Document Title

Tier 2 Summary

of the Fate and Behaviour in the Environment

of the Plant Protection Product Fenhexamid WG 50 (500 g/kg)

(Specification No.: 102000007271)

Substance(s)

FENHEXAMID
(Annex I renewal)

Data Requirements

Regulation EC/1141/2010

on the renewal of the inclusion of AIR2 active substances

in conjunction with

Directive 91/414/EEC and **Regulation EC/1107/2009**

According to OECD format guidance for industry data submissions

(SANCO/10387/2010 rev. 8 - on the renewal of active substances included in Annex I)

Annex III
Document M
Section 5 Point 9

Date

2012-02-10

Author(s)

[redacted] [redacted]

Bayer CropScience **Dr. Knoell Consult GmbH**

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IIIA 9 Fate and Behaviour in the Environment of the Plant Protection Product

IIIA 9.1 Rate of degradation in soil

Specific studies on the preparation have not been performed. The results of laboratory studies performed with the active substance as provided in Annex IIA in the context of Section 5, Point 7 are also applicable for the preparation. A short summary of the data is given in the subsections below.

IIIA 9.1.1 Aerobic degradation of the preparation in soil

From the studies on the route of degradation in soil it can be concluded that fenhexamid was rapidly degraded in soil to the final degradation product CO_2. In parallel to mineralisation, bound residues were formed. More than 13 degradates were found, seven of them could be identified or characterised. No metabolite accumulated in soil. None of the degradates exceeded 10% of the applied radioactivity at least 1 sampling date [redacted]ver one metabolite, the [C-C]biphenyl-KBR 2738 with BayerCropScience code BCS-CQ88719 (M24) was identified as a major compound formed in a range from 4.1-8.8% AR in maximum during 120 days of incubation. All metabolites reached their maximum concentration in soil in the first week after soil treatment and continuously declined until termination of the study.
The initial step of breakdown of the molecule involved a variety of oxidative C-C or C-O-C coupling reactions involving two or more fenhexamid moieties. As a result dimeric coupling products and trimeric coupling products of fenhexamid were found as metabolites. Based on the results from the processing of sterile soil it was concluded that these dimeric and trimeric transformation products of fenhexamid were formed in the microbial and/or enzyme-mediated but also partly in abiotic processes. Ultimately total mineralisation of the aromatic nucleus to carbon dioxide occurred via aerobic ring cleavage. The degradation pathway is given in Figure 9.1.1- 1.

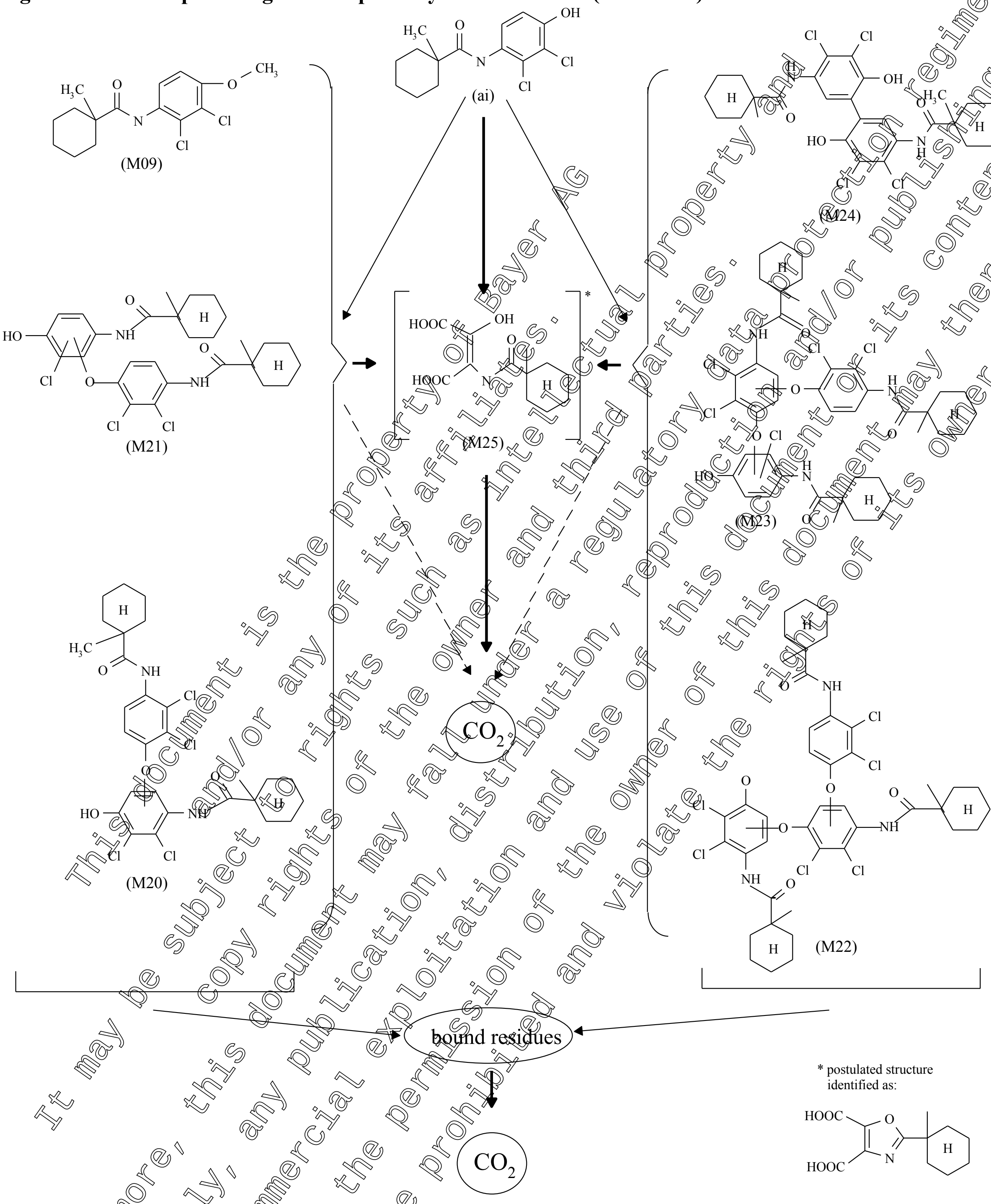
From the study on photodegradation of fenhexamid on soil surfaces it can be concluded that photodegradation will not significantly contribute to primary degradation of the parent compound. But it can contribute to the elimination of residues of fenhexamid in the environment by means of mineralisation of phenyl-ring containing metabolites in soil. No specific photolysis metabolites were formed during this study.

Based on the data presented on the route of degradation, it could be concluded that the parent compound itself represents the only relevant residue of concern in soil, since no metabolite or degradation product was found in an amount above 10% of the applied radioactivity.

The rate of degradation of fenhexamid in soil has been investigated in laboratory trials, which were run with eight soils and two radio labels one at the cyclohexane and one at the phenyl moiety under aerobic conditions at 20°C. The determined DT_{50} values were ≤ 1 day for all soils.

In order to derive reliable values for the half life of the [C-C]biphenyl-KBR 2738, BCS-CQ88719 (M24), further investigations of the degradation behaviour of the BCS-CQ88719 (M24) in four aerobic soils resulted in half-lives of 1.18 to 22.74 days (geometric mean: 5.10 days) for best fit evaluation following FOCUS kinetic guidance.

Figure 9.1.1- 1: Proposed degradation pathway for fenhexamid (KBR 2738) in aerobic soil



ai = Fenhexamid (KBR 2738)
M09 = methyl ether of KBR 2738
M20 = [C-O-C] dimer of KBR 2738
M21 = mono-deschlor [C-O-C] dimer of KBR 2738
M22 = trimer of KBR 2738
M23 = mono-deschlor trimer of KBR 2738
M24 = [C-C]biphenyl KBR 2738 (BCS-CQ88719)
M25 = BBJ 98-14 (aerobic soil metabolism study)

The data of the two aerobic soil degradation studies with the two radiolabels of fenhexamid and the aerobic soil degradation study with the major metabolite [C-C]biphenyl-KBR 2738 (M24) was recently re-evaluated according to the FOCUS kinetics guidance (Sanco/10058/2005, version 2.0, June 2006) to result in optimised degradation parameters of fenhexamid and its metabolite M24 for modelling and persistence endpoints.

Report:	**KIIIA 9.1.1 /01, [redacted].; 2012**
Title:	Kinetic Evaluation of the Aerobic Metabolism of [Cyclohexyl-1-14C]Fenhexamid (KBR 2738) in Soil for Modelling and Trigger Purposes
Document No:	**M-421881-01-1** (Report No: MEF-11/690)
Guidelines:	"Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration". Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 2006
GLP	No (calculation)

Materials and Methods: The aerobic degradation of [Cyclohexyl-1-^{14}C]fenhexamid and its metabolite BCS-CQ88719 was kinetically evaluated based on one laboratory study ([redacted], 2011) on 4 soils in total (20 °C, 55 % of maximum water holding capacity).
The kinetic evaluation of the laboratory degradation behaviour was done following a tiered approach, based on various model assumptions as given in the guidance. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, χ^2 statistic, randomness of residuals, and T-test significance.

