Document Title

Tier 2 Summary
of Ecotoxicological Studies
for the active substance Fenhexamid (KBR 2738)

(Specification no.: 102000006806)

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 II
Document M
Section 6, Point 8

Date

2012-02-03

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CONFIDENTIALITY STATEMENT

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IIA 8 ECOTOXICOLOGICAL STUDIES

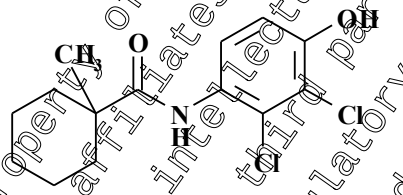
Identity of the active substance

Common name: Fenhexamid

CAS number: 126833-17-8

Chemical name (IUPAC): N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexanecarboxamide

Molecular structure:



Company code: KBR 2738

Tested metabolites

M10 = KBR 2738-benzoxazole (synonyme: Fenhexamid-benzoxazole)
M12 = 2-monochloro-KBR 2738 (synonymes: KBR 2738-3-deschloro, fenhexamid-3-deschloro)
M15 = KBR 2738-trishydroxyphenyl (synonyme: Fenhexamid-trishydroxyphenyl)
M24 = [C-C]biphenyl KBR 2738 (synonymes: KBR 2738-[C-C]biphenyl, fenhexamid-[C-C]biphenyl, BCS-CQ88719)
M39 = 1-methylcyclohexanecarboxylic acid (synonymes: KBR 2738-carbonic acid, KBR 2738-1-methylcychlohexancarbonsäure, BCS-BC75999)
M40 = 1-methylcyclohexanecarboxamide (synonyme: BCS-CQ6373)

IIA 8.1 Avian toxicity

No further studies with birds were required or conducted to address safety of fenhexamid.

IIA 8.1.1 Acute oral toxicity to a quail species, mallard duck or other bird species

Please refer to point IIA 8.1.1 (EU point IIA 8. 1.1) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.1.2 Avian dietary toxicity (5-day) test in a quail species or in a mallard duck

Please refer to point IIA 8.1.2 (EU point IIA 8.1.2) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.1.3 Avian dietary toxicity (5-day) test in a second unrelated species

Please refer to point IIA 8.1.3 (EU point 8.1.2) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.1.4 Subchronic and reproductive toxicity to birds

Please refer to point IIA 8.1.4 (EU point 8.1.3) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.2 Fish toxicity

In order to complete the aquatic risk assessment several acute toxicity studies to fish have been conducted with metabolites that can be formed in the aquatic environment. Short summaries of these studies are given below.

IIA 8.2.1 Acute toxicity of the active substance to fish

IIA 8.2.1.1 Rainbow trout

Please refer to point IIA 8.2.1.1 (EU point IIA 8.2.1) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.2.1.2 Warm water fish species

Please refer to point IIA 8.2.1.2 (EU point IIA 8.2.1) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.2.1.3 Acute toxicity of metabolites, degradation or reaction products

Metabolite M10

Report:	**IIA 8.2.1.3/01; [redacted], 2009**
Title:	Acute toxicity of fenhexamid-benzoxazole (tech.) to fish (*Oncorhynchus mykiss*) under static conditions
Document No:	**M-350526-01-1** (Rep. No: EBKBL003)
Guidelines:	EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985), OPPTS 850.1075 (Public Draft, 1996), EU Directive 92/69/EEC, C.1 (1992), OECD-Guideline No. 203 (1992)
GLP	Yes (certified laboratory)

Objective:
The aim of the study was to determine the acute toxicity of fenhexamid-benzoxazole (tech.) to Rainbow trout (*Oncorhynchus mykiss*), expressed as 96h-LC_{50} for mortality.

Material and methods:
Test item: fenhexamid-benzoxazole (tech.), analyzed content: 98.5% w / w, specified by batch code: BCS-AB54152-01-01, Origin batch no.: SES 10262-3-5, tox no.: 08294-00.
Test organism: Rainbow trout (*Oncorhynchus mykiss*), mean body length 4.3 cm, mean body weight 0.8 g., Lot F 1 / 09, were delivered on January 13, 2009. Fish were acclimated in culture tanks for at least 14 days prior to exposure. During the acclimation period, fish were fed daily with commercial trout food ([redacted], [redacted], Denmark). Feeding was discontinued 48 hrs prior to study initiation. There was < 5% mortality in the 14 days prior to start of the test. Photoperiod during the acclimation and exposure phase was 16 hrs light/ 8 hrs dark. The biomass loading during testing was 0.20 g fish / L test medium.
Ten fish in each test level were exposed for 96 h under static conditions to nominal (mean measured) concentrations of 0.125 (0.0636), 0.275 (0.159), 0.605 (0.408), 1.33 (1.11) and 2.90 (2.62) mg pure metabolite (p.m.)/L and compared to a water control and a solvent control. Dissolved oxygen concentrations ranged from 94 to 101% oxygen saturation, the pH values ranged from 7.0 to 7.4 and the water temperature ranged from 12.0°C to 12.8°C in all aquaria over the whole testing period. After 4, 24, 48, 72 and 96 hr specimens were evaluated for sublethal effects and mortality.

Fenhexamid - benzoxazole were analyzed in all test levels after 0 h, on day 2 and on day 4 of the exposure period to confirm nominal concentrations.

Findings:
Accompanying chemical analysis of fenhexamid-benzoxazole revealed recoveries between 77% and 95% of nominal values at test initiation. Mean measured values over the entire test period of 96 hours ranged between 52% and 92% of nominal values. Therefore all results were based on mean measured concentrations.
In the controls no mortality or sub-lethal effects were observed. In all test levels ≥ 0.159 mg p.m./L behavioural changes were observed during the entire exposure period. After 96 h of exposure, two fish exhibited laboured respiration at the test rate of 0.159 mg p.m./L (nominal). At the nominal test rate of 408 mg p.m./L, 3 fish exhibited behavioural effects ranging from laboured respiration, dark discoloration, abnormally long periods at the surface or bottom of aquarium, abdominal swelling and loss of equilibrium.

Cumulative mortality was observed as follows (10 fish per test level):

Exposure time	4 h		24 h		48 h		72 h		96 h	
Mean measured conc. metabolite [mg a.s./L]	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**
Control	0	0	0	0	0	0	0	0	**0**	**0**
Solvent control	0	0	0	0	0	0	0	0	**0**	**0**
0.0636	0	0	0	0	0	0	0	0	**0**	**0**
0.159	0	0	0	0	0	0	0	0	**0**	**0**
0.408	0	0	4	40	6	60	7	70	**7**	**70**
1.11	0	0	10	100	10	100	10	100	**10**	**100**
2.62	0	0	10	100	10	100	10	100	**10**	**100**

The test conditions met all validity criteria, given by the mentioned guidelines: < 5% mortality within the 48-hour settling-in period; < 10% mortality in the control (or one fish if less than ten are used); dissolved oxygen saturation > 60% throughout the test; pH variation < 1.0 units.

Conclusions:
The acute toxicity fenhexamid-benzoxazole (tech.) to rainbow trout (*Oncorhynchus mykiss*) has been investigated and based on mean measured concentrations, the 96 h - LC_{50} was calculated to be 0.391 mg p.m./L (C.I.95%: 0.271 – 0.571 mg/L). The NOEC (highest concentration without sub-lethal effects) is considered to be 0.0636 mg p.m./L. The minimum concentration causing 100% mortality (96 h) is 1.11 mg p.m./L, and the maximum concentration which did not cause any mortality (no-observed-lethal-effect concentration = NOLEC) after 96 h is 0.159 mg p.m./L.

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Metabolite M12

Report:	**IIA 8.2.1.3/02, [redacted] (2008)**
Title:	Acute toxicity of fenhexamid-3-deschloro (tech.) to fish (*Oncorhynchus mykiss*) under static conditions
Document No.	**M-345406-01-1** (Rep. No. EBKBL006)
Guidelines:	EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985), OPPTS 850.1075 (Public Draft, 1996), EU Directive 92/69/EEC, C.1 (1992), OECD-Guideline No. 203 (1992).
GLP	Yes (certified laboratory)

Objective:
The aim of the study was to determine the acute toxicity of fenhexamid-3-deschloro (tech.) to rainbow trout (*Oncorhynchus mykiss*), expressed as 96h-LC_{50} for mortality.

Material and methods:
Test item: fenhexamid-3-deschloro (tech.), report name (see CoA): KBR2738-3-deschloro, analyzed purity of active substance: 97.0% w/w, specified by batch code: AE 1186711-PU-01, origin batch code: KTS10369-2-3, AZ-No.: 13912.
Test organism: Rainbow trout (*Oncorhynchus mykiss*), mean body length 5.5 cm, mean body weight 2.0 g., Lot F 5 / 08, were delivered on July 21, 2008. Fish were acclimated in culture tanks for at least 14 days prior to exposure. During the acclimation period, fish were fed daily with commercial trout food

([redacted], Denmark). Feeding was discontinued 48 hrs prior to study initiation. Less than 5% mortality was observed in the 14 days prior to start of the test. Photoperiod during the acclimation and exposure phase was 16 hrs light/ 8 hrs dark and the biomass loading during testing was 0.50 g fish / L test medium.
Ten fish in each test level were exposed for 96 h under static conditions to nominal concentrations of 1.25, 2.50, 5.00, 10.0 and 20.0 mg pure metabolite (p.m.)/ L and compared to a water control and a solvent control. Dissolved oxygen concentrations ranged from 87 to 100% oxygen saturation, the pH values ranged from 6.9 to 7.2 and the water temperature ranged from 11.6°C to 12.2°C in all aquaria over the whole testing period. After 4, 24, 48, 72 and 96 hr specimens were evaluated for sublethal effects and mortality.

Fenhexamid-3-deschloro was analyzed in all test levels after 0 h, on day 2 and on day 4 of the exposure period to confirm nominal concentrations.

Findings:
Mean measured values of fenhexamid-3-deschloro over the entire test period of 96 hours ranged between 71% and 95% of nominal values.

In the controls no mortality or sub-lethal effects were observed. In test levels at and above 2.50 mg p.m./L, a range of behavioural changes were observed during the entire exposure period, including laboured respiration, dark discoloration, abnormally long periods on the bottom of aquarium, loss of equilibrium, mucous excretions, convulsions and death.

Cumulative mortality was observed as follows (10 fish per test level):

Exposure time	4 h		24 h		48 h		72 h		96 h	
Concentration of test item [mg p.m./L]	No. of dead	% dead	No. of dead	% dead	No. of dead	% dead	No. of dead	% dead	No. of dead	% dead
Control	0	0	0	0	0	0	0	0	**0**	**0**
Solvent control	0	0	0	0	0	0	0	0	**0**	**0**
1.25	0	0	0	0	0	0	0	0	**0**	**0**
2.50	0	0	0	0	0	0	1	10	**1**	**10**
5.00	0	0	0	0	4	40	4	40	**4**	**40**
10.0	0	0	4	40	10	100	10	100	**10**	**100**
20.0	0	0	2	20	10	100	10	100	**10**	**100**

The test conditions met all validity criteria, given by the mentioned guidelines: < 5% mortality within the 48-hour settling-in period; < 10% mortality in the control (or one fish if less than ten are used); dissolved oxygen saturation > 60% throughout the test; pH variation < 1.0 units.

Conclusions:
Test conditions met all validity criteria, given by the mentioned guidelines. The acute toxicity fenhexamid-3-deschloro (tech.) to rainbow trout (*Oncorhynchus mykiss*) has been investigated and based on nominal concentrations, the 96 h - LC_{50} was calculated by logit analysis to be 4.51 mg p.m./L (C.I.95%: 3.29 – 6.17 mg/L). The NOEC (highest concentration without sublethal effects) is considered to be 1.25 mg p.m./L. The minimum concentration causing 100% mortality (96 h) is 10.0 mg p.m./L. The maximum concentration which did not cause any mortality (no-observed-lethal-effect concentration = NOLEC) after 96h is 1.25 mg p.m./L.

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Metabolite M15

Report:	**IIA 8.2.1.3/03, [redacted] (2009)**
Title:	Acute toxicity of fenhexamid – trishydroxyphenyl (tech.) to fish *Oncorhynchus mykiss)* under static conditions – limit test
Document No:	**M-357294-01-1** (Rep. No: EBKBL012)
Guidelines:	EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985), OPPTS 850.1075 (Public Draft, 1996), EU Directive 92/69/EEC, C.1 (1992), OECD-Guideline No. 203 (1992).
GLP	Yes (certified laboratory)

Objective:
A limit test at 100 mg pure metabolite (p.m.) / L was performed in order to show that fish (*Oncorhynchus mykiss*) were not affected by the formulation at this test level.

Material and methods:
Test item: fenhexamid-trishydroxyphenyl (tech.), analyzed content of active substance: 98.7% w / w; specified by batch code: BCS-CO15598-01-01; origin batch code: RDL 306-12-5, tox no.: 08444-00.
Test organism: Rainbow trout *(Oncorhynchus mykiss)*, mean body length 5.5 cm, mean body weight 1.7 g. Lot F 1/09 was delivered on January 13, 2009. Fish were acclimated in culture tanks for at least 14 days prior to exposure. During the acclimation period, fish were fed daily with commercial trout food ([redacted], Denmark). Feeding was discontinued 48 hrs prior to and during the study. Photoperiod during the acclimation phase and testing was 16 hrs light/ 8 hrs dark. The biomass loading during testing was 0.64 g fish / L test medium.
Thirty fish (fifteen fish in each aquarium, a and b) were exposed in a limit test for 96 h under static test conditions to a nominal concentration of 101 (100) mg test item (pure metabolite) / L and compared to a water control (fifteen fish in each aquarium, a and b). Dissolved oxygen concentrations ranged from 89 to 101% oxygen saturation, the pH values ranged from 6.8 to 7.1 and the water temperature ranged from 12.0°C to 12.6°C in all aquaria over the whole testing period. After 4, 24, 48, 72 and 96 hr specimens were evaluated for sublethal effects and mortality.
Recoveries of fenhexamid-trishydroxyphenyl were measured in all test levels on day 0, day 2 and day 4 of the exposure period to confirm nominal concentrations.

