Document Title

Tier 2 Summary of the Fate and Behaviour in the Environment for the plant protection product

Spirotetramat OD 150

Material number 06424376

(EU-Dossier: citrus & lettuce)

Data Requirements

Directive 91/414/EEC
Annex IIIA
Section 5, Point 9
Document M

According to OECD format guidance for industry data submissions on plant protection products and their active substances

Date

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Bayer CropScience

OWNERSHIP STATEMENT

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IIIA 9 Fate and Behavior in the Environment

This Annex III dossier is submitted for the registration of Spirotetramat OD 150, an insecticidal preparation for spray application in Europe. Spirotetramat OD 150 is developed in priority for the control of sucking insects as aphids, whiteflies, scales and mealy bugs on a wide range of crops and contains 150 g as/L. The tetramic acid derivative Spirotetramat (proposed ISO name) belongs to a completely new chemical class of insecticides. It inhibits the lipid biosynthesis (LBI).

In this Point 9 of the dossier, estimations of Predicted Environmental Concentrations (PECs) of the active substance Spirotetramat (code BYI08330) is given, as they might result in accordance with the intended application pattern (cf. Table IIIA1 9-1).

Table IIIA1 9-1: Intended application pattern of Spirotetramat OD 150 in Europe

Crop	Country	Use	Application (spray)			Application rate per treatment			PHI
			Growth stage & season BBCH	Number (max)	Interval between applications (min)	kg as/hL (max)	Water L/ha (min max)	kg as/ha (min max)	days
Citrus: oranges mandarins, lemons, limes, etc.	EU-South	F	71 -78 (fully covered with leaves)	2	21	0.0096	1000 - 3000	0.96/m CH max 0.288	14
Lettuce	EU-North EU-South	F	42 - 45	2	14	0.0144	500-1000	0.072	7
Lettuce	EU	G	42 - 43	2	14	0.0144	500-1000	0.072	7

field (F) or glasshouse (G) use

Study authors may have used different names, short forms or codes for the active ingredient and their degradation products. In this summary, a single name for each metabolite is always used. The corresponding list is given at the end of this document.

It is a general assumption which has been experimentally proven with many products that formulants (inactive ingredients) present in a product have no influence on the rate of degradation. Therefore, data derived from experiments with the active substance or other preparations containing the active ingredient are also representative for the behavior of the active substance in Spirotetramat OD 150.

IIIA 9.1 Rate of degradation in soil

IIIA 9.1.1 Aerobic degradation of the preparation in soil

The results of laboratory studies performed with the active substance as provided in Annex IIA in the context of point 7.1 and 7.2 are also applicable for the preparation. A short summary of the data is given below:

The basic soil metabolism study showed that parent compound BYI08330 is quickly degraded: Already after 1-2 days more than 90% of the test item dissipated and declined. At study termination, evolved $^{14}CO_2$ (no volatile organics occurred) accounted for up to 19.4% of AR at DAT-50 (EU soils), and accounted for 15.3% of AR for the US soil after 360 days. During the course of the study a number of degradates was observed in all four soils. Besides the two main soil metabolites BYI08330-enol (max. 24.3% of AR at DAT-3) and BYI08330-ketohydroxy (max. 16.3%, DAT-1), two enol-dimers (more or less artificially formed) and BYI08330-MA-amide (max. 6.4%, DAT-179; were identified. In addition, two minor degradates were identified as BYI08330-desmethyl-enol and BYI08330-oxo-enol amounting to maximum 3.7% and 1.2% of AR, respectively.

Furthermore, the biotransformation of Spirotetramat was investigated in two soils using [azaspirodecenyl-3-^{14}C]BYI08330 for 127 days under outdoor climatic conditions realistic for the intended use. Thereby BYI08330 formulated as an OD 100 (pH 5) was applied at 94.6% of the highest recommended single use rate for field application (288 g/ha). The parent compound was quickly and thoroughly degraded, and already one day after application, only 53.6 and 72.2% of the applied test item were detectable in both soils. During the course of the study a number of degradates was observed in all four soils. Only two major degradates were detected, BYI08330-ketohydroxy (max. 25.3% AR, DAT-14) and BYI08330-enol (max. 7.8% AR, DAT-7). Three minor metabolites were identified as glyoxylic amide, benzoic acid and ketohydroxy-carboxy. The results obtained confirmed and completed the pathway already established in the guideline aerobic soil metabolism laboratory studies.
In the BYI08330 studies the soil processing procedure was optimized to get >90% extraction efficiency and >90% recovery of the test item at time zero. However, under the acidic extraction conditions needed for Spirotetramat, the major metabolite BYI08330-enol was found to be partly unstable. It degrades under the formation of BYI08330-ketohydroxy and others. Therefore, the degradation and metabolism of the BYI08330-enol in soil was investigated in a separate study (see below), and those results needed to be included in the proposed overall metabolic pathway of Spirotetramat in soil (see Figure IIIA1 9.1-1). This fact was also the reason to base the degradation kinetics of the major Spirotetramat metabolites on the BYI08330-enol study, but not on the parent study.

Thus, the biotransformation of [azaspirodecenyl-3-^{14}C] and [azaspiro-decenyl-5-^{14}C]BYI08330-enol was studied in three EU soils and one US soil for 119 days under aerobic conditions in the dark at 20 ±1 °C and at approx. 80% of 1/3 bar moisture (US soil) or 60% WHC_{max} (EU soils). BYI08330-enol dissipated following pronounced biphasic kinetics, with an extremely quick first phase. Within a second slower degradation phase, the test item declined to 2.7 to 6.1% of AR in the four soils at the end of the study at DAT-119. During the course of the study a number of degradates was observed in all four soils. Label-specific degradates were not observed throughout the entire study, and the degradation pathway found in before-mentioned study on Spirotetramat was confirmed. In addition, a metabolite previously not found, the BYI08330-oxo-ketohydroxy was identified. However, it was a very minor contaminant and was not quantifiable. In all four soils, BYI08330-ketohydroxy was analyzed at levels > 10%. BYI08330-enol-dimer 1 amounted once to 5.0% (DAT-60) in one soil, and BYI08330-enol-dimer 2 to a maximum of 3.6% (DAT-14). BYI08330-MA-amide amounted once >5% (5.2% at DAT-4), and

BYI08330-desmethyl-enol was max. 1.8% at DAT-4. All degradates were transient during the study and did not increase towards the end of the study.

The parent compound was well degraded on irradiated soil samples of phototransformation study on soil surface. However, the biotransformation in the dark controls was approx. four times faster and, considering real environmental conditions (e.g. in June at [redacted], Greece) even approx. 20 times faster compared to soil samples irradiated by natural sunlight. This kinetics results together with the findings that the pathway of degradation was similar indicate that a distinct phototransformation product is not to be expected in soil after the use of Spirotetramat under outdoor conditions.

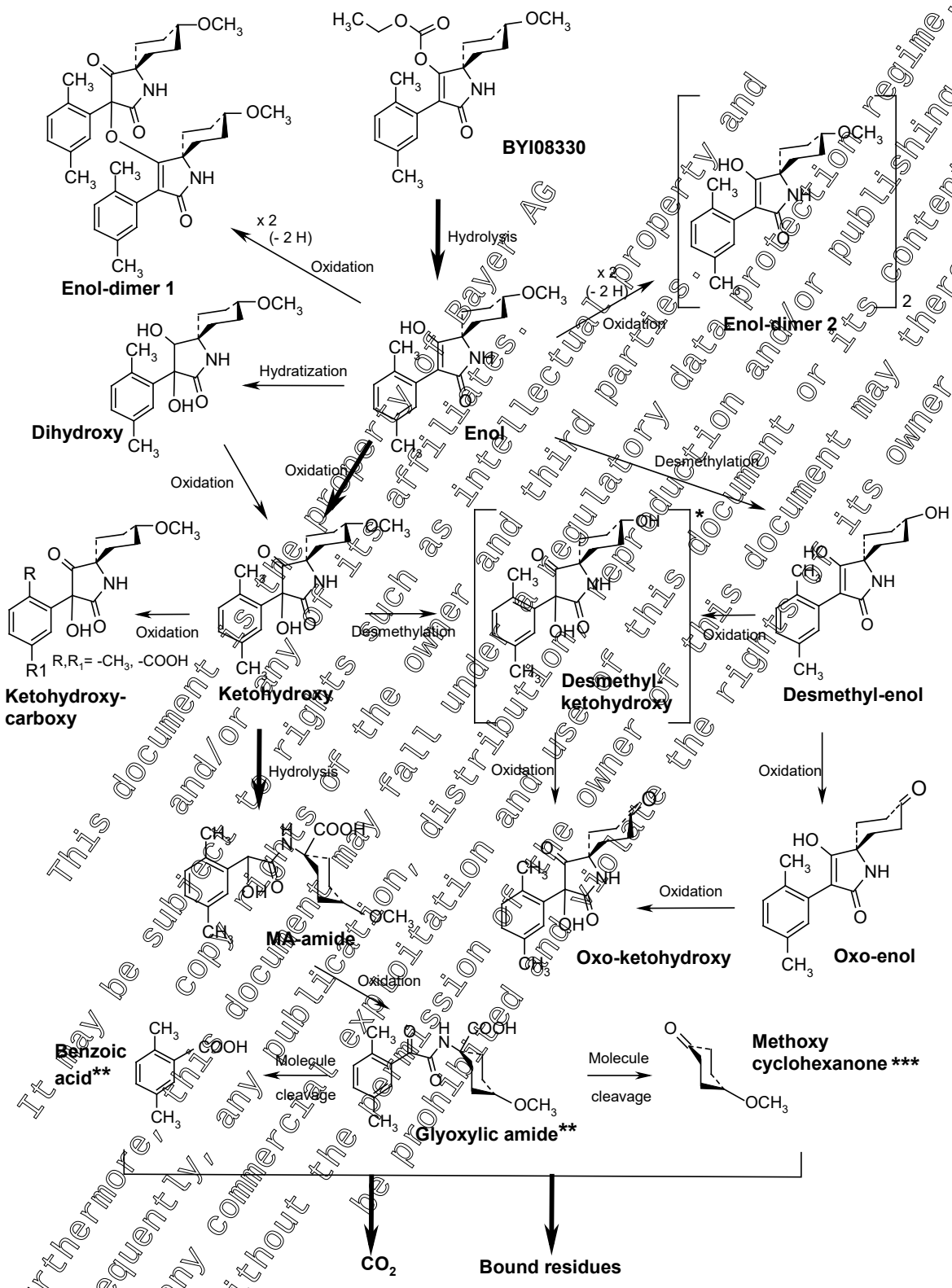
Referring to the behavior in the environment it can be concluded that the active substance Spirotetramat (BYI08330) predominantly degrades to the metabolite BYI08330-enol which is further oxidized to BYI08330-ketohydroxy. Subsequently BYI08330-ketohydroxy is hydrolytically opened to BYI8330-MA-amide, as it is included in the proposed overall metabolic scheme outlined in Figure IIIA1 9.1-1. All components are subject to further degradation to form non-extractable residues (NER) and CO_2. Based on the degradate profiles (also considering almost identical ones obtained within an anaerobic soil metabolism study; see next section) the pathway shown in Figure IIIA1 9.1-1 was proposed for degradation in soil.

The found normalized geometric mean BYI08330 DT_{50} value of 0.13 days is a suitable input parameter for environmental fate models. Further, the kinetics of biotransformation of Spirotetramat was investigated in two soils using ^{14}C-BYI08330 for 127 days under outdoor climatic conditions realistic for the intended use. Thereby ^{14}C-BYI08330 formulated as an OD 100 (pH 5) was applied at 94.6% of the highest recommended single use rate for field application (288 g/ha). The parent compound was quickly and thoroughly degraded, and a mean DT50 of approx. 2 days was estimated.

The investigation of BYI08330-enol as test item showed that it dissipates following a biphasic kinetics, with an extremely quick first phase. This portion is regarded as a strong bound fraction of BYI08330-enol in soil. The respective kinetic modeling of test item by using MatLab® (application KinGUI) indicated that the best fit DT50 (days) of test item resulted by using the bi-exponential model DFOP (double first order in parallel). This model yielded a mean BYI08330-enol DT_{50} value of 0.08 days (chi^2 statistics mean value of 7.7). Thus it can be concluded that BYI08330-enol is a fast degrading major metabolite of Spirotetramat in soil.

A more detailed kinetics modeling investigation based on the results of BYI08330-enol studies yielded geometric mean normalized $DT_{50\text{-ref}}$ values of 0.03 days for BYI08330-enol, 3.8 days for BYI08330-ketohydroxy and 1.0 day for BYI08330-MA-amide. They are suitable input parameters for environmental fate models. It must be noted, that the extremely short half life time of 0.03 days for BYI08330-enol may only be used for modeling purposes and in conjunction with the SFORB model or a kinetic sorption model as implemented in PEARL.

Based on the results obtained within a further laboratory soil degradation study using three aerobic soils it was shown that the metabolite 4-methoxy cyclohexanone is fast and steadily degrading in soil (DT50 < 1 day) and that there is no potential for accumulation of 4-methoxy cyclohexanone residues in viable soils. The observed higher level of 4-methoxy cyclohexanone residues in the laboratory study on phototransformation of BYI08330 on soil surface might have been caused by a decreasing viability of test soil during the strong irradiation in such a laboratory test system.



