Document Title

# Tier 2 Summary
## of Ecotoxicological studies
### for the Plant Protection Product Fenhexamid WG 50 (500 g/kg)
**(Specification No.: 102000007271)**

Substance(s)

# FENHEXAMID
## (Annex I renewal)

Data Requirements

**Regulation EC/1141/2010**

on the renewal of the inclusion of AIR2 active substances

**in conjunction with**

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

**According to OECD format guidance for industry data submissions**

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

**Annex IIIA**

**Section 6, Point 10**

**Document M**

Date

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# TABLE OF CONTENTS



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# IIIA 10 Ecotoxicological studies on the plant protection product

Fenhexamid WG 50 is a product in the form of water dispersible granules containing 500 g/kg fenhexamid. Throughout this summary dossier the product is referred to as Fenhexamid WG 50 and the active substance as fenhexamid.

In this chapter a risk assessment for Non-Target Organisms is presented for Fenhexamid WG 50, including its active substance fenhexamid, for the use as a fungicide in vine, strawberry and tomato. Ecotoxicity data used in the following risk assessment were derived from studies with the formulated product and the active substance.

Details of the studies are presented under Annex II, Section 6, Point 8 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).
Studies that have not been evaluated during the Annex I listing process are presented in the updated Annex II, Section 6, Point 8 in the context of AIR2 renewal submission.

Intended application pattern

The formulation containing 500 g/kg fenhexamid is intended for use as foliar spray applied fungicide for grapes, strawberries and tomatoes in the field.
The use pattern for this formulation is summarised as follows:

**Table 10 - 1: Application pattern of Fenhexamid WG 50 as used for the risk assessment**

| Crop | Timing of application BBCH | Max. number of applications | Application interval [d] | Maximum application rate per treatment [g a.s./ha] |
|---|---|---|---|---|
| Grapes | 1st 69-79<br>2nd 81-83 | 2 | BBCH timings [1)] | 800 |
| Strawberry (high rate) | 59-89 | 3 | 7 - 14 | 1000 |
| Strawberry (low rate) | 55-89 | 4 | 7 - 14 | 750 |
| Tomato | 55-89 | 3 | 7 - 14 | 750 |

[1)] 11 days are considered as a realistic minimum interval for the risk assessment

## General Remarks concerning Metabolites

In addition to the active substance, the metabolites listed in Table 10 -2 were addressed in the ecotoxicological risk assessment. For further details please refer to Document N, List of Metabolites.

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**Table 10 - 2: List of metabolites and synonymes adressed in the ecotoxicological risk assessment**

| No. | Name used in the summary (synonymes, short forms, code numbers) | Occurence |
|---|---|---|
| M10 | KBR 2738-benzoxazole<br>(synonyme: Fenhexamid-benzoxazole) | Photolysis, no relevant exposure |
| M12 | KBR 2738-3-deschloro<br>(synonymes: 2-monochloro-KBR 2738, fenhexamid-3-deschloro) | Water/sediment |
| M15 | KBR 2738-trishydroxyphenyl<br>(synonyme: Fenhexamid-trishydroxyphenyl) | Photolysis, no relevant exposure |
| M24 | [C-C]biphenyl KBR 2738<br>(synonymes: KBR 2738-[C-C]biphenyl, fenhexamid-[C-C]biphenyl, BCS-CQ88719) | Soil |
| M39 | 1-methylcyclohexanecarboxylic acid<br>(synonymes: KBR 2378-carbonic acid, KBR 2738-1-methylcychlohexancarbonsäure, BCS-BC75999) | Water/sediment |
| M40 | 1-methylcyclohexanecarboxamide<br>(synonyme: BCS-CQ6373) | Photolysis, no relevant exposure |

**Ecotoxicologically significant metabolites**

Metabolites, for which analytical methods have to be established for monitoring purposes, have to be addressed as significant metabolites. For these metabolites, significant quantities have been observed in at least one environmental compartment of either soil, water, plant or air.

However, none of the metabolites can be considered as hazardous or poses a higher risk to terrestrial and aquatic organisms than the parent compound.

**Ecotoxicologically relevant metabolites**

None of the metabolites of fenhexamid, which are addressed within this dossier and the corresponding Annex II for the active ingredient, is considered as ecotoxicologically relevant. None of the metabolites poses a higher risk to terrestrial and aquatic organisms than the parent compound.

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# IIIA 10.1 Effects on birds

**Toxicity of fenhexamid to birds**

The summary of the toxicity profile of the active substance fenhexamid to birds is provided in the following table.