Findings: For the parent compound fenhexamid the FOMC model was selected in all soils except [redacted] II (SFO) to estimate modelling (Table 9.1.1- 1) and persistence (Table 9.1.1- 2) endpoints. In addition formation fractions (FF) of BCS-CQ88719 (M24) were evaluated. All calculated half-lives for the parent fenhexamid were clearly below 1 day, even the DT_{90} did not exceed 3 days.

Table 9.1.1- 1: Optimised degradation parameters of fenhexamid for modelling endpoints and formation fractions (FF) of BCS-CQ88719 (M24).

Soil	**Model**	**k-rate$_{SFO}$ [1/day]**	**DT50$_{SFO}$ [days]**	**FF (M24)**
[redacted]	FOMC	1.682	0.41)[a]	0.11
[redacted]	FOMC	1.250	0.56)[a]	0.09
[redacted]	FOMC	1.931	0.36)[a]	0.06
[redacted] **II**	SFO	0.915	0.76	0.05

)[a] calculated from DT90 of bi-phasic model/3.32

Table 9.1.1-2: Optimised degradation parameters of fenhexamid for persistence endpoints.

Soil	**Model**	**DT50 [days]**	**DT90 [days]**
[redacted]	FOMC	0.16	1.37
[redacted]	FOMC	0.21	1.84
[redacted]	FOMC	0.08	1.19
[redacted] **II**	SFO	0.76	2.52

Report:	**KIIIA 9.1.1 /02, [redacted] 2011**
Title:	Kinetic Evaluation of the Aerobic Metabolism of [phenyl-UL-^{14}C]Fenhexamid (KBR 2738) in Soil for Modelling and Trigger Purposes
Document No:	**M-422395-01-1** (Report No: MEF-11/689)
Guidelines:	"Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration". Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference Sanco/10058/2005 version 2.0, 2006
GLP	No (calculation)

Materials and Methods: The aerobic degradation of [phenyl-UL-^{14}C] fenhexamid was kinetically evaluated based on one laboratory study ([redacted], 1996) on four soils (20 °C, 40 % of maximum water holding capacity, for one soil ([redacted]) 75% of 1/3 bar moisture).
The kinetic evaluation of the laboratory degradation behaviour was done following a tiered approach, based on various model assumptions as given in the guidance. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, χ^2 statistic, randomness of residuals, and T-test significance.

Findings: As kinetic function to estimate the modelling endpoint in all cases the SFO model was selected except [redacted] (FOMC), see Table 9.1.1- 3. As kinetic function to estimate the persistence endpoint in two cases the FOMC model ([redacted] and [redacted]) and in two cases the DFOP model ([redacted] and [redacted]) was selected, see Table 9.1.1- 4. Besides for soil [redacted], which has a half life of 1.06 days, all other calculated half-lives for the parent fenhexamid were clearly below 1 day, even the DT$_{90}$ did not exceed 10 days.

Table 9.1.1- 3: Optimised degradation parameters of fenhexamid for modelling endpoints.

Soil	Model	k-rate$_{SFO}$ [1/days]	DT50$_{SFO}$ [days]
[redacted]	SFO	2.023	0.34
[redacted]	SFO	2.362	0.29
[redacted]	FOMC	0.232	2.99)[a]
[redacted]	SFO	1.555	0.45

)[a] calculated from DT90 of FOMC model/3.32

Table 9.1.1- 4: Optimised degradation parameters of fenhexamid for persistence endpoints.

Soil	Model	DT50 [days]	DT90 [days]
[redacted]	FOMC	0.12	1.37
[redacted]	DFOP	0.27	0.96
[redacted]	FOMC	1.06	9.93
[redacted]	DFOP	0.41	1.63

Report:	**KIIIA 9.1.1 /03, [redacted] 2012**
Title:	Kinetic Evaluation of the Aerobic Metabolism of BCS-CQ88719 in Soil for Modelling Purposes
Document No:	**M-422686-01-1** (Report No: MEF-11/886)
Guidelines:	"Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration". Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference Sanco/10058/2005 version 2.0, 2006
GLP	No (calculation)

Materials and Methods: The aerobic degradation of [biphenyl-UL-^{14}C] BCS-CQ88719 was kinetically evaluated based on one laboratory study ([redacted], 2012) on 4 soils in total (20 °C, 55 % of maximum water holding capacity).
The kinetic evaluation of the laboratory degradation behaviour was done following a tiered approach, based on various model assumptions as given in the guidance. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, χ^2 statistic, randomness of residuals, and T-test significance.

Findings: For BCS-CQ88719 the FOMC and the DFOP model were selected each in two soils. Degradation parameters relevant for modelling are given in (Table 9.1.1- 5). The values from the four EU soils investigated are regarded as suitable and reliable for use as modelling endpoints in environmental exposure assessments.
Half-lives were calculated to range from 25.83 to 75.34 days.

Table 9.1.1-5: Optimised degradation parameters of BCS-CQ88719 for modelling endpoints.

Soil	Model	k-rateSFO [1/day]	DT50SFO [days]
[redacted]	FOMC	0.018	39.42)[a]
[redacted]	FOMC	0.027	25.83)[a]
[redacted]	DFOP	0.009)[b]	75.34
[redacted] II	DFOP	0.010)[b]	72.20

)[a] calculated from DT90 of FOMC model/3.32
)[b] calculated from k-slow

IIIA 9.1.2 Anaerobic degradation of the preparation in soil

Due to the proposed use patterns (application as a fungicide in fruits and vegetables) it can be justified that fenhexamid will not be exposed to anaerobic conditions. Therefore, a study on anaerobic degradation is considered not relevant.

IIIA 9.2 Field studies

IIIA 9.2.1 Soil dissipation testing on a range of representative soils

Due to the short half live of fenhexamid in soil (max. 1 day) a field dissipation study is not triggered.

IIIA 9.2.2 Soil residue testing

Soil residues relevant for succeeding crops can be predicted from soil dissipation data provided in IIIA 9.1.1 and 9.2.1 (see also IIIA 9.4). Therefore, no further soil residue testing is required.

IIIA 9.2.3 Soil accumulation testing

Due to the use pattern of the formulation and the degradation rate of the active substance no accumulation in soil would be expected.

IIIA 9.2.4 Aquatic (sediment) field dissipation

Not a data requirement according to Regulation 1107/2009/EEC or Directive 91/414/EEC.

IIIA 9.2.5 Forestry field dissipation

Not a data requirement according to Regulation 1107/2009/EEC or Directive 91/414/EEC.

IIIA 9.3 Mobility of the plant protection product in soil

Specific studies on the preparation have not been performed. The results of the studies performed with the active substance and its major soil metabolite [C-C]biphenyl-KBR 2738 (M24) provided in the Annex IIA Section 5, point 7 and subsequent addenda are also applicable for the preparation. A short summary of the data is given below.

The mobility of the parent fenhexamid was newly assessed in a batch-equilibrium adsorption/desorption study (see Table 9.3- 1) due to the insufficient stability of the parent. The mean K_{OC} of fenhexamid was determined as 517 mL/g (arithmetic) indicating that the compound has no or low leaching potential only. Taking also the very short half-life of ≤ 1 day into account, it seems obvious that a risk of contamination of groundwater from that compound has not to be taken into account.

Table 9.3- 1: Adsorption properties of Fenhexamid in soil

Compound	Adsorption coefficients (mean)		
	K_f [mL/g]	K_{oc} [mL/g]	1/n
Fenhexamid	13.91	517	0.8795

IIIA 9.3.1 Column leaching

The potential mobility of the active substance can be determined from the adsorption/desorption studies described under point 9.3. Due to its very low water solubility the mobility of the major soil metabolite [C-C]biphenyl-KBR 2738 (M24) could not be determined in batch equilibrium experiments therefore a soil column leaching study was performed to derive valuable K_{OC} values. K_{OC} values for the soil adsorption coefficients K_d calculated according to Lambert ranged from 15.2 to 19.8 mL/g

(mean: 17.3 mL/g). The respective organic carbon normalized soil adsorption coefficients (K_{OC}) ranged from 353 to 893 mL/g (mean: 668 mL/g).
The soil adsorption coefficients K_d calculated according to [redacted] ranged from 20.5 to 27.5 mL/g (mean: 23.7 mL/g). The respective organic carbon normalized soil adsorption coefficients (K_{OC}) ranged from 489 to 1214 mL/g (mean: 912 mL/g).
No ^{14}C-radioactivity was detected in the leachates. Approximately the whole radioactivity applied was found in the first segment (0-3 cm), only amounts of less than 1% of AR were found in the other segments below, indicating that the compound has no or low leaching potential only.

IIIA 9.3.2 Lysimeter studies

No concerns of groundwater contamination are to be expected following the application of the formulation or the active substance. This was also confirmed by the PEC_{gw} simulation (see IIIA 9.6.1 and IIIA 9.6.2). Therefore, lysimeter studies are not required.

IIIA 9.3.3 Field leaching studies

Field leaching studies have not been conducted for the active substance as sufficient information can be derived from the existing studies.

IIIA 9.3.4 Volatility - laboratory studies

No volatility studies on the preparation have been performed. Details of the volatility of the active substance are given in Annex IIIA, Section 1. The vapour pressure is also reported in Annex IIIA, Section 9.9.