*: postulated intermediate; ** and *** were identified in studies including light (dependent on radiolabel used)

Figure IIIA1 9.1-1: Proposed Metabolic Pathway for Spirotetramat (BYI08330) in Soil

IIIA 9.1.2 Anaerobic degradation of the preparation in soil

The results of laboratory studies performed with the active substance as provided in Annex IIA in the context of point 7.1.2 are also applicable for the preparation. A short summary of the data is given below:

Based on the degradate profiles obtained within an anaerobic soil metabolism study, a degradation pathway was proposed which is almost identical to the degradation pathway obtained in aerobic soil. It is concluded that BYI08330 applied to soil will be degraded rapidly in a subsequently flooded anaerobic soil situation, and will not form degradates different from those observed in soil under aerobic conditions, and/or known from abiotic hydrolysis experiments (see section later).

IIIA 9.2 Field studies

From all the laboratory studies and a radiolabeled outdoor study it can be concluded that Spirotetramat is a very fast degrading compound in soil, and all metabolites generated from BYI08330-enol, the predominant first metabolite, are further degraded and are expected not to accumulate in the environment. The soil dissipation testing in a range of representative soils and locations in the USA confirmed that findings.

The results of field studies provided in the active substance dossier Annex IIA in the context of point 7.3 are also applicable for the preparation. A short summary of the data is given below:

IIIA 9.2.1 Soil dissipation testing on a range of representative soils

In order to determine the residues during US terrestrial field dissipation trials an analytical method (FN-002-S05-02) for the determination of BYI08330 and its metabolites BYI08330-enol, BYI08330-ketohydroxy and BYI08330-MA-amide in soil and sediment by LC/MS/MS was developed and successfully validated for the determination of residues in soil and sediment. The method was evaluated by determining the average recoveries and relative standard deviation at the LOQ of 5 ng/g and at 5x LOQ (25 ng/g).

BYI08330 dissipated rapidly in soil under field conditions. The dissipation rates of BYI08330 calculated for four sites in the US, resulted in half-life (DT_{50}) values from 0.9 to 1.0 days and the periods required for 90% dissipation (DT_{90}) ranged 1.1 to 3.5 days with no apparent obvious correlation with soil properties or the management (bare ground Vs. cropped). The DT50 values of the combined residues of BYI08330 (i.e. BYI08330, BYI08330-enol, and BYI08330-ketohydroxy) ranged from 5.0 to 23.4 days and the DT90 values ranged from 16.7 to 77.8 days.

Residues of BYI08330 did not move below the surface layer (0 to 15 cm) in all the sites, except in Florida where residues of BYI08330-enol and BYI08330-ketohydroxy were detected above the LOQ at 15 to 30 cm layer between 1 day and 7 days after application. After that the residues completed degradation to less than LOQ and MDL. It should be noted that the Florida site represents a worst case condition with heavy rainfall and very light soil (95% sand in the surface layer) with very low organic matter (0.5 %). Therefore, leaching and groundwater contamination is not likely with BYI08330.

BYI08330 degraded to less than the MDL levels (0.5 µg/kg) within 14 days after application. The soil concentration the metabolites of BYI08330 were below the LOQ within 28 to 365 days after application. Based on these results, the carry over potential of soil residues from one year to another is very low.

Considering the results from laboratory soil metabolism studies and terrestrial field dissipation studies the major route(s) of dissipation for BYI08330 are degradation to BYI08330-enol and BYI08330-

ketohydroxy, subsequent biodegradation to non-extractable soil residues and mineralization to CO_2.

BYI08330 and its metabolites BYI08330-ketohydroxy and BYI08330-MA-amide showed no evidence of any degradation in the four soils during a maximum storage interval of 324 days in frozen storage and there was little variation in the results for the four soils. BYI08330-enol recoveries declined during storage, with the majority of the loss occurring during the first 30 days of storage. The primary causes of these low recoveries were degradation of BYI08330-enol to BYI08330-ketohydroxy and binding of the analyte to soil.

IIIA 9.2.2 Soil residue testing

This requirement is covered by soil dissipation studies which give also information on the soil residues of the active substance relevant for succeeding crops. The results of field studies provided in Annex IIA in the context of point 7.3 are also applicable for the preparation.

IIIA 9.2.3 Soil accumulation testing

This requirement is covered by soil dissipation studies which give also information on the soil residues of the active substance relevant for succeeding crops. The results of field studies performed with the active substance as provided in Annex II in the context of point 7.3 are also applicable for the preparation.

IIIA 9.2.4 Aquatic (sediment) field dissipation

This item is no requirement according to 91/414/EEC.

IIIA 9.2.5 Forestry field dissipation

This item is no requirement according to 91/414/EEC.

IIIA 9.3 Mobility of the plant protection product in soil

The results of studies investigating the adsorption and mobility of the active substance and its metabolites in soil, as provided in Annex IIA in the context of point 7.4, are also applicable for the preparation. A short summary of the data is given below.

Adsorption / desorption

Freundlich adsorption and desorption constants K_F and K_{OC} of Spirotetramat have been determined in batch equilibrium experiments with five different soils using radiolabeled test substance ([azaspirodecenyl-3-^{14}C]BYI08330). Since significant degradation of test item was observed in a pre-test, the main test was performed with sterilized soil. K_{OC} values for the different soils were in the range of 159 to 435 mL/g with a mean K_{OC} of 281 mL/g (1/n = 0.941). Based on this value, Spirotetramat can be classified as low mobile in soil.

Freundlich adsorption and desorption constants K_F and K_{OC} of BYI08330-enol, the major metabolite in soil, was attempted in batch equilibrium experiments with five different soils using radiolabeled test substance ([azaspirodecenyl-3-^{14}C]BYI08330-enol. However, the study showed that the sorption characteristics of BYI08330-enol to soil cannot be determined by a batch equilibrium test according to OECD Guideline 106. In order to asses the environmental behavior of the test item more suitable test methods had to be employed. Another option, i.e. a so-called time-dependent sorption study, demonstrated that sorption and binding of BYI08330-enol to soil is extremely fast and increases very rapidly with aging time in soil. The portion not tightly bound to soil, i.e. the portion that is releasable by aqueous solution from soil (weakly adsorbed), is degraded within a few hours. From these results it can be concluded that BYI08330-enol is absent from the soil pore water (either degraded or tightly bound to soil) within a very short period of time This study confirmed that the sorption characteristics of the test item BYI08330-enol to soil cannot be determined accurately by a batch equilibrium test according to OECD TG 106. Since only partial degradation of BYI08330-enol occurred during the course of a soil column leaching study performed with four soils the test system allowed the calculation of adsorption constants for the test item in soils. For the strongly bound BYI08330-enol fraction K_{OC} values between 828 and 1711 mL/g were calculated, resulting in a mean value of 1187 mL/g over four soil types. For the weakly adsorbed BYI08330-enol fraction K_{OC} values between 27 and ca. 99 mL/g were calculated, resulting in a mean value of 55 mL/g over four soil types. Based on the classification of soil mobility potential according to Briggs, the strongly adsorbed BYI08330-enol fraction is classified as immobile, and the weakly adsorbed BYI08330-enol fraction has an intermediate potential to leach through soil.

Freundlich adsorption and desorption constants K_F and K_{OC} of BYI08330-ketohydroxy, a major metabolite in soil, have been determined in batch equilibrium experiments with five different soils using [azaspirodecenyl-3-^{14}C]BYI08330-ketohydroxy. Since significant degradation of BYI08330-ketohydroxy was observed in a pre-test, the equilibration solution used was 0.01 M aqueous $CaCl_2$ solution spiked with 50 mg $HgCl_2$ as biocide. $K_{OC(ads)}$ values for the different soils were in the range of 41.0 to 99.1 mL/g with a mean K_{OC} of 63.7 mL/g (1/n = 0.922). Based on this value, BYI08330-ketohydroxy can be classified as intermediate to mobile in soil.

Freundlich adsorption and desorption constants K_F and K_{OC} of BYI08330-MA-amide have been determined in batch equilibrium experiments with five different soils using [hydroxy-^{14}C]BYI08330-MA-amide. The calculated adsorption constants K_F of the Freundlich isotherms for the four test soils ranged from 0.06 to 0.18, and the $K_{OC(ads)}$ values were in the range of 4.4 to 25.5 mL/g with a mean $K_{OC(ads)}$ of 9.3 mL/g (mean 1/n = 0.948). Based on this value, BYI08330-MA-amide can be classified as high mobile in soil. The desorption K_{des} values were 0.13 to 0.37 and higher than those obtained for K_F in the adsorption phase indicating a little stronger binding once adsorbed to soil.

BYI08330-enol dimers 1 and 2 were minor metabolites in the relevant metabolism studies. Nevertheless, their adsorption coefficients on soil were estimated by using the HPLC method according to OECD TG No. 121. Based on the resulting calibration equation for pH 6, the soil adsorption coefficients of BYI08330-enol dimer 1 were estimated to be log K_{OC} = 3.23 and K_{OC} = 1708. For the BYI08330-enol dimer 2 a log K_{OC} = 3.46 and a K_{OC} = 2896 were estimated. According to the Briggs' classification BYI08330-enol dimer 1 and BYI08330-enol dimer 2 would be categorized as immobile.

From all the before mentioned laboratory studies it is concluded that the mobility of Spirotetramat residues in soil is sufficiently understood. Since a long-term leaching simulations indicated that the PEC_{GW} values are generally far below 0.1 µg/L in all application scenarios relevant for the intended uses of Spirotetramat on citrus, oranges, mandarins, lemons, limes, etc. in EU-South, and on lettuce in EU-

North and EU-South, no concern with regard to groundwater contamination of parent compound and its metabolites is indicated, and a safe use is given in the EU.

IIIA 9.3.1 Column leaching

From the adsorption / desorption behavior of the active substance contained in the plant protection product it was concluded that its mobility in soil is very limited and that no need for column leaching studies is indicated.
Since the adsorption / desorption behavior of BYI08330-enol could not be determined accurately by a batch equilibrium study a soil column leaching study was performed for this metabolite with four soils. The outcome was summarized in the section before, already.

IIIA 9.3.2 Lysimeter studies

From the adsorption / desorption behavior of the active substance contained in Spirotetramat OD 150 it was concluded that its mobility in soil is very limited and that no need for lysimeter studies is indicated.

IIIA 9.3.3 Field leaching studies

From the adsorption / desorption behavior of the active substance contained in Spirotetramat OD 150 it was concluded that its mobility in soil is very limited and that no need for field leaching studies is indicated. The results of studies investigating the mobility of the active substance in soil, as provided in Annex II in the context of point 7.4 are also applicable for the preparation.

IIIA 9.3.4 Volatility - laboratory studies

No laboratory volatility studies on the preparation have been performed. Details of the volatility of the active ingredient are given in Annex II, Section 1, point 2.3 and section 5, point 7.4.9. The vapor pressure of Spirotetramat is very low with 3.6 x 10⁻⁹ Pa for 20°C.

IIIA 9.3.5 Volatility - field studies

This item is no current requirement according to 91/414/EEC.

IIIA 9.4 Predicted environmental concentrations in soil, active substance

Report:	**KIIIA 9.4/01, [redacted], B. 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Metabolites in Soil (PEC_{Soil}) - Use in Citrus in Europe.** BYI08330 (Spirotetramat); BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide
Report No & Document No	**MEF-06/282** **M-277210-01-1**
Guidelines:	No guideline available
GLP	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2006-08-30

Executive Summary

In the present study predicted environmental concentrations in soil (PEC_{Soil}) of the active substance Spirotetramat and its main soil metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide were calculated. The intended use of Spirotetramat in citrus was investigated for Europe. The calculations were based on several worst case assumptions for scenario and substance-specific input parameters that guarantee a conservative exposure assessment. Predicted environmental concentrations in soil (PEC_{Soil}) were calculated for the 0 to 5-cm soil layer.

Predicted environmental concentrations in soil (PEC_{Soil}) were calculated for the 0 to 5-cm soil layer for spray application in citrus. They amounted to 0.115, 0.0934, 0.031 and 0.005 mg/kg soil for parent compound, BYI08330-enol, BYI08330-ketohydroxy and BYI08330-MA-amide, respectively.

I. METHODS

Predicted environmental concentrations in soil (PEC_{Soil}) of Spirotetramat and its main metabolites in soil, BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide, were calculated for the use by spray application in citrus. Relevant degradation half-lives of the compounds are given in Table IIIA1 9.4-1.

Table IIIA1 9.4-1: Degradation half-lives of the compounds in soil

Compound	Worst case SFO- DT_{50} (d)
BYI08330	0.23
BYI08330-enol	2.6
BYI08330-ketohydroxy	12.1
BYI08330-MA-amide	3.9

According to Good Agricultural Practice (GAP) the recommended maximum Spirotetramat application rates depend on the actual crop development stage at which the application will be performed. If the application span covers a range of growth stages, the lower interception rate (in bold, Table IIIA1 9.4-2) resulting in worst case actual application data was used.

Depending on the date of application and on the corresponding development stage of the plants, a certain

portion of the plant protection product was assumed to be intercepted by the plant foliage, *i.e.* only the remaining amounts of Spirotetramat were assumed to reach the soil surface (Table IIIA1 9.4-2). The interception data were based on the FOCUS groundwater report (FOCUS, 2000) and on the current FOCUS guidance paper (FOCUS, 2002).