Findings:
Based on analytical determination of fenhexamid-trishydroxyphenyl (in water by HPLC - UV) measured values of 0% - 106% of nominal were found over the whole testing period of 96 hours. At test start (0 hours) 76% and 106% of the nominal concentrations were detected in aquarium a and b. On day 2 and day 4 of exposure no fenhexamid-trishydroxyphenyl was found. The stability of fenhexamid-trishydroxyphenyl in aqueous solution seemed to be pH dependent. Therefore an additional stability test was performed to determine possible hydrolysis of the test item under study similar conditions. This analysis revealed a complete degradation of the test item in test media within 30 minutes at pH 8.2.
Therefore, the results are expressed based on the nominal concentrations of the test item.

There were neither any sub-lethal effects nor any mortality in the control group, although all exposed fish manifested laboured respiration after 96 hours of exposure.

Cumulative mortality was observed as follows (with a total number of 30 fish tested in each test level / 15 fish per aquarium):

Exposure time	**4 h**		**24 h**		**48 h**		**72 h**		**96 h**	
Test level [mg p.m./L]	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**
Control a	0	0	0	0	0	0	0	0	**0**	**0**
Control b	0	0	0	0	0	0	0	0	**0**	**0**
100 a	0	0	0	0	0	0	0	0	**0**	**0**
100 b	0	0	0	0	0	0	0	0	**0**	**0**

The test conditions met all validity criteria, given by the mentioned guidelines: < 5% mortality within the 48-hour settling-in period; < 10% mortality in the control (or one fish if less than ten are used); dissolved oxygen saturation > 60% throughout the test; pH variation < 1.0 units.

Conclusions:
Test conditions met all validity criteria, given by the mentioned guidelines. In a limit test at 100 mg/L fenhexamid-trishydroxyphenyl (tech.) did not cause any mortality to Rainbow trout *Oncorhynchus mykiss*. Therefore the 96 h-LC_{50} is clearly above 100 mg p.m./L.

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Metabolite M24

Report:	**IIA 8.2.1.3/04; [redacted], 2012**
Title:	Acute toxicity of KBR 2738–[C-C] biphenyl (BCS-CQ88719) to fish (*Oncorhynchus mykiss*) under static conditions
Document No:	**M-422423-01-1** (Rep. No: EBKBP003)
Guidelines:	EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985), OPPTS 850.1075 (Public Draft, 1996), EU Directive 92/69/EEC, C.1 (1992), OECD-Guideline No. 203 (1992).
GLP	Yes (certified laboratory)

Objective:
The aim of the study was to determine the acute toxicity of the test item to Rainbow trout (*Oncorhynchus mykiss*), expressed as 96h-LC_{50}.

Material and methods:
Test item: KBR 2738 - [C-C]biphenyl (BCS-CQ88719), analyzed purity of active substance: 95.3 %; specified by origin batch number: BCOQ 6050-33-22, Batch code: BCS-CQ88719-01-01, LIMS number: 1133540, Certificate number: MZ 00456, tox no.: 09420-00.

Test organism: Rainbow trout (*Oncorhynchus mykiss*), mean body length 4.4 cm, mean body weight 0.8 g. Lot F 22 / 11 were delivered on September 15, 2011. The biomass loading for the controls in this test was 0.60 g fish / L test medium and 0.20 g fish / L test medium for the treatment aquaria.
Ten fish in each test level were exposed for 96 h under static conditions to nominal concentrations of 0.342, 0.751, 1.65, 3.63 and 8.00 mg test item / L against control and a solvent control with thirty fish.
During the test, fish were examined after four hours and then daily for mortalities and signs of poisoning.

Within the study the pH-value, the oxygen saturation level and the temperature were measured with commercial measurement devices, daily.
Dissolved oxygen concentrations ranged from 82 to 97% oxygen saturation, the pH values ranged from 6.7 to 7.3 and the water temperature ranged from 11.0°C to 12.6°C in all aquaria over the whole testing period. After 4, 24, 48, 72 and 96 hr specimens were evaluated for sublethal effects and mortality.

Findings:
The analytical determination of (in water by HPLC - UV) revealed mean recoveries of 99 to 109% of nominal over the whole testing period of 96 hours. Thus the analytical findings confirm the nominal concentration. Therefore the results of this study are given based on the nominal concentrations.
In the controls no mortalities or sub-lethal findings were observed.
In all test levels ≥ 0.342 mg test item / L behavioral changes were observed during the entire exposure period. After 96 h of exposure towards the nominal concentration of 0.342 mg test item / L six fish showed the following behavioural symptoms:

- remaining for unusually long periods on the bottom of the aquarium
- were inactive or displayed abnormally low activity

Cumulative mortality was observed as follows (10 fish per test level):

Exposure time	**4 h**		**24 h**		**48 h**		**72 h**		**96 h**	
BCS-CQ88719 [mg/L]	**no. of dead**	**% dead**	**no. of dead**	**% dead**	**no. of dead**	**% dead**	**no. of dead**	**% dead**	**no. of dead**	**% dead**
Control	0	0	0	0	0	0	0	0	**0**	**0**
Solvent control	0	0	0	0	0	0	0	0	**0**	**0**
0.342	0	0	0	0	0	0	0	0	**0**	**0**
0.751	0	0	0	0	0	0	0	0	**0**	**0**
1.650	0	0	0	0	0	0	0	0	**0**	**0**
3.630	0	0	3	30	7	70	9	90	**9**	**90**
8.000	1	10	10	100	10	100	10	100	**10**	**100**

Conclusions:
Test conditions met all validity criteria, given by the mentioned guidelines. There was less than 5% mortality within the 48-hour setting-in period and ≤ 10% mortality in the control(s). Dissolved oxygen saturation was greater or equal to 60% throughout the test and pH variation was ≤ 1.0 units.

Based on nominal concentrations the following results were determined:

Test item:	KBR 2738 – [C-C] biphenyl (BCS-CQ88719)
Test object:	Rainbow trout (*Oncorhynchus mykiss*)
Exposure:	96h static design
LC_{50} 96h (95% C.I.):	**2.62 mg test item/L (C.I. 95%: 2.12 – 3.27 mg/L)**
LOEC: (Lowest concentration with an effect)	0.342 mg test item/L
NOEC: (Highest concentration without toxic effects)	< 0.342 mg test item/L
NOLEC: (Highest concentration causing no mortality)	1.65 mg test item/L
100% mortality	8.0 mg/L test item

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Metabolite M39

Report:	**IIA 8.2.1.3/05; [redacted], 2012**
Title:	Acute toxicity of KBR 2738 - 1- methylcyclohexancarbonsäure (BCS-BC75999, tech.) to fish (*Oncorhynchus mykiss*) under static conditions (limit test)
Document No:	**M-422291-01-1** (Rep. No: EBKBL028)
Guidelines:	EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985), OPPTS 850.1075 (Public Draft, 1996), EU Directive 92/69/EEC, C.1 (1992), OECD-Guideline No. 203 (1992).
GLP	Yes (certified laboratory)

Objective:
A limit test at 10.0 mg test item/L was performed in order to demonstrate that fish (*Oncorhynchus mykiss*) were not affected by the test item at this test level.

Material and methods:
Test item: fenhexamid-1-methylcyclohexancarbonsäure (BCS-BC 75999 tech.), analyzed content: 98.1% w/w; specified by batch code: AE 0308769-01-01, Origin batch no.: SES 11033-2, tox no.: 09559-00.
Test organism: Rainbow trout (*Oncorhynchus mykiss*), mean body length 4.4 cm, mean body weight 0.8 g., Lot F 22 / 11, were delivered on September 15, 2011. The biomass loading during testing was 0.60 g fish/L test medium. All test fish were held in culture tanks on a 16/8 hour light/dark photoperiod and observed for at least 14 days prior to testing. During the acclimation period, fish were fed daily with commercial trout food ([redacted], Denmark). Feeding was discontinued 48 hrs prior to study initiation.
There was < 5% mortality in the 14 days prior to start of the test.
Thirty fish were exposed in a limit test for 96 h under static test conditions to a nominal concentration of 10.0 (9.81) mg test item (a.s.)/L against a water control and a solvent control with further 30 fish. Dissolved oxygen concentrations ranged from 82 to 92 oxygen saturation, the pH values ranged from 6.7 to 7.3 and the water temperature ranged from 11.0°C to 11.7°C in all aquaria over the whole testing period. After 4, 24, 48, 72 and 96 hr specimens were evaluated for sublethal effects and mortality. Fenhexamid - 1-methylcyclohexancarbonsäure were analyzed in all test levels after 0 h, on day 2 and on day 4 of the exposure period to confirm nominal concentrations.

Findings:
The analytical determination of BCS-BC75999 (in water by HPLC - UV) revealed a mean recovery of 103% of nominal over the whole testing period of 96 hours at the limit test concentration of 10 mg/L. The analytical findings confirm the nominal concentration. Therefore the results of this study are given based on the nominal concentrations.
There was less than 5% mortality within the 48-hour settling-in period and ≤ 10% mortality in the control(s). Dissolved oxygen saturation was greater or equal to 60% throughout the test and pH variation was ≤ 1.0 units.

Cumulative mortality was observed as follows (30 fish per test level):

Exposure time	4 h		24 h		48 h		72 h		96 h	
BCS-BC75999 tech. [mg/L]	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**	**No. of dead**	**% dead**
Control	0	0	0	0	0	0	0	0	**0**	**0**
Solvent control	0	0	0	0	0	0	0	0	**0**	**0**
10.0	0	0	0	0	0	0	0	0	**0**	**0**

Conclusions:
The limit test showed that at 10.0 mg test item/L the metabolite KBR 2738 - 1- methylcyclohexan-carbonsäure (BCS-BC75999, tech.) did not cause any mortality to Rainbow trout (*Oncorhynchus mykiss*). The 96h-LC_{50} is greater than 10.0 mg/L. There were no mortalities or sublethal effects noted at this concentration. The 96 h NOEC is ≤ 10.0 mg/L. The minimum concentration causing 100% mortality (96 h) is >10 mg/L, and the maximum concentration which did not cause any mortality no-observed-lethal-effect concentration = NOLEC) after 96 h is 10 mg /L.

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Metabolite M40

Report:	**IIA 8.2.1.3/06; [redacted], 2010**
Title:	BCS-CQ6373 (fenhexamid photolysis metabolite) – Acute toxicity to fish (*Oncorhynchus mykiss*) (limit test, orientating results)
Document No:	**M-369106-01-1** (Rep. No: EBKBL024)
Guidelines:	EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985), OPPTS 850.1075 (Public Draft, 1996), EU Directive 92/69/EEC, C.1 (1992), OECD-Guideline No. 203 (1992).
GLP	No (orientating limit test)

Objective: A limit test at 100 mg pure metabolite (p.m.) /L was performed in order to show that fish (*Oncorhynchus mykiss*) were not affected by the formulation at this test level.

Material and methods: Test item: Chemical code: BCS-CQ63763, certificate of analysis: AZ 16507, LIMS No.: 1008293, Chargen code: BCS-CQ63763-PU-01, purity: 99.3%, indication fungicide.
Basic techniques are used as described under OECD 203 with the following major differences:
-No analytical confirmation of the test item concentration under exposure conditions
-Reduced number of fish per test level
-No work under GLP
Preparation: The test substance was solved with DMF and added into the aquaria directly to yield the corresponding test concentration (maximum load of Dimethylformamide (DMF) in the aquaria is 1 mL / L).
Test animals and test conditions: Fish were not fed 48 hours prior to and during the study period. Mean body length: 2.9 ± 0.4 cm (x ± s), mean body weight: 0.3 ± 0.1 g (x ± s), loading density: 0.1 g fish / L, water: Volume = 15 L, pH 6.9 – 7.1, temperature: 12°C, dissolved oxygen: > 80% oxygen saturation, photo period: 16 hours light / 8 hours dark, total hardness: 2.7°dH reconstituted standard water prepared according to ISO was used.

Results: Cumulative Mortalities and Behavioural Observations (Symptoms)

Nominal concentration in mg test item/L	Findings (dead – affected with symptoms – total number tested)				Observations on the behaviour
	24 hours	48 hours	72 hours	96 hours	
Solvent control	0-0-5	0-0-5	0-0-5	0-0-5	
100	0-0-5	0-0-5	0-0-5	0-1-5 BO, DF	Clear test medium

BO = lying on the bottom of the aquarium, DF = darkened coloration

Conclusion: Fish LC_{50} (96 hours) > 100 mg p.m. / L (orientating results)

IIA 8.2.2 Chronic toxicity to fish

Not performed with fenhexamid, as fish early life stage test is available.

IIA 8.2.3 Chronic toxicity test (28 day exposure) to juvenile fish

Not performed with fenhexamid, as fish early life stage test is available.

IIA 8.2.4 Fish early life stage toxicity test

Please refer to point IIA 8.2.4 (EU point IIA 8.2.2.2) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.2.5 Fish life cycle test

In view of the fish early life stage study and the study on bioconcentration (see IIA 8.2.6) no fish lifecycle test was performed with fenhexamid.

IIA 8.2.6 Bioconcentration potential in fish

IIA 8.2.6.1 Bioconcentration potential of the active substance in fish

Please refer to point IIA 8.2.6.1 (EU point IIA 8.2.3) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.2.6.2 Bioconcentration potential of metabolites, degradation and reaction products

Please refer to point IIA 8.2.6.2 (EU point IIA 8.2.3) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.2.7 Aquatic bioavailability/biomagnification/depuration

No EC data requirement according to Regulation 1107/2009/EEC or Directive 91/414/EEC..