IIIA 9.3.5 Volatility - field studies

Field volatility studies have not been performed and are not required.

IIIA 9.4 Predicted environmental concentrations in soil, active substance

The critical PEC_{soil} values to be used in the ecotoxicological risk assessment are summarised in Table 9.4- 1.

Table 9.4- 1: Maximum PEC_{soil} values for fenhexamid

Crop	$PEC_{soil,max}$ [mg/kg]
Vines 2 × 0.8 kg a.s./ha	0.320
Strawberries (high use rate) 3 × 1.0 kg a.s./ha	0.659
Strawberries (low use rate) 4 × 0.75 kg a.s./ha	0.498
Tomatoes 3 × 0,75 kg a.s./ha	0.247

PEC_{soil} modelling approach

Calculations were based on a simple first tier approach (Excel sheet) assuming even distribution of the compound in upper 0-5 cm soil layer. A standard soil density of 1.5 g/cm^3 was assumed. For the active substance PEC_{soil} values were calculated for certain days after the global maximum concentration.

Time weighted average concentrations were calculated as maximum of the moving average actual PEC_{soil} values.

Crop interception data which correspond to the intended growth stages were taken from the FOCUS groundwater guidance paper (FOCUS 2002) (see also Table 9.4- 2).

Table 9.4- 2: FOCUS Interception rates

Crop	Growth stage [BBCH code] *(approx.)*	Description	Interception [%]
Vine	69-79	flowering	70
	81-83	ripening	85
Strawberry (high use rate)	59-89	flowering	60
Strawberry (low use rate)	55-89	flowering	60
Tomato	55-89	flowering	80

PEC_{soil} of fenhexamid

Report:	**KIIIA 9.4/01, [redacted] 2012**
Title:	FHM PEC_{soil} EU: Predicted Environmental Concentrations in Soil - Use in Vines, Strawberries, and Tomatoes in the EU
Document No:	**M-422692-01-1** (Report No: MEF-11/909)
Guidelines:	Soil Persistence Models and EU registration: Report of the FOCUS Soil Modelling Work Group, 1996; EC Document Reference 7617VI/96
GLP	No (calculation)

Methods and Materials: The predicted environmental concentrations in soil (PEC_{soil}) of fenhexamid were calculated for use of the fungicide as a spray application at a variety of rates in various crops (grapes, strawberries and tomatoes).

The calculations were based on the maximum intended application rate together with the maximum intended number of applications per season and (for multi-application sequences) the minimum interval between the applications.

For vines the shortest possible application interval is achieved with a 1st application as late as possible (BBCH 79) and the 2nd application as early as possible (BBCH 81). This interval (approximately 11 days) is assumed to be the worst case for multiple applications in vines.

Detailed application data used for simulation of PEC_{soil} compared with the data for the intended uses were compiled in Table 9.4- 3.

Substance Specific Parameters: The characterisation of the degradation behaviour of fenhexamid was based on two laboratory studies. A conservative $DT50_{SFO}$ = 2.99 days is used in the standard European risk assessment.

Table 9.4- 3: Application pattern used for PEC_{soil} calculations of fenhexamid

Crop / scenario	No. of applications	Min. application interval [days]	Application rate [kg a.s./ha]	BBCH	Plant interception [%]	Amount reaching the soil per treatment [kg a.s./ha]
Vine	2	11	2 × 0.8	79 81	70 85	0.24 0.12

Crop / scenario	No. of applications	Min. application interval [days]	Application rate [kg a.s./ha]	BBCH	Plant interception [%]	Amount reaching the soil per treatment [kg a.s./ha]
Strawberry (high use rate)	3	7	3 × 1	59-89	3 × 60	3 × 0.40
Strawberry (low use rate)	4	7	4 × 0.75	55-89	4 × 60	4 × 0.30
Tomato	3	7	3 × 0.75	55-89	3 × 80	3 × 0.15

Findings: The PEC_{soil} and the time weighted average values (TWA_{soil}) of fenhexamid after application in grapes, strawberries and tomatoes are summarised in the following tables.

Table 9.4- 3: PEC_{soil} (actual) and TWA_{soil} of fenhexamid in grapes and tomatoes

		Grapes		Tomatoes	
	Time [days]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]
Initial	0	0.320	-	0.247	-
Short term	1	0.254	0.286	0.196	0.221
	2	0.201	0.256	0.156	0.198
	4	0.127	0.209	0.098	0.161
Long term	7	0.063	0.158	0.049	0.122
	21	0.002	0.065	0.002	0.050
	28	< 0.001	0.049	< 0.001	0.038
	50	< 0.001	0.028	< 0.001	0.021
	100	< 0.001	0.014	< 0.001	0.011

Table 9.4- 5: PEC_{soil} (actual) and TWA_{soil} of fenhexamid in strawberries (high use rate and low use rate)

		Strawberries (high use rate)		Strawberries (low use rate)	
	Time [days]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]
Initial	0	0.659	-	0.498	-
Short term	1	0.523	0.589	0.395	0.444
	2	0.415	0.528	0.313	0.398
	4	0.261	0.430	0.197	0.324
Long term	7	0.130	0.326	0.098	0.246
	21	0.005	0.134	0.004	0.101
	28	0.001	0.101	< 0.001	0.077
	50	< 0.001	0.057	< 0.001	0.043
	100	< 0.001	0.028	< 0.001	0.021

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 Point IIIA 9.4).

IIIA 9.4.2 Short-term PECs values - 24hours, 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 Point IIIA 9.4).

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 Point IIIA 9.4).

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

Predicted environmental concentrations in soil were calculated for all major metabolites in soil, i.e. metabolites which were detected in soil degradation studies in amounts >10% of the applied parent compound. These metabolites are not automatically relevant with regard to their environmental, biological, eco-toxicological or toxicological properties.
The critical PEC_{soil} values used in the ecotoxicological risk assessment for the fenhexamid metabolite M24 (BCS-CQ88719) are summarised in Table 9.5- 1.

Table 9.5- 1: Maximum PEC_{soil} values for the fenhexamid metabolite M24 (BCS-CQ88719)

Crop	**$PEC_{soil,max}$ [mg/kg]**
Vines 2 × 0.8 kg a.s./ha	0.039
Strawberries (high use rate) 3 × 1.0 kg a.s./ha	0.132
Strawberries (low use rate) 4 × 0.75 kg a.s./ha	0.128
Tomatoes 3 × 0.75 kg a.s./ha	0.049

PEC_{soil} of the fenhexamid metabolite M24 (BCS-CQ88719).

Report:	**KIIIA 9.5/01, [redacted] 2012**
Title:	FHM PEC_{soil} EU: Predicted Environmental Concentrations in Soil - Use in Vines, Strawberries, and Tomatoes in the EU
Document No:	**M-422692-01-1** (Report No: MEF-11/909)
Guidelines:	Soil Persistence Models and EU registration: Report of the FOCUS Soil Modelling Work Group, 1996 EC Document Reference 7617VI/96
GLP	No (calculation)

Methods and Materials: The predicted environmental concentrations in soil (PEC_{soil}) of the fenhexamid metabolite M24 (BCS-CQ88719) were calculated for use of the fungicide as a spray application at a variety of rates in various crops (grapes, strawberries and tomatoes).The calculations were performed as described for the active substance in section 9.4.
The application pattern used in the calculations is described in Table 9.4- 3.
Compound specific parameters are summarised in Table 9.5- 2.

Table 9.5- 2: Compound specific input parameters for the fenhexamid metabolite M24 (BCS-CQ88719)

Compound	DT_{50} [days]	Max occur. in soil [%]	Molar mass [g/mol]	Molar mass corr. factor
BCS-CQ88719	75.34	4.4	602.4	1.9934

Findings: The PEC_{soil} and the time weighted average values (TWA_{soil}) of the fenhexamid metabolite M24 (BCS-CQ88719) after application in grapes, strawberries and tomatoes are summarised in Table 9.5- 3 and Table 9.5- 4.

Table 9.5- 3: PEC_{soil} (actual) and TWA_{soil} of the fenhexamid metabolite M24 (BCS-CQ88719) in grapes and tomatoes

		Grapes		Tomatoes	
	Time [days]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]
Initial	0	0.039	-	0.049	-
Short term	1	0.039	0.039	0.049	0.049
	2	0.039	0.039	0.049	0.049
	4	0.038	0.039	0.048	0.049
Long term	7	0.037	0.038	0.046	0.048
	21	0.032	0.036	0.041	0.045
	28	0.030	0.035	0.038	0.044
	50	0.025	0.032	0.031	0.040
	100	0.016	0.026	0.020	0.032

Table 9.5- 4: PEC_{soil} (actual) and TWA_{soil} of the fenhexamid metabolite M24 (BCS-CQ88719) in strawberries (high use rate and low use rate)

		Strawberries (high use rate)		Strawberries (low use rate)	
	Time [days]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]
Initial	0	0.132	-	0.128	-
Short term	1	0.131	0.131	0.127	0.127
	2	0.129	0.131	0.125	0.127
	4	0.127	0.129	0.123	0.125
Long term	7	0.124	0.128	0.120	0.124
	21	0.109	0.120	0.105	0.116
	28	0.102	0.116	0.099	0.113
	50	0.083	0.106	0.081	0.102
	100	0.053	0.086	0.051	0.084

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 Point IIIA 9.5).