Table IIIA1 9.4-2: Spirotetramat OD 150 application data for citrus in EU

Crop	BBCH Code	Intended BYI08330 application rate [g a.s./ha]	Interval between applications [d]	Interception [%]	Amount of BYI08330 applied to the bare ground [a] [g a.s./ha]
Citrus	**71** - 78	2 x 96/mCH [b] max 2 x 288	21	70	2 x 86.4

a) The actual amount of BYI08330 applied onto bare ground within the model due to interception by the plant foliage.
b) mCH = per meter of tree height (max 3 m)

Basic equations to calculate PEC and TWA values for the parent compound:

The initial PEC_{Soil} (mg/kg) of the active ingredient from a single application depends on the application rate A (g/ha) of the compound, on the crop interception C (% of A), on the bulk density BD of the dry soil (standard value: 1.5 g/cm³) and on the assumed mixing depth d (standard value: 5 cm), according to

$$PEC_{s,init} = A \cdot (1 - 0.01 \cdot C) \cdot \frac{1}{100 \cdot BD \cdot d} \qquad \text{[eq. 1]}$$

In single application scenarios, the initial PEC_{Soil} value is equal to the overall maximum. Based on the maximum PEC_{Soil} and assuming first-order kinetics with degradation rate k (in d^{-1}), the soil concentrations over time are given by

$$PEC_s(t) = PEC_{s,max} \cdot e^{-k \cdot t} \qquad \text{[eq. 2]}$$

For first-order kinetics, the degradation or dissipation rate is related to the corresponding DT_{50} value by

$$k = \ln(2) / DT_{50} \qquad \text{[eq. 3]}$$

For a comparison with effect endpoints from long-term (chronic) ecotoxicological studies, it is sometimes more appropriate to use time-weighted average (TWA) exposure concentrations. For first-order kinetics, the TWA concentrations are given by

$$TWA(t) = PEC_{s,max} \cdot \frac{1}{k \cdot t} \cdot (1 - e^{-k \cdot t}) \qquad \text{[eq. 4]}$$

Basic equations to calculate PEC and TWA values for the metabolites:

For the calculation of the maximum PEC_{Soil} of a metabolite, the maximum amount of a metabolite, $X_{Met,s,max}$ (% of applied parent compound) that was observed in a degradation study, and the molar masses of parent, M_{Par}, and metabolite, M_{Met} (g/mol), must be taken into account:

$$PEC_{Met,s,init} = A \cdot (1 - 0.01 \cdot C) \cdot \frac{1}{100 \cdot BD \cdot d} \cdot 0.01 \cdot X_{Met,s,max} \cdot \frac{M_{Met}}{M_{Par}} \qquad \text{[eq. 5]}$$

PEC_{Soil} and TWA_{Soil} values of a metabolite are calculated correspondingly to the parent (eq. 2 and 4), using the degradation rate of the metabolite, k_{Met}.

The calculations were carried out on a DELL P4 computer running Windows XP Professional Version 2002 Service Pack 1, using a Microsoft® Excel 2002 spreadsheet, in which the relevant equations had been implemented.

II. RESULTS AND DISCUSSION

The resulting maximum PEC_{Soil} values, as well as the maximum time weighted average PEC_{Soil} values (TW_{Soil}) calculated for Spirotetramat are summarized in Table IIIA1 9.4-3.

Table IIIA1 9.4-3: Maximum PEC_{Soil} and TWA_{Soil} values in the 5 cm soil layer resulting from application of Spirotetramat OD 150 in citrus

Time frame (d)	Spirotetramat	
	PEC_{Soil} (mg/kg)	TWA_{Soil} (mg/kg)
0	0.115	-
1	0.006	0.036
2	< 0.001	0.019
4	< 0.001	0.010
7	< 0.001	0.005
14	< 0.001	0.003
21	< 0.001	0.002
28	< 0.001	0.001
42	< 0.001	0.001
50	< 0.001	0.001
100	< 0.001	0.001

Report: **KIIA 9.4/02, [redacted], B, 2006**

Title: **Predicted Environmental Concentrations of Spirotetramat and its Main Metabolites in Soil (PEC_{Soil}) - Use in Leafy Vegetables in Europe:** BYI08330 (Spirotetramat), BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide

Report No & Document No **MEF-06/387, M-277222-01-1**

Guidelines: No guideline available

GLP No (calculation)

Testing laboratory and dates: Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2006-08-30

Executive Summary

In the present study predicted environmental concentrations in soil (PEC_{Soil}) of the active substance Spirotetramat and its main soil metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide were calculated. The intended use of Spirotetramat in leafy vegetables (i.e. lettuce, cabbage) was investigated for Europe. The calculations were based on several worst case assumptions for scenario and substance-specific input parameters that guarantee a conservative exposure assessment.

Predicted environmental concentrations in soil (PEC_{Soil}) were calculated for the 0 to 5-cm soil layer for spray application in lettuce. They amounted to 0.029, 0.024, 0.009 and 0.001 mg/kg soil for parent compound, BYI08330-enol, BYI08330-ketohydroxy and BYI08330-MA-amide, respectively.

I. METHODS

Predicted environmental concentrations in soil (PEC_{Soil}) of Spirotetramat and its main metabolites in soil, BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide, were calculated for the use by spray application in lettuce. Relevant degradation half-lives of the compounds are given in Table IIIA1 9.4-1, already

According to Good Agricultural Practice (GAP) the recommended maximum Spirotetramat application rates depend on the actual crop development stage at which the application will be performed. If the application span covers a range of growth stages, the lower interception rate (in bold, Table IIIA1 9.4-4) resulting in worst case actual application data was used.

Depending on the date of application and on the corresponding development stage of the plants, a certain portion of the plant protection product was assumed to be intercepted by the plant foliage, *i.e.* only the remaining amounts of Spirotetramat were assumed to reach the soil surface (Table IIIA1 9.4-4). The interception data were based on the FOCUS groundwater report (FOCUS, 2000) and on the current FOCUS guidance paper (FOCUS, 2002).

Table IIIA1 9.4-4: Spirotetramat OD 150 application data for lettuce in EU

Crop	BBCH Code	Intended BYI08330 application rate [g a.s./ha]	Interval between applications [d]	Interception [%]	Amount of BYI08330 applied to the bare ground [a)] [g a.s./ha]
Leafy vegetables (i.e. lettuce)	**42** - 43	2 x 72	14	70	2 x 21.6

a) The actual amount of BYI08330 applied onto bare ground within the model due to interception by the plant foliage.

The basic equations to calculate PEC and TWA values were shown earlier in this section, already.

II. RESULTS AND DISCUSSION

The resulting maximum PEC_{Soil} values, as well as the maximum time weighted average PEC_{Soil} values (TW_{Soil}) calculated for Spirotetramat are summarized in Table IIIA1 9.4-5.

Table IIIA1 9.4-5: Maximum PEC_{Soil} and TWA_{Soil} values in the 5 cm soil layer resulting from application of Spirotetramat OD 150 in lettuce

Time frame	Spirotetramat	
(d)	PEC_{Soil} (mg/kg)	TWA_{Soil} (mg/kg)
0	0.029	-
1	0.001	0.009
2	< 0.001	0.005
4	< 0.001	0.002
7	< 0.001	0.001
14	< 0.001	< 0.001
21	< 0.001	< 0.001
28	< 0.001	< 0.001
42	< 0.001	< 0.001
50	< 0.001	< 0.001
100	< 0.001	< 0.001

IIIA 9.4.1 Initial PECs value

For better transparency the various PEC_{Soil} values reflecting the initial, short- and long-term PEC_{Soil} are presented side by side, see Table IIIA1 9.4-3 for citrus and Table IIIA1 9.4-5 for lettuce.

IIIA 9.4.2 Short-term PECs values – 24 hours, 2 and 4 days after last application

For better transparency the various PEC_{Soil} values reflecting the initial, short- and long-term PEC_{Soil} are presented side by side, see Table IIIA1 9.4-3 for citrus and Table IIIA1 9.4-5 for lettuce.

IIIA 9.4.3 Long-term PECs values - 7, 28, 50 and 100 days after last application

For better transparency the various PEC_{Soil} values reflecting the initial, short- and long-term PEC_{Soil} are presented side by side, see Table IIIA1 9.4-3 for citrus and Table IIIA1 9.4-5 for lettuce.

IIIA 9.5 Predicted environmental concentrations in soil, for rel. metabolites

For better transparency the information and the executive summaries related to the PEC_{Soil} calculations of the metabolites of Spirotetramat are presented by both reports summarized in Section 9.4, already.

Report: **KIIIA 9.5/01, [redacted], B, 2006**

Title: **Predicted Environmental Concentrations of Spirotetramat and its Main Metabolites in Soil (PEC_{Soil}) - Use in Citrus in Europe.**
BYI08330 (Spirotetramat); BYI08330-enol, -ketohydroxy, -MA-amide

Report No & Document No: **MEF-06/282**
M-277210-01-1

Guidelines: No guideline available

GLP: No (calculation)

Testing laboratory and dates: Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2006-08-30

Report:	**KIIIA 9.5/02, [redacted], B. 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Metabolites in Soil (PEC_{Soil}) - Use in Leafy Vegetables in Europe:** BYI08330 (Spirotetramat); BYI08330-enol, -ketohydroxy, -MA-amide
Report No & Document No	**MEF-06/387** **M-277222-01-1**
Guidelines:	No guideline available
GLP	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2006-08-30

The resulting maximum PEC_{Soil} values, as well as the maximum time weighted average PEC_{Soil} values (TW_{Soil}) calculated for BYI08330-enol, BYI08330-ketohydroxy and BYI08330-MA-amide are summarized in Table IIIA1 9.5-1 for citrus and in Table IIIA1 9.5-2 for lettuce.

Table IIIA1 9.5-1: Maximum PEC_{Soil} and TWA_{Soil} values of BYI08330-enol, -ketohydroxy and -MA-amide in the 5 cm soil layer resulting from application of Spirotetramat OD 150 in citrus

Time frame	BYI08330-enol		BYI08330-ketohydroxy		BYI08330-MA-amide	
(d)	PEC_{Soil} (mg/kg)	TWA_{Soil} (mg/kg)	PEC_{Soil} (mg/kg)	TWA_{Soil} (mg/kg)	PEC_{Soil} (mg/kg)	TWA_{Soil} (mg/kg)
0	0.093		0.031		0.005	
1	0.072	0.082	0.029	0.030	0.005	0.005
2	0.055	0.073	0.027	0.029	0.004	0.005
4	0.033	0.058	0.024	0.027	0.003	0.004
7	0.015	0.043	0.020	0.025	0.002	0.003
14	0.002	0.025	0.014	0.021	< 0.001	0.002
21	< 0.001	0.017	0.009	0.018	< 0.001	0.001
28	< 0.001	0.013	0.006	0.015	< 0.001	0.001
42	< 0.001	0.008	0.003	0.012	< 0.001	0.001
50	< 0.001	0.007	0.002	0.010	< 0.001	0.001
100	< 0.001	0.004	< 0.001	0.005	< 0.001	< 0.001

Table IIIA1 9.5-2: Maximum PEC_{Soil} and TWA_{Soil} values of BYI08330-enol, -ketohydroxy and -MA-amide in the 5 cm soil layer resulting from application of Spirotetramat OD 150 in lettuce

Time frame	BYI08330-enol		BYI08330-ketohydroxy		BYI08330-MA-amide	
	PEC_{Soil}	TWA_{Soil}	PEC_{Soil}	TWA_{Soil}	PEC_{Soil}	TWA_{Soil}
(d)	(mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)
0	0.024		0.009		0.001	
1	0.018	0.021	0.008	0.008	0.001	0.001
2	0.014	0.018	0.008	0.008	0.001	0.001
4	0.008	0.015	0.007	0.008	0.001	0.001
7	0.004	0.011	0.006	0.007	< 0.001	0.001
14	< 0.001	0.006	0.004	0.006	< 0.001	0.001
21	< 0.001	0.004	0.003	0.005	< 0.001	0.001
28	< 0.001	0.003	0.002	0.004	< 0.001	< 0.001
42	< 0.001	0.002	0.001	0.003	< 0.001	< 0.001
50	< 0.001	0.002	< 0.001	0.003	< 0.001	< 0.001
100	< 0.001	0.001	< 0.001	0.001	< 0.001	< 0.001

During the dossier evaluation the RMS concluded that specimen environmental concentrations in soil of a photometabolite of Spirotetramat, i.e. of 4-methoxy cyclohexanone, should be given, also (see following report Report KIIIA1 9.5/03).

Report:	**KIIIA1. 9.5/03, [redacted], B. 2007**
Title:	**Predicted Environmental Concentrations of 4-methoxy cyclohexanone in soil (PEC_{soil})**
Report No & Document No	**MEF-07/478 M-295000-01-1**
Guidelines:	No guideline available
GLP	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2007-11-15

Executive Summary

Predicted environmental concentrations in soil (PEC_{soil}) of a photometabolite of Spirotetramat, i.e. of 4-methoxy cyclohexanone were calculated for the use by spray application in citrus. The calculations were based on several worst case assumptions for scenario and substance-specific input parameters that guarantee a conservative exposure assessment. Predicted environmental concentrations in soil (PEC_{soil}) were calculated for the 0 to 5-cm soil layer.

The resulting calculated maximum PEC_{soil} for 4-methoxy cyclohexanone in the 0 to 5-cm soil layer was very low, amounting to 0.004 mg/kg soil, only.

I. METHODS

Predicted environmental concentrations in soil (PEC_{soil}) of a photometabolite of Spirotetramat, i.e. of 4-methoxy cyclohexanone were calculated for the use by spray application in citrus. That use was selected

as an example to give an overall range of PEC_{soil} representative of the other uses in Europe.