IIA 8.3 Aquatic species other than fish and aquatic species field testing

In order to complete the aquatic risk assessment several acute studies on aquatic species (other than fish) have been conducted with metabolites that can be formed in the aquatic environment. Short summaries of these studies are given below.

IIA 8.3.1 Acute toxicity to aquatic invertebrates

After Annex I listing of fenhexamid additional studies with fenhexamid metabolites were performed. Short summaries of these studies are given below. A study, performed with the active substance, is given under point IIA 8.3.1.1 (EU point IIA 8.2.4) of the EU dossier submitted for Annex I listing.

IIA 8.3.1.1 Acute toxicity (24 and 48 hour) for Daphnia preferably (*Daphnia magna*)

Metabolite M10

Report:	**IIA 8.3.1.1/02; [redacted], 2009**
Title:	Acute toxicity of fenhexamide-benzoxazole to the waterflea *Daphnia magna* in a static laboratory test system
Document No:	**M-345853-01-1** (Rep. No: EBKBL002)
Guidelines:	OECD Guideline 202, (2004) U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72-2 (1982) EEC Directive 92/69/EEC, part C.2 (1992) OPPTS Guideline 850.1010 Draft (1996), modified JMAFF 12 Nousan No. 8147 (2000)
GLP	Yes (certified laboratory)

Objective: The study was performed to detect possible effects of the test item on mobility of *Daphnia magna* caused by 48 hours of exposure in a static laboratory test system, expressed as EC_{50} for immobilisation.

Material and methods: Fenhexamide-benzoxazole, batch code: BCS-AB54152-01-01, origin batch no.: SES 10262-3-5, purity: 98.5 % w/w (TOX 08294-00); *Daphnia magna* (1st instars < 24 h old, 6 x 5 animals per concentration), exposed in a static test system for 48 hours to nominal concentrations of 0, 0.625, 1.25, 2.50, 5.00 and 10.0 mg pure metabolite (p.m.) /L without feeding.
The content of fenhexamide-benzoxazole in exposure media was measured for verification of the exposed test item concentrations.

Findings: The accompanying chemical analysis of fenhexamide-benzoxazole in the freshly prepared test solutions at test initiation ranged between 72% and 91% (mean: 84%) of the corresponding nominal concentrations. The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 46% and 79% (mean: 63%) of nominal. The results showed a decreasing amount of the test item over the two days of incubation.
Accompanying to the analytical results, the observed precipitations in the test solutions on day 0 of test concentration of 5 and 10 mg p.m./L, indicated that the test item was not fully dissolved in the test medium. Thus for calculation of the EC_{50}, mean measured test concentrations (mean of analytical measurements of day 0 and day 2) were used.
No contaminations of fenhexamide-benzoxazole were detected in samples from untreated water control.

Toxicity to *Daphnia magna* (based on mean measured concentrations):

Mean measured concentration (mg p.m./L)	Exposed daphnids (=100%)	Immobilised daphnids			
		24 h		48 h	
		n	%	n	%
Control	30	0	0	0	0
Solvent control *	30	0	0	0	0
0.42 (0.625)	30	0	0	0	0
0.90 (1.25)	30	3	10	11	36.7
1.85 (2.50)	30	17	56.7	25	83.3
4.20 (5.00)	30	27	90.0	30	100
7.05 (10.0)	30	30	100	30	100

* Solvent control + 0.1 mL dimethylformamide/L
( ) corresponding to nominal test concentration

Observations: No immobilities or other effects on behaviour occurred in untreated control within 48 hours of exposure.

Conclusions: Based on mean measured concentrations of fenhexamide-benzoxazole, the EC_{50} for immobilisation after 48 hours of static exposure was 1.13 mg p.m./L (95% confidence limits: 0.96 to 1.32 mg p.m./L).
The corresponding EC_{50} for immobilisation after 24 hours of static exposure was 1.81 mg p.m./L (95% confidence limits: 1.52 to 2.15 mg p.m./L).

Statistical results of probit analysis conducted for determination of EC_{50} values:

Probit analysis for data obtained after	EC_{50} mg p.m./L (mean measured)	lower 95% CI mg p.m./L (mean measured)	upper 95% CI mg p.m./L (mean measured)
24 hours	1.81	1.52	2.15
48 hours	**1.13**	0.96	1.32

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Metabolite M12

Report:	**IIA 8.3.1.1/03; [redacted]; 2009**
Title:	Acute toxicity of fenhexamid-3-deschloro to the waterflea *Daphnia magna* in a static laboratory test system
Document No:	**M-345837-01-1** (Rep. No: EBKBL005)
Guidelines:	OECD Guideline 202 (2004) U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72-2 (1982) EEC Directive 92/69/EEC, part C.2 (1992) OPPTS Guideline 850.1010 Draft (1996), modified JMAFF 12 Nousan No. 8147 (2000)
GLP	Yes (certified laboratory)

Objective: The study was performed to detect possible effects of the test item on mobility of *Daphnia magna* caused by 48 hours of exposure in a static laboratory test system, expressed as EC_{50} for immobilisation.

Material and methods: Fenhexamide-3-deschloro, batch code: AE 1186711-PU-01, origin batch no.: KTS10369-2-3, purity: 97.0% w/w (AZ 13912); *Daphnia magna* (1st instars < 24 h old, 6 × 5 animals per concentration), exposed in a static test system for 48 hours to nominal concentrations of 0, 1.94, 4.27, 9.39, 20.7 and 45.5 mg pure metabolite (p.m.)/L without feeding. The content of fenhexamide-3-deschloro in exposure media was measured for verification of the exposed test item concentrations.

Findings: The accompanying chemical analysis of fenhexamide-3-deschloro in the freshly prepared test solutions at test initiation revealed recoveries between 88% and 102% (mean: 97%) of the corresponding nominal concentrations.
The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 89% and 101% (mean: 95%) of nominal, demonstrating that the nominal concentrations have been successfully maintained over the entire test period. Therefore the results are based on the nominal concentration. No contaminations of fenhexamide-3-deschloro were detected in samples from untreated water control.

Toxicity to *Daphnia magna* (based on nominal concentrations):

Nominal test concentration (mg p.m./L)	Exposed daphnids (=100%)	Immobilised daphnids			
		24 h		48 h	
		n	%	n	%
Control	30	0	0	0	0
Solvent control*	30	0	0	0	0
1.94	30	1	3.3	1	3.3
4.27	30	0	0	0	0
9.39	30	5	16.7	8	26.7
20.7	30	6	20.0	24	80.0
45.5	30	15	50.0	30	100

* Solvent control + 0.18 mL dimethylformamide/L

Observations: No immobilities or other effects on behaviour occurred in untreated control within 48 hours of exposure.

Conclusions: Based on nominal concentrations of fenhexamide-3-deschloro, the EC_{50} for immobilisation after 48 hours of static exposure was 12.6 mg p.m./L (95% confidence limits could not be determined due to mathematical reasons).
The corresponding EC_{50} for immobilisation after 24 hours of static exposure was 52.4 mg p.m./L (95% confidence limits: 28.6 to 95.8 mg p.m./L).

Statistical results of probit analysis conducted for determination of EC_{50} values:

Probit analysis for data obtained after	EC_{50} mg p.m./L (nominally)	lower 95% CI mg p.m./L (nominally)	upper 95% CI mg p.m./L nominally
24 hours	52.4	28.6	95.8
48 hours	**12.6**	n.d.	n.d.

n.d. = not determined due to mathematical reasons

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Metabolite M15

Report:	**IIA 8.3.1.1/04; [redacted], 2009**
Title:	Acute toxicity of fenhexamid-trishydroxyphenyl (tech.) to the waterflea *Daphnia magna* in a static laboratory test system
Document No:	**M-358250-01-1** (Rep. No: EBKBL011)
Guidelines:	OECD Guideline 202, (2004) U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72-2 (1982) EEC Directive 92/69/EEC, part C.2 (1992) OPPTS Guideline 850.1010 Draft (1996), modified JMAFF 12 Nousan No. 8147 (2000)
GLP	Yes (certified laboratory)

Objective: The study was performed to detect possible effects of the test item on mobility of *Daphnia magna* caused by 48 hours of exposure in a static laboratory test system, expressed as EC_{50} for immobilisation.

Material and methods: Fenhexamide-trishydroxyphenyl (tech.), batch code: BCS-CO15598-01-01, origin batch no.: RDL 306-12-5, purity: 98.7% w/w (TOX 08444-00); *Daphnia magna* (1st instars < 24 h old, 6 x 5 animals per concentration), exposed in a static test system for 48 hours to nominal concentrations of 0, 6.25, 12.5, 25.0, 50.0 and 100 mg pure metabolite (p.m.) /L without feeding.
The content of fenhexamide-trishydroxyphenyl in exposure media was measured for verification of the exposed test item concentrations.

Findings: Neither in samples from start of exposure nor in samples from test termination any amounts of fenhexamid-trishydroxyphenyl were found.
The stability of fenhexamid-trishydroxyphenyl in aqueous solution seemed to be pH dependent. Therefore an additional stability test was performed to determine possible hydrolysis of the test item under study conditions. The accompanying chemical analysis revealed a complete degradation of the test item in Elendt M7 media within 30 minutes at pH 8.2. Therefore the observed biological effects have to be related to the sum of degradation products of fenhexamid-trishydroxyphenyl in aqueous solution.
Nevertheless, the results are expressed based on the nominal concentrations of the test item.

Toxicity to *Daphnia magna* (based on mean nominal concentrations):

Nominal test concentration (mg p.m./L)	Exposed daphnids (=100%)	Immobilised daphnids			
		24 h		48 h	
		n	%	n	%
Control	30	0	0	0	0
6.25	30	0	0	0	0
12.5	30	0	0	0	0
25	30	5	17	7	23
50	30	30	100	30	100
100	30	30	100	30	100

Observations: No immobilities or other effects on behaviour occurred in untreated control within 48 hours of exposure.

Conclusions: Based on the initial nominal concentrations of fenhexamide-trishydroxyphenyl, the EC_{50} for immobilisation after 48 hours of static exposure was 26 mg p.m./L (95% confidence limits: 19 to 37 mg p.m./L).
The corresponding EC_{50} for immobilisation after 24 hours of static exposure was 27 mg p.m./L (95% confidence limits: 19 to 37 mg p.m./L).

Statistical results of probit analysis conducted for determination of EC_{50} values:

Probit analysis for data obtained after	EC_{50} mg p.m./L (nominally)	lower 95% CI mg p.m./L (nominally)	upper 95% CI mg p.m./L (nominally)
24 hours	27	19	37
48 hours	**26**	19	37

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Metabolite M24

Report:	**KIIA 8.3.1.1/05; [redacted], 2012**
Title:	Acute toxicity of BCS-CQ88719 (KBR 2738-[C-C] biphenyl to the waterflea *Daphnia magna* in a static laboratory test system – Limit test
Document No:	**M-423120-01-1** (Rep. No: EBKBL030)
Guidelines:	OECD Guideline 202, (2004) EC Council Regulation No 440/2008, Method C 2 (2008)
GLP	Yes (certified laboratory)

Objective: The study was performed, to verify the absence of treatment-related effects on mobility of *Daphnia magna* over 48 hours under static exposure conditions, when exposed to a limit concentration of 20 mg BCS-CQ88719 per litre test solution.

Material and methods: BCS-CQ88719 (KBR 2738 - [C-C]biphenyl) ,batch BCS-CQ88719-01-01, purity: 95.3% w/w (TOX 09420-00), *Daphnia magna* (1st instars < 24 h old, 10 × 5 animals per concentration), exposed in a static test system for 48 hours to nominal concentrations of 0 (pure water control + solvent control) and 20 mg pure metabolite/L without feeding.
The content of BCS-CQ88719 in exposure media was measured for verification of the test item concentrations.

Findings: No immobilities or other effects on behaviour occurred in untreated control within 48 hours of exposure.
The accompanying chemical analysis of BCS-CQ88719 revealed recoveries of 100% of nominal at the start and 111% of nominal at the end of the exposure period.
No contaminations of BCS-CQ88719 were detected in samples from untreated water control.

Since the nominal concentration of 20 mg/L has been successfully maintained over the entire test period all reported results are based on the nominal concentration.

Toxicity to *Daphnia magna* (based on nominal concentrations):

Treatment group	Exposed daphnids (=100%)	Immobilised daphnids			
		24 h		48 h	
		n	%	n	%
Pure water control	50	0	0	0	0
Solvent control*)	50	0	0	0	0
20 mg BCS-CQ88719 / L	50	0	0	14	28

*) 0.1 mL dimethylformamide

Conclusions: Based on the observed immobilisation rate of 28% during 48 hours of exposure to a limit concentration of 20 mg BCS-CQ88719/L, the corresponding EC_{50} is higher than 20 mg pure metabolite /L.

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Metabolite M39

Report:	**KIIA 8.3.1.1/06; [redacted]; 2012**
Title:	Acute toxicity of BCS-BC7599 (KBR 2738 – carbonic acid) to the waterflea *Daphnia magna* in a static laboratory test system
Document No:	**M-423128-01-1** (Rep. No: EBK2004)
Guidelines:	OECD Guideline 202, (2004) EC Council Regulation No 440/2008, Method C 2 (2008)
GLP	Yes (certified laboratory)

Objective: The study was performed, to detect possible effects of BCS-BC75999 on mobility of *Daphnia magna* caused by 48 hours of exposure in a static laboratory test system, expressed as EC_{50} for immobilisation.