IIIA 9.5.2 Short-term PECs values - 24hours, 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 Point IIIA 9.5).

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 Point IIIA 9.5).

IIIA 9.6 Predicted environmental concentrations in ground water (PECgw)

IIIA 9.6.1 Active substance PECgw value

PEC_{gw} modelling approach

The predicted environmental concentrations in groundwater (PEC_{gw}) for the active substance were calculated using the simulation model PEARL following the recommendations of the FOCUS working group on groundwater scenarios.

Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the FOCUS recommendations (see Table 9.4-2).

PEC_{gw} of fenhexamid

Report:	**KIIIA 9.6.1/01, [redacted] 2012**
Title:	FHM PEC_{gw} EU: Predicted Environmental Concentrations in Groundwater Recharge Based on Model FOCUS PEARL - Use in Vines, Strawberries, and Tomatoes in the EU
Document No:	**M-422694-02-1** (Report No: MEF-11/910)
Guidelines:	FOCUS groundwater scenarios in the EU plant protection product review process. Report of the FOCUS Groundwater Scenarios Workgroup. EC Document Reference Sanco/321/2000 rev.2
GLP	No (calculation)

Materials and Methods: The predicted environmental concentrations in groundwater (PEC_{gw}) for fenhexamid were calculated using the simulation model FOCUS PEARL 4.4.4. The simulation covered the use of fenhexamid as foliar sprayed fungicide in grapes, strawberries and tomatoes.

The calculations were based on the maximum intended application rate together with the maximum intended number of applications per season and (for multi-application sequences) the minimum interval between the applications.

For vines the shortest possible application interval is achieved with a 1st application as late as possible (BBCH 79) and the 2nd application as early as possible (BBCH 81). This interval (approximately 11 days) is assumed to be the worst case for multiple applications in vines.

Detailed application data including growth stages and crop interception rates used for simulation of PEC_{gw} were compiled in Table 9.6.1- 1.

Table 9.6.1- 1: Application pattern used for PEC_{gw} calculations of fenhexamid

Crop / scenario	No. of application	Min. application interval [days]	Application rate [kg a.s./ha]	BBCH	Plant interception [%]	Amount reaching the soil per treatment [kg a.s./ha]
Vine	2	11	2 × 0.8	79 81	70 85	0.24 0.12
Strawberry (high use rate)	3	7	3 × 1	59-89	3 × 60	3 × 0.40
Strawberry (low use rate)	4	7	4 × 0.75	55-89	4 × 60	4 × 0.30
Tomato	3	7	3 × 0.75	55-89	3 × 80	3 x 0.15

Substance Specific Parameters: The characterisation of the degradation behaviour of fenhexamid was based on laboratory studies. A DT_{50} of 0.5 days was used in the simulation. The sorption behaviour was described with the arithmetic mean K_{OC} value of the adsorption constants determined in soils. The input parameters for fenhexamid are summarised in Table 9.6.1- 2.

Table 9.6.1- 2: Substance specific input parameter for fenhexamid

Compound	$DT_{50\ soil}$ [days]	K_{oc} [L/kg]	K_{om} [L/kg]	Freundlich coefficient 1/n
Fenhexamid	0.5	517	299.9	0.888

Findings: The 80th percentile concentrations of fenhexamid following the use of fenhexamid as foliar spray applied fungicide in grapes, strawberries and tomatoes are given in Table 9.6.1- 3.

Table 9.6.1- 3: Maximum PEC_{gw} of fenhexamid following application to grapes, strawberries (high rate use and low rate use) and tomatoes

Crop	PEC_{gw} (all scenarios) [µg/L]
Vine	< 0.001
Strawberry (high use rate)	< 0.001
Strawberry (low use rate)	< 0.001
Tomato	< 0.001

Conclusion: The results showed that when fenhexamid is used at rates given in Table 9.6.1- 1, the PEC_{gw} values were below 0.001 µg/L in all crops considered.

IIIA 9.6.2 Relevant metabolites, degradation and reaction products PECgw values

Predicted environmental concentrations in groundwater were calculated for those soil metabolites which should be subject to further assessment according to the guidance document on the assessment of the relevance of metabolite in groundwater (Sanco/221/2000 –rev.10- final, 25 February 2003). The metabolites are not automatically relevant in groundwater.

PEC$_{gw}$ of the fenhexamid metabolite M24 (BCS-CQ88719)

Report:	**KIIIA 9.6.2/01, [redacted] 2012**
Title:	FHM PEC$_{gw}$ EU: Predicted Environmental Concentrations in Groundwater Recharge Based on Model FOCUS PEARL - Use in Vines, Strawberries, and Tomatoes in the EU
Document No:	**M-422694-02-1** (Report No: MEF-11/910)
Guidelines:	FOCUS groundwater scenarios in the EU plant protection product review process, Report of the FOCUS Groundwater Scenarios Workgroup. EC Document Reference Sanco/321/2000 rev.2
GLP	No (calculation)

Materials and Methods: The PEC$_{gw}$ for the fenhexamid metabolite M24 (BCS-CQ88719) were calculated using the approach, scenarios and application rates described for the use of fenhexamid in Point 9.6.1.

Compound specific input data are summarised in Table 9.6.2- 1.

Table 9.6.2- 1: Compound specific input parameters for the fenhexamid metabolite M24 (BCS-CQ88719)

Compound	**DT$_{50\ soil}$ [days]**	**K$_{oc}$ [L/kg]**	**K$_{om}$ [L/kg]**	**Freundlich coefficient 1/n**	**Formation fraction [%]**
M24 (BCS-CQ88719)	45.2	912	529	0.9	0.04

Findings: The 80th percentile concentrations of the fenhexamid metabolite M24 (BCS-CQ88719) following the use of fenhexamid as foliar spray applied fungicide in grapes, strawberries and tomatoes are given in Table 9.6.2- 2.

Table 9.6.2- 2: Maximum PEC$_{gw}$ of the fenhexamid metabolite M24 (BCS-CQ88719) following application to grapes, strawberries (high rate use and low rate use) and tomatoes

Crop	**PEC$_{gw}$ (all scenarios) [µg/L]**
Vine	< 0.001
Strawberry (high use rate)	< 0.001
Strawberry (low use rate)	< 0.001
Tomato	< 0.001

Conclusion: The results showed that when fenhexamid is used at rates given in Table 9.6.1- 1, the PEC$_{gw}$ values were below 0.001 µg/L in all crops considered.

IIIA 9.6.3 Additional field testing

No additional field testing was required.

IIIA 9.6.4 Information on impact on water treatment procedure

The compound would not be expected to reach water treatment plants in sufficient concentrations to have any impact on water treatment procedure.

IIIA 9.7 Predicted environmental concentrations in surface water (PECsw)

No specific information is available for the preparation, however the information on the active substance submitted in the relevant Annex IIA, Section 7 documents is also applicable. A summary of this information is presented below.

Summary of fate and behaviour of fenhexamid in water

In sterile aquatic systems reflecting environmental pH and temperature conditions fenhexamid was found to be stable to hydrolysis. Consequently it is not expected that hydrolytic processes will contribute to the degradation of fenhexamid in the environment.

Studies investigating the photochemical degradation in water showed that solar radiation will significantly contribute to the degradation of fenhexamid in aquatic systems and also can contribute to the elimination of residues of fenhexamid by means of mineralisation of the phenyl-ring. More than 14 degradation products or metabolite fractions were observed in the irradiated aqueous solution. The breakdown of the parent compound proceeded via dechlorination (M12), stepwise hydroxylation (M15) and subsequent cleavage of the phenyl-ring.

The benzoxazole metabolite of KBR 2738, M10 (WAK 7004), which was formed in amounts of approximately 24 % of applied radioactivity, was further metabolized very fast (DT_{50} << 1 d).

In a phototransformation experiment with fenhexamid published in Chemosphere vol. 81, pp. 844-852 (Maheswari et al. 2010) another new aqueous photometabolite occurred in amounts up to 15% of AR and was identified as 1-methyl cyclohexane carboxamide (M40). Different photo sensitive additives like acetone, etc. and humic substances like humic acids, etc. were utilized in those phototransformation experiments. The metabolite is added into the aquatic degradation pathway shown in Figure 9.7- 1.

