1.1
1942784	2009, E-fate supplemental data for: BAS 650 F: Anaerobic aquatic metabolism, DACO: 8.2.3.5.5,8.2.3.5.6,IIA 7.8.2
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1871415	2007, BAS 650 F - Acute toxicity study on the rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a flow through system over 96 hours, DACO: 9.5.2.1,9.5.2.3,IIA 8.2.1.1
1871416	2007, BAS 650 F - Acute toxicity study on the bluegill sunfish ( <i>Lepomis macrochirus</i> ) in a flow-through-system over 96 hours, DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
1871417	2007, BAS 650 F - Acute toxicity study on the bluegill sunfish ( <i>Lepomis macrochirus</i> ) in a flow-through-system over 96 hours, DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
1871420	2007, BAS 650 F - Acute toxicity on the common carp ( <i>Cyprinus carpio</i> ) in a flow-through system over 96 hours, DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
1871422	2007, BAS 650 F - Acute toxicity on the common carp ( <i>Cyprinus carpio</i> ) in a flow-through system over 96 hours, DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
1871423	2009, BAS 650 F - Acute toxicity study with the fathead minnow ( <i>Pimephales promelas</i> ), DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
1871424	2009, BAS 650 F - Acute toxicity study with the fathead minnow ( <i>Pimephales promelas</i> ), DACO: 9.5.2.2,9.5.2.3,IIA 8.2.1.2
1871425	2008, Acute toxicity study of Reg.No. 5178870 (metabolite of BAS 650 F) to freshwater fish, <i>Oncorhynchus mykiss</i> , DACO: 9.5.2.3,9.5.2.4,IIA 8.2.1.3
1871427	2008, Acute toxicity study of Reg.No. 5178870 (metabolite of BAS 650 F) to freshwater fish, <i>Oncorhynchus mykiss</i> , DACO: 9.5.2.3,9.5.2.4,IIA 8.2.1.3
1871430	2008, Acute toxicity study of Reg.No. 5211623 to freshwater fish, <i>Oncorhynchus mykiss</i> , DACO: 9.5.2.3,9.5.2.4,IIA 8.2.1.3
1871432	2008, Acute toxicity study of Reg.No. 5211623 to freshwater fish, <i>Oncorhynchus mykiss</i> , DACO: 9.5.2.3,9.5.2.4,IIA 8.2.1.3
1871434	2006, BAS 650 F - Early life-stage test on the fathead minnow ( <i>Pimephales promelas</i> ) in a flow through system, DACO: 9.5.3.1,IIA 8.2.4
1871435	2006, BAS 650 F - Early life-stage test on the fathead minnow ( <i>Pimephales promelas</i> ) in a flow through system, DACO: 9.5.3.1,IIA 8.2.4
1871438	2008, Bioaccumulation and metabolism of 14C BAS 650 F in bluegill sunfish ( <i>Lepomis macrochirus</i> ), DACO: 9.5.6,IIA 8.2.6.1
1871441	2008, Bioaccumulation and metabolism of 14C BAS 650 F in bluegill sunfish ( <i>Lepomis macrochirus</i> ), DACO: 9.5.6,IIA 8.2.6.1
1871442	2010, Acute toxicity of BAS 650 F (Reg.No. 4993353) to <i>Daphnia magna</i> STRAUS in a 48 hour static test (Including amendment no. 1), DACO: 9.3.2,IIA 8.3.1.1
1871443	2008, Acute toxicity of Reg.No. 5178872 (metabolite of BAS 650 F) to <i>Daphnia magna</i> STRAUS in a 48 hour static test, DACO: 9.3.2,IIA 8.3.1.1
1871445	2008, Acute toxicity of Reg.No. 5178872 (metabolite of BAS 650 F) to <i>Daphnia magna</i> STRAUS in a 48 hour static test, DACO: 9.3.2,IIA 8.3.1.1
1871447	2010, Acute toxicity of BAS 650 F (Reg.No. 4993353) to <i>Daphnia magna</i> STRAUS in a 48 hour static test (Including amendment no. 1), DACO: 9.3.2,IIA 8.3.1.1
1871451	2008, Acute immobilisation test with Reg.No. 5178870 (metabolite of BAS 650 F) in <i>Daphnia magna</i> , DACO: 9.3.2,IIA 8.3.1.1
1871456	2008, Acute immobilisation test with Reg.No. 5211623 in <i>Daphnia magna</i> , DACO: 9.3.2,IIA 8.3.1.1
1871457	2008, Acute immobilisation test with Reg.No. 5211623 in <i>Daphnia magna</i> , DACO: 9.3.2,IIA 8.3.1.1
1871460	2008, Acute immobilisation test with Reg.No. 5178870 (metabolite of BAS 650 F) in <i>Daphnia magna</i> , DACO: 9.3.2,IIA 8.3.1.1