Material and methods: BCS-BC75999, batch AE0308769-01-01, purity: 98.1% w/w (TOX 09559-00); *Daphnia magna* (1st instars < 24 h old; 6 × 5 animals per concentration), exposed in a static test system for 48 hours to nominal concentrations of 0 (pure water control) 6.25, 12.5, 25.0, 50.0 and 100 mg pure metabolite/L without feeding.
The content of BCS-BC75999 in exposure media was measured for verification of the test item concentrations.

Findings: The accompanying chemical analysis of BCS-BC75999 in the freshly prepared test solutions at test initiation ranged between 94% and 103% (mean: 100%) of the corresponding nominal concentrations.
The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 98% and 105% (mean: 102%) of nominal, demonstrating stability in the test system.
No contaminations of BCS-BC75999 were detected in samples from untreated water control.
Since the nominal test concentrations have been successfully maintained over the entire test period all reported results are based on the nominal concentration.

Toxicity to *Daphnia magna* (based on nominal concentrations):

Nominal test concentrations (mg pure metabolite / L)	Exposed daphnids (=100%)	Immobilised daphnids			
		24 h		48 h	
		n	%	n	%
Control	30	0	0	0	0
6.25	30	0	0	0	0
12.5	30	0	0	0	0
25	30	0	0	3	10
50	30	0	0	5	16.7
100	30	3	10	6	20

Conclusions: Statistical EC_{50} calculation based on nominal concentrations of BCS-BC75999, revealed the following results.

Probit analysis for data obtained after	EC_{50} mg pure metabolite / L (nominally)	Lower 95% CI mg pure metabolite / L (nominally)	Upper 95% CI mg pure metabolite / L (nominally)
24 hours	**n.d.**	n.d.	n.d.
48 hours	**138**	32.9	582

n.d.: not determined due to inappropriate database

IIA 8.3.1.2 Acute toxicity (24 and 48 hour) for representative species of aquatic insects

As the products containing the active substance fenhexamid are not to be used directly on surface water, studies on representative species from the groups of aquatic insects are not triggered.

IIA 8.3.1.3 Acute toxicity (24 and 48 hour) for representative species of aquatic crustaceans (species unrelated to Daphnia)

As the products containing the active substance fenhexamid are not to be used directly on surface water, studies on representative species from the groups of aquatic insects, aquatic crustaceans (species unrelated to Daphnia) are not triggered.

IIA 8.3.1.4 Acute toxicity (24 and 48 hour) for representative species of aquatic gastropod molluscs.

As the products containing the active substance fenhexamid are not to be used directly on surface water, studies on representative species from the group of aquatic gastropod molluscs are not triggered.

IIA 8.3.2 Chronic toxicity to aquatic invertebrates

IIA 8.3.2.1 Chronic toxicity in Daphnia magna (21-day)

Please refer to point IIA 8.3.2.1 (EU point IIA 8.2.5) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.3.2.2 Chronic toxicity for representative species of aquatic insects

As the products containing the active substance fenhexamid are not to be used directly on surface water, studies on representative species from the groups of aquatic insects are not triggered.

IIA 8.3.2.3 Chronic toxicity for representative species of aquatic gastropod molluscs

A chronic toxicity test on aquatic gastropods is not triggered for fenhexamid because formulated products containing the active substance are not proposed for direct application on surface water.

IIA 8.3.3 Aquatic field testing

Since the preparations containing the active substance fenhexamid are not to be used directly on surface water, aquatic field studies are not triggered.

IIA 8.4 Effects on algal growth and growth rate (2 species)

In order to complete the aquatic risk assessment several studies on algal species have been conducted with metabolites that can be formed in the aquatic environment. Short summaries of these studies are given below. Studies, performed with the active substance are given under point IIA 8.4 (EU point IIA 8.2.6) of the EU dossier submitted for Annex I listing.

Metabolite M10

Report:	**KIIA 8.4/03; [redacted]; 2010**
Title:	*Pseudokirchneriella subcapitata* growth inhibition test with fenhexamid-benzoxazole (techn.)
Document No:	**M-362991-01-1** (Rep. No: EBKBL007)
Guidelines:	OECD Guideline 201: "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (March 23, 2006)
GLP	Yes (certified laboratory)

Objective: The aim of the study was to determine the influence of the test item on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and EC_x for growth rate of algal biomass (cells per volume).

Material and methods: Fenhexamid-benzoxazole (techn.) purity: 98.5% was tested, specified by origin batch number: SES 10262-3-5, certificate number: AZ 15230 and customer order number: TOX08294-00. *Pseudokirchneriella subcapitata* (freshwater microalgae, formerly known as *Selenastrum capricornutum*) were exposed in a chronic multigeneration test for 3 days under static exposure conditions to nominal (geometric mean measured) concentrations of 0.238 (0.163), 0.763 (0.553), 2.44 (1.90), 7.81 (5.63) and 25.0 (9.25) mg pure metabolite (p.m.)/L in comparison to controls. The pH values ranged from 7.8 to 8.2 in the controls and the incubation temperature ranged from 21.9°C to 22.1°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7944 lux.
Quantitative amounts of fenhexamid-benzoxazole were measured in all treatment groups and in the controls on day 0 and day 3 of the exposure period.

Findings: Test conditions met all validity criteria, given by the mentioned guideline.

The analytical findings of fenhexamid-benzoxazole in the treatment levels found on day 0 were 38% to 76% of nominal (average 67%). On day 3 analytical findings of 36% to 80% of nominal (average 65%) were found. Because of low analytical findings due to the limited solubility of fenhexamid-benzoxazole, all results are based on geometric mean measured test concentrations.

The static 72 hour algae growth inhibition test provided the following effects:

Geometric mean measured concentration [mg p.m./L]	Cell number after 72 h (means) per mL	(0-72h)-average specific growth rates [days^{-1}]	Inhibition of average specific growth rate [%]*	Doubling time of algae cells [days]
Water control	574 000	1.350	-	0.516
Solvent control	555 000	1.338	-	0.513
Pooled controls	565 000	1.344	-	0.518
0.163	546 000	1.333	0.8	0.520
0.553	538 000	1.328	1.2	0.522
1.90	486 000	1.295	3.7	0.535
5.63	383 000	1.215	9.6	0.570
9.25	318 000	1.153	14.2	0.601

test initiation with 10,000 cells/mL
*compared to pooled controls

Conclusions: The (0 - 72 h)-E_rC_{50} for fenhexamid-benzoxazole (techn.) is > 9.25 mg p.m./L and the (0 - 72 h) - NOE_rC is 0.553 mg p.m./L based on geometric mean measured concentration.

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Metabolite M12

Report:	**KIIA 8.4/04; [redacted]; 2009**
Title:	*Pseudokirchneriella subcapitata* growth inhibition test with fenhexamid-3-deschloro (techn.)
Document No:	**M-345417-01-1** (Rep. No: EBKBL004)
Guidelines:	OECD Guideline 201: "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (March 23, 2006)
GLP	Yes (certified laboratory)

Objective: The aim of the study was to determine the influence of the test item on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and ECx for growth rate of algal biomass (cells per volume).

Material and methods: Fenhexamid-3-deschloro (techn.) purity: 97.0% was tested, specified by origin batch number: KTS10369-2-3, certificate number: AZ 13912 and LIMS number: 0700881.
Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as *Selenastrum capricornutum*) were exposed in a chronic multigeneration test for 3 days under static exposure conditions to nominal concentrations of 0.238, 0.763, 2.44, 7.81 and 25.0 mg pure metabolite (p.m.) /L in comparison to controls. The pH values ranged from 8.0 to 8.7 in the controls and the incubation temperature ranged from 21.9°C to 22.1°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7146 lux.

Quantitative amounts of fenhexamid-3-deschloro were measured in all treatment groups and in the controls on day 0 and day 3 of the exposure period.

Findings: Test conditions met all validity criteria, given by the mentioned guideline.
The analytical findings of fenhexamid-3-deschloro in the treatment levels found on day 0 were 71% to 102% of nominal (average 90%). On day 3 analytical findings of 84% to 94% of nominal (average 89%) were found. All results are based on nominal test concentrations of the metabolite.

The static 72 hour algae growth inhibition test provided the following effects:

Nominal concentration [mg p.m./L]	Cell number after 72 h (means) per mL	(0-72h)-average specific growth rates [days^{-1}]	Inhibition of average specific growth rate [%]*	Doubling time of algae cells [days]
Control	523 000	1.316	-	0.527
Solvent control	507 000	1.301	-	0.533
Pooled control	515 000	1.309	-	0.530
0.238	450 000	1.267	3.2	0.547
0.763	465 000	1.279	2.2	0.542
2.44	415 000	1.240	5.2	0.559
7.81	305 000	1.138	13.0	0.609
25.0	283 000	1.115	14.8	0.622

test initiation with 10,000 cells/mL
* compared to pooled controls

Conclusions: The (0 - 72 h)-E_rC_{50} for fenhexamid-3-deschloro (techn.) is > 25.0 mg p.m./L and the (0 - 72 h) - NOE_rC is 0.763 mg p.m./L.

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Metabolite M15

Report:	**KIIA 8.4/05; [redacted]; 2010**
Title:	*Pseudokirchneriella subcapitata* growth inhibition test with fenhexamid-trishydroxyphenyl
Document No:	**M-367188-01-1** (Rep. No: EBKBL010)
Guidelines:	OECD Guideline 201: "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (March 23, 2006)
GLP	Yes (certified laboratory)

Objective: The aim of the study was to determine the influence of the test item on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and ECx for growth rate of algal biomass (cells per volume).

Material and methods: Fenhexamid-trishydroxyphenyl analysed purity: 98.7 % w/w was tested, specified by origin batch no.: RDL 306-12-5, TOX no.: 08444-00 and LIMS no.: 0836109.
Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as *Selenastrum capricornutum*) were exposed in a chronic multigeneration test for 3 days under static exposure conditions to nominal concentrations of 0.954, 3.05, 9.77, 31.3 and 100 mg pure metabolite (p.m.)/L in comparison to a control. The pH values ranged from 7.8 to 8.8 in the controls and the incubation temperature ranged from 21.8°C to 21.9°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 8090 lux. Quantitative amounts of fenhexamid-

trishydroxyphenyl were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

Findings: Test conditions met all validity criteria, given by the mentioned guideline.
The content of fenhexamid-trishydroxyphenyl in exposure media was measured for verification of the exposed test item concentrations. Neither in samples from start of exposure nor in samples from test termination was any amount of fenhexamid-trishydroxyphenyl found. The stability of fenhexamid-trishydroxyphenyl in aqueous solution seemed to be pH dependent. Therefore an additional stability test was performed to determine possible hydrolysis of the test item under study conditions. The accompanying chemical analysis revealed a complete degradation of the test item in Elendt M7 media within 30 minutes at pH 8.2. Nevertheless, the results are expressed based on the nominal concentrations of the test item.

The static 72 hour algae growth inhibition test provided the following effects:

Nominal concentration [mg p.m./L]	Cell number after 72 h (means) per mL	(0-72h)-average specific growth rates [days^{-1}]	Inhibition of average specific growth rate [%]	Doubling time of algae cells [days]
Control	415 000	1.240	-	0.559
0.954	370 000	1.203	3.0	0.576
3.05	217 000	1.025	17.3	0.676
9.77	63 000	0.607	51.0	1.14
31.3	25 000	0.286	76.9	2.42
100	12 000	0.000	100.0	-

Test initiation with 10,000 cells/mL

Conclusions: The (0 - 72 h)-E_rC_{50} for fenhexamid-trishydroxyphenyl is 10.1 mg p.m./L (95% CI: 7.83 - 13.1 mg p.m. /L) and the (0 - 72 h) - NOE_rC is 0.954 mg p.m./L.

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Metabolite M24

Report:	**KIIA 8.4/06; [redacted] 2012**
Title:	*Pseudokirchneriella subcapitata* growth inhibition test with KBR 2738–[C-C] biphenyl (BCS-CQ88719)
Document No:	**M-422987-01-1** (Rep. No: EBKBP002)
Guidelines:	OECD Guideline 201, "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (March 23, 2006)
GLP	Yes (certified laboratory)

Objective: The aim of the study was to determine the influence of the test item on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and ECx for growth rate of algal biomass (cells per volume).

Material and methods: KBR 2738–[C–C] biphenyl (BCS-CQ88719) analysed purity: 95.3 % was tested, specified by origin batch no.: BCOO 6050-33-22, customer order no.: TOX09420-00 and LIMS no.: 1133540.
Pseudokirchneriella subcapitata were exposed in a chronic multigeneration test for 3 days under static exposure conditions to geometric mean measured (nominal) test concentrations of 0.159 (0.192), 0.526

(0.613), 1.67 (1.96), 5.37 (6.26) and 13.3 (20.0) mg pure metabolite/L in comparison to controls. The pH values ranged from 7.8 to 8.2 in the controls and the incubation temperature ranged from 19.4°C to 23.0°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7939 lux.
Quantitative amounts of KBR 2738–[C–C] biphenyl (BCS-CQ88719) were measured in the treatment group and in the controls on day 0 and day 3 of the exposure period.

Findings:
Test conditions met all validity criteria, given by the mentioned guideline(s). The analytical findings of KBR 2738 – [C – C] biphenyl (BCS-CQ88719) in the treatment levels found on day 0 were 68 % to 90 % of nominal (average 84 %). On day 3 analytical findings of 66 % to 87 % of nominal (average 79 %) were found. Based on the analytical findings all results are given as geometric mean concentrations of the test item in the test medium.