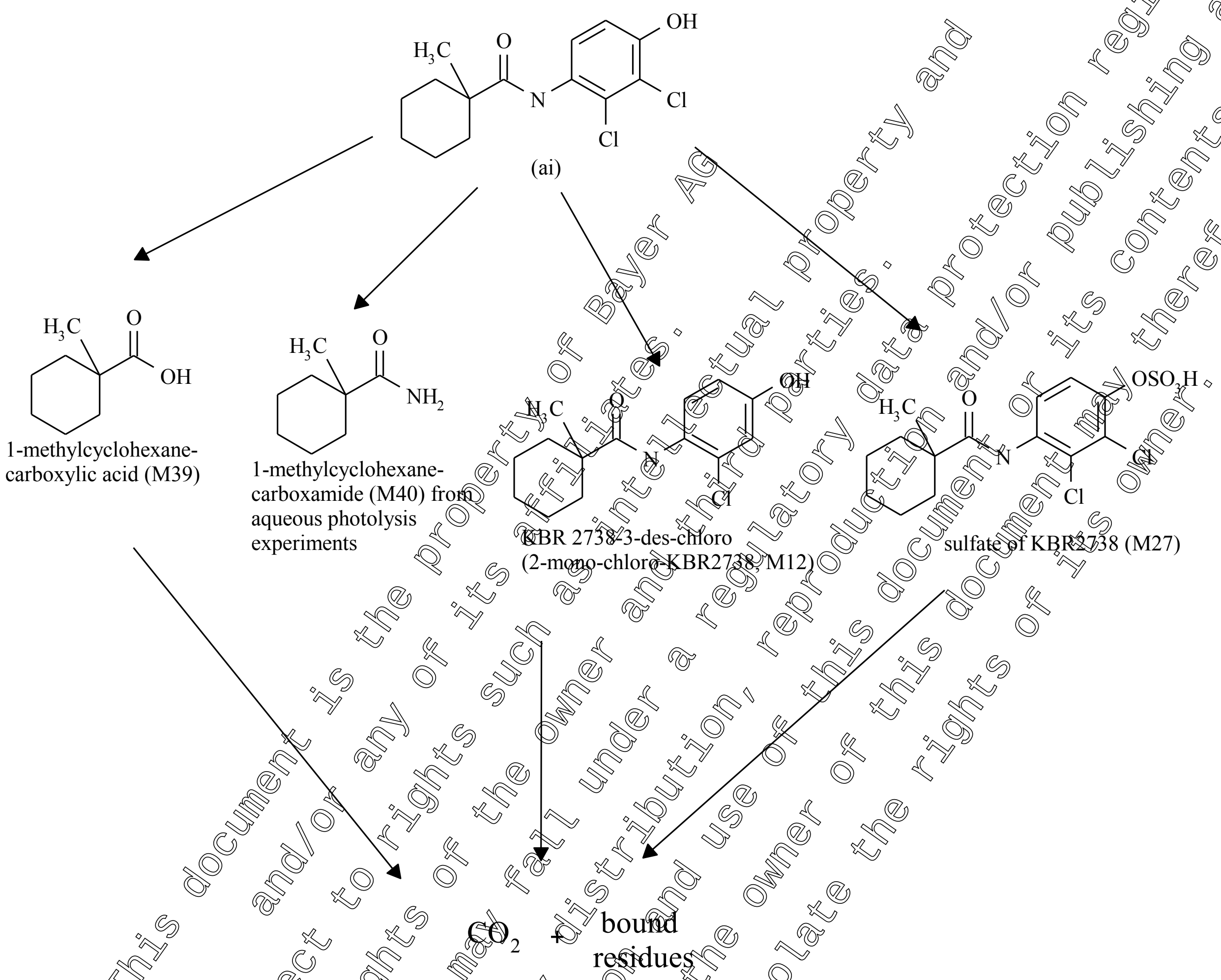
All photolysis metabolites are of transient nature and therefore not taken into consideration for modelling purposes.

In natural water/sediment systems the compound has to be regarded as a rapidly dissipating and thoroughly metabolised substance. The DT_{50} values of fenhexamid were calculated to range between 2 and 15 days referring to the entire system. More than 15 metabolites were formed, but no metabolite accumulated. Using the [cyclohexyl-1-^{14}C] labeled fenhexamid (KBR2738) two major metabolites identified as 1-methylcyclohexanecarboxylic acid (M39) and 2-monochloro-KBR 2738 (M12, synonym: KBR 2738-3-deschloro) occurred in an aquatic environment in amounts up to 8.9 % and 7.5 %, respectively. The sulfate of KBR 2738 (M27) which occurred in amounts up to 4.2% of applied radioactivity only was not taken into account in further risk assessments. Fenhexamid was relatively fast degraded in the water/sediment systems to the final degradation product CO_2. A significant portion of the radioactivity was translocated to the sediment. However, in two systems the fraction of the bound residues started to decline after about 30 to 60 days and was gradually mineralised to carbon dioxide, indicated by the large amounts of $^{14}CO_2$ at the end of those studies.

Regarding the different results concerning the degradation behaviour of fenhexamid in the aquatic environment, the parent compound itself has to be regarded as the only relevant residue.

The proposed metabolic pathway of fenhexamid in water/sediment systems including the additional photolysis metabolite is shown in Figure 9.7- 1.

Figure 9.7- 1: Proposed metabolic pathway for KBR 2738 under aerobic conditions of water/sediment and in addition one major metabolite occurring in an external aqueous photolysis study



The data of the two aerobic water/sediment degradation studies with the two radiolabels of fenhexamid was recently re-evaluated according to the FOCUS kinetics guidance (Sanco/10058/2005, version 2.0, June 2006) to result in optimised degradation parameters of fenhexamid and its metabolite M12 and M39 for modelling and persistence endpoints.

Report:	**KIIIA 9.7/01, [redacted].; 2011**
Title:	Kinetic Evaluation of the Aerobic Aquatic Metabolism of [Cyclohexyl-1-^{14}C]-Fenhexamid (KBR 2738) and its metabolites for modelling and persistence endpoints
Document No:	**M-422393-01-1** (Report No: MEF-11/757)
Guidelines:	“Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration”. Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference Sanco/10058/2005 version 2.0, 2006
GLP	No (calculation)

Materials and Methods: The degradation and dissipation behaviour of [cyclohexyl-1-14C]fenhexamid (KBR 2738) and its metabolites 1-methylcyclohexanecarboxylic acid (M39) and N-(2-chloro-4-hydroxyphenyl)-1-methyl-cyclohexanecarboxamide (M12) in an aquatic environment was investigated by kinetic evaluation of two aerobic water-sediment systems ([redacted] and [redacted], at 20 °C in the dark ([redacted], 2011)).

The kinetic evaluation of the laboratory degradation behaviour was done following a tiered approach, based on various model assumptions as given in the guidance. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, χ^2 statistic, randomness of residuals, and T-test significance.

Findings: Analyses of the kinetics of fenhexamid (parent = P) and its metabolites (M) considering the total system (Level I, degradation) and the single phases separately (Level I, dissipation) were done. Parameters of the selected models for fenhexamid are shown in Table 9.7- 2, Table 9.7- 4, Table 9.7- 6 (modelling endpoints) and Table 9.7- 3, Table 9.7- 5, and Table 9.7- 7 (persistence endpoints) for the total system (Level I, degradation) and for the single phases (Level I, dissipation) of fenhexamid, M39, and M12.

Table 9.7- 2: SFO degradation and dissipation parameters for modelling endpoints of fenhexamid

Evaluation level / type of parameter	Phase	--- [redacted] ---			--- [redacted] ---		
		Model	k-rate (1/days)	DT_{50} (days)	Model	k-rate (1/days)	DT_{50} (days)
PI / deg.	Total system	SFO	0.062	11.14	FOMC	0.037	18.49)^a
PI / diss.	Water	SFO	0.123	5.65	FOMC	0.127	5.47)^a
PI / diss.	Sediment	SFO	0.028	25.08	SFO	0.027	26.09

)^a calculated by $DT90_{FOMC}/3.32$

Table 9.7- 3: Degradation and dissipation parameters for persistence endpoints of fenhexamid

Evaluation level / type of parameter	Phase	-- [redacted] --			-[redacted]-		
		Model	DT_{50} (days)	DT_{90} (days)	Model	DT_{50} (days)	DT_{90} (days)
PI / deg.	Total system	HS	10.96	45.60	DFOP	14.60	60.64
PI / diss.	Water	DFOP	5.45	19.74	DFOP	2.41	14.98
PI / diss.	Sediment	FOMC	22.20	102.68	FOMC	22.81	108.55

Table 9.7- 4: SFO degradation and dissipation parameters for modelling endpoints of M39 (1-methylcyclohexanecarboxylic acid)

Evaluation level / type of parameter	Phase	--- [redacted] ---			--- [redacted] ---		
		Model	k-rate (1/days)	DT_{50} (days)	Model	k-rate (1/days)	DT_{50} (days)
MI / deg.	Total system	SFO (parent SFO)	0.111	6.23	SFO (parent FOMC)	0.083	8.33
MI / diss.	Water	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
MI / diss.	Sediment	SFO	0.030	22.98	SFO	0.030	23.26

Table 9.7- 5: Degradation and dissipation parameters for persistence endpoints of M39 (1-methylcyclo-hexanecarboxylic acid)

Evaluation level / type of parameter	Phase	-- [redacted] --			- [redacted] -		
		Model	DT_{50} (days)	DT_{90} (days)	Model	DT_{50} (days)	DT_{90} (days)
MI / deg.	Total system	SFO (parent HS)	6.42	21.32	SFO (parent DFOP)	7.97	26.48
MI / diss.	Water	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
MI / diss.	Sediment	FOMC	17.65	113.81	SFO	23.26	77.28

Table 9.7-6: SFO degradation and dissipation parameters for modelling endpoints of M12 (KBR 2738-3-des-chloro)

Evaluation level / type of parameter	Phase	--- [redacted] ---			--- [redacted] ---		
		Model	k-rate (1/days)	DT_{50} (days)	Model	k-rate (1/days)	DT_{50} (days)
MI / deg.	Total system	n.a.	n.a.	n.a.	SFO (parent FOMC)	0.010	68.90
MI / diss.	Water	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
MI / diss.	Sediment	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Table 9.7- 7: Degradation and dissipation parameters for persistence endpoints of M12 (KBR 2738-3-des-chloro)

Evaluation level / type of parameter	Phase	-- [redacted] --			- [redacted] -		
		Model	DT_{50} (days)	DT_{90} (days)	Model	DT_{50} (days)	DT_{90} (days)
MI / deg.	Total system	n.a.	n.a.	n.a.	SFO (parent DFOP)	73.79	245.12
MI / diss.	Water	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
MI / diss.	Sediment	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Report:	**KIIIA 9.7/02, [redacted].; 2011**
Title:	Kinetic Evaluation of the Aerobic Aquatic Metabolism of [Phenyl-UL-^{14}C] Fenhexamid (KBR 2738) for modelling and persistence endpoints
Document No:	**M-422394-01-1** (Report No: MEF-11/057)
Guidelines:	"Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration". Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference Sanco/10058/2005 version 2.0, 2006
GLP	No (calculation)

Materials and Methods: The degradation and dissipation behaviour of [phenyl-UL-^{14}C] fenhexamid (KBR 2738) in an aquatic environment was investigated by kinetic evaluation of two aerobic water-sediment systems ([redacted] and [redacted], at 20-21 °C in the dark; [redacted] (1997)).