A DT 50 of 0.6 days and a formation fraction of max. 10% was taken for the calculations.

According to Good Agricultural Practice (GAP) recommended maximum Spirotetramat application rates depend on the actual crop development stage at which the application will be performed. Depending on the date of application and on the corresponding development stage of the plants, a certain portion of the plant protection product was assumed to be intercepted by the plant foliage, *i.e.* only the remaining amounts of Spirotetramat were assumed to reach the soil surface. For citrus 2 x 86.4 g/ha were assumed to reach the bare ground (interval 14 days). The interception data were based on the FOCUS groundwater report (FOCUS, 2000), the current FOCUS guidance paper (FOCUS, 2002). All calculations assumed field applications. This is an extremely conservative assumption for those crops grown in greenhouses only.

For the calculation of PEC_{Soil} of 4-methoxy cyclohexanone the initial application rate of the parent was mol-mass corrected. A maximum occurrence of 10% 4-methoxy cyclohexanone in soil was assumed.

For basic equations to calculate PEC and TWA values see chapter 5 of the report.

II. RESULTS AND DISCUSSION

The resulting maximum PEC_{Soil} values, as well as the maximum time weighted average PEC_{soil} values (TW_{Soil}) calculated for 4-methoxy cyclohexanone are summarized in Table IIIA1. 9.5-3.

Table IIIA1. 9.5-3: Maximum PEC_{soil} and TWA_{soil} values in the 5 cm soil layer resulting from application of Spirotetramat in <u>citrus</u>

Time frame		4-methoxy cyclohexanone	
Period	[days]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]
Initial	0	0.004	
Short-term	1	0.001	0.002
	2	< 0.001	0.002
	4	< 0.001	0.001
Long-term	7	< 0.001	0.000
	14	< 0.001	0.000
	21	< 0.001	0.000
	28	< 0.001	0.000
	42	< 0.001	0.000
	50	< 0.001	0.000
	100	< 0.001	0.001

IIIA 9.5.1 Initial PECs value

For better transparency the various PEC_{Soil} values reflecting the initial, short- and long-term PEC_{Soil} are presented side by side (see above in Table IIIA1 9.5-1 to Table IIIA1. 9.5-3).

IIIA 9.5.2 Short-term PECs values – 24 hours, 2 and 4 days after last application

For better transparency the various PEC_{Soil} values reflecting the initial, short- and long-term PEC_{Soil} are presented side by side (see above in Table IIIA1 9.5-1 to Table IIIA1. 9.5-3).

IIIA 9.5.3 Long-term PECs values - 7, 28, 50 and 100 days after last application

For better transparency the various PEC_{Soil} values reflecting the initial, short- and long-term PEC_{Soil} are presented side by side (see above in Table IIIA1 9.5-1 to Table IIIA1. 9.5-3).

IIIA 9.6 Predicted environmental concentrations in ground water (PEC_{gw})

IIIA 9.6.1 Active substance PEC_{gw} value

The potential for translocation into groundwater of Spirotetramat and its main soil metabolites has been assessed in order to give a comprehensive picture on the mobility behaviour of residues in soil resulting from the use of Spirotetramat OD 150 in Europe.

Report:	**KIIIA 9.6.1/01, [redacted], B., 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Soil Metabolites in Groundwater Recharge (PEC_{gw}) Based on Calculations with FOCUS PEARL - Use in Citrus in Europe.** BYI08330 (Spirotetramat), BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide
Report No & Document No:	**MEF-06/280 M-277121-02-1**
Guidelines:	No guideline available
GLP:	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, performed the study in August 2006. Completion date: 2006-08-30, 2nd version of report dated 2007-05-31.

Executive Summary

The predicted environmental concentrations in groundwater recharge (PEC_{gw}) of BYI08330 (Spirotetramat) and its main metabolites BYI08330-enol, BYI08330-ketohydroxy and BYI08330-MA-amide were calculated for the use in citrus using the simulation model FOCUS-PEARL 3.3.3. The realistic worst case leaching scenarios (weather, soil and crop data) proposed by FOCUS (2000)[1] were used for the calculation of PEC_{gw} values. The calculations were based on several worst case assumptions and substance-specific input parameters that guarantee a conservative exposure assessment. Two spray applications of Spirotetramat in citrus were simulated per season, determined by a maximum application rate of 288 g a.s. /ha each.

For all relevant FOCUS scenarios the leaching simulations for Spirotetramat and its metabolites resulted in PEC_{gw} values below 0.001 µg/L. Thus it can be concluded that Spirotetramat applications in citrus in Europe are highly unlikely to cause groundwater concentrations above the trigger value of 0.1 µg/L.

[1] FOCUS (2000): FOCUS groundwater scenarios in the EU plant protection product review process. Final report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202pp, Date December 2000

FOCUS (2002): Generic Guidance for FOCUS Groundwater Scenarios. Version 1.1, Date April 2002, Amending FOCUS (2000)

I. METHODS

Predicted environmental concentrations of the active substance Spirotetramat (BYI08330) and its main metabolites in ground water recharge (PEC_{gw}) were estimated for the spray use of the insecticide. The concentrations were calculated utilizing the simulation model FOCUS-PEARL (version 3.3.3).

The substance data used in the calculations are summarized in following Table IIIA1 9.6.1-1.

Table IIIA1 9.6.1-1: Summary of substance-specific parameters used

Parameter	BYI08330 (Spirotetramat)	BYI08330-enol	BYI08330-ketohydroxy	BYI08330-MA-amide
Geom. mean $DT_{50\ -\ ref}$ in soil [d]	0.13	0.03 *)	3.8	1.0
Arithmetic mean K_{oc} value [mL/g]	281	55	63.7	9.3
Arithmetic mean Freundlich exponent 1/n	0.94	1	0.92	0.95

*): As it is not possible to use DT_{50} values below 0.1 d in the PEARL 3.3.3 version, a DT_{50} value of 0.1 d was used instead of the calculated value of 0.03 d, which represents worst case for enol in this case.

A spray application of Spirotetramat in citrus was investigated. According to Good Agricultural Practice (GAP) the recommended maximum Spirotetramat application rates depend on the actual crop development stage at which the application will be performed. If the application span covers a range of growth stages, the lower interception rate (in bold, Table IIIA1 9.6.1-1) resulting in worst case actual application data was used.

Depending on the date of application and on the corresponding development stage of the plants, a certain portion of the plant protection product was assumed to be intercepted by the plant foliage, *i.e.* only the remaining amounts of Spirotetramat were assumed to reach the soil surface (Table IIIA1 9.6.1-2). The interception data were based on the FOCUS groundwater report (FOCUS, 2000) and on the current FOCUS guidance paper (FOCUS, 2002).

Table IIIA1 9.6.1-2: Relevant application details of Spirotetramat OD 150 in citrus

Crop	BBCH Code	Intended BYI08330 application rate [g a.s./ha]	Interval between applications [d]	Interception [%]	Amount of BYI08330 applied to the bare ground [a)] [g a.s./ha]
Citrus	**71** - 78	2 x 96 [b] max 2 x 288 [b]	21	70	2 x 86.4

a) The actual amount of BYI08330 applied onto the bare ground within the model due to interception by the plant foliage
b) mCH = per meter of tree ("canopy") height (max 3 m)

The FOCUS Groundwater Scenarios Workgroup developed nine scenarios that cover a wide range of pedo-climatic conditions in the European Union. Soil and weather data in these scenarios were selected to address realistic worst case conditions with regard to leaching. Table IIIA1 9.6.1-3 summarizes key characteristics of these scenarios; details are documented in FOCUS (2000, 2002).

Table IIIA1 9.6.1-3: Characteristics of the FOCUS groundwater scenarios, FOCUS, 2000

Scenario	Mean annual temperature	Mean annual rainfall*	Topsoil texture (USDA)	Topsoil organic carbon	Topsoil pH
[redacted]	11.4°C	648 mm + I	silty clay loam	1.4%	7.3
[redacted]	9.2°C	786 mm	sandy loam	1.5%	5.7
[redacted]	4.3°C	638 mm	loamy sand	4.1%	5.5
[redacted]	8.8°C	900 mm	loam, silt loam	2.1%	7.0
[redacted]	10.4°C	1038 mm	loam	2.2%	5.1
[redacted]	13.3°C	857 mm + I	loam	1.0%	6.3
[redacted]	14.8°C	1150 mm	loam	3.8%	4.2
[redacted]	18.1°C	493 mm + I	silt loam	0.9%	6.6
[redacted]	16.2°C	500v + I	loam	0.8%	7.0

* "+ I" indicates crop specific irrigation

The leaching simulations were based on the standard input files of the official implementation of the FOCUS Groundwater Scenarios for the PEARL model. Default values were used for all parameters, except for the substance-specific data. All simulation runs were organized by means of the FOCUS shell of PEARL, using the automatically generated input and output files.

The PEARL simulations were run over 26 years as proposed by FOCUS (2000, 2002) for pesticides which are applied every year. The first six years represent a so-called 'warm up' period. Only the last 20 years are taken into account for an assessment of the leaching potential. The leaching simulations were run for citrus according to FOCUS (2000), for the corresponding FOCUS scenarios. The application dates for the respective BBCH stage and location are listed in Table IIIA1 9.6.1-4.

Table IIIA1 9.6.1-4: Application dates of in the FOCUS scenarios for citrus

Scenario	Application date
[redacted]	7.11., 28.11.
[redacted]	7.11., 28.11.
[redacted]	7.11., 28.11.
[redacted]	7.11., 28.11.

The version 3.3.3 of FOCUS-PEARL was used here, which includes the simulation model PEARL 1.5.8-F2 in combination with the FOCUS shell PEARL GUI 3.0. The PEARL model, which allows the consideration of kinetic sorption, is standard software used in the European and Dutch pesticide registration process. A detailed description is given in FOCUS (2000).

II. RESULTS AND DISCUSSION

Following the proposal of the FOCUS Groundwater Scenarios Workgroup (FOCUS, 2000), the percolate concentrations at 1 m soil depth were evaluated. With regard to potential contamination of the

groundwater, this shallow evaluation depth reflects a worst case. The effective long-term groundwater concentrations will be lower, due to dilution in the upper groundwater layer. The 80th percentile of the annual average percolate concentration is taken as the PEC_{gw} value for each FOCUS scenario. The leaching simulations resulted in PEC_{gw} values below 0.1 µg/L for Spirotetramat and its main metabolites, for all relevant FOCUS scenarios.

Table IIIA1 9.6.1-5: PEC_{gw} values of Spirotetramat and its main metabolites from use in citrus in Europe calculated with FOCUS-PEARL 3.3.3

Scenario	BYI08330 (Spirotetramat) µg/L	BYI08330-enol µg/L	BYI08330-ketohydroxy µg/L	BYI08330-MA-amide µg/L
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001

Report:	**KIIIA 9.6.1/02, [redacted], B, 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Soil Metabolites in Groundwater Recharge (PEC_{gw}) Based on Calculations with FOCUS PEARL - Use in Leafy Vegetables in Europe:** BYI08330 (Spirotetramat); BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide
Report No & Document No:	**MEF-06/385 M-277164-02-1**
Guidelines:	No guideline available
GLP:	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, performed the study in August 2006. Completion date: 2006-08-30, 2nd version of report dated 2007-05-31.

Executive Summary

The predicted environmental concentrations in groundwater recharge (PEC_{gw}) of BYI08330 and its main metabolites BYI08330-enol, BYI08330-ketohydroxy and BYI08330-MA-amide were calculated for the use in leafy vegetables (i.e. lettuce, cabbage) using the simulation model FOCUS-PEARL 3.3.3. The realistic worst case leaching scenarios (weather, soil and crop data) proposed by FOCUS (2000)[1] were used for the calculation of PEC_{gw} values. The calculations were based on several worst case assumptions and substance-specific input parameters that guarantee a conservative exposure assessment. Two spray applications of Spirotetramat in leafy vegetables were simulated per season, determined by a maximum application rate of 072 g a.s. /ha each. For all relevant FOCUS scenarios the leaching simulations for Spirotetramat and its metabolites resulted in PEC_{gw} values below 0.001 µg/L. Thus it can be concluded that Spirotetramat applications in leafy vegetables in Europe are highly unlikely to cause groundwater

[1] FOCUS (2000): FOCUS groundwater scenarios in the EU plant protection product review process. Final report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202pp, Date December 2000

FOCUS (2002): Generic Guidance for FOCUS Groundwater Scenarios. Version 1.1, Date April 2002, Amending FOCUS (2000)

concentrations above the trigger value 0.1 µg/L.

I. METHODS

Predicted environmental concentrations of the active substance Spirotetramat (BYI08330) and its main metabolites in ground water recharge (PEC_{gw}) were estimated for the spray use of the insecticide. The concentrations were calculated utilizing the simulation model FOCUS-PEARL (version 3.3.3). The substance data used in the calculations are summarized in following Table IIIA1 9.6.1-6.

Table IIIA1 9.6.1-6: Summary of substance-specific parameters used

Parameter	BYI08330 (Spirotetramat)	BYI08330-enol	BYI08330-ketohydroxy	BYI08330-MA-amide
Geom. mean $DT_{50\ -\ ref}$ in soil [d]	0.13	0.03 *)	3.8	1.0
Arithmetic mean K_{oc} value [mL/g]	281	55	63.7	9.3
Arithmetic mean Freundlich exponent 1/n	0.94	1	0.92	0.95

*): As it is not possible to use DT_{50} values below 0.1 d in the PEARL 3.3.3 version, a DT_{50} value of 0.1 d was used instead of the calculated value of 0.03 d, which represents worst case for enol in this case.