The static 72 hour algae growth inhibition test provided the following effects:

Geometric mean measured concentration [mg p.m./L]	Cell number after 72 h (means) per mL	(0-72h)-average specific growth rates [days^{-1}]	Inhibition of average specific growth rate [%]
Control	1022000	1.540	-
Solvent control	1176000	1.588	-
Pooled control	1099000	1.564	-
0.159	1151000	1.579	-1.0
0.526	983000	1.527	2.4
1.67	1063000	1.555	0.6
5.37	143000	0.884	43.5
13.3	156000	0.910	41.8

Test initiation with 10,000 cells/mL
-% inhibition: Increase in growth relative to the control

Conclusions: The (0 - 72 h)-E_rC_{50} for KBR 2738-[C-C] biphenyl (BCS-CQ88719) is 14.2 mg p.m./L (95% CI: 9.49-32.5 mg p.m./L), the (0-72h) E_rC_{10} is 1.45 mg p.m./L (95% CI: 0.297-2.66 mg p.m./L) and the (0-72h)-NOE_rC is 1.67 mg p.m./L.

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Metabolite M39

Report:	**KIIA 8.4/07; [redacted]; 2012**
Title:	*Pseudokirchneriella subcapitata* growth inhibition test with KBR 2738-carbonic acid (BCS-BC75999)-limit test
Document No:	**M-422978-01-1** (Rep. No: EBKBL027)
Guidelines:	OECD Guideline 201: "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (March 23, 2006)
GLP:	Yes (certified laboratory)

Objective: The objective of this 72 hour growth inhibition test is, to verify the assumption that the test item will cause no adverse effects on the growth of the green algae *Pseudokirchneriella subcapitata*.

Material and methods: KBR 2738 – carbonic acid (BCS-BC75999) analysed purity: 98.1 % was tested, specified by origin batch no.: SES 11033-2-1, customer order no.: TOX09559-00 and LIMS no.: 1134275.
Pseudokirchneriella subcapitata were exposed in a chronic multigeneration test for 3 days under static exposure conditions to the nominal concentration of 10.0 mg pure metabolite (p.m.)/L in comparison to controls. The pH values ranged from 7.8 to 7.9 in the controls and the incubation temperature ranged from 20.7°C to 21.5°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7206 lux.
Quantitative amounts of KBR 2738 – carbonic acid (BCS-BC75999) were measured in the treatment group and in the controls on day 0 and day 3 of the exposure period.

Findings: Test conditions met all validity criteria given by the mentioned guideline(s).
The analytical finding of KBR 2738 – carbonic acid (BCS-BC75999) in the treatment level found on day 0 was 103 % of nominal. On day 3 analytical finding of 102 % of nominal was found. All results are based on nominal test concentrations of the metabolite.

The static 72 hour algae growth inhibition test provided the following effects:

Nominal concentration [mg p.m./L]	Cell number after 72 h (means) per mL	(0-72h)-average specific growth rates [days^{-1}]	Inhibition of average specific growth rate [%]
Control	483000	1.292	-
Solvent control	479000	1.289	-
Pooled control	481000	1.291	-
10.0	449000	1.269	1.8

Test initiation with 10,000 cells/mL

Conclusions: The (0 - 72h)-E_rC_{50} for KBR 2738 – carbonic acid (BCS-BC75999) is > 10.0 mg p.m./L.

IIA 8.5 Effects on sediment dwelling organisms

IIA 8.5.1 Acute test

Fenhexamid and metabolites: This test is not triggered as fenhexamid and its metabolites have no insecticidal activity with special mode of action (growth regulators), and are of low toxicity (48h EC_{50} > 1.0 mg/L and 21d NOEC > 0.1 mg/L) to aquatic invertebrates.

IIA 8.5.2 Chronic test

Report:	**KIIA 8.5.2/02; [redacted], 2002**
Title:	Fenhexamid: Chronic toxicity test with midge larvae (*Chironomus riparius*) in a water/sediment system.
Document No:	**M-033777-01-1** (Rep. No: 1022.021.173)
Guidelines:	Proposal for a new OECD Guideline 218: "Sediment-Water Chironomid Toxicity Test Using Spiked Sediment" (2001)
GLP	Yes (certified laboratory)

Objective: The study was performed to determine the potential chronic effects of fenhexamid on midge larvae (*Chironomus riparius*) under static test conditions.

Material and methods: Fenhexamid (tech.), purity: 99.0% (Batch-No.: 203050032, Article-No.: 0005442613); Larvae of *Chironomus riparius* (1st instars 2-3 days old, 6 beakers with 20 animals each, per test concentration and control) were exposed for 28 days in a static test system to nominal concentrations of 0, 100, 320 and 1000 mg a.s./kg (dry weight) in a water-sediment system (spiked sediment). The pH varied between 6.28 and 8.53. Dissolved oxygen concentration varied between 6.59 and 8.52 mg/L and between 77 and 100% of air saturation during the 28 days of the study. The temperatures recorded in the test solutions were between 20.0 and 22.3°C. The room temperature ranged between 19.0 and 20.5°C. The light intensity was 630 - 850 lux (mean 740 lux).

Findings:
Analytical findings: The measured test concentrations in the overlying water for nominal test concentrations of control, 100, 320 and 1000 mg a.s./kg were control, 19.4, 39.3 and 38.2 mg a.s./L on day 0, control, 5.5, 11.2 and 21.0 mg a.s./L on day 7 and control, 6.7, 18.0 and 28.1 mg a.s./L on day 28. In the pore water concentrations of control, 2.2, 3.4 and 11.0 mg a.s./L were found on day 0, control, 9.5, 21.2 and 26.8 mg a.s./L on day 7 and control, 8.8, 28.9 and 68.7 mg a.s./L on day 28. In the sediment concentrations of control, 63.0, 203.8 and 802.1 mg a.s./kg were found on day 0, control, 65.9, 226.3 and 955.9 mg a.s./kg on day 7 and control, 29.4, 153.9 and 445.9 mg a.s./kg on day 28 (all concentrations based on dry weight of the sediment). Therefore, all results based on nominal concentrations.

Biological findings: First emergence was observed on day 12. At test termination (day 28), a mean cumulative emergence of 84, 74, 48 and 5% was observed in the control, 100, 320 and 1000 mg a.s./kg test concentrations, respectively.
Average development rates of 0.069, 0.068, 0.069 and 0.069 day^{-1} were observed for the control, 100, 320 and 1000 mg a.s./kg test concentrations, respectively. Statistical analysis (Dunnett's t-test) showed that fenhexamid had no statistically significant effect on the development rate of midges at any of the test concentrations ($p>0.936$).
Average emergence rates were 0.84, 0.74, 0.48 and 0.05 for the control, 100, 320 and 1000 mg a.s./kg test concentrations, respectively. Statistical analysis (Dunnett's t-test) showed that fenhexamid had no statistically significant effect on the emergence rate of midges at 100 mg a.s./kg ($p=0.508$). Fenhexamid had a statistically significant effect on the emergence rate of midges at the 320 and 1000 mg a.s./kg test concentrations ($p=0.001$ and $p<0.001$, respectively).
Influence on the emergence and development after 28 days (based on nominal concentrations):^

	NOEC (mg a.s./kg dry weight)	**LOEC (mg a.s./kg dry weight)**
Emergence ratio	100	320
Development rate	1000	> 1000

Conclusion: The NOEC for fenhexamid in the 28 day study with *Chironomus riparius* was 100 mg a.s./kg dry weight. The LOEC was 320 mg a.s./kg dry weight.

IIA 8.6 Effects on aquatic plants

This test is not triggered as fenhexamid and its metabolites are not herbicides or growth regulators. Nevertheless, such a study is available for fenhexamid and reported herein for the sake of formal completeness.

Report:	**KIIA 8.6/01; [redacted].; 1998**
Title:	Fenhexamid tech. (TM 402): A 14-day toxicity test with duckweed (*Lemna gibba*).

Document No:	**M-006182-01-1** (Report No: 443 A-103)
Guidelines:	US EPA, Pesticide Assessment Guidelines, FIFRA Subdivision J, Hazard Evaluation: Nontarget Plants (1982)
GLP	Yes (certified laboratory)

Objective: The objective of this study was to evaluate the acute toxicity of fenhexamid technical (TM-402) to duckweed, *Lemna gibba* G3, over a 14-day exposure period under static test conditions.

Materials and methods: Test item: Fenhexamid (code: TM-402), purity: 97.7%, batch No.: 898805001. Over a 14-day period *Lemna gibba* G3 (Wildlife cultures) was exposed for 14 days under static conditions to nominal (day 0 measured) concentrations of negative control, solvent control, 0.14 (0.13), 0.28 (0.28), 0.55 (0.57), 1.1 (1.1) and 2.2 (2.3) mg a.s./l. Endpoints were biomass development and frond count.
Measured concentrations at test initiation were between 95 and 104 % of nominal, and ranged from less than the limit of quantitation to 19% at test termination. Due to the decline in concentrations to levels <70% of nominal, the test results were based on the day 0 analysis.

Findings:

Toxicity to aquatic plants:

Test item	**Fenhexamid (a.s.)**
Test system	***Lemna gibba***
Exposure	**14 d, static**
E_rC_{50} (growth rate of dry weight, day 0-7) [mg/L] (95% confidence limits)	> 2.3 n. d.
Lowest observed effect concentration (LOE_rC) [µg/L]	0.57
Highest tested concentration without effects (NOEAC) [µg/L]	0.28

n.d.: could not be determined

Observations: Observations of chlorosis, necrosis or dead fronds were recorded for duckweed exposed to fenhexamid techn. at all test concentrations. However, the numbers were small (< 3%) and the pattern observed was not concentration-responsive.

Conclusion: The EC_{50} has been determined as >2.3 mg a.s./L.

IIA 8.7 Effect on bees

No further studies with bees were required or conducted to address safety of fenhexamid.

IIA 8.7.1 Acute oral toxicity

Please refer to point IIA 8.7.1 / IIA 8.7.2 (EU point IIA 8.3.1.1) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.7.2 Acute contact toxicity

Please refer to point IIA 8.7.1 / IIA 8.7.2 (EU point IIA 8.3.1.1) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.7.3 Toxicity of residues on foliage to honey bees

For assessment of possible risk to bees resulting from plant protection products containing fenhexamid toxicity tests with the respective formulations are available which are summarized under the corresponding Annex III Document, Tier II, Section 6, point 10.5. Therefore, a bee residue toxicity test is not triggered.

IIA 8.7.4 Bee brood feeding test

Please refer to the statement above (IIA 8.7.3).

IIA 8.8 Effects on non-target terrestrial arthropods

In order to complete the risk assessment two studies on non terrestrial arthropods have been conducted. Short summaries of these studies are given below.

IIA 8.8.1 Effects on non-target terrestrial arthropods using artificial substrates

IIA 8.8.1.1 Parasitoid

After Annex I listing of fenhexamid an additional study with the lead formulation Fenhexamid WG 50 was performed. A short summary of this study is given below. The former study, performed with the lead formulation, is given under point IIA 8.8.1.1 (EU point IIA 8.3.2) of the EU dossier submitted for Annex I listing.

Report:	**KIIA 8.8.1.1/02; [redacted], 2009**
Title:	Toxicity to the parasitoid wasp *Aphidius rhopalosiphi* (DESTEPHANI-PEREZ) (Hymenoptera: Braconidae) using a laboratory test Fenhexamid WG 50
Organisation	[redacted]
Document No:	**M-327444-01-1** (Report-No: EBKBL009)
Guidelines:	[redacted] (2000), [redacted] (2001)
GLP	Yes (certified laboratory)

Objective: The aim of the study was to determine the toxicity of freshly dried residues of Fenhexamid WG 50 applied onto glass cover slides to the parasitoid wasp *Aphidius rhopalosiphi*.

Materials and methods: Test item: A water dispersable granules formulation of Fenhexamid WG 50, specified by sample description: FAR01338-00; specification no.: 10200007271; batch ID: EM20002826 [analysed content of active ingredient: 49.7%w/w; date of completed analysis: 17 OCT 2008, [redacted] Analysis & Services, [redacted]].
Test organism: the parasitoid wasp *Aphidius rhopalosiphi*, approx. 48 h old adults.

The experiment was performed in a controlled environment room at a temperature of 19.0 - 20.5°C and a relative humidity of 60 - 87%, with very short deviations down to 56%. The light / dark cycle was 16:8 hours. The light intensity was 541 - 747 Lux in the mortality phase, 669 - 2860 Lux in the parasitation phase and 7730 - 18850 Lux in the reproduction phase of the study.
The test item was applied at rates of 1.0, 1.8, 3.2, 5.6 and 10.0 kg product/ha and the effects were compared to a water treated control. A toxic reference (a.i.: dimethoate) applied at 0.0003 kg product/ha (0.1 g a.i./ha) was included to indicate the relative susceptibility of the test organisms and the test system.
Mortality of 60 females was assessed 2, 24 and 48 hours after exposure.
From the water control and the dose rates 1.0, 1.8, 3.2, 5.6 and 10.0 kg product/ha, 15 impartially chosen females per treatment were each transferred to a cylinder containing untreated barley plants infested with *Rhopalosiphum padi* for a period of 24 hours. The number of mummies was assessed 11 days later. Mortality and reproduction in each of the treatments are summarized below.

Findings: The results can be considered as valid, as all validity criteria of the test were met. Mortality in the water control was 0% (≤ 13% required), corrected mortality of the reference item was 100% (> 50% required), mean reproduction per female in water control was 12.9 (≥ 5 required) and not more than 2 wasps produced zero reproduction in the water control (0 wasps in this study).