The kinetic evaluation of the laboratory degradation behaviour was done following a tiered approach, based on various model assumptions as given in the guidance. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, χ^2 statistic, randomness of residuals, and T-test significance.

Findings: Analyses of the kinetics of fenhexamid (parent = P) considering the total system (Level I, degradation) and the single phases separately (Level I, dissipation) were done.
Parameters of the selected models for fenhexamid are shown in Table 9.7- 8 (modelling endpoints) and Table 9.7- 9 (persistence endpoints) for the total system (Level I, degradation) and for the single phases (Level I, dissipation) of fenhexamid.

Table 9.7- 8: SFO degradation and dissipation parameters for modelling endpoints of [phenyl-UL-^{14}C] fenhexamid

Evaluation level / type of parameter	Phase	[redacted]			--- [redacted] ---		
		Model	**k-rate (1/days)**	**DT$_{50}$ (days)**	**Model**	**k-rate (1/days)**	**DT$_{50}$ (days)**
PI / deg.	Total system	SFO	0.047	14.71	SFO	0.102	6.77
PI / diss.	Water	DFOP	0.150	4.61)^a	DFOP	0.176	3.93)^a
PI / diss.	Sediment	HS	0.023)^b	29.88	SFO	0.066	10.58

)^a calculated by DT90$_{DFOP}$/3.32
)^b k-rate of slow phase

Table 9.7- 9: Degradation and dissipation parameters for persistence endpoints of [phenyl-UL-^{14}C] fenhexamid

Evaluation level / type of parameter	Phase	--- [redacted] ---			--- [redacted] ---		
		Model	**DT$_{50}$ (days)**	**DT$_{90}$ (days)**	**Model**	**DT$_{50}$ (days)**	**DT$_{90}$ (days)**
PI / deg.	Total system	DFOP	13.91	57.73	SFO	6.77	22.48
PI / diss.	Water	DFOP	1.62	15.32	DFOP	2.28	13.06
PI / diss.	Sediment	FOMC	14.98	116.37	SFO	10.58	35.16

PEC$_{sw}$ values for ecotoxicological risk assessment

The critical PEC$_{sw}$ values used in the ecotoxicological risk assessment are summarised in Tables 9.7- 10 and 9.7- 11.

Table 9.7- 10: Maximum PEC$_{sw}$ values for fenhexamid at FOCUS Step 2 and 3

Crop	**FOCUS Step**	**PEC$_{sw, max}$ [µg/L] – scenario**	**PEC$_{sed, max}$ [µg/L] – scenario**
Vine	2	25.86	67.03
	3	14.19 – R3 stream	16.96 – D6 ditch
Strawberry (high use rate)	2	11.88	33.30
	3	6.326 – D6 ditch	2.630 – D6 ditch
Strawberry (low use rate)	2	9.145	26.18
	3	4.747 – D6 ditch	1.994 – D6 ditch
Tomato	2	8.913	24.98
	3	4.747 – D6 ditch	1.994 – D6 ditch

Table 9.7- 11: Maximum PEC$_{sw}$ values for fenhexamid at FOCUS Step 4 after application in vines

Buffer	Scenario	PEC$_{sw}$ [µg/L] Drift Reduction
		0%
5m	D6 (ditch, 1st) R1 (pond, 1st) R1 (stream, 1st) R2 (stream, 1st) R3 (stream, 1st) R4 (stream, 1st)	8.469 0.865 7.333 9.829 10.34 7.332

PEC$_{sw}$ modeling approach

FOCUS$_{sw}$ is a four step tiered approach:

Step 1: In this, the most conservative step, all inputs are considered as a single loading to the water body and a worst-case PEC$_{sw}$ and PEC$_{sed}$ is calculated.

Step 2: A refinement is made whereby individual loadings into the water body from different entry routes are considered. Scenarios are also considered for northern and southern Europe separately but no specific crop scenarios are defined.

Step 3: An exposure assessment using realistic worst-case scenarios is made. The scenarios are representative of agricultural conditions in Europe and consider weather, soil, crop and different water-bodies. Simulations use the models PRZM, MACRO and TOXSWA.

Step 4: PEC values are refined by considering mitigation measures or specific scenario descriptions on a case-by-case basis.

FOCUS Step 1: A standard ditch (Table 9.7- 11) is defined with a set distance of the crop to the water of 1 m and 90th percentile drift values. Inputs from all routes of entry are considered as a single entry event, multiple applications are also treated as a single input. After entry into surface water, drift loadings are subsequently distributed between water and sediment (within 1 d), according to the compound's K$_{oc}$. The input due to drainage, run-off and erosion is set to 10% of the initial loading. This input is distributed instantaneously between the water and sediment, degradation is assumed to follow first order kinetics. Calculations use the FOCUS Step 1 and 2 Calculator.

FOCUS Step 2: Using the standard ditch (Table 9.7- 12) inputs into the water body are considered as a series of individual loadings. Drift inputs are distributed between the water and sediment considering sorption and partitioning between the water and sediment. Input by run-off, erosion and drainage is evaluated as a single entry 4 days after the last treatment at 2-5% of the soil residue depending on the season and region of application (Northern or southern Europe) (Table 9.7- 13). The run-off and drainage input is assumed to distribute instantaneously between water and sediment. Degradation in the water and sediment is assumed to follow first order kinetics. Calculations use the FOCUS Step 1 and 2 Calculator.

Table 9.7- 12: Standard ditch defined for FOCUS Step 1 and Step 2 calculations

Depth of Water Layer	30 cm
Thickness of sediment layer	5 cm
Content of organic carbon in sediment	5 g/100g dry sediment
Dry bulk density of sediment	0.8 g/cm^3
Ratio of surface area field: water body	10

Table 9.7- 131: Run-off and drainage input loadings for step 2 calculations

Application window	Northern Europe	Southern Europe
October – February	5%	4%
March - May	2%	4%
June – September	2%	3%

FOCUS Step 3: At Step 3 the FOCUS working group defined 10 realistic worst-case scenarios representative of agronomic conditions in Europe. The occurrence of these scenarios throughout Europe was also identified so that an appropriate subset of scenarios relevant to a specific country and crop can be defined. The scenarios were divided into six scenarios where drainage is the relevant entry route and four where run-off is relevant, spray drift is considered for alls scenarios. Three water bodies have been defined, stream, pond and ditch (Table 9.7- 14 and Table 9.7- 15).

Table 9.7- 14: Water bodies defined for FOCUS Step 3 scenarios

	Width [m]	Length [m]	Average water depth [m]	Average residence time [days]
Pond	30	30	1	50
Stream	1	100	0.3-0.5	0.1
Ditch	1	100	0.3	5

Table 9.7- 15: Sediment properties for FOCUS step 3 scenarios

Sediment layer depth	5 cm
Organic carbon content	5 g/100 g
Dry bulk density	800 kg/m^3
Porosity	60 cm^3/100 cm^3

Scenarios relevant for the use in vine, strawberry and tomato in Europe: The scenarios considered as most relevant for vine, strawberry and tomato are D6, R1, R2, R3 and R4.

Calculation tool: The FOCUS SWASH tool is a utility which enables the input of relevant data into the simulation models MACRO for inputs due to drainage, PRZM for entries due to run-off and erosion and TOXSWA which simulated the behaviour in the water body.

PEC$_{sw}$ of fenhexamid

Report:	**KIIIA 9.7 /03; [redacted].; 2012**
Title:	FHM PEC$_{sw}$ EU: Predicted Environmental Concentrations in Surface Water and Sediment. Use in Vines, Strawberries, and Tomatoes in the EU
Document No:	**M-422697-02-1** (Report No: MEF-11/917)
Guidelines:	FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document

	Reference SANCO/4802/2001-rev2 2003
GLP	No (calculation)

Materials and Methods:

PEC_{sw} and PEC_{sed} values have been calculated in accordance with the $FOCUS_{sw}$ approach for the use of fenhexamid in grapes, strawberries and tomatoes.