A spray application of Spirotetramat in citrus was investigated. According to Good Agricultural Practice (GAP) the recommended maximum Spirotetramat application rates depend on the actual crop development stage at which the application will be performed. If the application span covers a range of growth stages, the lower interception rate (in bold, Table IIIA1 9.6.1-1) resulting in worst case actual application data was used.

Depending on the date of application and on the corresponding development stage of the plants, a certain portion of the plant protection product was assumed to be intercepted by the plant foliage, *i.e.* only the remaining amounts of Spirotetramat were assumed to reach the soil surface (Table IIIA1 9.6.1-7). The interception data were based on the FOCUS groundwater report (FOCUS, 2000) and on the current FOCUS guidance paper (FOCUS, 2002).

Table IIIA1 9.6.1-7: Relevant application details of Spirotetramat OD 150 in leafy vegetables

Crop	BBCH Code	Intended BYI08330 application rate [g a.s./ha]	Interval between applications [d]	Interception [%]	Amount of BYI08330 applied to the bare ground a) [g a.s./ha]
Leafy vegetables (lettuce, cabbage)	**42-43**	2 x 72	14	70	2 x 21.6

a) The actual amount of BYI08330 applied onto the bare ground within the model due to interception by the plant foliage.

The FOCUS Groundwater Scenarios Workgroup developed nine scenarios that cover a wide range of pedo-climatic conditions in the European Union. Soil and weather data in these scenarios were selected to address realistic worst case conditions with regard to leaching. Table IIIA1 9.6.1-3 summarizes key characteristics of these scenarios; details are documented in FOCUS (2000, 2002).

The leaching simulations were based on the standard input files of the official implementation of the FOCUS Groundwater Scenarios for the PEARL model. Default values were used for all parameters, except for the substance-specific data. All simulation runs were organized by means of the FOCUS

shell of PEARL, using the automatically generated input and output files.

The PEARL simulations were run over 26 years as proposed by FOCUS (2000, 2002) for pesticides which are applied every year. The first six years represent a so-called 'warm up' period. Only the last 20 years are taken into account for an assessment of the leaching potential.

The leaching simulations were run for lettuce according to FOCUS (2000), for the corresponding FOCUS scenarios. The application date for lettuce was set as relative application to 30 days after emergence for the first application following one more application after 14 days. As lettuce is not defined in the FOCUS groundwater scenarios, cabbage was used as surrogate.

The version 3.3.3 of FOCUS-PEARL was used here, which includes the simulation model PEARL 1.5.8-F2 in combination with the FOCUS shell PEARL GUI 3.0. The PEARL model, which allows the consideration of kinetic sorption, is standard software used in the European and Dutch pesticide registration process. A detailed description is given in FOCUS (2000).

II. RESULTS AND DISCUSSION

Following the proposal of the FOCUS Groundwater Scenarios Workgroup (FOCUS, 2000), the percolate concentrations at 1 m soil depth were evaluated. With regard to potential contamination of the groundwater, this shallow evaluation depth reflects a worst case. The effective long-term groundwater concentrations will be lower, due to dilution in the upper groundwater layer. The 80th percentile of the annual average percolate concentration is taken as the PEC_{gw} value for each FOCUS scenario. For all relevant FOCUS scenarios the leaching simulations in leafy vegetables resulted in PEC_{gw} values of Spirotetramat and its main metabolites below 0.1 µg/L.

Table IIIA1 9.6.1-8: PEC_{gw} values of Spirotetramat and its main metabolites from use in leafy vegetables (i.e. lettuce, cabbage) in Europe calculated with FOCUS-PEARL 3.3.3

Scenario	BYI08330 (Spirotetramat)	BYI08330-enol	BYI08330-ketohydroxy	BYI08330-MA-amide
	µg/L	µg/L	µg/L	µg/L
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001

IIIA 9.6.2 Relevant metabolites, degradation and reaction products PEC_{GW} values

The potential for translocation into groundwater of Spirotetramat and its main soil metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide has been assessed in one section in order to give a comprehensive picture on the mobility behavior of residues in soil resulting from the use of Spirotetramat OD 150 (refer to point 9.6.1 before).

Report:	**KIIIA 9.6.2/01, [redacted], B. 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Soil Metabolites in Groundwater Recharge (PEC_{gw}) Based on Calculations with FOCUS PEARL - Use in Citrus in Europe.** BYI08330 (Spirotetramat); BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide
Report No & Document No:	**MEF-06/280** **M-277121-02-1**
Guidelines:	No guideline available
GLP:	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2nd version of report dated 2007-05-31.

Report:	**KIIIA 9.6.2/02, [redacted], B. 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Soil Metabolites in Groundwater Recharge (PEC_{gw}) Based on Calculations with FOCUS PEARL - Use in Leafy Vegetables in Europe:** BYI08330 (Spirotetramat); BYI08330-enol, BYI08330-ketohydroxy, BYI08330-MA-amide
Report No & Document No:	**MEF-06/385** **M-277164-02-1**
Guidelines:	No guideline available
GLP:	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER. Completion date: 2nd version of report dated 2007-05-31.

During the dossier evaluation the RMS concluded that specimen environmental concentrations in groundwater of a photometabolite of Spirotetramat, i.e. of 4-methoxy cyclohexanone, should be given, also.

Report:	**KIIA1. 9.6.2/03, [redacted], B. 2007**
Title:	**Predicted Environmental Concentrations of 4-methoxy cyclohexanone in Groundwater Recharge (PEC_{gw}) Based on Calculations with FOCUS PEARL. Use in Citrus, Pome and Stone Fruit, Leafy-, Fruiting Vegetables, Grapes and Hops in Europe**
Report No & Document No	**MEF-07/477** **M-294996-01-1**
Guidelines:	No guideline available
GLP	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2007-11-15

Executive Summary

The predicted environmental concentrations in groundwater recharge (PEC_{gw}) of the Spirotetramat metabolite 4-methoxy cyclohexanone were calculated for the use in citrus, pome and stone fruit, leafy and fruiting vegetables, grapes and hops using the simulation model FOCUS-PEARL 3.3.3. The initial spirotetramat (BYI08330)-parent application rates were mol-mass corrected. A maximum occurrence of

10% of 4-methoxy cyclohexanone in soil was assumed.

The leaching simulations resulted in PEC_{gw} values below 0.001 µg/L for 4-methoxy cyclohexanone in all crops and all relevant FOCUS scenarios.

I. METHODS

As described in the reports KIIIA1. 9.6.2/01 and /02 before. Predicted environmental concentrations in soil (PEC_{soil}) of a photometabolite of Spirotetramat, i.e. of 4-methoxy cyclohexanone were calculated for the use by spray application in various crops. For the calculation of PEC_{gw} of 4-methoxy cyclohexanone the initial application rate of the parent was mol-mass corrected. A DT 50 of 0.6 days and a formation fraction of max. 10% was taken for the calculations.

II. RESULTS AND DISCUSSION

Following the proposal of the FOCUS Groundwater Scenarios Workgroup (FOCUS, 2000), the percolate concentrations at 1 m soil depth were evaluated. With regard to potential contamination of the groundwater, this shallow evaluation depth reflects a worst case. The effective long-term groundwater concentrations will be lower, due to dilution in the upper groundwater layer. The 80th percentile of the annual average percolate concentration is taken as the PEC_{gw} value for each FOCUS scenario (for the the uses in Italy see Table 7 - Table 11 of the report).

The leaching simulations resulted in PEC_{gw} values below 0.001 µg/L for 4-methoxy cyclohexanone in all crops and all relevant FOCUS scenarios.

IIIA 9.6.3 Additional field testing

Based on the presented results of PEC_{GW} calculations it can be concluded that the use of the preparation according to the intended use pattern is highly unlikely to trigger concerns regarding the risk for a potential groundwater contamination. Therefore, additional field testing with the preparation is not considered necessary.

IIIA 9.6.4 Information on impact on water treatment procedure

Residues of the active substance of this preparation and/or their metabolites are not expected to reach water treatment plants in amounts which could have impact on the water treatment procedure. In addition, oxygen consumption tests presented in Annex IIA, Section 6, Point 8.7 showed that the active substance was non-toxic to aerobic waste water bacteria from activated sewage sludge. Therefore, no impact on water treatment procedures is anticipated.

IIIA 9.7 Predicted environmental concentrations in surface water (PEC_{SW})

Summary on the fate and behavior of Spirotetramat in water

The fate and behavior of Spirotetramat in aquatic systems was investigated under standardized laboratory conditions, using radiolabeled as well as unlabeled test substance. Under dark conditions Spirotetramat was found to be degradable by abiotic degradation processes. Hydrolysis is regarded as relevant for the degradation of BYI08330 in the environment, especially under neutral and alkaline conditions. The hydrolytic half-life at pH 7 and 25°C (20°C) is expected to be in the range of 8.6 days (13 days). In the total pH range tested (pH 4 to 9) the formation of BYI08330-enol as the only common hydrolysis product was observed. From a separate study investigating the hydrolysis of the major degradate it was concluded that hydrolysis is not relevant for the degradation of BYI08330-enol in the environment, since the hydrolytic half-life at pH 4, 7 and 9 at 25°C is expected to be > 1 year.

Based on the experimental DT50 of 2.7 days for BYI08330 in sterile pure buffered water and related predicted environmental DT50 (e.g. of 12.9 solar summer days at Phoenix, AZ, USA or 19.9 summer days at [redacted], Greece) it was concluded that photo-transformation of BYI08330 in aqueous systems is a significant route for the elimination of this compound. However, that basic tests are to be performed under sterile conditions in highly purified buffer of pH 5, in order to help distinguish between hydrolytic or/and biotic and direct photolytic reactions. Thus, it was expected that the behavior will be different in natural aqueous systems, since in the case of BYI08330 biodegradation will happen quickly, hydrolysis will be faster with increasing pH, as well as indirect reactions might compete with the re-arrangement reactions observed in the prevailing study. This expectations were confirmed by an investigation of the phototransformation of [^{14}C]BYI08330 (labels #1 and #2) in sterile natural water by a supportive study. Based on the experimental DT50 of 0.2 days for BYI08330 and related predicted environmental DT50 (e.g. of 0.6 solar summer days at Phoenix, AZ, USA or 1.0 summer days at [redacted], Greece) it is concluded that photo-transformation of BYI08330 in aqueous systems is a significant route for the elimination of this compound in natural water. This test clearly showed that competition of hydrolysis and indirect photo-reactions does not allow the light-induced re-arrangement reactions of parent compound observed in highly purified buffer of pH 5. Together with the well-known fast biodegradation this was the justification to consider the products formed in the natural water study as relevant for the overall pathway of Spirotetramat degradation in water (see Figure IIIA 9.7-1), but not the re-arrangement photoproducts found in the highly artificial laboratory study performed in sterile pure buffer.

From a laboratory study investigating the route and rate of degradation in two natural water/sediment systems under aerobic laboratory conditions in the dark at 20 °C it is concluded that BYI08330 once entering aqueous systems will be degraded rapidly and thoroughly, mainly via the metabolites BYI08330-enol and BYI08330-ketohydroxy. DT50 values of 1.00 and 1.02 days were calculated for BYI08330 in the water phase, and 1.06 and 1.05 days in case of the entire systems, respectively. For use as persistence endpoints conservative one compartment (Level I) SFO dissipation half-lives of BYI08330, BYI08330-enol and BYI08330-ketohydroxy were derived for the water and the sediment compartment in a special modeling study. The biphasic model FOMC model was tested, though did not improve the outcome for any of the compounds. SFO total system degradation half-lives were derived to be used as modeling endpoints for both compartments at FOCUS surface water STEP 2 level and STEP 3 level.

The results of a laboratory study investigating the route and rate of degradation in a completely anaerobic water/sediment system in the dark at 20 °C showed that BYI08330 once entering an anaerobic natural aqueous environment will also be degraded rapidly, mainly to the metabolite BYI08330-enol well

known from the studies in aerobic soil and water/sediment systems, already. The first-order degradation rate calculated for BYI08330 in anaerobic water, sediment, and in the entire system resulted in half-lives of 2.8, 3.1, and 2.8 days, respectively.