1871462	2009, M650F02 (Metabolite of BAS 650 F): <i>Daphnia magna</i> , acute immobilisation test, DACO: 9.3.2,IIA 8.3.1.1
1871464	2009, M650F02 (Metabolite of BAS 650 F): <i>Daphnia magna</i> , acute immobilisation test, DACO:

	9.3.2,IIA 8.3.1.1
1871465	2008, Chronic toxicity of BAS 650 F (Reg.No. 4993353) to <i>Daphnia magna</i> STRAUS in a 21 day semi-static test, DACO: 9.3.3,IIA 8.3.2.1
1871466	2008, Chronic toxicity of BAS 650 F (Reg.No. 4993353) to <i>Daphnia magna</i> STRAUS in a 21 day semi-static test, DACO: 9.3.3,IIA 8.3.2.1
1871470	2008, M650F03 <i>Daphnia magna</i> reproduction test, DACO: 9.3.3,IIA 8.3.2.1
1871472	2008, M650F03 <i>Daphnia magna</i> reproduction test, DACO: 9.3.3,IIA 8.3.2.1
1871474	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of the fresh water diatom <i>Navicula pelliculosa</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871475	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of the blue-green alga <i>Anabaena flos-aquae</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871476	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of the green alga <i>Pseudokirchneriella subcapitata</i> (Including amendment no. 1), DACO: 9.8.2,9.8.3,IIA 8.4
1871479	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of the green alga <i>Pseudokirchneriella subcapitata</i> (Including amendment no. 1), DACO: 9.8.2,9.8.3,IIA 8.4
1871482	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of the fresh water diatom <i>Navicula pelliculosa</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871483	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of the blue-green alga <i>Anabaena flos-aquae</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871484	2008, Effect of Reg.No. 5178870 (metabolite of BAS 650 F) on the growth of green alga, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871485	2008, Effect of Reg.No. 5211623 on the growth of green alga, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871486	2008, Effect of Reg.No. 5178870 (metabolite of BAS 650 F) on the growth of green alga, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871489	2008, Effect of Reg.No. 5211623 on the growth of green alga, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871492	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of the marine diatom <i>Skeletonema costatum</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871493	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of the marine diatom <i>Skeletonema costatum</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1871503	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of <i>Lemna gibba</i> in a semi-static test, DACO: 9.8.5,IIA 8.6
1871506	2009, Effect of BAS 650 F (Reg.No. 4993353) on the growth of <i>Lemna gibba</i> in a semi-static test, DACO: 9.8.5,IIA 8.6
1871507	2006, Effects of BAS 650 F (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory, DACO: 9.2.4.1,9.2.4.2,IIA 8.7.1,IIA 8.7.2
1871508	2006, Effects of BAS 650 F (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory, DACO: 9.2.4.1,9.2.4.2,IIA 8.7.1,IIA 8.7.2
1871542	2008, Effects of Reg.No. 5211623 (metabolite of BAS 650 F, M650F04) on reproduction of soil mites <i>Hypoaspis aculeifer</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.1
1871543	2008, Effects of Reg.No. 5178870 (metabolite of BAS 650 F, M650F03) on reproduction of soil mites <i>Hypoaspis aculeifer</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.1
1871544	2008, Effects of Reg.No. 5211623 (metabolite of BAS 650 F, M650F04) on reproduction of soil mites <i>Hypoaspis aculeifer</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.1
1871545	2008, Effects of Reg.No. 5178870 (metabolite of BAS 650 F, M650F03) on reproduction of soil mites <i>Hypoaspis aculeifer</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.1