**Table 10.1- 1: Avian toxicity data of fenhexamid**

| Test species | Test design | Ecotoxicological endpoint | Reference |
|---|---|---|---|
| Fenhexamid | | | |
| Bobwhite quail | acute, oral | $LD_{50}$ > 2000 mg a.s./kg bw | [redacted] (1995)<br>VB038<br>M-006224-01-1<br>IIA 8.1.1/01 (EU point IIA, 8.1.1/01) |
| Bobwhite quail | 5-day feeding | $LC_{50}$ > 5000 mg a.s./kg feed<br>$LDD_{50}$ > 968 mg a.s./kg bw/d | [redacted], 2002<br>VB042<br>M-006291-02-1<br>IIA 8.1.2/01 (EU point IIA, 8.1.2/01) |
| Mallard duck | 5-day feeding | $LC_{50}$ > 5000 mg a.s./kg feed<br>$LDD_{50}$ > 1408 mg a.s./kg bw/d | [redacted], 2002<br>VE008<br>M-006310-02-1<br>IIA 8.1.3/01 (EU point IIA, 8.1.2/02) |
| Bobwhite quail | 23-weeks feeding chronic, reproduction | NOEC 2074 mg a.s./kg feed<br>NOAEL 154 mg a.s./kg bw/d | [redacted], 1997<br>SXR/REP06<br>M-006223-02-1<br>IIA 8.1.4/01 (EU point IIA, 8.1.3/01) |

**Dose conversion for the NOEL of 2074 mg/kg feed from the avian reproduction study with fenhexamid**

The EU list of endpoints for fenhexamid (EFSA review report 6497/VI/99-rev.2 (19.10.2000) provides the NOAEL for use in $TER_{LT}$ calculation for birds as 2074 ppm. According to EFSA GD (2009), the risk assessment is based on endpoints and exposure expressed in daily dietary doses. Conversion of the diet concentration of 2074 ppm (= mg/kg feed) is proposed as follows.

**Table 10.1- 2: Dose conversion for avian reproduction NOAEL (2074 ppm = 154 mg as/kg bw/d)**

| **Bodyweight** | | | |
|---|---|---|---|
| males | start (day 0) | 201 g bw | [redacted] 1997, Table 1 |
| | end | 216 g bw | |
| | mean M | 208.5 g bw | |
| females | start (day 0) | 198 g bw | |
| | end | 241 g bw | |
| | Mean F | 219.5 g bw | |
| **Overall mean bodyweight** | (mean M + mean F) / 2 | 214 g bw | |
| | | 0.214 kg bw | |
| | | | |

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| **Food consumption** | | | |
|---|---|---|---|
| Average of daily feed consumption over 23 weeks | g food / pair / day | 31.87 g food | [redacted] 1997, Table 2 |
| | g food / bird / day | 15.93 g food | |
| | kg food / bird / day | 0.016 kg food | |
| | | | |
| **Relative food consumption** | 0.016 / 0.214 = 0.074 kg food / kg bird/ day | | |
| | | | |
| **Fenhexamide concentration at NOAEL** | 2074 mg as/kg feed | | |
| **Daily dietary dose** | 0.074 x 2074 = **154** mg as/kg bw/day | **NOAEL for $TER_{LT}$** | |

## Metabolites

The metabolism of fenhexamid in plants was investigated in grapes, tomatoes and apples. The rate of degradation on plants is quite low and the majority of radioactivity remained on the surface of the fruits as unchanged parent compound. Most of the identified metabolites were hydroxy-derivatives of fenhexamid, but no metabolite exceeded an amount of 3.2% of the total radioactive residue. Furthermore, all main metabolites identified in plants were also detected in the rat metabolism study. (see also Annex II, point 6.1).

The toxicity of these metabolites is considered to be included in the toxicity testing with the active ingredient on birds and mammals, especially in subchronic and chronic tests.

## Risk assessment for birds

The risk assessment procedure follows the EFSA Guidance Document on Risk Assessment for Birds & Mammals (2009). The risk assessment follows a tiered approach to assess the effects of plant protection products on birds based on current regulatory requirements.

The risk is considered acceptable, if the 'Toxicity Exposure Ratio' (TER) value pass the trigger values of ≥ 10 for acute exposure and ≥ 5 for chronic exposure.

If the TER values are below the trigger values in certain areas, a refined risk assessment based on more relevant and realistic conditions is performed for those particular areas.

## Calculation of Toxicity Exposure Ratio (TER)

The calculation of acute and long-term Toxicity to Exposure Ratio (TER) is defined as follows:

Acute risk: $TER_A$ = $LD_{50}$ [mg a.s./kg bw] / DDD

Long-term risk: $TER_{LT}$ = NO(A)EL [mg a.s./kg bw/d] / DDD

The endpoints for acute and long-term risk assessment derive from acute and reproduction studies respectively, and are expressed as dose [mg] per kg body weight per day.

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**Calculation of Daily Dietary Dose (DDD)**

Acute exposure:

The daily dietary dose for a single application is given by the following equation:

$DDD_{single\ application}$ = application rate [kg/ha] × shortcut value ($SV_{90}$)

In case of multiple applications the $DDD_{single\ application}$ should be multiplied with an appropriate multiple application factor ($MAF_{90}$).

$DDD_{multiple\ applications} = DDD_{single\ application} \times MAF_{90}$

Long-term exposure:

For a single application the daily dietary dose is given by the following equation:

$DDD_{single\ application}$ = application rate [kg/ha] × shortcut value ($SV_m$) × TWA

For multiple applications the $DDD_{single\ application}$ should be multiplied with an appropriate multiple application factor ($MAF_m$).

$DDD_{multiple\ applications} = DDD_{single\ application} \times MAF_m$

Where

DDD Daily dietary dose

MAF Multiple application factor

TWA Time weighted average factor (= $f_{twa}$) based on a default time window of 21 days and a $DT_{50}$ of 10 days leading to a value of 0.53

Shortcut value SV = FIR/bw x RUD: Value for exposure estimate based on species and crop.