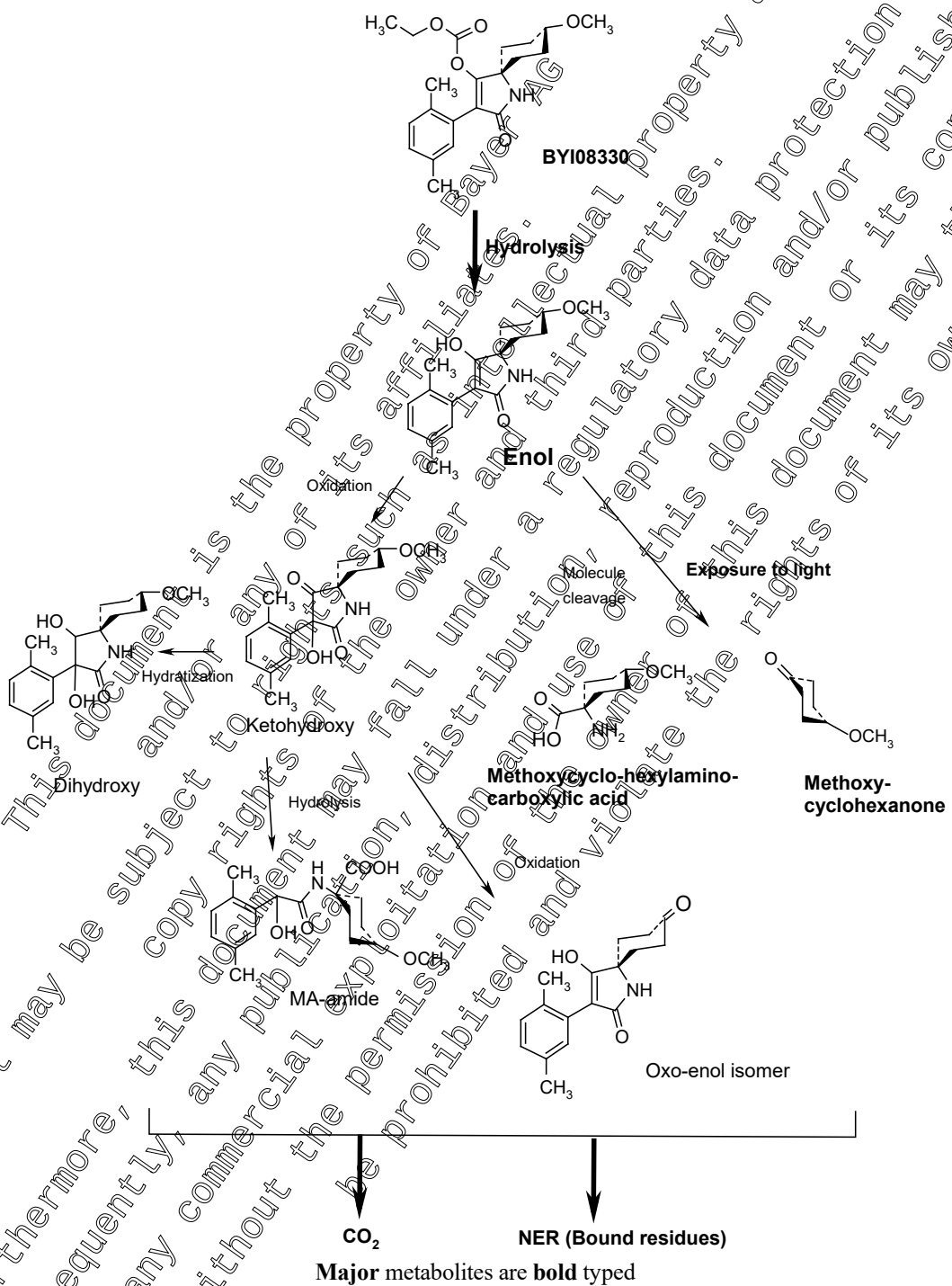


Figure IIIA 9.7-1: Proposed overall pathway of Spirotetramat in aquatic systems

IIIA 9.7.1 Initial PEC_{SW} value for static water bodies

Report:	**KIIIA 9.7.1/01, [redacted], B. 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Metabolites in Surface Water and Sediment ($PEC_{sw/sed}$) - Use in Citrus in Europe** BYI08330 (Spirotetramat), BYI08330-enol, BYI08330-ketohydroxy, BYI08330-methoxy cyclohexanone, BYI08330-methoxy cyclohexylamino carboxylic acid
Report No & Document No	**MEF-06/281 M-277190-01-1**
Guidelines:	No guideline available
GLP	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2006-08-30

Executive Summary

Predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{Sed}) of Spirotetramat and its main soil metabolites, BYI08330-enol and BYI08330-ketohydroxy, as well as the photolytic metabolites BYI08330-methoxy cyclohexanone and BYI08330-methoxy cyclohexylamino carboxylic acid were calculated for the use by spray application in citrus. FOCUS STEP 2 calculations were conducted for all compounds. FOCUS STEP 3 and 4 calculations were conducted for Spirotetramat only. The calculated maximum PEC_{SW} and PEC_{Sed} values for Spirotetramat according to FOCUS STEP 2 were 11.6 µg/L and 6.5µg/kg, respectively. The calculated maximum PEC_{SW} and PEC_{Sed} values for Spirotetramat according to FOCUS STEP 3 and 4 are summarized in Table **9.7.1-5** and Table 9.7.1-6.

I. METHODS

In the present study the calculation of PEC_{SW} and PEC_{Sed} of Spirotetramat (BYI08330) and its main soil metabolites, BYI08330-enol and BYI08330-ketohydroxy as well as the photolytic metabolites BYI08330-methoxy cyclohexanone and BYI08330-methoxy cyclohexylamino carboxylic acid in surface water (PEC_{SW}) and sediment (PEC_{Sed}), for the use in citrus.

In section 3 of report MEF-06/281 all the specific input parameters for the before-mentioned substances were described. A summary is given by the following Table 9.7.1-1.

Table 9.7.1-1: Summary of major substance parameters used for modeling of PEC_{SW} and PEC_{Sed} values

BYI08330	
Geometric mean DT50 in soil:	0.13 days (1st order)
Arithmetic mean K_{OC}:	281 mL/g (1/n of 0.941)
DT50 in aquatic systems:	0.78 days (1st order) for dissipation from water, sediment and total system (in case of FOCUS Step 1 & 2) For FOCUS SWASH calculations, $DT50_{water}$ = 0.78 d for the water phase; a worst case default value of $DT50_{sed}$ = 1000 d for the sediment phase, as no reliable separate (water/sediment) half-lives could be derived
BYI08330-enol, main metabolite in soil and aquatic systems	
Maximum amount in soil:	100% (worst case default)
Maximum amount in water/sediment:	97.5%
Molar mass correction factor:	0.81
Geometric mean DT_{50-ref} in soil:	1.16 days (SFO DT50 re-calculated from FOMC DT90)
K_{OC} (worst case):	75 mL/g (1/n was set to 1 since no value could be determined in the batch equilibrium study)
DT50 in aquatic systems:	47.3 days for dissipation from water, sediment and total system (in case of FOCUS Step 1 & 2)
BYI08330-ketohydroxy, metabolite in soil and aquatic systems	
Maximum amount in soil:	24%
Maximum amount in water/sediment:	40.5%
Molar mass correction factor:	0.85
Geometric mean DT_{50-ref} in soil:	38 days
Arithmetic mean K_{OC}:	63.7 mL/g (1/n of 0.92)
DT50 in aquatic systems:	The worst case default DT_{50} of 1000 d was used for the water-, sediment- and total system in the FOCUS STEP 1 and 2 calculations
BYI08330-methoxy cyclohexanone, metabolite in irradiated aquatic systems	
Maximum amount in soil:	Max occurrence rate in soil was set to 0%, since it was not found as metabolite in soil
Maximum amount in water/sediment:	17.5% (phototransformation in natural water study)
Molar mass correction factor:	0.34
K_{OC}:	2.6 mL/g (estimated with EPI-WIN (U.S EPA, 2000)
DT50 in aquatic systems:	The worst case default DT_{50} of 1000 d was used for the water-, sediment- and total system in the FOCUS STEP 1 and 2 calculations
BYI08330-methoxy cyclohexylammo carboxylic acid, metabolite in irradiated aquatic systems	
Maximum amount in soil:	Max occurrence rate in soil was set to 0%, since it was not found as metabolite in soil
Maximum amount in water/sediment:	11.3% (phototransformation in natural water study)
Molar mass correction factor:	0.46
K_{OC}:	10 mL/g (estimated with EPI-WIN (U.S EPA, 2000)
DT50 in aquatic systems:	The worst case default DT_{50} of 1000 d was used for the water-, sediment- and total system in the FOCUS STEP 1 and 2 calculations

The spray application of Spirotetramat in citrus was investigated. According to Good Agricultural Practice (GAP) the recommended maximum Spirotetramat application rates depend on the actual crop development stage at which the application will be performed. For the PEC calculations the application dates given as crop stage had to be converted to seasons and calendar dates for STEPS 1 & 2 (in FOCUS 1.1) and STEP 3 (FOCUS SWASH 2.1), respectively. Details about the application data are given in Table 9.7.1-1.

Table 9.7.1-1: Application data for Spirotetramat OD 150 in citrus in Europe

Crop	BBCH Code	Intended BYI08330 application rate [g a.s./ha]	Interval between applications [d]	Interception [%]	Amount of BYI08330 applied to bare ground [a] [g a.s./ha]	Region and season of application (Step1-2)
Citrus	**71** - 78	2 x 96/mCH [b] max 2 x 288	21	70	2 x 86.4	Southern Europe (Oct – Feb)

a) The actual amount of BYI08330 applied onto bare ground within the model due to interception by the plant foliage.
b) mCH = per meter of tree height (max 3 m)

For STEP 1 & 2, following the recommendations of FOCUS (2001) for compounds applied at growth stages of BBCH 40 or later, the crop interception was set to “full canopy” (i.e., 70% crop interception for citrus).
For STEP 3 actual application dates are calculated by the so-called PAT (pesticide application timer), which is build in the SWASH program components PRZM and MACRO. Thereby the application date given by the user, defines the beginning of the period of potential application. With the maximum length of this period given (normally 30 days after the last application) the PAT ensures that there is at least 10 mm of rainfall in the 10 days following application and that at the same time there are less than 2 mm of rain each day in a five day period, centered on the day of application. If no date is found within the application period by this method, the above conditions are relaxed.
The calendar dates chosen for STEP 3 calculations for the beginning of the application period as given by FOCUS 2001 are summarized together with the actual dates calculated by the PAT in Table 25 of report MEF-06/281. Interception is calculated within the SWASH program for STEP 3 calculations. Thus the nominal application rates are used as input for the FOCUS surface water tools.

The estimation of predicted environmental concentrations in surface water has been defined by the FOCUS surface water group as a tiered approach with 3 steps FOCUS (2001). Thus the lowest tier, STEP 1, is the most conservative approach. Spray drift, run-off and drainage are considered as entry routes of a substance into surface water. At STEP 1, inputs of spray drift, run-off, erosion and drainage are evaluated as a single loading to the water body, and worst-case water and sediment concentrations are calculated. At STEP 2, loadings are refined as a series of individual applications, resulting in drift to the water body, followed by a run-off, erosion or drainage event occurring four days after the last application. The amount lost via run-off is determined by the crop interception, the region of use (North or South Europe) and season of application. At STEP 3 an exposure assessment using realistic worst-case scenarios is performed. These scenarios consider specific combinations of weather, soil, crops and water body and require the use of the deterministic models PRZM, MACRO and TOXSWA.

For all steps PEC values for water and sediment are provided. Thereby the loading of the sediment is described as a function of its sorption properties and time (STEP 2 and higher). Unlike degradation the dissipation of a compound from the water layer may happen due to transport to the sediment. Because these transport processes are explicitly considered in the FOCUS surface water tools, degradation rather than dissipation parameters have to be used.

For STEP 1 and 2 a standard ditch is defined as shown in Table 9.7.1-2.

Table 9.7.1-2: Standard ditch in STEP 1 and 2

Depth of water layer	30 cm
Thickness of sediment layer	5 cm
Content of organic carbon in the sediment	5 g (100 g dry sediment)$^{-1}$
Dry bulk density of the sediment	0.8 g cm^{-3}
Ratio of surface area field : water body	10

The distance between crop and water is set to 1 m with the exception of orchards, hops, vine where it is set to 3 m. Drift loadings are calculated as the 90th percentile values based on the drift values published by BBA (2000).

For STEP 1 the input of pesticides into surface water by spray drift, run-off, erosion and drainage is evaluated as a single entry event. Correspondingly, multiple applications are treated as single entry event carrying the total amount applied. After entry into surface water, drift loadings are distributed between water and sediment within one day according to the K_{OC} of the compound considered. The input by the run-off, erosion and drainage entry event is set to 10% of the amount applied. It is distributed instantaneously between water and sediment phase. The degradation in the water and in the sediment phase is assumed to follow single first order kinetics. Soil metabolites are treated like actives for run-off, erosion and drainage entry where the application rate is defined by the maximum occurrence of the metabolite in soil. Aquatic metabolites are treated accordingly using the maximum total occurrence in the water-sediment system.

For STEP 2 the pesticide input by spray drift is evaluated by a series of individual loadings, according to the number of applications. Drift inputs are distributed between water and sediment assuming simplified sorption kinetics. The substance input by run-off, erosion and drainage is evaluated as a single entry event which follows four days after the last application. The input by this entry event is set to 2 to 5% of the soil residue depending on region and season of application. It is distributed instantaneously between water and sediment phase. The degradation in the water and in the sediment phase is assumed to follow single first order kinetics.

For STEP 3 of the European surface water assessment, the FOCUS working group defined 10 realistic worst-case scenarios, which collectively represent agronomic (soil, slope, crop) and climatic conditions in the EU. These scenarios cover about 33% of the agricultural land (FOCUS, 2001). They were divided into six drainage scenarios and four run-off scenarios according to the relevant entry route. All scenarios consider entry by spray drift. Three typical water bodies with specific residence time and catchment area attached – pond, ditch, and stream – were defined and associated with the scenarios. All water bodies are characterized by a specific base flow which is related to their catchment area. Only for the stream scenario pesticide is applied simultaneously in a certain part of the catchment (see table 15 of report MEF-06/281). Overall, the highest PEC_{SW} estimates from the ten scenarios are likely to represent at least a 90th percentile worst-case for surface water exposure in the EU. Table 14 of report MEF-06/281 gives a summary of agro-climatic characteristics of the STEP 3 scenarios, table 15 and 16 of report MEF-06/281 show the properties of the surface water bodies used including the characterization of the sediment.