1871546	2008, Effects of Reg.No. 5211623 (metabolite of BAS 650 F, M650F04) on reproduction of the collembola <i>Folsomia candida</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.1
1871547	2008, Effects of Reg.No. 5178870 (metabolite of BAS 650 F, M650F03) on reproduction of the collembola <i>Folsomia candida</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.1
1871548	2008, Effects of Reg.No. 5211623 (metabolite of BAS 650 F, M650F04) on reproduction of the collembola <i>Folsomia candida</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.1
1871549	2008, Effects of Reg.No. 5178870 (metabolite of BAS 650 F, M650F03) on reproduction of the collembola <i>Folsomia candida</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.1

1871550	2007, Amended final report: Acute toxicity of Reg. No. 5178870 (Metabolite of BAS 650 F, M650F03) on earthworms ( <i>Eisenia fetida</i> ), DACO: 9.2.3.1,IIA 8.9.1
1871551	2007, Acute toxicity of BAS 650 F on earthworms ( <i>Eisenia fetida</i> ) in artificial soil with 5% peat, DACO: 9.2.3.1,IIA 8.9.1
1871552	2006, Acute toxicity of Reg. No. 5211623 (metabolite of BAS 650 F, M650F04) on earthworms ( <i>Eisenia fetida</i> ), DACO: 9.2.3.1,IIA 8.9.1
1871553	2007, Amended final report: Acute toxicity of Reg. No. 5178870 (Metabolite of BAS 650 F, M650F03) on earthworms ( <i>Eisenia fetida</i> ), DACO: 9.2.3.1,IIA 8.9.1
1871554	2007, Acute toxicity of BAS 650 F on earthworms ( <i>Eisenia fetida</i> ) in artificial soil with 5% peat, DACO: 9.2.3.1,IIA 8.9.1
1871555	2006, Acute toxicity of Reg. No. 5211623 (metabolite of BAS 650 F, M650F04) on earthworms ( <i>Eisenia fetida</i> ), DACO: 9.2.3.1,IIA 8.9.1
1871556	2008, Acute toxicity of Reg.No. 5178872 (metabolite of BAS 650 F, M650F01) on earthworms ( <i>Eisenia fetida</i> ) - Amended report, DACO: 9.2.3.1,IIA 8.9.1
1871557	2008, Acute toxicity of Reg.No. 5178872 (metabolite of BAS 650 F, M650F01) on earthworms ( <i>Eisenia fetida</i> ) - Amended report, DACO: 9.2.3.1,IIA 8.9.1
1871558	2008, Effects of Reg.No. 5178870 (metabolite of BAS 650 F, M650F03) on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.2
1871559	2008, Effects of Reg.No. 5211623 (metabolite of BAS 650 F, M650F04) on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.2
1871560	2008, Effects of Reg.No. 5178870 (metabolite of BAS 650 F, M650F03) on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.2
1871561	2008, Effects of Reg.No. 5211623 (metabolite of BAS 650 F, M650F04) on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil, DACO: 9.2.3.1,IIA 8.9.2
1942729	2005, Ecotoxicology supplemental data for: Reg.No. 4993353 - Avian dietary LC50 test in chicks of the bobwhite quail ( <i>Colinus virginianus</i> ), DACO: 9.6.2.4,9.6.2.5,IIA 8.1.2
1942730	2005, Ecotoxicology supplemental data for: Reg.No. 4993353 - Avian dietary LC50 test in ducklings of the mallard duck ( <i>Anas platyrhynchos</i> ), DACO: 9.6.2.4,9.6.2.5,IIA 8.1.2
1942733	2006, Ecotoxicology supplemental data for: BAS 650 F - Early life-stage test on the fathead minnow ( <i>Pimephales promelas</i> ) in a flow through system, DACO: 9.5.3.1,IIA 8.2.4
1942735	2007, Ecotoxicology supplemental data for: BAS 650 00 F - Determination of the inhibitory effect on the cell multiplication of unicellular green algae <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1942736	2007, Ecotoxicology supplemental data for: Effect of BAS 650 00 F on seedling emergence of ten species of terrestrial plants, DACO: 9.8.6,IIIA 10.8.1.1
1942737	2007, Ecotoxicology supplemental data for: Effect of BAS 650 00 F on vegetative vigour of ten species of terrestrial plants, DACO: 9.8.6,IIIA 10.8.1.1