Mortality and reproduction of *Aphidius rhopalosiphi* under laboratory conditions

Mortality (48 hours after treatment) / Reproduction							
		Mortality [%]			Reproduction		
Treatment	**kg prod./ha**	**Uncorr.**	**Corr.**	**P-Value (*)**	**Rate**	**Red. rel. to Control [%]**	**P-Value(#)**
Control	0	0	0		12.9	0	
Test item	1.0	1.7	1.7	1.000 n.sign.	22.9	-77.0	0.002.sign.
Test item	1.8	1.7	1.7	1.000 n.sign.	14.7	-13.9	1.000 n.sign
Test item	3.2	1.7	1.7	1.000 n.sign.	11.2	13.4	1.000 n.sign
Test item	5.6	1.7	1.7	1.000 n.sign.	15.2	-17.5	1.000 n.sign
Test item	10.0	3.3	3.3	1.000 n.sign.	17.2	-33	0.552 n.sign.
Reference item	0.0003	100	100		n.d.	n.d.	
LR$_{50}$: > 10.0 kg product/ha							
* Fisher's Exact test, two-sided, p-values are adjusted according to Bonferroni-Holm # Wilcoxon test, two-sided, p-values are adjusted according to Bonferroni-Holm n.d. not detected n.sign. not significant sign. significant							

Observations: In the highest dose rate of 10.0 kg product/ha 3.3% of uncorrected mortality was observed after 48 hours. At the lower rates of 1.0, 1.8, 3.2 and 5.6 kg product/ha 1.7% mortality was detected. In the reference item group, 100% of the wasps were dead after 48 hours of exposure
No reduction in reproductive success relative to the control at the 1.0, 1.8, 5.6 and 10.0 kg product/ha rates was found. Only 13.4% reduction was detected at the 3.2 kg product/ha rate.

Conclusion: In this laboratory test the effects of Fenhexamid WG 50 residues on the survival of *Aphidius rhopalosiphi* were determined at 1.0, 1.8, 3.2, 5.6 and 10.0 kg product/ha, applied to glass plates.
In the highest dose rate of 10.0 kg product/ha, 3.3% corrected mortality was observed. At the lower rates of 1.0, 1.8, 3.2 and 5.6 kg product/ha 1.7% mortality was detected.
No reduction in reproductive success relative to the control at the 1.0 and 1.8 kg product/ha rate was found. A slight reduction of only 13.4% was detected at the 3.2 kg product/ha rate of Fenhexamid WG 50. At the highest rates of 5.6 and 10.0 kg product/ha no reduction could be observed.

The LR_{50} was estimated to be > 10.0 kg product/ha.

IIA 8.8.1.2 Predatory mites

After Annex I listing of fenhexamid an additional study with the lead formulation Fenhexamid WG 50 was performed. A short summary of this study is given below. The former study, performed with the lead formulation, is given under point IIA 8.8.1.2 (EU point IIA 8.3.2) of the EU dossier submitted for Annex I listing.

Report:	**KIIA 8.8.1.2/02; [redacted], 2009**
Title:	Toxicity to the predatory mite *Typhlodromus pyri* SCHEUTEN (Acari, Phytoseiidae) using an laboratory test Fenhexamid WG 50
Organisation	[redacted]
Document No:	**M-327443-01-1** (Rep. No: CW08/068)
Guidelines:	[redacted] (2000); [redacted]. (2001)
GLP	Yes (certified laboratory)

Objective: The aim of the study was to investigate the lethal and sublethal toxicity of Fenhexamid WG 50 to the predatory mite *Typhlodromus pyri* when exposed to a glass surface.

Materials and methods: A water dispersible granules formulation of Fenhexamid WG 50 was tested, specified by sample description: FAR01338-00; specification no.: 102000007271; batch ID: EM20002826, (analysed content of active ingredient: 49.7 %w/w; date of completed analysis: 17 OCT 2008, [redacted]).
The test item was applied at rates of 1.0, 1.8, 3.2, 5.6 and 10.0 kg product/ha and the effects were compared to a water treated control. A toxic reference (a.i.: dimethoate) applied at 0.0108 kg product/ha (4 g a.i./ha) was included to indicate the relative susceptibility of the test organisms and the test system.
Mortality of 100 protonymphs was assessed 1, 4, 7, 10, 12 and 14 days after exposure by counting the number of living and dead mites. The number of escaped mites was calculated as the difference from the total number exposed.
The reproduction rate of surviving mites was then evaluated over the period of 7-14 days after treatment by counting the total number of offspring (eggs and larvae) produced.

Findings: The mortality / escaping rate in the control groups up to day 7 after treatment was 3%. The mean corrected mortality of the nymphs, and the mean reproduction rate of the surviving females exposed to the test item and the toxic reference is given below:

Mortality – 7 days after treatment / Reproduction

		Mortality [%]			Reproduction		
Treatment	**kg prod./ha**	**Uncorr.**	**Corr.**	**P-Value(*)**	**Rate**	**Red. rel.to Control [%]**	**P-Value(#)**
Control	0	3.0			5.6		
Test item	1000	8.0	5.2	0.854 n.sign.	6.2	-11.5	0.930 n.sign.
Test item	1800	0.0	-3.1	0.854 n.sign.	5.3	6.3	0.985 n.sign.
Test item	3200	7.0	4.1	0.854 n.sign.	6.8	-21.2	0.581 n.sign.
Test item	5600	9.0	6.2	0.669 n.sign.	6.5	-16.5	0.794 n.sign.
Test item	10000	4.0	1.0	1.000 n.sign.	5.8	-3.2	0.999 n. sign.
Reference item	0.011	94.0	93.8		n.d.	n.d.	
LR_{50}: > 10 kg product/ha; 95% Confidence Interval: (-) (calculated with Probit analysis)							
* Fisher's Exact test, two-sided, p-values are adjusted according to [redacted] # one-way ANOVA, p-values are adjusted according to [redacted] n.d. not detected, n.sign. not significant, sign. significant							

Conclusion: In this laboratory test the effects of Fenhexamid WG 50 residues on the survival and reproduction of the predatory mite *Typhlodromus pyri* were determined at the rates of 1.0, 1.8, 3.2, 5.6 and 10.0 kg product/ha applied to glass cover slides.
In all dose rates tested no statistically significant effects on survival or reproduction could be observed. In the highest dose rate of 10.0 kg product/ha of Fenhexamid WG 50 there was 1% corrected mortality. There was no reduction in reproductive success relative to the control at this rate (-3.2%). At the lower rates of 5.6 and 3.2 kg product/ha of Fenhexamid WG 50 6.2 and 4.1% corrected mortality were found with no reduction of reproduction (-16.5 and -21.1% respectively). With 1.8 kg product/ha no mortality occurred (-3.1% corr.) with a reduction of reproductive success of 6.3%. At the lowest rate of 1.0 kg product/ha a corrected mortality of 5.2% could be observed but with no reduction of reproduction (-11.5%).
The LR_{50} was estimated to be >10 kg product/ha.

IIA 8.8.1.3 Ground dwelling predators

Please refer to point IIA 8.8.1.3 (EU point IIA 8.3.2) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.8.1.4 Foliage dwelling predators

Please refer to point IIA 8.8.1.4 (EU point IIA 8.3.2) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.8.2 Effects on non-target terrestrial arthropods in extended laboratory/semi-field tests

Based on the results of the studies reported under points IIA 8.8.1.1 to IIA 8.8.1.4 extended laboratory/semi-field studies on predatory mites, parasitoids and further non-target arthropod species are not triggered.

IIA 8.8.2.1 Parasitoid

See point IIA 8.8.2.

IIA 8.8.2.2 Predatory mites

See point IIA 8.8.2.

IIA 8.8.2.3 Ground dwelling predatory species

See point IIA 8.8.2.

IIA 8.8.2.4 Foliage dwelling predatory species

See point IIA 8.8.2.

IIA 8.8.2.5 Other terrestrial invertebrates

See point IIA 8.8.2.

IIA 8.9 Effects on earthworms

In order to complete the risk assessment fro fenhexamid two studies on earthworms have been conducted addressing either the parent substance or a metabolite which can be formed in soil. Short summaries of these studies are given below.

IIA 8.9.1 Acute toxicity to earthworms

Please refer to point IIA 8.9.1 (EU point IIA 8.4.1) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.9.2 Sublethal effects

Report:	**KIIA 8.9.2/01; [redacted], 1999**
Title:	Influence of Fenhexamid WG 50 on the Reproduction of Earthworms (*Eisenia fetida*)
Document No.:	**M-024530-01-1** (Rep. No: HBF/Rg 316)
Guidelines:	ISO 11268-2 (1996), BBA Guideline for the Testing of Plant Protection Products Within Registration, Part VI (1994)
GLP	Yes (certified laboratory)

Objective: The purpose of this study was to determine the sublethal effects of the test item on reproduction, mortality and growth of the earthworm *Eisenia fetida* using an artificial soil in a laboratory test.

Materials and Methods: Test item: Fenhexamid WG 50, (a.i.-content: 49.0%, specification: Development-No.: 3000175474, Article-No.: 04820002, TOX-No.: 5108-00)
Reference Item: Under the same conditions a study was carried out with the reference substance Derosal (a.i. content: 36% Carbendazim).
Adult earthworms *(Eisenia fetida,* about 3 months old) were exposed in an artificial soil (69% fine quartz sand, 20% kaolin, 10% dried, finely ground peat, 1% dried, finely ground cattle manure and 1% $CaCO_3$) to the application rates of 1, 2 and 5 kg a.i./ha (mixed into soil). After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offsprings was determined.
Incubation conditions during study were constant light (400 - 800 Lux) and a temperature of 20±2 °C.

Findings: Effects on mortality, growth and reproduction of the earthworms.

Test substance	**Fenhexamid WG 50**			
Test object	***Eisenia fetida***			
Exposure	**56 d**			
application rates (kg a.s. / ha)	control	1	2	5
Mortality of adult earthworms (%) after 28 days	0	0	0	0
Weight increase of adult earthworms (%)	34	39	46	40
Number of offsprings per surviving adult	23	24	24	24

Observations: There was no mortality in the test higher than the limit for natural mortality (< 10%) according to test guidelines. Reproduction was greater than the acceptable reproductive output of 30 juvenils per ten adults after 8 weeks. Soil moisture was maintained in acceptable ranges throughout the test. These results along with those from the positive control study indicate that this is a valid test.

Conclusions: Mortality or a body weight reduction of adult earthworms was not observed at any application rate in this study. Also the number of offsprings was not reduced at any application rate.

Therefore, the NOEC is set at 5 kg a.s./ha, corresponding to 6.667 mg a.i./kg dws (recalculated for 5cm soil depth).
Refined recalculation: 19.8 mg/kg soil (based on 5000 g Fenhexamid/10000m², size of test boxes = 198 cm² and 500 g dry weight test substrate per test box).

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Metabolite M24

Report:	**KIIA 8.9.2/02; [redacted], 2012**
Title:	Fenhexamid-BCS-CQ88719: Sublethal toxicity to the earthworm *Eisenia fetida* in artificial soil with 5% peat
Document No:	**M-422055-01-1** (Rep. No: 121048007S)
Guidelines:	OECD 222 (2004), ISO 11268-2 (1998)
GLP	Yes (certified laboratory)

Objective:

The purpose of this study was to determine the sublethal effects of the test item on reproduction, mortality and growth of the earthworm *Eisenia fetida* by dermal and alimentary uptake using an artificial soil. The test was performed according to the recommendations of the OECD Guideline 222 (2004) and the International Standard ISO 11268-2 (1998) as a limit test.

Materials and Methods:

Test item Fenhexamid-BCS-CQ88719, Batch code: BCS-CQ88719-01-01, Origin Batch No.: BCOO 6050-33-22, LIMS No.:1133540, Customer Order No.: TOX 09420-00, Substance code No.: BCS-CQ88719, analysed purity: 95.3 % w/w.
Adult earthworms (*Eisenia fetida andrei*, about 2 months old) were exposed to 100 mg test item/kg soil dry weight (d.w.) containing 73.7 % quartz sand, 20 % kaolin clay, 5 % sphagnum peat and 0.3 % CaCO3, at 18.1 – 21.3 °C and a photoperiod light : dark = 16 h : 8 h (590 lx) and were fed with horse manure. Mortality and biomass change were determined after 4 weeks and reproduction was determined after 8 weeks.
Toxic standard: 5 &10 mg Nutidazim 50 FLOW/kg soil d.w.; control: quartz sand, solvent control: none.

Findings:

Effects on mortality, growth and reproduction of the earthworms

Test item **Test object** **Exposure**	**Fenhexamid-BCS-CQ88719** ***Eisenia fetida*** **Artificial soil**		
	Mortality	Biomass change	Reproduction
	[mg test item/kg d.w.]		
LOEC	> 100	> 100	> 100
LC_{50}/EC_{50}	> 100	> 100	> 100
95% confidence limit	-	-	-
NOEC	100	≥ 100	≥ 100

Observations:

Fenhexamid-BCS-CQ88719 [mg test item/kg d.w.]		
	Control	**100**
Mortality of adult worms after 4 weeks		
Mortality (%)	0	0
Biomass change (change in fresh weight after 4 weeks relative to initial fresh weight)		
Mean (mg)	98.4	108.9
Mean (%)	26.6	29.5
Number of juveniles per surviving adult worm after 8 weeks		
Mean	6.4	6.7
Number of juveniles per replicate after 8 weeks		
Mean	63.6	67.3
Reduction of reproduction per treatment (%)		
% to control	-	5.7

No statistically significant differences between the control and test item were calculated for biomass and reproduction (Student-t-test, $p \leq 0.05$, one-sided smaller

All validity criteria were met and a reference test with the toxic standard assured a high sensitivity of the test system.

Conclusion:
Fenhexamid-BCS-CQ88719 showed no statistically significantly adverse effects on mortality, growth and reproduction of the earthworm *Eisenia fetida* in artificial soil at 100 mg test item/kg soil dry weight, i.e. the highest concentration tested. Therefore, the overall No-Observed-Effect-Concentration (NOEC) was determined to be ≥ 100 mg test item/kg soil d.w., and the Lowest-Observed-Effect-Concentration (LOEC) was determined to be > 100 mg test item/kg soil d.w.