The PEC calculations were carried out taking into account substance entry via spray-drift, run-off and drainflow, according to the FOCUS surface water requirements. For fenhexamid (substance specific parameters in Table 9.7- 16) step 1 - 4 simulations were carried out using the simulation tools STEPS 1 & 2 in FOCUS 1.1 and FOCUS SWASH 2.1.

FOCUS Steps 1-2 calculations were based on the maximum intended application rate together with the maximum intended number of applications per season and the shortest application interval. Details of the parameters used in the calculations are summarised in Table 9.7- 17.

For vines the shortest possible application interval is achieved with a 1st application as late as possible (BBCH 79) and the 2nd application as early as possible (BBCH 81). This interval (approximately 11 days) is assumed to be the worst case for multiple applications in vines.

Table 9.7- 16: Compound specific parameters of fenhexamid

Water solubility	24 mg/L (pH 7.0, 20°C)
Vapour pressure	4×10^{-7} Pa (20°C)
Adsorption coefficient (K_{oc})	517 L/kg
Freundlich coefficient (1/n)	0.880
DT_{50} soil (geomean at 20°C and 100% field capacity)	0.57 days (STEP 1+2, not-normalised) 0.54 days (STEP 3+4, normalised)
DT_{50} water/sediment	11.97 days
Maximum occurrence in sediment	100 %
Plant uptake factor	0.5

Table 9.7- 17: Application pattern used for PEC_{sw} calculations of fenhexamid (for FOCUS step 1&2)

Crop / scenario	BBCH	Application interval (min) [days]	Application rate [kg a.s./ha]	Crop group	Season	Crop cover
Vine	79-81	11	2 × 0.8	vines / late	June - Sep.	full canopy
Strawberry (high use rate)	59	7	3 × 1	arable crops	June - Sep.	full canopy
Strawberry (low use rate)	55	7	4 × 0.75	arable crops	June - Sep.	full canopy
Tomato	55	7	3 × 0.75	arable crops	June - Sep.	full canopy

At FOCUS step 3 actual application dates were determined by the PAT (pesticide application timer) included within SWASH. Details of the parameters used in the calculations are summarised in Table 9.7- 18.

Table 9.7- 18: Application dates of fenhexamid for the FOCUS Step 3 calculations

Crop scenario	Vine, late	Strawberry (high use rate)	Strawberry (low use rate)	Tomato
Application rate	2 × 0.8 kg/ha	3 × 1 kg/ha	4 × 0.75 kg/ha	3 × 0.75 kg/ha
Application interval	11 days	7 days	7 days	7 days
Application dates				
D6	09-Aug, 20-Aug	24-Jun, 06-Jul, 17-Jul	24-Jun, 06-Jul, 17-Jul, 27-Jul	24-Jun, 06-Jul, 17-Jul
R1	17-Sep, 06-Oct	-	-	-
R2	31-Jul, 11-Aug	12-Jun, 16-Jul, 23-Jul	05-Jun, 12-Jun, 16-Jul, 23-Jul	05-Jun, 12-Jun, 26-Jul
R3	28-Aug, 23-Sep	11-Jul, 18-Jul, 30-Jul	11-Jul, 18-Jul, 30-Jul, 07-Aug	11-Jul, 18-Jul, 30-Jul
R4	25-Jul, 13-Aug	05-Jun, 12-Jun, 23-Jun	05-Jun, 12-Jun, 23-Jun, 30-Jun	05-Jun, 12-Jun, 23-Jun

For an aquatic risk assessment the worst-case concentration considering either a single application or multiple applications should be considered, especially in case that the dominant entry route is via drift. Therefore, both multiple applications (in accordance with the use patterns) and single applications were considered.

Findings:

Step 1 and 2: The maximum PEC values for Steps 1 and 2 are given in Table 9.7- 19 for single and multiple applications in vine, strawberries and tomatoes.

Table 9.7- 19: Maximum PEC_{sw} and PEC_{sed} values for fenhexamid at Steps 1 and 2

Crop	**Step**	**Fenhexamid**		
		$PEC_{sw, max}$ [µg/L]	**$PEC_{sw, 21 d TWA}$ [µg/L]**	**$PEC_{sed, max}$ [µg/kg]**
Vine, late 2 × 0.8 kg/ha	1	358.5	197.8	1630
	2 (N-EU Multi)	25.86	10.68	66.85
	2 (S-EU Multi)	25.86	10.70	67.03
	2 (N-EU Single)	21.41	7.958	49.40
	2 (S-EU Single)	21.41	7.978	49.58
Strawberry (high use rate) 3 × 1 kg/ha	1	619.5	352.2	3060
	2 (N-EU Multi)	11.88	5.246	33.08
	2 (S-EU Multi)	11.88	5.270	33.30
	2 (N-EU Single)	9.197	3.451	21.52
	2 (S-EU Single)	9.197	3.476	21.74
Strawberry (low use rate) 4 × 0.75 kg/ha	1	619.5	352.2	3060
	2 (N-EU Multi)	9.145	4.119	26.01
	2 (S-EU Multi)	9.145	4.138	26.18
	2 (N-EU Single)	6.898	2.588	16.14
	2 (S-EU Single)	6.898	2.607	16.30
Tomato 3 × 0.75 kg/ha	1	464.7	264.2	2300
	2 (N-EU Multi)	8.913	3.934	24.81
	2 (S-EU Multi)	8.913	3.953	24.98
	2 (N-EU Single)	6.898	2.588	16.14
	2 (S-EU Single)	6.898	2.607	16.30

Step 3: The maximum PEC$_{sw}$ and PEC$_{sed}$ values for relevant FOCUS Step 3 scenarios are given in Table 9.7- 20 for vine, in Table 9.7- 21 for strawberries (high use rate), in Table 9.7- 22 for strawberries (low use rate) and in Table 9.7- 23 for tomato. Time dependent PEC values or time-weighted average concentrations are not included in this summary, because they were not used in the risk assessment. However, all values are given in the report.

Table 9.7- 20: Maximum PEC$_{sw}$ and PEC$_{sed}$ of fenhexamid for all relevant scenarios at Step 3 following late application to vine

	Single application		Multiple application	
Scenario	**PEC$_{sw, max}$ [µg/L]**	**PEC$_{sed, max}$ [µg/kg]**	**PEC$_{sw, max}$ [µg/L]**	**PEC$_{sed, max}$ [µg/kg]**
D6 (ditch)	13.72	14.27	14.07	16.96
R1 (pond)	0.488	1.403	0.744	2.464
R1 (stream)	10.06	1.417	8.879	1.374
R2 (stream)	13.49	1.021	11.90	0.993
R3 (stream)	14.19	3.092	12.52	2.851
R4 (stream)	10.06	1.400	8.878	1.298

Table 9.7- 21: Maximum PEC$_{sw}$ and PEC$_{sed}$ of fenhexamid for all relevant scenarios at Step 3 following application to strawberries (high use rate)

	Single application		Multiple application	
Scenario	**PEC$_{sw, max}$ [µg/L]**	**PEC$_{sed, max}$ [µg/kg]**	**PEC$_{sw, max}$ [µg/L]**	**PEC$_{sed, max}$ [µg/kg]**
D6 (ditch)	6.326	2.630	4.616	2.229
R2 (stream)	5.617	0.930	4.075	0.905
R3 (stream)	5.906	1.309	4.286	1.271
R4 (stream)	4.190	1.953	3.044	2.209

Table 9.7- 22: Maximum PEC$_{sw}$ and PEC$_{sed}$ of fenhexamid for all relevant scenarios at Step 3 following application to strawberries (low use rate)

	Single application		Multiple application	
Scenario	**PEC$_{sw, max}$ [µg/L]**	**PEC$_{sed, max}$ [µg/kg]**	**PEC$_{sw, max}$ [µg/L]**	**PEC$_{sed, max}$ [µg/kg]**
D6 (ditch)	4.747	1.994	3.195	1.565
R2 (stream)	4.212	0.323	2.828	0.838
R3 (stream)	4.430	0.988	2.974	1.126
R4 (stream)	3.142	1.451	2.112	1.641

Table 9.7- 23: Maximum PEC$_{sw}$ and PEC$_{sed}$ of fenhexamid for all relevant scenarios at Step 3 following application to tomatoes

	Single application		Multiple application	
Scenario	**PEC$_{sw, max}$ [µg/L]**	**PEC$_{sed, max}$ [µg/kg]**	**PEC$_{sw, max}$ [µg/L]**	**PEC$_{sed, max}$ [µg/kg]**
D6 (ditch)	4.747	1.994	3.463	1.691
R2 (stream)	4.212	0.323	3.055	0.843
R3 (stream)	4.430	0.988	3.213	0.959
R4 (stream)	3.142	1.451	2.282	1.649

Step 4:

The FOCUS Step 4 PEC_{sw} and PEC_{sed} values for the relevant scenarios are given in the following tables for single and multiple application of fenhexamid in vine. Time dependent PEC values or time-weighted average concentrations are not included in this summary, because they were not used in the risk assessment. Howver, all values are given in the report.