RUD Residue per unit dose: residues on feed items normalized on an application rate of 1 kg a.s./ha.

$_{90}$ 90th percentile values for acute exposure, extension for MAF, RUD and SV

$_m$ mean values for reproductive/long-term exposure, extension for MAF, RUD and SV

**Standard exposure scenario for Tier 1 risk assessment**

The main potential exposure route for birds is expected to be consumption of contaminated feed.

The risk assessment on screening level as well as the Tier 1 risk assessment is based on standard scenarios (combination of indicator species (screening level) or generic focal species (Tier 1) and crop). Default ("shortcut"-) values for the exposure estimate will be used as provided in Appendix A of the EFSA Guidance (2009) representing a worst case assessment.

**The screening step before the actual risk assessment as described in the guidance based on indicator species level will be omitted.**

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It is assumed that:

- animals satisfy their entire food demand in the treated area (PT = 1),
- over an acute time frame (hours) the animals feed on items containing maximum residues (90$^{th}$ percentile), whereas they would ingest food containing mean residues over a long-term period (days to weeks),
- the multiple application factor (MAF) for the acute or long-term exposure is based on default values based on a generic $DT_{50}$ value of 10 days, considering the actual (maximum) number of applications and the interval between them,
- long-term predicted environmental concentrations to be compared with chronic endpoints can be calculated as the time-weighted average concentration. Default assumptions are a time window of 21 days and a $DT_{50}$ of 10 days leading to a time weighted average factor (= $f_{twa}$) of 0.53. This factor is equally valid for feed items consisting of vegetation as well as of arthropods.

**Avian generic focal species for Tier 1 risk assessment**

According to the EFSA Guidance (2009) the following generic focal species have to be addressed in Tier 1 risk assessment.

**Table 10.1- 3: Shortcut values for avian generic focal species according to EFSA (2009)**

| Crop | Growth stage (BBCH) | Generic focal species | Representative species | Shortcut value (SV) | |
|---|---|---|---|---|---|
| | | | | For long-term RA based on $RUD_m$ | For acute RA based on $RUD_{90}$ |
| Vineyard | ≥ 20 | Small insectivorous bird "redstart" | Black Redstart | 9.9 | 25.7 |
| | ≥ 40 | Small granivorous bird "finch" | Linnet | 3.4 | 7.4 |
| | ≥ 40 | Small omnivorous bird "lark" | Woodlark | 3.3 | 7.2 |
| | Ripening (81-85) | Frugivorous bird "trush/starling" | Song thrush | 14.4 | 28.9 |
| Strawberry | ≥ 40 | Small omnivorous bird "lark" | Woodlark | 4.4 | 9.6 |
| | Late (61-89) | Frugivorous bird "starling" | Starling | 13.4 | 27.0 |
| | ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail | 9.7 | 25.2 |
| Fruiting vegetables | Fruit stage (71-89) | Frugivorous bird "crow" | Crow 1) | 32.0 | 57.4 |
| | ≥ 50 | Small granivorous bird "finch" | Linnet | 3.4 | 7.4 |
| | ≥ 50 | Small omnivorous bird "lark" | Woodlark | 3.3 | 7.2 |
| | Fruit stage (71-89) | Frugivorous bird "starling" | Starling 2) | 20.7 | 49.4 |
| | ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail | 9.7 | 25.2 |

1) RUD unit specified for gourds; 2) RUD unit specified for tomato

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## Summary of calculated TER values for birds

**Table 10.1- 4: Summary of all acute TER calculations as given under point 10.1.1**

| Active substance | Crop | Generic focal species | $SV_{90}$ | $TER_A$ | Refinement |
|---|---|---|---|---|---|
| Fenhexamid | Grape (2 × 0.8 kg/a.s./ha) | Small insectivorous bird "redstart" | 25.7 | > 75 | No |
| | | Small granivorous bird "finch" | 7.4 | > 260 | No |
| | | Small omnivorous bird "lark" | 7.2 | > 267 | No |
| | | Frugivorous bird "Trush/starling" | 28.9 | > 67 | No |
| | Strawberry (3 × 1.0 kg a.s./ha) [1)] | Small omnivorous bird "lark" | 9.6 | > 130 | No |
| | | Frugivorous bird "starling" | 27.0 | > 46 | No |
| | | Small insectivorous bird "wagtail" | 25.2 | > 50 | No |
| | Fruiting vegetables (Tomato) (3 × 0.75 kg a.s./ha) | Frugivorous bird | 57.4 | > 29 | No |
| | | Small granivorous bird | 7.4 | > 225 | No |
| | | Small omnivorous bird | 7.2 | > 231 | No |
| | | Frugivorous bird "starling" | 49.4 | > 34 | No |
| | | Small insectivorous bird "wagtail" | 25.2 | > 66 | No |