1942738	2008, Ecotoxicology supplemental data for: Effect of Reg.No. 5178870 (metabolite of BAS 650 F) on the growth of green alga, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1942739	2008, Ecotoxicology supplemental data for: Effect of Reg.No. 5211623 on the growth of green alga, <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1942740	2008, Ecotoxicology supplemental data for: BAS 651 00 F - Determination of the inhibitory effect on the cell multiplication of the unicellular green algae <i>Pseudokirchneriella subcapitata</i> KORSHIKOV, DACO: 9.8.2,9.8.3,IIA 8.4
1942745	2008, Ecotoxicology supplemental data for: Chronic toxicity of the pyrimidylamine (BAS 650 F) formulation BAS 650 00 F to the non-biting midge <i>Chironomus riparius</i> - A spiked sediment study, DACO: 9.9,IIA 8.5.2
1942747	2008, Ecotoxicology supplemental data for: Chronic toxicity of BAS 650 F (Reg.No. 4993353) to <i>Daphnia magna</i> Straus in a 21 day semi-static test, DACO: 9.3.3,IIA 8.3.2.1
1942760	2008, Ecotoxicology supplemental data for: M650F03 - <i>Daphnia magna</i> reproduction test, DACO: 9.3.3,IIA 8.3.2.1
1942768	2009, Ecotox supplemental data for: Effect of BAS 650 F (Reg.No. 4993353) on the growth of <i>Lemna gibba</i> in a semi-static test, DACO: 9.8.5,IIA 8.6
1942769	2009, Ecotoxicology supplemental data for: Effect of BAS 650 F (Reg.No. 4993353) on the growth of the fresh water diatom <i>Navicula pelliculosa</i> , DACO: 9.8.2,9.8.3,IIA 8.4

1942771	2009, Ecotoxicology supplemental data for: Effect of BAS 650 F (Reg.No. 4993353) on the growth of the blue-green alga <i>Anabaena flos-aquae</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1942772	2009, Ecotoxicology supplemental data for: Effect of BAS 650 F (Reg.No. 4993353) on the growth of the marine diatom <i>Skeletonema costatum</i> , DACO: 9.8.2,9.8.3,IIA 8.4
1942773	2010, Ecotoxicology supplemental data for: Bioaccumulation and metabolism of 14C BAS 650 F in bluegill sunfish ( <i>Lepomis macrochirus</i> ), DACO: 9.5.6,IIA 8.2.6.1
1942774	2009, Ecotoxicology supplemental data for: Effect of BAS 650 F (Reg.No. 4993353) on the growth of the green alga <i>Pseudokirchneriella subcapitata</i> (Including amendment no. 1), DACO: 9.8.2,9.8.3,IIA 8.4
1942775	2009, Ecotoxicology supplemental data for: BAS 650 F - Acute toxicity to eastern oyster ( <i>Crassostrea virginica</i> ) under flow-through conditions, following OPPTS Guideline (draft) 850.1025, DACO: 9.4.2,9.4.3,9.4.4,IIA 8.11.1
1942776	2009, Ecotoxicology supplemental data for: BAS 650 F - 1-generation reproduction study on the mallard duck ( <i>Anas platyrhynchos</i> ) by administration in the diet (Including amendment no. 1), DACO: 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
1942777	2009, Ecotoxicology supplemental data for: BAS 650 F - 1-generation reproduction study on the bobwhite quail ( <i>Colinus virginianus</i> ) by administration in the diet (Including amendment nos. 1 and 2), DACO: 9.6.3.1,9.6.3.2,9.6.3.3,IIA 8.1.4
1942778	2009, Ecotoxicology supplemental data for: BAS 651 00 F: A toxicity test to determine the effects of the test substance on seedling emergence of ten species of plants, DACO: 9.8.6,9.8.7,IIIA 10.8.2.1
1942779	2009, Ecotoxicology supplemental data for: BAS 651 00 F: A toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plants, DACO: 9.2.8,9.3.5,9.4.6,9.5.4,9.6.4,9.6.6,9.8.6,9.9,IIIA 10.10.1,IIIA 10.8.1.2
1942788	2010, Ecotoxicology supplemental data for: BAS 650 00 F: A 10-day whole sediment toxicity test with <i>Leptocheirus plumulosus</i> using spiked sediment, DACO: 9.9,IIA 8.5.1
1963080	2010, Waiver request for chronic marine studies with Ametoctradin, DACO: 9.5.3.1,IIA 8.2.4,IIA 8.3.2
1871495	2010, BAS 650 00 F: A 10-day whole sediment toxicity test with <i>Leptocheirus plumulosus</i> using spiked sediment, DACO: 9.9,IIA 8.5.1