FOCUS SWASH holds substance, application and scenario data, and starts the deterministic process models MACRO, PRZM and TOXSWA. The one-dimensional leaching models MACRO and PRZM are used to calculate drainage, and run-off and erosion fluxes to the surface water body, respectively. Pesticide interception is calculated dynamically based on maximum interception capacity and actual leaf

area index. Intercepted substance may degrade on the canopy and enter the soil surface by wash-off. The drainage entry is calculated by MACRO assuming a tile drain system. The flow to the drains is implemented as sink term into the vertical flow equation using seepage potential theory. Because the MACRO model also considers macropore flow the drain flow may originate from matrix and macropore flow. MACRO considers a 6-year warm-up period with annual applications and a subsequent 16-month assessment period.

Runoff and erosion loadings into surface water are calculated by the PRZM model based on the USDA Soil Conservation Service curve number methodology and a watershed-scale variation of the Universal Soil Loss Equation. PRZM runs a 20-year simulation with annual applications. A representative 12-month period out of these 20 years for different use patterns is selected and the results imported into TOXSWA. Both leaching models account for uptake by plant roots and can optionally adapt substance degradation rates for the effects of soil temperature and moisture using an Arrhenius-type equation and the [redacted] equation ([redacted], 1974), respectively.

The behavior of pesticides in a water body is simulated using the TOXSWA model. TOXSWA considers water and sediment layer, both implemented as one-dimensional domains connected by an interface. Thereby the water layer has a horizontal extension and the sediment a vertical one. TOXSWA handles transient hydrology and pesticide fluxes resulting from runoff, erosion and drainage calculated by the models described above. Entry via spray drift is added within TOXSWA directly.

For a number of parameters the SWASH tool provides default values which were used in the calculations presented here if not stated otherwise. Selected default parameter values used by FOCUS SWASH were:

- Half life on crop canopy: 10 days
- Wash-off factor from crop: 0.05 mm^{-1}
- Uptake factor: 0.5

The spray drift exposure can be significantly reduced by vegetated buffer zones as it is assessed by STEP 4. Drift rates for different width of vegetated buffer strips are given in the report of the FOCUS Working Group on Surface Water Scenarios (FOCUS, 2001) and are also implemented in the TOXSWA shell (Focus drift calculator). These rates are essentially identical to values in the German Drift Tables (Rautmann, 2001), which quantify deposition from spray drift for different distances between treated field and water body with different quantities for single and multiple applications. The drift rates used in this report were calculated for the specific applications using the FOCUS Drift Calculator implemented in the TOXSWA shell.

For the stream scenarios (without mitigation), the drift rates and mean deposition by air used by TOXSWA are higher than the values generated by the FOCUS Drift Calculator. The reason for this is, that the drift values implemented in TOXSWA are the sum of the direct drift input from the adjacent field and the indirect drift input from the upstream water catchment, which is assumed to be treated at the same time and which is 20% of the direct input. Drift rates, given by the FOCUS Drift Calculator for stream scenarios, were therefore corrected for the additional 20% of the direct input and manually edited in the TOXSWA shell (drift deposition in the water body per drift event). The values for each individual scenario in citrus and for a ditch are as follows:

- No buffer 11.134%
- 5 m 7.514%
- 10 m 3.357%

For comparison of exposure and ecotoxicological data, time weighted average concentrations of PEC_{SW}, PEC_{Sed}, TWA_{SW} and TWA_{Sed}, respectively, were calculated for time periods of 1, 2, 4, 7, 14, 21, 28, 42, 50 and 100 days by FOCUS STEP 1 & 2 and TOXSWA (STEP 3).

For the FOCUS surface water calculations the tools STEPS 1 & 2 in FOCUS 1.1 and FOCUS SWASH 2.1 were used. The FOCUS SWASH 2.1 tool included the models MACRO 4.3 b, PRZM 3.2.1.b and TOXSWA 2.1.1.F1. All calculations were performed on a DELL P IV running Microsoft® Windows XP, Service Pack 1.

II. RESULTS AND DISCUSSION

Due to the quantity of output only maximum PEC_{SW} and PEC_{Sed} values for the metabolites BYI08330-enol, BYI08330-ketohydroxy are shown here. STEP 2 calculations were made for all compounds considered. STEP 3 calculations were conducted for the parent only. Detailed input and output for all calculations including TWA values are listed in the Appendix of report MEF-06/281.

The results of the STEP 1 and 2 calculations for Spirotetramat for the applications to citrus are shown in Table 9.7.1-3, the results of respective STEP 3 and 4 in Table 9.7.1-4 and Table 9.7.1-5.

Table 9.7.1-3: Maximum PEC_{SW} and PEC_{Sed} values of Spirotetramat according to FOCUS STEP 1 and 2 for applications to citrus

Time after max. peak D	PEC_{SW} µg/L	TWA_{SW} µg/L	PEC_{Sed} µg/kg	TWA_{Sed} µg/kg
$PEC_{max, step 1}$	84.9311		196.2367	
0	11.6438	---	6.5250	---
1	3.9181	7.7810	2.9269	4.7259
2	1.5787	5.2647	1.2127	3.3979
4	0.2664	3.0249	0.2799	2.0102
7	0.0168	1.7688	0.0195	1.1933
14	< 0.0001	0.8859	< 0.0001	0.5983
21	< 0.0001	0.5906	< 0.0001	0.3989
28	< 0.0001	0.4429	< 0.0001	0.2992
42	< 0.0001	0.2953	< 0.0001	0.1994
50	< 0.0001	0.2480	< 0.0001	0.1675
100	< 0.0001	0.1240	< 0.0001	0.0838

Table 9.7.1-4: Maximum PEC_{SW} values of Spirotetramat according to FOCUS STEP 3 and 4 for applications to citrus

Scenario	$PEC_{SW\ MAX}$ (µg/L)	$PEC_{SW\ MAX}$ (µg/L)	$PEC_{SW\ MAX}$ (µg/L)	$PEC_{SW\ MAX}$ (µg/L)
Application rate	2 x 96 g/ha	2 x 192 g/ha	2 x 288 g/ha	2 x 288 g/ha
Tree height	1 m	2 m	3 m	3 m
Buffer	0	0	0	5 m
D6 ([redacted]) ditch	2.810	5.621	8.430	5.864
R4 [redacted] ditch	4.338	4.338	6.507	-

Table 9.7.1-5: Maximum PEC_{Sed} values of Spirotetramat according to FOCUS STEP 3 and 4 for applications to citrus

Scenario	$PEC_{Sed\ MAX}$ (µg/kg)	$PEC_{Sed\ MAX}$ (µg/kg)	$PEC_{Sed\ MAX}$ (µg/kg)	$PEC_{Sed\ MAX}$ (µg/kg)
Application rate	2 x 96 g/ha	2 x 192 g/ha	2 x 288 g/ha	2 x 288 g/ha
Tree height	1 m	2 m	3 m	3 m
Buffer	0	0	0	5 m
D6 ([redacted]) ditch	1.429	2.804	4.157	2.921
R4 [redacted] ditch	0.504	0.504	0.753	-

Table 9.7.1-6 gives the short- and long-term PEC_{sw} and time-weighted average TWA_{sw} values of Spirotetramat based on the degradation properties of Spirotetramat in aquatic systems. These percentage values can be combined with initial concentrations from any entry route to calculate the respective short-term and long-term exposure. Time periods for the TWA_{sw} were determined according the EU Directive 95/36/EC.

Table 9.7.1-6: Short- and long-term PEC_{sw} and TWA_{sw} of Spirotetramat in aquatic systems over time as % of the initial maximum for applications to citrus

Days post entry into surface water body	PEC_{sw} (%)	TWA_{sw} (%)
0	100.00	-
1	41.12	66.26
2	16.91	46.75
4	2.86	27.33
7	0.20	16.04
14	< 0.01	8.04
21	< 0.01	5.36
28	< 0.01	4.02
42	< 0.01	2.68

Report: **KIIIA 9.7.1/02, [redacted]; B, 2006**

Title: **Predicted Environmental Concentrations of Spirotetramat and its Main Metabolites in Surface Water and Sediment ($PEC_{SW/Sed}$) - Use in Leafy Vegetables in Europe**
BYI08330 (Spirotetramat), BYI08330-enol, BYI08330-ketohydroxy, BYI08330-methoxy cyclohexanone, BYI08330-methoxy cyclohexylamino carboxylic acid

Report No & Document No: **MEF-06/386**
M-277176-01-1

Guidelines: No guideline available

GLP: No (calculation)

Testing laboratory and dates: Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2006-08-30

Executive Summary

Predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{Sed}) of Spirotetramat and its main soil metabolites, BYI08330-enol and BYI08330-ketohydroxy as well as the photolytic metabolites BYI08330-methoxy cyclohexanone and BYI08330-methoxy cyclohexylamino carboxylic acid were calculated for the use by spray application in leafy vegetables (e.g. lettuce). FOCUS STEP 2 calculations were conducted for all compounds. FOCUS STEP 3 calculations were conducted for Spirotetramat only.

The calculated maximum PEC_{SW} and PEC_{Sed} values for Spirotetramat according to FOCUS STEP 2 were 0.59 µg/L and 0.33µg/kg, respectively. The calculated maximum PEC_{SW} and PEC_{Sed} values for Spirotetramat according to FOCUS STEP 3 are summarized in Table 9.7.1-9.

I. METHODS

In the present study the calculation of PEC_{SW} and PEC_{Sed} of Spirotetramat (BYI08330) and its main soil metabolites, BYI08330-enol and BYI08330-ketohydroxy as well as the photolytic metabolites BYI08330-methoxy cyclohexanone and BYI08330-methoxy cyclohexylamino carboxylic acid in surface water (PEC_{SW}) and sediment (PEC_{Sed}), for the use in leafy vegetables (e.g. lettuce).

In section 3 of report MEF-06/386 all the specific input parameters for the before-mentioned substances were described. A summary was given by Table 9.7.1-1 already.

The spray application of Spirotetramat in the above-mentioned crops was investigated. According to Good Agricultural Practice (GAP) the recommended maximum Spirotetramat application rates depend on the actual crop development stage at which the application will be performed. For the PEC calculations the application dates given as crop stage had to be converted to seasons and calendar dates for STEPS 1 & 2 (in FOCUS 1.1) and STEP 3 (FOCUS SWASH 2.1), respectively. Details about the application data are given in Table 9.7.1-7.

Table 9.7.1-7: Application data for Spirotetramat OD 150 in leafy vegetables in Europe

Crop	BBCH Code	Intended BYI08330 application rate [g a.s./ha]	Interval between applications [d]	Interception [%]	Amount of BYI08330 applied to bare ground [a)] [g a.s./ha]	Region and season of application (Step1-2)
Leafy vegetables (e.g. lettuce)	**42** - 43	2x 72	14	70	2 x 21.6	Southern Europe (Mar - May)

a) The actual amount of BYI08330 applied onto bare ground within the model due to interception by the plant foliage

For STEP 1 & 2, following the recommendations of FOCUS (2001) for compounds applied at growth stages of BBCH 40 or later, the crop interception was set to “full canopy” (i.e., 70% crop interception for leafy vegetables).

For STEP 3 actual application dates are calculated by the so-called PAT (pesticide application timer), which is build in the SWASH program components PRZM and MACRO. Thereby the application date given by the user, defines the beginning of the period of potential application. With the maximum length of this period given (normally 30 days after the last application) the PAT ensures that there is at least 10 mm of rainfall in the 10 days following application and that at the same time there are less than 2 mm of rain each day in a five day period, centered on the day of application. If no date is found within

the application period by this method, the above conditions are relaxed.

The calendar dates chosen for STEP 3 calculations for the beginning of the application period as given by FOCUS 2001 are summarized together with the actual dates calculated by the PAT in Table 25 of report MEF-06/386.

More details on the calculations related to STEPS 1 to 3 were given earlier in this section already. The distance between crop and water is set to 1 m. Drift loadings are calculated as the 90th-percentile values based on the drift values published by BBA (2000).

For comparison of exposure and ecotoxicological data, time weighted average concentrations of PEC_{SW}, PEC_{Sed}, TWA_{SW} and TWA_{Sed}, respectively, were calculated for time periods of 1, 2, 4, 7, 14, 21, 28, 42, 50 and 100 days by FOCUS STEP 1 & 2 and TOXSWA (STEP 3).

For the FOCUS surface water calculations the tools STEPS 1 & 2 in FOCUS 1.1 and FOCUS SWASH 2.1 were used. The FOCUS SWASH 2.1 tool included the models MACRO 4.3 b, PRZM 3.21.b and TOXSWA 2.1.1.F1. All calculations were performed on a DELL PTV running Microsoft® Windows XP, Service Pack 1.

II. RESULTS AND DISCUSSION

Due to the quantity of output only maximum PEC_{SW} and PEC_{Sed} values for the metabolites BYI08330-enol, BYI08330-ketohydroxy are shown here. STEP 2 calculations were made for all compounds considered. STEP 3 calculations were conducted for the parent only. Detailed input and output for all calculations including TWA values are listed in the Appendix of report MEF-06/386.

The results of the STEP 1 and 2 calculations for Spirotetramat for the applications to citrus are shown in Table 9.7.1-8, the results of respective STEP 3 in Table 9.7.1-9.