[1)] worst case, covering lower rate of 4 × 0.75 kg a.s./ha

**Table 10.1- 5: Summary of all reproductive (long-term) TER calculations as given under point 10.1.2**

| Active substance | Crop | Generic focal species | $SV_m$ | $TER_{LT}$ | Refinement |
|---|---|---|---|---|---|
| Fenhexamid | Grape (2 × 0.8 kg/a.s./ha) | Small insectivorous bird "redstart" | 6.3 | 24 | No |
| | | Small granivorous bird "finch" | 2.2 | 71 | No |
| | | Small omnivorous bird "lark" | 2.1 | 73 | No |
| | | Frugivorous bird "Trush/starling" | 9.2 | 17 | No |
| | Strawberry (3 × 1.0 kg a.s./ha) [1)] | Small omnivorous bird "lark" | 4.7 | 33 | No |
| | | Frugivorous bird "starling" | 14.2 | 11 | No |
| | | Small insectivorous bird "wagtail" | 10.3 | 15 | No |
| | Fruiting vegetables (Tomato) (3 × 0.75 kg a.s./ha) | Frugivorous bird "crow" | 25.4 | 6.1 | No |
| | | Small granivorous bird | 2.7 | 57 | No |
| | | Small omnivorous bird | 2.6 | 59 | No |
| | | Frugivorous bird "starling" | 16.5 | 9.4 | No |
| | | Small insectivorous bird "wagtail" | 7.7 | 20 | No |

[1)] worst case, covering lower rate of 4 × 0.75 kg a.s./ha

**Conclusion:** According to the presented risk assessment, , the risk to birds from the use of the product of Fenhexamid WG 50 is acceptable.

## IIIA 10.1.1 Acute toxicity exposure ratio ($TER_A$) for birds

### Tier 1 acute toxicity exposure ratio for birds

The tier 1 risk assessment has been performed for grapes for an application rate of 2 × 0.8 kg fenhexamid/ha at a minimum application interval of 11 days, for strawberries for an application rate of 3 × 1.0 kg/ha at a minimum application interval of 7 days covering the lower rate of 4 × 0.75 kg/ha and for tomatoes for an application rate of 3 × 0.75 kg fenhexamid/ha at a minimum application interval of 7 days.

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**Table 10.1.1- 1: Tier 1 acute TER calculation for birds**

| Crop | Generic focal species | $LD_{50}$ [mg/kg bw] | DDD Appl. rate [kg/ha] | DDD $SV_{90}$ | DDD $MAF_{90}$ | DDD | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|---|---|
| Fenhexamid | | | | | | | | |
| Grape | Small insectivorous bird “redstart” | > 2000 | 0.8 | 25.7 | 1.3 | 26.7 | > 75 | 10 |
| | Small granivorous bird “finch” | | | 7.4 | | 7.7 | > 260 | |
| | Small omnivorous bird “lark” | | | 7.2 | | 7.5 | > 267 | |
| | Frugivorous bird “Trush/starling” | | | 28.9 | | 30.1 | > 67 | |
| Strawberry | Small omnivorous bird “lark” | > 2000 | 1.0 | 9.6 | 1.6 | 15.4 | > 130 | 10 |
| | Frugivorous bird “starling” | | | 27.0 | | 43.2 | > 46 | |
| | Small insectivorous bird “wagtail” | | | 25.2 | | 40.3 | > 50 | |
| Fruiting vegetables (Tomato) | Frugivorous bird (“crow”) | > 2000 | 0.75 | 57.4 | 1.6 | 68.9 | > 29 | 10 |
| | Small granivorous bird (“finch”) | | | 7.4 | | 8.9 | > 225 | |
| | Small omnivorous bird (“lark”) | | | 7.2 | | 8.6 | > 231 | |
| | Frugivorous bird “starling” | | | 49.4 | | 59.3 | > 34 | |
| | Small insectivorous bird “wagtail” | | | 25.2 | | 30.2 | > 66 | |

All TER values are above the Annex VI trigger of 10 for acute exposure. Accordingly an unacceptable acute risk to birds from the use of Fenhexamid WG 50 according to the proposed use pattern can be excluded.

**Acute risk assessment for birds drinking contaminated water**

The acute risk from water in puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil is covered by the long-term risk assessment under Point 10.1.2 of this dossier.

## IIIA 10.1.2 Short-term toxicity exposure ratio ($TER_{ST}$) for birds

**Tier 1 short-term toxicity exposure ratio for birds**

According to the risk assessment scheme of EFSA GD birds and mammals (2009) a short-term risk assessment is not required for fenhexamid.

**Tier 1 long-term toxicity exposure ratio for birds**

The tier 1 risk assessment has been performed for grapes for an application rate of 2 × 0.8 kg

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fenhexamid/ha at a minimum application interval of 11 days, for strawberries for an application rate of 3 × 1.0 kg/ha at a minimum application interval of 7 days covering the lower rate of 4 × 0.75 kg/ha and for tomatoes for an application rate of 3 × 0.75 kg fenhexamid/ha at a minimum application interval of 7 days.