IIA 8.10 Effects on soil microbial activity

In order to complete the risk assessment for fenhexamid one study on microbial activity has been conducted. A short summary of this study is given under IIA 8.10.1

IIA 8.10.1 Nitrogen transformation

After Annex I listing of fenhexamid an additional study with the lead formulation Fenhexamid WG 50 was performed. A short summary of this study is given below. The former study, performed with the active substance, is given under point IIA 8.10.1 (EU point IIA 8.5) of the EU dossier submitted for Annex I listing.

Report:	**KIIIA 8.10.1/02; [redacted], 2009**
Title:	Fenhexamid WG 50 W: Determination of effects on nitrogen transformation in soil
Document No:	**M-359659-01-1** (Rep. No: FRM-N-131/09)
Guidelines:	OECD 216; adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation Test.
GLP	Yes (certified laboratory)

Objectives: The objective of the test was to determine the influence of 2.68 mg and 26.80 mg of Fenhexamid WG 50 W/kg dry weight soil on nitrogen transformation in an agricultural soil

Material and Methods: Fenhexamid WG 50 W (49.7 % w/w analysed content, specification No.: 102000007271, batch ID: EM20002826, Material No.: 05419441, Sample Description: FAR01338-00), was used in the test. A loamy sand soil (according to DIN 'mittel lehmiger Sand') was exposed for 28 d to 2.68 mg and 26.80 mg test item/kg dry weight soil. Application rates were equivalent to 2.01 kg and 20.12 kg test item/ha. Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation
The coefficient of variation in the control at the end of the study was 1 %. Therefore the validity criteria for the study, which requires a coefficient of variation ≤ 15 % in the control, was fulfilled.

Findings: Effects on non-target soil microorganisms

Time Interval (days)	Application rates											
	Fenhexamid WG 50 W											
	Control			2.68 mg/kg dry weight soil				26.80 mg/kg dry weight soil				
	Nitrate-N 1)			Nitrate-N 1)			% difference to control	Nitrate-N 1)			% difference to control	
0-7	0.72	±	0.07	1.05	±	0.40	**45** n.s.	0.79	±	0.52	**9** n.s.	
7-14	3.27	±	0.13	3.35	±	0.07	**3** n.s.w	3.51	±	0.40	**8** n.s.w	
14-28	1.76	±	0.06	1.79	±	0.09	**1** n.s.	1.75	±	0.17	**1** n.s.	

1) Rate: Nitrate-N in mg/kg dry weight soil/time interval/day, mean of 3 replicates and standard deviation
n.s. = No statistically significant difference to the control (Student-t Test, two-sided, a = 0.05)
n.s.w = No statistically significant difference to the control (Welch-t Test, two-sided, a = 0.05)

Observations: During the 28-day test, 2.68 mg Fenhexamid WG 50 W/kg dry weight soil caused a temporary stimulation of the daily nitrate rates at the time interval 0-7 days after treatment. At the end of the test (14-28 day interval), differences in the nitrate-N rates between control soil samples and treated soil samples are < 25 % and meet the trigger values of above mentioned guideline for a termination of the study.

Conclusion: If used as recommended, Fenhexamid WG 50 W should not have an impact on nitrogen transformation in soils.

IIA 8.10.2 Carbon mineralization

Please refer to IIA 8.10.2 (EU point IIA 8.5) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)".

IIA 8.10.3 Rates of recovery following treatment

Fenhexamid shows no long term effects and is not used as a soil sterilant.

IIA 8.11 Effects on marine and estuarine organisms

No EC data requirement according to Regulation 1107/2009/EEC or Directive 414/1991/EEC.

IIA 8.11.1 Marine or estuarine organisms acute toxicity LC50/EC50

See above (IIA 8.11).

IIA 8.11.2 Marine/Estuarine fish – salinity challenge

See above (IIA 8.11).

IIA 8.12 Effects on terrestrial vascular plants

Report:	**KIIA 8.12/01; [redacted], 1999**
Title:	Herbicidal Screening Data for KBR 2738 WG 50
Document No:	**M-017075-01-1** (Rep. No: DOM 99105)
Guidelines:	OECD Non-Target Plant Testing Guideline Proposal
GLP	No

Objective: Information concerning the potential effects of crop protection products (CPP's) on non-target plants is required in some countries as part of the registration process. Screening data are used to show whether the product causes phytotoxic effects on non-target plants under procedures as recommended by OECD (see appendix I) for non- herbicidal CPP's.

Material and methods: Fenhexamid WG 50 (content: KBR 2738 49 % a.i; FL.-No.: 0222 based on 04258/0214).
Spray treatments are applied in an automatic spray chamber for screening tests to the soil surface in which plants were subsequently grown and to the foliage of emerged plants. The spray chamber is adjusted as follows: water application rate to the target area 1000 L/ha; the material was applied in single applications of 625, 1250, 2500 and 5000 g a.i./ha.
The plants were kept at 22 °C/15 °C in a day/night rhythm. The relative humidity in the test chamber was 50% and the duration of illumination (8000 lux) was 14 hours to 10 hours in a day/night rhythm. Plants for the foliar treatments were grown for approximately 2 weeks prior to application. The final evaluation was done 17 days after treatment.
Plants for pre-emergence treatments were sawn, sprayed with the test material, and placed in the appropriate growing conditions. The final evaluation was done 21 days after treatment.

Evaluation of phytotoxicity was done by visual observations using a rating scale of 0 to 100%, where 100% was complete destruction of above ground parts and 0% was no visual damage (normal growth) as compared to untreated plants.

Findings and Observations: When applied to soil (pre-emergence) no effect was observed on most of the tested plant species. Only slight effects (20-30 %) were observable at 2500 and 5000 g a.i./ha on *Galium aparine* (cleavers, GALAP, rubiaceae, dicotyledonae), respectively.
When applied to foliage (post-emergence) no effect was observed on most of the tested plant species Only slight effects (30 %) were observable at 5000 g a.i./ha on *Setaria viridis* (green bristlegrass, SETVI, gramineae, monocotyledonae) and *Beta vulgaris* (sugarbeet, BEAVA, chenopodianceae, dicotyledonae).

For details of screening results see the tables below.

Visual injury observed at the completion of the pre-emergence test:

Species	Results (% effect) at different application rates			
	625 g a.s./ha	1250 g a.s./ha	2500 g a.s./ha	5000 g a.s./ha
Zea mays	0	0	0	0
Alopecurus myosuroides	0	0	0	0
Avena fatua	0	0	0	0
Echinochloa crus-galli	0	0	0	0
Setaria viridis	0	0	0	0
Beta vulgaris	0	0	0	0
Abutilon theophrasti	0	0	0	0
Amaranthus retroflexus	0	0	0	0
Galium aparine	0	0	20	30
Ipomoea hederacea	0	0	0	0
Sinapis alba	0	0	0	0

Visual injury observed at the completion of the foliar applied test:

Species	Results (% effect) at different application rates			
	625 g a.s./ha	1250 g a.s./ha	2500 g a.s./ha	5000 g a.s./ha
Zea mays	0	0	0	0
Alopecurus myosuroides	0	0	0	0
Avena fatua	0	0	0	0
Echinochloa crus-galli	0	0	0	0
Setaria viridis	0	0	0	30
Beta vulgaris	0	0	0	30
Abutilon theophrasti	0	0	0	0
Amaranthus retroflexus	0	0	0	0
Galium aparine	0	0	0	0
Ipomoea hederacea	0	0	0	0
Sinapis alba	0	0	0	0

Conclusions:
None of the five monocotyledoneous and six dicotyledoneous plant species out of seven plant families showed any relevant (>=50%) phytotoxic effect at KBR 2738 rates from 625 to 5000 g a.s./ha.

IIA 8.13 Effects on terrestrial vertebrates other than birds/wild mammal toxicity

No EC data requirement.

IIA 8.14 Effects on other non-target organisms (flora and fauna) believed to be at risk

IIA 8.14.1 Summary of preliminary data: biological activity & dose range finding

Herbicidal activity
Screening data concerning herbicidal activity are not presented.
The relevant information is covered by the guideline studies on representative species, which are presented under point 8.12 of this section 6.

Insecticidal activity
Screening data concerning insecticidal activity are not presented.

The relevant information is covered by the guideline studies on representative species, which are presented under the points 8.7 and 8.8 of this section 6.

Further information
Further information on the biological activity of fenhexamid is given in the respective chapters (IIA, point 3 and IIIA, point 6).

IIA 8.14.2 A critical assessment as to the relevance of the preliminary test data to potential impact on non-target species

Risk assessments for all non-target species are performed in product specific Annex III dossiers.

IIA 8.15 Effects on biological methods for sewage treatment

Please refer to point IIA 8.15 (EU point IIA 8.7) of the EU dossier submitted in the context of Annex I listing and the relevant data submitted during the EU evaluation process according to the Review Report of Fenhexamid (6497/VI/99-rev.2, from October, 2000)“

IIA 8.16 Other/special studies

No other/special studies were considered necessary.

IIA 8.16.1 Other/special studies – laboratory studies

No other/special studies were considered necessary.

IIA 8.16.2 Other/special studies – field studies

No other/special studies were considered necessary.

IIA 8.17 Summary and evaluation of points IIA 7 and IIA 8.1 to 8.16

Fate and behaviour in the environment

The fate and behaviour of fenhexamid in soil has been investigated in a series of laboratory studies and, when required, supported with data from field experiments.

Summary on the fate and behaviour 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 at least 1 sampling date however 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 formation of these dimeric and trimeric transformation products of fenhexamid was a matter of microbial and/or enzyme-mediated and in part abiotic processes.
Ultimately total mineralisation of the aromatic nucleus to carbon dioxide occurred via aerobic ring cleavage.
It can be concluded from the study concerning the photodegradation of fenhexamid on soil surfaces 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.
On the basis of the data presented on the route of degradation, it is clear that the parent compound itself represents the only relevant residue of concern in soil, because 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.

The results of the adsorption/desorption studies (batch equilibrium) with fenhexamid showed that the compound has to be classified as a substance with no or only low leaching potential (mean K_{OC} = 517). 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 result in mean K_{OC} values of 668 mL/g and 912 mL/g depending on the model used for calculation. Therefore no problems concerning the groundwater contamination will be expected, which was also confirmed by the PEC_{gw} computer simulation.

Summary on the fate and behaviour in water

In sterile aquatic systems fenhexamid was stable to hydrolysis. Under the experimental conditions no formation of hydrolysis products was observed. Considering the hydrolytic stability determined under environmental pH and temperature conditions 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, stepwise hydroxylation and subsequent cleavage of the phenyl-ring. The degradation products were WAK 7004 *(M10)*, KBR 5613 *(M12)*, KBR 2931 *(M13)*, BBJ 99-11 (*M14*, two isomers, parts of metabolite fraction 5), BBJ 99-13 (*M15*, may be 3 isomers), succinic acid (*M26*, part of metabolite fraction 1) and CO_2. One metabolite (WAK 7004 = *M10*) and one metabolite fraction (containing BBJ 99-13 = *M15*) exceeded 10% of the applied radioactivity.
In a phototransformation experiment with fenhexamid published in Chemosphere vol. 81, pp. 844-852 ([redacted] 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.
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. 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.

Summary on the fate and behaviour in air
Due to the low vapour pressure 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.

Effects on non-target organisms
In the following, the endpoints for fenhexamid and for fenhexamid metabolites resulting from ecotoxicological studies are given. An assessment of ecotoxicological data is only possible in connection with the label recommendations and the environmental exposure resulting from the use according to good agricultural practice. Therefore the risk assessment is performed in the Annex III dossier of the lead formulation and the respective dossiers for national formulations.