1871497	2010, BAS 650 00 F: A 10-day whole sediment toxicity test with <i>Leptocheirus plumulosus</i> using spiked sediment, DACO: 9.9,IIA 8.5.1
1871498	2008, Chronic toxicity of the pyrimidylamine (BAS 650 F) formulation BAS 650 00 F to the non-biting midge <i>Chironomus riparius</i> - A spiked sediment study, DACO: 9.9,IIA 8.5.2
1871499	2008, Chronic toxicity of the pyrimidylamine (BAS 650 F) formulation BAS 650 00 F to the non-biting midge <i>Chironomus riparius</i> - A spiked sediment study, DACO: 9.9,IIA 8.5.2
1871511	2008, Effects of BAS 650 00 F on populations of predatory mites ( <i>Acari</i> , <i>Phytoseiidae</i> e.g. <i>Typhlodromus pyri</i> ) under field conditions in a vineyard - 4 early applications, DACO: 9.2.5,IIA 8.8.2.2
1871512	2008, Effects of BAS 650 00 F on populations of predatory mites ( <i>Acari</i> , <i>Phytoseiidae</i> e.g. <i>Typhlodromus pyri</i> ) under field conditions in a vineyard - 4 late applications, DACO: 9.2.5,IIA 8.8.2.2
1871515	2008, Effects of BAS 650 00 F on populations of predatory mites ( <i>Acari</i> , <i>Phytoseiidae</i> e.g. <i>Typhlodromus pyri</i> ) under field conditions in a vineyard - 4 late applications, DACO: 9.2.5,IIA 8.8.2.2
1871520	2008, Effects of BAS 650 00 F on populations of predatory mites ( <i>Acari</i> , <i>Phytoseiidae</i> e.g. <i>Typhlodromus pyri</i> ) under field conditions in a vineyard - 4 early applications, DACO: 9.2.5,IIA 8.8.2.2
1871522	2008, A field study to evaluate the effects of BAS 650 00 F on predatory mites ( <i>Acari</i> : <i>Phytoseiidae</i> ) in a vineyard in Southern France - 4 early applications, DACO: 9.2.5,IIA 8.8.2.2
1871523	2008, A field study to evaluate the effects of BAS 650 00 F on predatory mites ( <i>Acari</i> : <i>Phytoseiidae</i> ) in a vineyard in Southern France - 4 late applications, DACO: 9.2.5,IIA 8.8.2.2
1871525	2008, A field study to evaluate the effects of BAS 650 00 F on predatory mites ( <i>Acari</i> : <i>Phytoseiidae</i> ) in a vineyard in Southern France - 4 late applications, DACO: 9.2.5,IIA 8.8.2.2
1871528	2008, A field study to evaluate the effects of BAS 650 00 F on predatory mites ( <i>Acari</i> : <i>Phytoseiidae</i> ) in a vineyard in Southern France - 4 early applications, DACO: 9.2.5,IIA 8.8.2.2

1871533	2008, Effects of BAS 650 00 F on predatory mites (Acari, Phytoseiidae) under field conditions in vine (late application), DACO: 9.2.5,IIA 8.8.2.2
1871535	2008, Effects of BAS 650 00 F on predatory mites (Acari, Phytoseiidae) under field conditions in vine (early application), DACO: 9.2.5,IIA 8.8.2.2
1871536	2008, Effects of BAS 650 00 F on predatory mites (Acari, Phytoseiidae) under field conditions in vine (late application), DACO: 9.2.5,IIA 8.8.2.2
1871540	2008, Effects of BAS 650 00 F on predatory mites (Acari, Phytoseiidae) under field conditions in vine (early application), DACO: 9.2.5,IIA 8.8.2.2
1871629	2008, BAS 651 00 F - Acute toxicity in the bobwhite quail ( <i>Colinus virginianus</i> ) after single oral administration (LD50), DACO: 9.6.4,IIIA 10.1.6
1871630	2008, BAS 651 00 F - Acute toxicity in the bobwhite quail ( <i>Colinus virginianus</i> ) after single oral administration (LD50), DACO: 9.6.4,IIIA 10.1.6
1871631	2007, BAS 651 00 F - Acute toxicity study on the rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a static system over 96 hours, DACO: 9.5.4,IIIA 10.2.2.1
1871632	2007, BAS 651 00 F - Acute toxicity study on the rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a static system over 96 hours, DACO: 9.5.4,IIIA 10.2.2.1
1871633	2007, BAS 651 00 F - Determination of the acute effect on the swimming ability of the water flea <i>Daphnia magna</i> STRAUS, DACO: 9.3.2,9.3.5,IIIA 10.2.2.2