Table 9.7.1-8: Maximum PEC_{SW} and PEC_{Sed} values of Spirotetramat according to FOCUS STEP 1 and 2 for applications to leafy vegetables

Time after max. peak	PEC_{SW}	TWA_{SW}	PEC_{Sed}	TWA_{Sed}
d	µg/L	µg/L	µg/kg	µg/kg
$PEC_{max, step 1}$	18.1209		49.0592	
0	0.5851	---	0.3279	---
1	0.1969	0.3910	0.1471	0.2375
2	0.0793	0.2646	0.0609	0.1707
4	0.0134	0.1520	0.0141	0.1010
7	0.0008	0.0889	0.0010	0.0600
14	< 0.0001	0.0445	< 0.0001	0.0301
21	< 0.0001	0.0297	< 0.0001	0.0200
28	< 0.0001	0.0223	< 0.0001	0.0150
42	< 0.0001	0.0148	< 0.0001	0.0100
50	< 0.0001	0.0125	< 0.0001	0.0084
100	< 0.0001	0.0062	< 0.0001	0.0042

Table 9.7.1-9: Maximum PEC_{SW} and PEC_{Sed} values of Spirotetramat according to FOCUS STEP 3 for applications to leafy vegetables - early & late application

Scenario	Water body	$PEC_{SW\ MAX}$ (µg/L)	$PEC_{Sed\ MAX}$ (µg/kg)
		No buffer zone	No buffer zone
D3 [redacted]	ditch	0.399	0.119
D4 [redacted]	pond	0.0129	0.007
D4 [redacted]	stream	0.324	0.021
D6 ([redacted])	ditch	0.398	0.108
R1 [redacted]	pond	0.0129	0.006
R1 [redacted]	stream	0.261	0.033
R2 ([redacted])	stream	0.350	0.026
R3 [redacted]	stream	0.368	0.071
R4 [redacted]	stream	0.261	0.034

Table 9.7.1-10 gives the short- and long-term PEC_{SW} and time-weighted average TWA_{SW} values of Spirotetramat based on the degradation properties of Spirotetramat in aquatic systems. These percentage values can be combined with initial concentrations from any entry route to calculate the respective short-term and long-term exposure. Time periods for the TWA_{SW} were determined according the EU Directive 95/36/EC.

Table 9.7.1-10: Short- and long-term PEC_{sw} and TWA_{sw} of Spirotetramat in aquatic systems over time as % of the initial maximum for applications to leafy vegetables - early & late application

Days post entry into surface water body	PEC_{SW} (%)	TWA_{SW} (%)
0	100.00	-
1	41.12	66.26
2	16.91	46.75
4	2.86	27.33
7	0.20	16.04
14	< 0.01	8.04
21	< 0.01	5.36
28	< 0.01	4.02
42	< 0.01	2.68

IIIA 9.7.2 Initial PEC_{SW} value for slow moving water bodies

Loading of the active substances to slow moving water bodies is expected to be below or similar to those in static water bodies as a function of water body size, depth and dilution. As the worst-case assessment described under point 9.7.1 assumes only a 30 cm deep water body for lentic systems, higher values are

not expected for lotic systems. For the same reason, no short-term or long-term PEC values for slow moving water bodies were calculated separately.

IIIA 9.7.3 Short-term PEC_{SW} values for static water bodies

Short-term and long-term PEC_{SW} are reported side by side to allow a better comparison of the data. For short-term PEC_{SW} refer to point 9.7.1.

IIIA 9.7.4 Short-term PEC_{SW} values for slow moving water bodies

Regarding risk assessment PEC_{SW} values calculated for standing water bodies (refer to point 9.7.1) can be considered as worst case in comparison to slow moving water bodies, because dilution as in moving water bodies is excluded (refer also to point 9.7.2).

IIIA 9.7.5 Long-term PEC_{SW} values for static water bodies

Short-term and long-term PEC_{SW} are reported side by side to allow a better comparison of the data. For long-term PEC_{SW} refer to point 9.7.1.

IIIA 9.7.6 Long-term PEC_{SW} values for slow moving water bodies

Regarding risk assessment PEC_{SW} values calculated for standing water bodies (refer to point 9.7.1) can be considered as worst case in comparison to slow moving water bodies, because dilution as in moving water bodies is excluded.

IIIA 9.8 PEC_{SW} for relevant metabolites

In order to provide a comprehensive picture on the various PEC_{SW} values reflecting the initial, short- and long-term PEC_{SW} values of metabolites in static and slow moving water bodies, this point is covered by the reports described under Point 9.7.1. Metabolites addressed under this point are not automatically relevant with regard to their biological, eco-toxicological or toxicological properties.

Report:	**KIIIA 9.8/01, [redacted], B, 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Metabolites in Surface Water and Sediment ($PEC_{sw/sed}$) - Use in Citrus in Europe** BYI08330 (Spirotetramat), BYI08330-enol, BYI08330-ketohydroxy, BYI08330-methoxy cyclohexanone, BYI08330-methoxy cyclohexylamino carboxylic acid
Report No & Document No	**MEF-06/281** **M-277190-01-1**
Guidelines:	No guideline available
GLP	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2006-08-30

Report:	**KIIIA 9.8/02, [redacted], B. 2006**
Title:	**Predicted Environmental Concentrations of Spirotetramat and its Main Metabolites in Surface Water and Sediment ($PEC_{SW/Sed}$) - Use in Leafy Vegetables in Europe** BYI08330 (Spirotetramat), BYI08330-enol, BYI08330-ketohydroxy, BYI08330-methoxy cyclohexanone, BYI08330-methoxy cyclohexylamino carboxylic acid
Report No & Document No	**MEF-06/386** **M-277176-01-1**
Guidelines:	No guideline available
GLP	No (calculation)
Testing laboratory and dates:	Bayer CropScience AG, Metabolism and Environmental Fate, D-[redacted], GER, Completion date: 2006-08-30

In the following Table 9.8-1 the results of the STEP 2 calculations for the metabolites to citrus in Southern Europe are shown.

In Table 9.8-2 the results of the STEP 2 calculations for the metabolites to leafy vegetables in Europe are shown.

Table 9.8-1: Maximum PEC_{SW} and PEC_{Sed} values of BYI08330-enol and BYI08330-ketohydroxy according to FOCUS STEP 2 for applications to citrus

Compound	PEC_{SW} (µg/L)	PEC_{Sed} (µg/kg)
BYI08330-enol	15.5829	8.0004
BYI08330-ketohydroxy	8.5861	5.3408
BYI08330-methoxy cyclohexanone	1.3870	0.0359
BYI08330-methoxy cyclohexylamino carboxylic acid	1.2064	0.1192

Table 9.8-2: Maximum PEC_{SW} and PEC_{Sed} values of BYI08330-enol and BYI08330-ketohydroxy according to FOCUS STEP 2 for applications to leafy vegetables

Compound	PEC_{SW} (µg/L)	PEC_{Sed} (µg/kg)
BYI08330-enol	0.9495	0.5054
BYI08330-ketohydroxy	0.6623	0.4153
BYI08330-methoxy cyclohexanone	0.0699	0.0018
BYI08330-methoxy cyclohexylamino carboxylic acid	0.0608	0.0060

IIIA 9.8.1 Initial PEC_{SW} value for static water bodies

This point is covered by the tables before under Point 9.8.

IIIA 9.8.2 Initial PEC_{SW} value for slow moving water bodies

Since static water bodies represent a worst case due to missing dilution no additional PEC_{SW} calculations were conducted for slow moving water bodies.

IIIA 9.8.3 Short-term PEC_{SW} values for static water bodies

In order to provide a comprehensive picture on the various PEC_{SW} values reflecting the initial, short- and long-term PEC_{SW} values of metabolites in static and slow moving water bodies, this point is covered by the reports described under Point 9.7.1. Metabolites addressed under this point are not automatically relevant with regard to their biological, eco-toxicological or toxicological properties.

IIIA 9.8.4 Short-term PEC_{SW} values for slow moving water bodies

Since static water bodies represent a worst case due to missing dilution no additional PEC_{SW} calculations were conducted for slow moving water bodies.

IIIA 9.8.5 Long-term PEC_{SW} values for static water bodies

In order to provide a comprehensive picture on the various PEC_{SW} values reflecting the initial, short- and long-term PEC_{SW} values of metabolites in static and slow moving water bodies, this point is covered by the reports described under Point 9.7.1. Metabolites addressed under this point are not automatically relevant with regard to their biological, eco-toxicological or toxicological properties.

IIIA 9.8.6 Long-term PEC_{SW} values for slow moving water bodies

Since static water bodies represent a worst case due to missing dilution no additional PEC_{SW} calculations were conducted for slow moving water bodies.

IIIA 9.8.7 Additional field studies

No additional testing of the active substance in surface water and sediment under field conditions is deemed necessary. The fate of the compounds in aquatic systems is well understood from laboratory experiments. Results from these experiments can be used to derive exposure concentrations in worst case standard scenarios.

IIIA 9.9 Fate and behavior in air

Reactions with OH radicals and ozone contribute to the degradation of BYI08330 and BYI08330-enol in the air to a high extent. The chemical stabilities in air are not determined by an attack at one single site, but at different parts of the molecule. This should result in the formation of various primary radicals leading to secondary oxidation products, which can be eliminated from the air by wet and/or dry deposition.
On account of an estimated chemical lifetime of both compounds in the air of at the most 3 hours it is to be expected that they can not be transported in gaseous phase over large distances and can not accumulate in the air.

IIIA 9.9.1 Spray droplet size spectrum - laboratory studies

This item is no requirement according to 91/414/EEC.

IIIA 9.9.2 Drift - field evaluation

This item is no requirement according to 91/414/EEC.

IIIA 9.10 Other/special studies

The fate and behavior of Spirotetramat in the environment is well described by the studies summarized in the respective Annex II, section 5, point 7. No other special studies were conducted for Spirotetramat OD 150.

IIIA 9.10.1 Other/special studies - laboratory studies

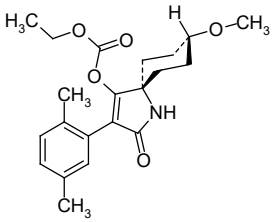
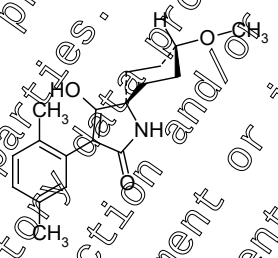
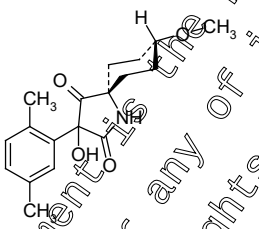
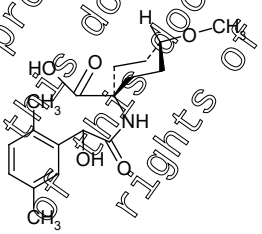
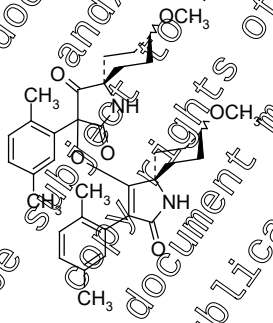
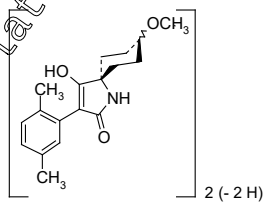
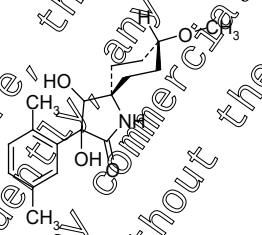
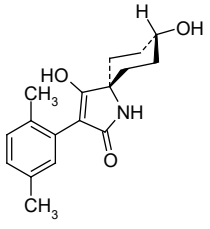
See statement before.

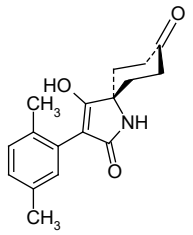
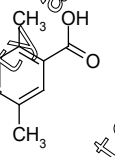
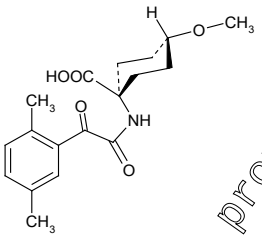
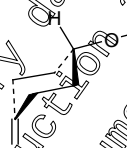
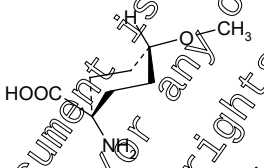
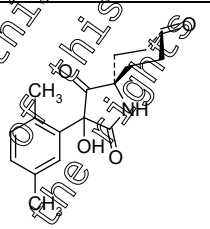
IIIA 9.10.2 Other/special studies - field studies

See statement before.

List of Active Substance Spirotetramat (BYI08330) and its Metabolites

The following tables show the structures, codes and names of the active ingredient BYI08330 and all related metabolites referred to within this document. The **bold** typed compounds are of main interest for this summary.

Structure and name used in this summary	Structure and name used in this summary
 **Spirotetramat (code: BYI08330)**	 **BYI08330-enol**
 **BYI08330-ketohydroxy**	 **BYI08330-MA-amide**
 BYI08330-enol-dimer 1	 BYI08330-enol-dimer 2
 BYI08330-dihydroxy	 BYI08330-desmethyl-enol

Structure and name used in this summary	Structure and name used in this summary
 BYI08330-oxo-enol	 BYI08330-benzoic acid
 BYI08330-glyoxylic amide	 **BYI08330-methoxy cyclohexanone**
 **BYI08330-methoxy cyclohexylamino carboxylic acid**	 BYI08330-oxo-ketohydroxy