Table 9.7- 2: Maximum PEC_{sw} and PEC_{sed} of fenhexamid for all relevant scenarios at Step 4 following application to vine with a 5 m buffer zone

		Single application		Multiple application	
Buffer	**Scenario**	**$PEC_{sw, max}$ [µg/L]**	**$PEC_{sed, max}$ [µg/kg]**	**$PEC_{sw, max}$ [µg/L]**	**$PEC_{sed, max}$ [µg/kg]**
		Drift reduction 0%		**Drift reduction 0%**	
5 m	D6 (ditch)	8.297	8.838	8.469	10.47
	R1 (pond)	0.567	1.618	0.865	2.845
	R1 (stream)	7.333	1.037	6.452	1.004
	R2 (stream)	9.829	0.746	8.649	0.725
	R3 (stream)	10.34	2.269	9.095	2.073
	R4 (stream)	7.332	1.024	6.451	0.948

IIIA 9.7.1 Initial PECsw value for static water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.7).

IIIA 9.7.2 Initial PECsw value for slow moving water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.7).

IIIA 9.7.3 Short-term PECsw values for static water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.7).

IIIA 9.7.4 Short-term PECsw values for slow moving water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.7).

IIIA 9.7.5 Long-term PECsw values for static water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.7).

IIIA 9.7.6 Long-term PECsw values for slow moving water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.7).

IIIA 9.8 PECsw for relevant metabolites

Metabolites considered in this section are those major metabolites which could be present in water either due to spray-drift, run-off or drainage and that should be considered for aquatic risk assessment. The critical PEC_{sw} values for the metabolites used in the ecotoxicological risk assessment are summarised in Table 9.8- 1.

Table 9.8- 1: Maximum PEC_{sw} values for metabolites at FOCUS Step 2

Crop	Compound	$PEC_{sw, max}$ [µg/L]
Vine	BCS-CQ88719 (M24)	1.664
	2-monochloro-KBR 2738 (M12)	1.529
	1-methylcyclohexanecarboxylic acid (M39)	1.701
Strawberry (high use rate)	BCS-CQ88719 (M24)	3.054
	2-monochloro-KBR 2738 (M12)	0.639
	1-methylcyclohexanecarboxylic acid (M39)	0.791
Strawberry (low use rate	BCS-CQ88719 (M24)	2.914
	2-monochloro-KBR 2738 (M12)	0.500
	1-methylcyclohexanecarboxylic acid (M39)	0.587
Tomato	BCS-CQ88719 (M24)	2.291
	2-monochloro-KBR 2738 (M12)	0.479
	1-methylcyclohexanecarboxylic acid (M39)	0.594

PEC_{sw} of Fenhexamid metabolites

For fenhexamid the metabolites BCS-CQ88719 (M24), 2-monochloro-KBR 2738 (KBR 2738-3-des-chloro, M12) and 1-methylcyclohexanecarboxylic acid (M39) were assessed.

Report:	**KIIIA 9.8 /01; [redacted] 2012**
Title:	FHM PEC_{sw} EU: Predicted Environmental Concentrations in Surface Water and Sediment. Use in Vines, Strawberries and Tomatoes in the EU
Document No:	**M-422697-02-1** (Report No: MEF-11/917)
Guidelines:	FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev2 2003
GLP	No (calculation)

Materials and Methods: PEC_{sw} for the metabolites were calculated using the approach, scenarios and application rates described for the calculations for the parent compound in Point 9.7. Input parameters for the metabolites are described in Table 9.8- 2.

Table 9.8- 2: Compound specific input parameters for fenhexamid metabolites

Parameter	Unit	BCS-CQ88719 (M24)	2-monochloro-KBR 2738 (M12)	1-methylcyclo-hexanecarboxylic acid (M39)
Molar mass	g/mol	602.4	267.8	142.2
Aqueous solubility at 25ºC	mg/L	0.0001	44.71	811
K_{oc}	L/kg	912	3635	22.13
Maximum in soil	%	4.4	0	0
Maximum in water / sediment	%	0	7.5	14.2
DT_{50} soil	days	48.51	0.00001	0.00001
DT_{50} water	days	1000	68.90	7.21
DT_{50} sediment	days	1000	68.90	7.21

Findings:

Step 1 and 2: The maximum PEC values for the metabolites of fenhexamid at Step 1 and Step 2 are given in Table 9.8- 3 to Table 9.8- 6 for vines, strawberries and tomatoes. Time dependent PEC values or time-weighted average concentrations are not included in this summary, because they were not used in the risk assessment. However, all values are given in the report.

Table 9.8- 3: Maximum PEC_{sw} and PEC_{sed} values for metabolites of fenhexamid following application to vine

Crop	FOCUS step	BCS-CQ88719 (M24)		2-monochloro-KBR 2738 (M12)		1-methylcyclohexanecarboxylic acid (M39)	
		PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Vine	1	21.11	192.5	2.846	< 0.001	2.861	< 0.001
	2 (N-EU Multi)	1.109	10.12	1.529	13.14	1.701	0.223
	2 (S-EU Multi)	1.664	15.17	1.529	13.14	1.701	0.223
	2 (N-EU Single)	0.598	5.455	1.423	7.782	1.430	0.186
	2 (S-EU Single)	0.897	8.182	1.423	7.782	1.430	0.186

Table 9.8- 4: Maximum PEC_{sw} and PEC_{sed} values for metabolites of fenhexamid following application to strawberries (high use rate)

Crop	FOCUS step	BCS-CQ88719 (M24)		2-monochloro-KBR 2738 (M12)		1-methylcyclohexanecarboxylic acid (M39)	
		PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Strawberries (high use rate)	1	39.58	361.0	1.834	< 0.001	1.844	< 0.001
	2 (N-EU Multi)	2.036	18.57	0.639	6.926	0.791	0.104
	2 (S-EU Multi)	3.054	27.85	0.639	6.926	0.791	0.104
	2 (N-EU Single)	0.748	6.818	0.611	3.343	0.615	0.080
	2 (S-EU Single)	1.121	10.23	0.611	3.343	0.615	0.080

Table 9.8- 5: Maximum PEC_{sw} and PEC_{sed} values for metabolites of fenhexamid following application to strawberries (low use rate)

Crop	FOCUS step	BCS-CQ88719 (M24)		2-monochloro-KBR 2738 (M12)		1-methylcyclo-hexanecarboxylic acid (M39)	
		PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Strawberries (low use rate)	1	39.58	361.0	1.834	< 0.001	1.844	< 0.001
	2 (N-EU Multi)	1.943	17.72	0.500	6.171	0.587	0.077
	2 (S-EU Multi)	2.914	26.57	0.500	6.171	0.587	0.077
	2 (N-EU Single)	0.561	5.114	0.458	2.507	0.461	0.060
	2 (S-EU Single)	0.841	7.671	0.458	2.507	0.461	0.060

Table 9.8- 6: Maximum PEC_{sw} and PEC_{sed} values for metabolites of fenhexamid following application to tomatoes

Crop	FOCUS step	BCS-CQ88719 (M24)		2-monochloro-KBR 2738 (M12)		1-methylcyclo-hexanecarboxylic acid (M39)	
		PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Tomatoes	1	29.68	270.7	1.375	< 0.001	1.383	< 0.001
	2 (N-EU Multi)	1.527	13.93	0.479	5.195	0.594	0.078
	2 (S-EU Multi)	2.291	20.89	0.479	5.195	0.594	0.078
	2 (N-EU Single)	0.561	5.114	0.458	2.507	0.461	0.060
	2 (S-EU Single)	0.841	7.671	0.458	2.507	0.461	0.060

IIIA 9.8.1 Initial PECsw value for static water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.8).

IIIA 9.8.2 Initial PECsw value for slow moving water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.8).

IIIA 9.8.3 Short-term PECsw values for static water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.8).

IIIA 9.8.4 Short-term PECsw values for slow moving water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.8).

IIIA 9.8.5 Long-term PECsw values for static water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.8).

IIIA 9.8.6 Long-term PECsw values for slow moving water bodies

For better transparency the various PEC_{sw} values reflecting the initial, short- and long-term PECs are presented side by side (see Point 9.8).

IIIA 9.8.7 Additional field studies

No additional field studies on the formulation have been performed or are required.

IIIA 9.9 Fate and behaviour in air

Based on the very low vapour pressure of 4×10^{-7} Pa at 20 °C significant volatilisation of fenhexamid is not to be expected. In addition, estimates of the chemical lifetime in the troposphere resulted in half lives < 1 day. According to these results an accumulation of fenhexamid in the air and a contamination by wet or dry deposition are not to be expected. The relevant residue for quantitation in air is the parent compound only.

IIIA 9.9.1 Spray droplet size spectrum - laboratory studies

Not a data requirement according to Regulation 1107/2009/EEC or Directive 91/414/EEC.

IIIA 9.9.2 Drift - field evaluation

Not a data requirement according to Regulation 1107/2009/EEC or Directive 91/414/EEC.

IIIA 9.10 Other/special studies

Not a data requirement according to Regulation 1107/2009/EEC or Directive 91/414/EEC.

IIIA 9.10.1 Other/special studies - laboratory studies

Not a data requirement according to Regulation 1107/2009/EEC or Directive 91/414/EEC.

IIIA 9.10.2 Other/special studies - field studies

Not a data requirement according to Regulation 1107/2009/EEC or Directive 91/414/EEC.