1871634	2007, BAS 651 00 F - Determination of the acute effect on the swimming ability of the water flea <i>Daphnia magna</i> STRAUS, DACO: 9.3.2,9.3.5,IIIA 10.2.2.2
1871635	2008, BAS 651 00 F - Determination of the inhibitory effect on the cell multiplication of the unicellular green algae <i>Pseudokirchneriella subcapitata</i> KORSHIKOV, DACO: 9.8.2,9.8.3,9.8.6,IIIA 10.2.2.3
1871636	2008, BAS 651 00 F - Determination of the inhibitory effect on the cell multiplication of the unicellular green algae <i>Pseudokirchneriella subcapitata</i> KORSHIKOV, DACO: 9.8.2,9.8.3,9.8.6,IIIA 10.2.2.3
1871637	2006, Assessment of side effects of BAS 651 00 F to the honey bee, <i>Apis mellifera</i> L. in the laboratory, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
1871638	2006, Assessment of side effects of BAS 651 00 F to the honey bee, <i>Apis mellifera</i> L. in the laboratory, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
1871639	2008, Effects of BAS 651 00 F on the green lacewing <i>Chrysoperla carnea</i> STEPH. under laboratory conditions - Rate-response-test, DACO: 9.2.8,IIIA 10.5.1
1871640	2008, Effects of BAS 651 00 F on the green lacewing <i>Chrysoperla carnea</i> STEPH. under laboratory conditions - Rate-response-test, DACO: 9.2.8,IIIA 10.5.1
1871641	2007, Effect of BAS 651 00 F on the parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) in a laboratory trial, DACO: 9.2.8,IIIA 10.5.1
1871642	2007, Effect of BAS 651 00 F on the parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) in a laboratory trial, DACO: 9.2.8,IIIA 10.5.1
1871643	2009, Effect of BAS 651 00 F on the predatory mite ( <i>Typhlodromus pyri</i> ) in a laboratory trial (Including amendment no. 1), DACO: 9.2.8,IIIA 10.5.1
1871644	2009, Effect of BAS 651 00 F on the predatory mite ( <i>Typhlodromus pyri</i> ) in a laboratory trial (Including amendment no. 1), DACO: 9.2.8,IIIA 10.5.1
1871645	2008, Effect of BAS 651 00 F on the parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) in an extended laboratory trial (Including amendment no. 1), DACO: 9.2.8,IIIA 10.5.2
1871646	2008, Effect of BAS 651 00 F on the parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) in an extended laboratory trial (Including amendment no. 1), DACO: 9.2.8,IIIA 10.5.2
1871647	2008, Acute toxicity of BAS 651 00 F on earthworms ( <i>Eisenia fetida</i> ) in artificial soil with 5% peat (Including amendment no. 1), DACO: 9.2.8,IIIA 10.6.2
1871648	2008, Acute toxicity of BAS 651 00 F on earthworms ( <i>Eisenia fetida</i> ) in artificial soil with 5% peat (Including amendment no. 1), DACO: 9.2.8,IIIA 10.6.2
1871649	2007, Sublethal toxicity of BAS 651 00 F to the earthworm <i>Eisenia fetida</i> in artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.3
1871650	2007, Sublethal toxicity of BAS 651 00 F to the earthworm <i>Eisenia fetida</i> in artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.3
1871651	2007, Effects of BAS 651 00 F on the reproduction of the collembolans <i>Folsomia candida</i> in

	artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.6
1871652	2007, Effects of BAS 651 00 F on the reproduction of the collembolans <i>Folsomia candida</i> in artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.6
1871653	2009, Effects of BAS 651 00 F on the activity of soil microflora (Carbon transformation test) (Including amendment no. 1), DACO: 9.2.8,IIIA 10.7.1
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1871655	2009, Effects of BAS 651 00 F on the activity of soil microflora (Nitrogen transformation test) (Including amendment no. 1), DACO: 9.2.8,IIIA 10.7.1
1871656	2009, Effects of BAS 651 00 F on the activity of soil microflora (Nitrogen transformation test) (Including amendment no. 1), DACO: 9.2.8,IIIA 10.7.1