Summary of effects of fenhexamid on birds

Test Species	Test substance	Test System	Exposure duration	Results (mg a.s./kg b.w.)	Reference
Bobwhite quail	a.s.	acute oral	single	LD_{50} > 2000	[redacted] (1995) VB038 M-006224-01-1 KIIA 8.1.1/01 (EU: KIIA 8.1.1/01)
Bobwhite quail	a.s.	dietary test	5 d	LDD_{50} > 968 (LC_{50} = >5000 mg/kg feed)	[redacted] (1995) GMU/VB-042 M-006291-02-1 KIIA 8.1.2/01 (EU: KIIA 8.1.2/01)
Mallard duck	a.s.	dietary test	5 d	LDD_{50} > 1408 (LC_{50} = >5000 mg/kg feed)	[redacted] 2002 VE008 M-006310-02-1 KIIA 8.1.3/01 (EU: KIIA 8.1.2/02)
Bobwhite quail	a.s.	dietary test, reproduction	23 w	NOAEL 154 (NOEC 2074 mg/kg feed)	[redacted] 1997 SXR/REP06 M-006223-02-1 KIIA 8.1.4/01 (EU: KIIA 8.1.3/01)

Summary of effects of fenhexamid on water organisms

Test species	Test substance	Test system	Exposure duration	Results (mg a.s./L)	Reference
Rainbow trout	a.s.	acute, flow through	96 h	LC_{50}: 1.24	[redacted], 1995 DOM 95001 M-006071-01-1 KIIA 8.2.1.1/01 (EU: KIIA 8.2.1/01)
Bluegill sunfish	a.s.	acute, flow through	96 h	LC_{50}: 3.17	[redacted], 1995 DOM 95002 M-006072-01-1 KIIA 8.2.1.2/01 (EU: KIIA 8.2.1/02)
Rainbow trout	M10	Acute, static	96 h	LC_{50}: 0.391 mg p.m./L	[redacted], 2009 EBKBL003 M-350526-01-1 KIIA 8.2.1.3/01
Rainbow trout	M12	Acute, static	96 h	LC_{50}: 4.51 mg p.m./L	[redacted] (2008) EBKBL006 M-345406-01-1 KIIA 8.2.1.3/02
Rainbow trout	M15	Acute, static	96 h	LC_{50}: 100 mg p.m./L	[redacted] (2009) EBKBL012 M-357294-01-1 KIIA 8.2.1.3/03
Rainbow trout	M24	Acute, static	96 h	LC_{50}: 2.62 mg p.m./L	[redacted] (2012) EBKBP003 M-422423-01-1 KIIA 8.2.1.3/04
Rainbow trout	M39	Acute, static	96 h	LC_{50}: > 10 mg p.m./L	[redacted] (2012) EBKBL028 M-422291-01-1 KIIA 8.2.1.3/05
Rainbow trout	M40	Acute, static	96 h	LC_{50}: > 100	[redacted] (2010) EBKBL024 M-369106-01-1 KIIA 8.2.1.3/06
Rainbow trout	a.s.	ELS, flow-through	96 d	NOEC: 0.101	[redacted], 1997 DOM 96050 M-006184-01-1 KIIA 8.2.4/01 (EU: KIIA 8.2.2.2/01)
Bluegill sunfish	^{14}C-a.s.	Bioconcentration, chronic	28 d	mean-whole fish BCF: 159 based on parent: 80	[redacted], 1996 DOM 95086 M-006069-01-1 KIIA 8.2.6.1/01 (EU: KIIA 8.2.3/01) [redacted], 1997 PF4204 M-003791-01-1 KIIA 8.2.6.2/01 (EU: KIIA 8.2.3/02)
Daphnia magna	a.s.	acute, static	48 h	EC_{50}: > 18.8	[redacted] (1995) HBF/DM139

Test species	Test substance	Test system	Exposure duration	Results (mg a.s./L)	Reference
					M-006075-01-1 KIIA 8.3.1.1/01 (EU: KIIA 8.2.4/01)
Daphnia magna	M10	Static	96 h	LC_{50}: 0.391	[redacted] (2009) EBKBL002 M-345853-01-1 KIIA 8.3.1.1/02
Daphnia magna	M12	Static	48 h	EC_{50}: 4.51	[redacted] (2009) EBKBL005 M-345837-01-1 KIIA 8.3.1.1/03
Daphnia magna	M15	Static	48 h	LC_{50}: > 100	[redacted] (2009) EBKBL014 M-358250-01-1 KIIA 8.3.1.1/04
Daphnia magna	M24	Static	48 h	EC_{50}: > 20	[redacted] (2012) EBKBL030 M-423120-01-1 KIIA 8.3.1.1/05
Daphnia magna	M39	Static	48 h	EC_{50}: 138	[redacted] (2012) EBKBP004 M-423128-01-1 KIIA 8.3.1.1/06
Daphnia magna	a.s.	Semi-static	21d	NOEC: 1.0	[redacted] (1996) HBF/RDM56 M-006068-01-1 KIIA 8.3.2.1/01 (EU: KIIA 8.2.5/01)
Selenastrum capricornutum	a.s.	growth rate, static	120 h	E_rC_{50}: 8.43	[redacted] (1995) AJO/128695 M-006073-01-1 KIIA 8.4/01 (EU: KIIA 8.2.6/01)
Scenedesmus subspicatus	a.s.	growth rate, static	72 h	E_rC_{50}: >26.1	[redacted] (1996) AJO/133595 M-006070-01-1 KIIA 8.4/02 (EU: KIIA 8.2.6/02)
Pseudokirchneriella subcapitata	M10	growth rate, static	72 h	E_rC_{50}: > 9.25	[redacted] (2010) EBKBL007 M-362991-01-1 KIIA 8.4/03
Pseudokirchneriella subcapitata	M12	growth rate, static	72 h	E_rC_{50}: > 25	[redacted] (2009) EBKBL004 M-345417-01-1 KIIA 8.4/04
Pseudokirchneriella subcapitata	M15	Growth rate, static	72 h	E_rC_{50}: 10.1	[redacted] (2010) EBKBL010 M-367188-01-1 KIIA 8.4/05

Test species	Test substance	Test system	Exposure duration	Results (mg a.s./L)	Reference
Pseudokirchneriella subcapitata	M24	Growth rate, static	72 h	E_rC_{50}: > 14.2	[redacted] (2012) EBKBP002 M-422987-01-1 KIIA 8.4/06
Psedokirchneriella subcapitata	M39	Growth rate, static	72 h	E_rC_{50}: > 10	[redacted] (2012) EBKBL027 M-422978-01-1 KIIA 8.4/07
Chironomus riparius	a.s.	chronic, static, water-sediment system (spiked water)	28 d	EC_{15}: 11.4	[redacted] (1999) HBF/CH35 M-024548-01-1 KIIA 8.5.2/01 (EU: KIIA 8.2.7/01)
Chironomus riparius	a.s.	chronic, static, water-sediment system (spiked sediment)	28 d	(NOEC: 100 mg a.s./kg dry weight sediment)	[redacted] (2002) 1022.021.173 M-033777-01-1 KIIA 8.5.2/02
Lemna gibba	a.s.	static	14 d	EC_{50}: > 2.3	[redacted]. (1998) 443 A-103 M-006182-01-1 KIIA 8.6/01

Summary of effects of fenhexamid on honey bees

Species	Test substance	Results LD_{50} µg a.s./bee	Reference
Apis mellifera foraging bees	a.s.	oral 48h >102.1 contact 48h >200	[redacted] (1995) 94124/01-BLEU M-006350-01-1 KIIA 8.7.1/01, KIIA 8.7.2/01 (EU: KIIA 8.3.1.1/01)
Apis mellifera foraging bees	a.s.	oral 48h >189 contact 48h >188	[redacted] (1995) 951048058 M-006340-01-1 KIIA 8.7.1/02, KIIA 8.7.2/02 (EU: KIIA 8.3.1.1/02)

Impacts of fenhexamid WG 50 on Non-Target Arthropods in laboratory studies

Test subjects	Maximum Application Rate	Exposure	Results [kg a.s./ha]	Reference
Aphidius rhopalosiphi	> 2 kg a.s./ha	Spray deposits on glass plates, 48 h	LR_{50}: > 2	[redacted] (1995) BAY-95-1 M-006379-01-1 KIIA 8.8.1.1/01 (EU: KIIA 8.3.2/02)
Aphidius rhopalosiphi	> 5 kg a.s./ha	Spray deposits on glass plates, 48 h	LR_{50}: > 5	[redacted] (2009) CW08/069 M-327444-01-1 KIIA 8.8.1.1/02
Typhlodromus pyri	> 2 kg a.s./ha	Spray deposits on glass plates, 14d	LR_{50}: > 2	[redacted] (1995) 95-001-1022 M-006380-01-1 KIIA 8.8.1.2/01 (EU: KIIA 8.3.2/01)
Typhlodromus pyri	> 5 kg a.s./ha	Spray deposits on glass plates, 14 d	LR_{50}: > 5	[redacted] (2009) CW08/068 M-327443-01-1 KIIA 8.8.1.2/02
Aleochara bilineata	> 2 kg a.s./ha	Spray deposits on quartz sand	LR_{50}: > 2	[redacted] (1996) SXR/AL 30 M-006378-01-1 KIIA 8.8.1.3/01 (EU: KIIA 8.3.2/04)
Coccinella septempunctata	> 2 kg a.s./ha	Spray deposits on glass plates, 69 d	LR_{50}: > 2	[redacted] (1996) SXR/CS 10 M-006377-01-1 KIIA 8.8.1.4/01 (EU: KIIA 8.3.2/03)

Summary of effects of fenhexamid on earthworms

Test species	Test substance	Duration of Exposure	Results	Reference
Eisenia fetida	a.s.	14 d	LC_{50} [mg/kg dws] >1000	[redacted] (1995) HBF/Rg 210 M-006331-01-1 KIIA 8.9.1/01 (EU: KIIA 8.4.1/01)
Eisenia fetida	WG 50	56 d	NOEC [mg a.s./kg dws] 19.8	[redacted] (1999) HBF/Rg 316 M-024530-01-1 KIIA 8.9.2/01
Eisenia fetida	M24	56 d	NOEC [mg p.m./kg dws] ≥ 100	[redacted] (2012) 121048007S M-422055-01-1 KIIA 8.9.2/02

dws. = dry weight soil

Summary of effects of fenhexamid on soil micro-organisms

Test system	Test substance	Duration of Exposure	Results	Reference
N-cycle, 2 soils	a.s.	42 d	No meaningful influence at 1 and 10 kg a.s./ha in both soils	[redacted] (1995b) AJO/126194 M-006371-01-1 KIIA 8.10.1/01 (EU: KIIA 8.5/02)
N-cycle, 1 soil	Fenhexamid WG 50	28 d	No effects at 2.01 and 20.1 kg test item/ha (equivalent to 2.68 mg and 26.8 mg test item/kg dry weight soil)	[redacted] (2009) FRM-N-131/09 KIIIA 8.10.1/02
C-cycle, 2 soils	a.s.	28 d	No effects at 1 and 10 kg a.s./ha in both soil	[redacted] (1995a) AJO/126094 M-006374-01-1 KIIA 8.10.2/01 (EU: KIIA 8.5/01)
Activ. sludge	a.s.	30 min.	EC_{50} = 8160 mg/L	[redacted] (1995) 555A/95 M-006383-01-2 KIIA 8.15/01 (EU: KIIA 8.7/01)

Summary of effects of fenhexamid to non-target terrestrial higher plants

Test	Test species	Ecotoxicological endpoint	Reference
<u>Fenhexamid WG 50</u> screening	*Zea mays* *Alopecurus myosuroides* *Avena fatua* *Echinochloa crus-galli* *Setaria virdis* *Beta vulgaris* *Abutilon theophrasti* *Amaranthus retroflexus* *Galium aparine* *Ipomea hederacea* *Sinapsis alba*	applied at rates from 625 to 5000 g a.s./ha <u>Seedling emergence</u> slight effects (20-30%) were observed at 2.5-5 kg a.s./ha on cleavers <u>Vegetative vigour</u> slight effects (30%) were observed at 5 kg a.s./ha on green bristlegrass and sugarbeet	[redacted] (1999) DOM 99105 M-017075-01-1 KIIA 8.12/01

Abbreviations

Abbreviation	Explanation	Definition
a.s.	Active substance	
a.i.	Active ingredient	
AR	Applied Radioactivity	
AV	Avoidance Factor	
BCF	Bioconcentration factor	
bw	Body weight	
calc.	Calculated	
C.L.	Confidence limit	
d	Day	
DDD	Daily dietary exposure	
DT_{50}	Half-life of disappearance	Period required for 50 % dissipation
DT_{90}		Period required for 90 % dissipation
d.wt.s.	Dry weight substrate	
EAC	Ecologically acceptable concentration	
EC_{50}	Median effective concentration	Effective concentration for 50 % of test organisms
ELS	Early life stage	
E_bC_{50}	EC related to biomass	
E_dC_{50}	EC related to cell density	
E_rC_{50}	EC related to growth rate	
E_yC_{50}	EC related to yield	
ER_{50}	Median effective rate	
f	female	
FIR / bw	Food Intake Rate	daily food intake per body weight of animal
h	Hour	
ha	Hectare	
HC_5	Hazardous concentration 5%	Concentration (HCp) derived from a distribution of species sensitivities, that indicates that a certain percentage (p) of all species have a sensitivity at or below this concentration. In the case of HC_5, p=5%.
HQ	Hazard Quotient	
LC_{50}	Lethal concentration, median	Lethal concentration for 50 % of test organisms
LD_{50}	Lethal dose, median	Lethal dose for 50 % of test organisms
LDD_{50}	Lethal dietary dose, median	Lethal dietary dose for 50 % of test organisms
LLC	Lowest lethal concentration	
LLD	Lowest lethal dose	
LOAEC	Lowest observed adverse effect concentration	
LOEC	Lowest observed effect concentration	
LOEL	Lowest observed effect level	
LOER	Lowest observed effect rate	
LR_{50}	Lethal rate 50%	
log P_{ow}	N-Octanol/Water partition coefficient	expressed as logarithm to base ten
m	male	
MAF	Multiple application factor	

Abbreviation	Explanation	Definition
met.	metabolite	
NOAEC	No observed adverse effect concentration	
NOEAEC	No observed environmental adverse effect concentration	
NOEC	No observed effect concentration	
NOEL	No observed effect level	
NOER	No observed effect rate	
NOLEC	No observed lethal effect concentration	
PEC	Predicted environmental concentration	
PEC_{GW}	PEC in ground water	
PEC_i	PEC initial	
PEC_{max}	PEC maximal	Maximal PEC during multiple applications
PEC_{soil}	PEC in soil	
PEC_{sw}	PEC in surface water	
PEC_{twa}	PEC time weighted average	
p.m.	Pure metabolite	
PD	Portion of Diet	Proportion of different food types in the diet
PT	Portion of Time	Proportion of diet obtained in treated area
Q_{HC}	Hazard quotient contact	Dose/contact LD_{50} (dose = field application rate)
Q_{HO}	Hazard quotient oral	Dose/oral LD_{50}
RUD	Residue per Unit Dose	Estimates (from literature) of residues in food sources, converted to an application rate of 1 kg/ha
SV	Shortcut value	
TER	Toxicity exposure ratio	
TER_A	TER acute	Toxicity exposure ratio for acute exposure
TER_{ST}	TER short term	Toxicity exposure ratio for short-term exposure
TER_{LT}	TER long term	Toxicity exposure ratio for chronic exposure
TG	Technical Grade	
TRR	Total Radioactive Residues	
TWA	Time weighted average	
w	Week	
<	less than	
≤	less than or equal to	
>	greater than	
≥	greater than or equal to	