**Table 10.1.2- 1: Tier 1 long-term TER calculation for birds**

| Crop | Generic focal species | NO(A)EL [mg/kg bw/d] | DDD | | | | DDD | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|---|---|---|
| | | | Appl. Rate [kg/ha] | $SV_m$ | $MAF_m$ | $f_{twa}$ | | | |
| Fenhexamid | | | | | | | | | |
| Grape | Small insectivorous bird “redstart” | 154 | 0.8 | 9.9 | 1.5 | 0.53 | 6.3 | 24 | 5 |
| | Small granivorous bird “finch” | | | 3.4 | | | 2.2 | 71 | |
| | Small omnivorous bird “lark” | | | 3.3 | | | 2.1 | 73 | |
| | Frugivorous bird “Trush/starling” | | | 14.4 | | | 9.2 | 17 | |
| Strawberry | Small omnivorous bird “lark” | 154 | 1.0 | 4.4 | 2.0 | 0.53 | 4.7 | 33 | 5 |
| | Frugivorous bird “starling” | | | 13.4 | | | 14.2 | 11 | |
| | Small insectivorous bird “wagtail” | | | 9.7 | | | 10.3 | 15 | |
| Fruiting vegetables (Tomato) | Frugivorous bird (“crow”) | 154 | 0.75 | 32.0 | 2.0 | 0.53 | 25.4 | 6.1 | 5 |
| | Small granivorous bird (“finch”) | | | 3.4 | | | 2.7 | 57 | |
| | Small omnivorous bird (“lark”) | | | 3.3 | | | 2.6 | 59 | |
| | Frugivorous bird “starling” | | | 20.7 | | | 16.5 | 9.4 | |
| | Small insectivorous bird “wagtail” | | | 9.7 | | | 7.7 | 20 | |

All TER values are above the trigger of 5 for long-term exposure. Accordingly the long-term risk to birds from the use of Fenhexamid WG 50 according to the proposed use pattern is acceptable.

**Long-term risk assessment for birds drinking contaminated water**

An assessment of the risk potentially posed by consumption of contaminated drinking water is required according to the EFSA Guidance Document for Birds and Mammals (2009).

Due to the incidental nature of occurrence of drinking water reservoirs on agricultural fields (as compared to the contamination of food items growing or dwelling on those fields), a separate assessment of this exposure route is considered appropriate at least on the first-tier level.

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Two scenarios were identified as relevant for assessing the risk of pesticides via drinking water to birds and mammals:

- Leaf scenario, only relevant for birds possibly drinking water from puddles in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation. This scenario is only relevant for acute exposure.
  As Fenhexamid WG 50 is applied in grapes, strawberries and tomatoes, no pools in leaf axils where an acute exposure possibly might occur are to be expected.
- Puddle scenario. Birds and mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil. This scenario is only relevant for acute and long-term exposure.

An "escape clause" recommended in the EFSA Guidance Document for Birds and Mammals (2009) allows for screening the need for a quantitative risk assessment by a comparison between the application rate and the toxicity of the respective substance. This escape clause specifies that *"due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals ..., no specific calculations of exposure and TER are necessary when the ratio of effective application rate (=* application rate × MAF) *(in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg)."* [1].

**Table 10.1.2- 2: Evaluation of potential concern for exposure of birds drinking water (escape clause)**

| Compound | Koc [L/kg] | Application rate * $MAF_m$ [g a.s./ha] [1)] | NO(A)EL [mg a.s./kg bw/d] | Ratio (Application rate *MAF) / NO(A)EL | "Escape clause" No concern if ratio | Conclusion |
|---|---|---|---|---|---|---|
| Fenhexamid | 517 | 1000 × 2.0 | 154 | 13.0 | **≤ 3000** | No concern |

[1)] Critical GAP for application in strawberries (high rate) used as worst case approach.

This evaluation confirms that the risk for birds from drinking water that may contain residues from the use of Fenhexamid WG 50 is acceptable.

## IIIA 10.1.3 In case of bait, the concentration of active substance in the bait

Not applicable for spray application.

## IIIA 10.1.4 In case of pellets, granules, pills or treated seed

Not applicable for spray application.

### IIIA 10.1.4.1 Amount of a.s. in or on each pellet, granule, pill or treated seed

Not applicable for spray application.

[1] EFSA (2009): Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA, p. 69

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## IIIA 10.1.4.2 Proportion of the $LD_{50}$ for the a.s. in 100 particles / gram particles

Not applicable for spray application.

## IIIA 10.1.5 In the case of pellets, granules and pills, their size and shape

Not applicable for spray application.

## IIIA 10.1.6 Acute oral toxicity of the preparation to the more sensitive species

According to the "Guidance Document on Terrestrial Ecotoxicology" of October 2002, studies with the formulation are considered necessary only where they will clearly add essential information. Since the studies with the active ingredient show no acute toxicity, a further acute study on birds with the formulation was not taken into consideration due to animal welfare reasons.

## IIIA 10.1.7 Supervised cage or field trials

The risk assessment based on the active substance indicates acceptable acute, short-term and long-term risks to birds (see Points 10.1.1 and 10.1.2 of this dossier). For this reason and also considering animal welfare, no supervised cage or field study with the preparation was deemed necessary.

## IIIA 10.1.8 Acceptance of bait, granules or treated seed by birds

Not applicable for spray application.

## IIIA 10.1.9 Effects of secondary poisoning

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log $K_{OW}$ > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.
The log $P_{OW}$ of fenhexamid was determined to be 3.52 (see Annex IIA, point 2.8). Thus a risk assessment for secondary poisoning was performed for the active substance of Fenhexamid WG 50.

**Risk assessment for bioaccumulation and food chain behaviour for birds**

The risk assessment according to EFSA (2009) follows a tiered approach to assess the effects of plant protection products on birds and mammals.
The risk is considered acceptable, if the 'Long-term Toxicity Exposure Ratio' ($TER_{LT}$) value pass the trigger values of ≥ 5 for long-term exposure.
If the TER values are below the trigger values, a refined risk assessment based on more relevant and realistic conditions is performed for those particular areas.