1871657	2009, BAS 651 00 F: A toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plants, DACO: 9.8.6,IIIA 10.8.1.2
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1871797	2007, BAS 650 00 F - Determination of the acute effect on the swimming ability of the water flea <i>Daphnia magna</i> STRAUS, DACO: 9.3.5,9.9,IIA 8.5.1
1871798	2007, BAS 650 00 F - Determination of the acute effect on the swimming ability of the water flea <i>Daphnia magna</i> STRAUS, DACO: 9.3.5,9.9,IIA 8.5.1
1871806	2007, BAS 650 00 F - Acute toxicity study on the rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a static system over 96 hours, DACO: 9.5.4,IIIA 10.2.1.1
1871807	2007, BAS 650 00 F - Acute toxicity study on the rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a static system over 96 hours, DACO: 9.5.4,IIIA 10.2.2.1
1871809	2007, BAS 650 00 F - Determination of the inhibitory effect on the cell multiplication of unicellular green algae <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,9.8.6,IIIA 10.2.2.3
1871810	2007, BAS 650 00 F - Determination of the inhibitory effect on the cell multiplication of unicellular green algae <i>Pseudokirchneriella subcapitata</i> , DACO: 9.8.2,9.8.3,9.8.6,IIIA 10.2.2.3
1871811	2006, Effects of BAS 650 00 F (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
1871813	2006, Effects of BAS 650 00 F (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
1871816	2006, Effect of BAS 650 00 F on the predatory mite ( <i>Typhlodromus pyri</i> ) in a laboratory trial, DACO: 9.2.8,IIIA 10.5.1
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1871819	2007, Effect of BAS 650 00 F on the parasitic wasp ( <i>Aphidius rhopalosiph</i> ) in a laboratory trial, DACO: 9.2.8,IIIA 10.5.1
1871820	2007, Effect of BAS 650 00 F on the parasitic wasp ( <i>Aphidius rhopalosiph</i> ) in a laboratory trial, DACO: 9.2.8,IIIA 10.5.1
1871822	2008, Effects of BAS 650 00 F on the green lacewing <i>Chrysoperla carnea</i> STEPH under laboratory conditions - Rate-response test, DACO: 9.2.8,IIIA 10.5.1
1871823	2008, Effects of BAS 650 00 F on the green lacewing <i>Chrysoperla carnea</i> STEPH under laboratory conditions - Rate-response test, DACO: 9.2.8,IIIA 10.5.1
1871824	2007, Effect of BAS 650 00 F on the parasitic wasp ( <i>Aphidius rhopalosiph</i> ) in an extended laboratory trial, DACO: 9.2.8,IIIA 10.5.2
1871825	2007, Effect of BAS 650 00 F on the parasitic wasp ( <i>Aphidius rhopalosiph</i> ) in an extended laboratory trial, DACO: 9.2.8,IIIA 10.5.2
1871829	2006, Acute toxicity of BAS 650 00 F on earthworms ( <i>Eisenia fetida</i> ) in artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.2
1871831	2006, Acute toxicity of BAS 650 00 F on earthworms ( <i>Eisenia fetida</i> ) in artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.2

1871834	2007, Sublethal toxicity of BAS 650 00 F to the earthworm <i>Eisenia fetida</i> in artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.3
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1871837	2007, Effects of BAS 650 00 F on the reproduction of the collembolans <i>Folsomia candida</i> in artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.6
1871838	2007, Effects of BAS 650 00 F on the reproduction of the collembolans <i>Folsomia candida</i> in artificial soil with 5% peat, DACO: 9.2.8,IIIA 10.6.6
1871839	2009, Effects of BAS 650 00 F on the activity of soil microflora (nitrogen transformation test) (Including amendment no. 1), DACO: 9.2.8,IIIA 10.7.1
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### 3.0 Value

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1933097	2010. BASF response to Completeness Check Clarifications/Deficiencies, 2010-0958 – Intium Technical Fungicide 2010-0960 – Zampro Fungicide, 2010-0963 – BAS 650 00 F Fungicide: Value. 505pp.