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**Calculation of Toxicity Exposure Ratio (TER)**

The long-term Toxicity to Exposure Ratio (TER) depends on the selection of the suitable endpoint and is defined as follows (EFSA 2009):

Long-term risk: $TER_{LT}$ = NO(A)EL [mg a.s./kg bw/d] / DDD

**Calculation of Daily Dietary Dose (DDD) for earthworm eating birds**

$DDD_{earthworm} = PEC_{worm} \times FIR / bw$

Residues in earthworms are calculated according to the following equation:

$PEC_{worm} = PEC_{soil} \times BCF$

The bioconcentration factor ($BCF = C_{worm}/C_{soil}$) is calculated according to the following equation:

$BCF = (0.84 + 0.012\ P_{ow}) / f_{oc} \times K_{oc}$

Where

$K_{OC}$ = Organic carbon adsorption coefficient

$f_{OC}$ = Organic carbon content of soil (take 0.02 as a default value)

**Calculation of Daily Dietary Dose (DDD) for fish-eating birds**

$DDD_{fish} = PEC_{fish} \times FIR / bw$

Residues in fish are calculated according to the following equation:

$PEC_{fish} = PEC_{sw} \times BCF_{fish}$

**Avian generic focal species for Tier 1 risk assessment**

According to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) the following generic focal species have to be addressed in the Tier 1 risk assessment.

**Table 10.1.9- 1: Avian generic focal species for the Tier 1 risk assessment of secondary poisoning**

| Generic avian indicator species | Body weight [g] | Example | FIR/bw |
|---|---|---|---|
| Earthworm eater | 100 | Blackbird | 1.05 |
| Fish eater | 1000 | Heron | 0.159 |

**Long-term TER calculation for earthworm-eating birds**

The risk assessment has been performed for application in strawberries (high rate). This is a worst-case covering all other uses according to the intended GAP.

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**Table 10.1.9- 2: Tier 1 long-term TER calculation for earthworm-eating birds**

| Compound | Fenhexamid | Origin of value |
|---|---|---|
| **$BCF_{worm}$ calculation:** | | |
| $P_{OW}$ | 3311 | AII 2.8 |
| $K_{OC}$ [mL/g] | 517 | IIA 7.4 / IIIA 9.3 |
| $f_{OC}$ | 0.02 | default |
| $BCF_{worm}$ | 3.92 | |
| **$PEC_{worm}$ calculation:** | | |
| $PEC_{soil}$ (twa, 21 d)[mg/kg] 1) | 0.134 | IIIA 9.4 |
| $PEC_{worm}$ [mg/kg] | 0.53 | |
| **DDD calculation:** | | |
| FIR/bw | 1.05 | default |
| DDD [mg/kg bw/d] | 0.55 | |
| **$TER_{LT}$ calculation:** | | |
| NO(A)EL [mg/kg bw/d] | 154 | IIIA 10.1 |
| $TER_{LT}$ | 280 | |
| Trigger | 5 | |
| Refined risk assessment required? | No | |

1) Worst case $PEC_{soil}$ (twa, 21 d) for the use in strawberries (high rate) (covering all other uses)

The TER value for the use in strawberries (high rate) as worst case scenario is above the trigger of 5. Accordingly the risk to earthworm eating birds from the use of Fenhexamid WG 50 according to the proposed use pattern is acceptable.

### Long-term TER calculation for fish-eating birds

The risk assessment has been performed for application in vine. This is a worst-case covering all other uses according to the intended GAP.

**Table 10.1.9- 3: Tier 1 long-term TER calculation for fish-eating birds**

| Compound | Fenhexamid | Origin of value |
|---|---|---|
| **$PEC_{fish}$ calculation:** | | |
| $BCF_{fish}$ | 80 | IIA 8.2.6.1/02 (EU point IIA, 8.2.3/02) |
| $PEC_{SW}$ (twa, 21 d)[mg/L] 1) | 0.0107 | AIII, 9.7 |
| $PEC_{fish}$ [mg/kg] | 0.86 | |
| **DDD calculation:** | | |
| FIR/bw | 0.159 | Default |
| DDD [mg/kg bw/d] | 0.14 | |
| **$TER_{LT}$ calculation:** | | |
| NO(A)EL [mg/kg bw/d] | 154 | IIIA, 10.1 |
| $TER_{LT}$ | 1131 | |
| Trigger | 5 | |
| Refined risk assessment required? | No | |

1) Worst case $PEC_{SW}$ (twa, 21 d) for the use in vine as given in chapter 9.7 (covering all other uses)

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The TER value for the use in vine as worst case scenario is above the trigger of 5. Accordingly the risk to fish eating birds from the use of Fenhexamid WG 50 according to the proposed use pattern is acceptable.

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## IIIA 10.2 Effect on aquatic organisms

**Toxicity of fenhexamid to aquatic organisms**
A summary of the aquatic toxicity profile is provided below for fenhexamid.

**Table 10.2- 1: Toxicity of fenhexamid to aquatic organisms**

| Test organism | Test system | Endpoint [mg a.s./L] | | Reference |
|---|---|---|---|---|
| Acute toxicity to fish | | | | |
| *Oncorhynchus mykiss* (rainbow trout) | Flow through 96 h | $LC_{50}$ | **1.24** | [redacted] (1995) DOM95001 M-006071-01-1 IIA 8.2.1.1/01 (EU point IIA, 8.2.1/01) |
| *Lepomis macrochirus* (bluegill sunfish) | Flow through 96 h | $LC_{50}$ | 3.17 | [redacted] (1995) DOM95002 M-006072-01-1 IIA 8.2.1.2/01 (EU point IIA, 8.2.1/02) |
| Chronic toxicity to fish | | | | |
| *Oncorhynchus mykiss* (rainbow trout) | Early Life Stage flow-through 96 d | NOEC | **0.101** | [redacted] (1997) DOM96050 M-006184-01-1 IIA 8.2.4/01 (EU point IIA, 8.2.2.2/01) |
| Acute toxicity to aquatic invertebrates | | | | |
| *Daphnia magna* (water flea) | Static 48 h | $EC_{50}$ | > **18.8** | [redacted] (1995) HBF/DM139 M-006075-01-1 IIA 8.3.1.1/01 (EU point IIA, 8.2.4/01) |
| Chronic toxicity to aquatic invertebrates | | | | |
| *Daphnia magna* (water flea) | Semi-static 21 d | NOEC | **1.0** | [redacted] (1996) HBF/RDM56 M-006068-01-1 IIA 8.3.2.1/01 (EU point IIA, 8.2.5/01) |
| Sediment dwelling organisms | | | | |
| *Chironomus riparius* (chironomid) | Chronic test - spiked water 28 d | $EC_{15}$ | **11.4** | [redacted] (1999) HBF/CH35 M-024548-01-1 IIA 8.5.2/01 (EU point IIA, 8.2.7/01) |
| *Chironomus riparius* (chironomid) | Chronic test – spiked sediment 28 d | NOEC | **100** mg a.s./kg | [redacted] (2002) 1022.021.173 M-033777-01-1 IIA 8.5.2/02 |

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**Table 10.2- 1: Toxicity of fenhexamid to aquatic organisms (continued)**

| Test organism | Test system | Endpoint [mg a.s./L] | Reference |
|---|---|---|---|
| Effects on algal growth | | | |
| *Selenastrum capricornutum* (green alga) | Static 120 h | $E_rC_{50}$ **8.43** | [redacted] (1995) AJO/128695 M-006073-01-1 IIA 8.4/01 (EU point IIA, 8.2.6/01) |
| *Scenedesmus subspicatus* (green alga) | Static 72 h | $E_rC_{50}$ > 26.1 | [redacted] (1996) AJO/133595 M-006070-01-1 IIA, 8.4/02 (EU point IIA, 8.2.6/02) |
| Aquatic plants | | | |
| *Lemna gibba* (duck weed) | Static 14 d | $EC_{50}$ > **2.3** [1)] | [redacted]. (1998) 443 A-103 M-006182-01-1 IIA, 8.6/01 |

**Endpoints in bold** considered relevant for the risk assessment
1) based on the number of fronds and plant dry weight

**Table 10.2- 2: Toxicity of fenhexamid metabolites to aquatic organisms**

| Test organism | Test system | Endpoint [mg p.m./L] | Reference |
|---|---|---|---|
| **M10** | | | |
| Acute toxicity to fish | | | |
| *Oncorynchus mykiss* (rainbow trout) | Static 96 h | $LC_{50}$ 0.391 | [redacted] (2009) EBKBL003 M-350526-01-1 IIA 8.2.1.3/01 |
| Acute toxicity to aquatic invertebrates | | | |
| *Daphnia magna* (water flea) | Static 48 h | $EC_{50}$ 1.13 | [redacted] (2009) EBKBL002 M-345853-01-1 IIA 8.3.1.1/02 |
| Effects on algal growth | | | |
| *Pseudokirchneriella subcapitata* (green alga) | Static 72 h | $E_rC_{50}$ > 9.25 | [redacted] (2010) EBKBL007 M-362991-01-1 IIA 8.4/03 |

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**Table 10.2- 2: Toxicity of fenhexamid metabolites to aquatic organisms (continued)**

| Test organism | Test system | Endpoint [mg p.m./L] | | Reference |
|---|---|---|---|---|
| **M12** | | | | |
| Acute toxicity to fish | | | | |
| *Oncorynchus mykiss* (rainbow trout) | Static 96 h | $LC_{50}$ | **4.51** | [redacted] (2008) EBKBL006 M-345406-01-1 IIA 8.2.1.3/02 |
| Acute toxicity to aquatic invertebrates | | | | |
| *Daphnia magna* (water flea) | Static 48 h | $EC_{50}$ | **12.6** | [redacted] (2009) EBKBL005 M-345837-01-1 IIA 8.3.1.1/03 |
| Effects on algal growth | | | | |
| *Pseudokirchneriella subcapitata* (green alga) | Static 72 h | $E_rC_{50}$ | **> 25** | [redacted] (2009) EBKBL004 M-345417-01-1 IIA 8.4/04 |
| **M15** | | | | |
| Acute toxicity to fish | | | | |
| *Oncorhynchus mykiss* (rainbow trout) | Static 96 h | $LC_{50}$ | > 100 | [redacted] (2009) EBKBL012 M-357294-01-1 IIA 8.2.1.3/03 |
| Acute toxicity to aquatic invertebrates | | | | |
| *Daphnia magna* (water flea) | Static 48 h | $EC_{50}$ | 26 | [redacted] (2009) EBKBL011 M-358250-01-1 IIA 8.3.1.1/04 |
| Effects on algal growth | | | | |
| *Pseudokirchneriella subcapitata* (green alga) | Static 72 h | $E_rC_{50}$ | 10.1 | [redacted] (2010) EBKBL010 M-367188-01-1 IIA 8.4/05 |
| **M24** | | | | |
| Acute toxicity to fish | | | | |
| *Oncorynchus mykiss (rainbow trout)* | Static 96 h | $LC_{50}$ | **2.62** | [redacted] (2012) EBKBP003 M-422423-01-1 IIA 8.2.1.3/04 |
| Acute toxicity to aquatic invertebrates | | | | |
| *Daphnia magna* (water flea) | Static 48 h | $EC_{50}$ | **> 20** | [redacted] (2012) EBKBL030 M-423120-01-1 IIA 8.3.1.1/05 |
| Effects on algal growth | | | | |

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| Test organism | Test system | Endpoint [mg p.m./L] | | Reference |
|---|---|---|---|---|
| *Pseudokirchneriella subcapitata* (green alga) | Static 72 h | $E_rC_{50}$ | **14.2** | [redacted] (2012) EBKBP002 M-422987-01-1 IIA 8.4/06 |

**Table 10.2- 2: Toxicity of fenhexamid metabolites to aquatic organisms (continued)**

| Test organism | Test system | Endpoint [mg p.m./L] | | Reference |
|---|---|---|---|---|
| **M39** | | | | |
| Acute toxicity to fish | | | | |
| *Oncorynchus mykiss (rainbow trout)* | Static 96 h | $LC_{50}$ | **> 10** | [redacted] (2012) EBKBL028 M-422291-01-1 IIA 8.2.1.3/05 |
| Acute toxicity to aquatic invertebrates | | | | |
| *Daphnia magna* (water flea) | Static 48 h | $EC_{50}$ | **138** | [redacted] (2012) EBKBP004 M-423128-01-1 IIA 8.3.1.1/06 |
| Effects on algal growth | | | | |
| *Pseudokirchneriella subcapitata* (green alga) | Static 72 h | $E_rC_{50}$ | **> 10** | [redacted] (2012) EBKBL027 M-422978-01-1 IIA 8.4/07 |
| **M40** | | | | |
| Acute toxicity to fish | | | | |
| *Oncorhynchus mykiss* (rainbow trout) | Static, limit test 96 h | $LC_{50}$ | > 100 | [redacted] (2010) EBKBL024 M-369106-01-1 IIA 8.2.1.3/06 |

**Endpoints in bold** considered relevant for the risk assessment
p.m. = pure metabolite

## Metabolites

In a study performed with fenhexamid with respect to environmental fate and behaviour in water and sediment, two major metabolites were identified (M39 and M12) which occurred in an aquatic environment in amounts up to 8.9% and 7.5%, respectively. Therefore, a quantitative risk assessment is presented for M39 and M12. A quantitative risk assessment risk assessment is also conducted for the major soil metabolite M24.

With the photolysis metabolites M10, M15 and M40 aquatic studies have been conducted and results are presented. All photolysis metabolites are of transient nature and therefore, due to the very limited potential exposure, they were not taken into consideration for the quantitative risk assessment.

**Summary of data derived from studies with the formulated product**

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A summary of the aquatic toxicity profile of Fenhexamid WG 50 is provided in Table 10.2- 3. For more details on the respective studies reference is made to Point 10.2.2 of this dossier.

**Table 10.2- 3: Toxicity of Fenhexamid WG 50 to aquatic organisms**

| Test organism | Test system | Endpoint [mg a.s./L] | | Reference |
|---|---|---|---|---|
| Acute toxicity to fish | | | | |
| *Oncorhynchus mykiss* (rainbow trout) | Semi-static 96 h | $LC_{50}$ | 1.30 (2.66 mg product/L) | [redacted] (1996) DOM 95042 M-006209-01-1 KIIIA 10.2.2.1/01 |
| Acute toxicity to aquatic invertebrates | | | | |
| *Daphnia magna* (water flea) | Static 48 h | $EC_{50}$ | 105 (211 mg product/L) | [redacted] (1995) HBF/DM 144 M-006218-01-1 KIIIA 10.2.2.2/01 |
| Effects on algal growth | | | | |
| *Selenastrum capricornutum* (green alga) | Static 72 h | $E_rC_{50}$ | 18.26 (36.3 mg product /L) | [redacted] (1999) DOM 98086 M-006205-01-1 KIIIA 10.2.2.3/01 |

These results indicate that the formulated product is not more toxic than expected, based on the active substance content.
Therefore, as the active substance is not more toxic when it is formulated, the risk assessment to aquatic organisms for application of Fenhexamid WG 50 can be based on the ecotoxicological data and PEC values of the active substance fenhexamid.

**Selection of endpoints for risk assessment**
In general the lowest endpoint values are considered. However, some special points have to be addressed.

**Selection of algae endpoints for risk assessment**
Processes in ecosystems are dominantly rate driven and therefore, the unit development per time (growth rate) appears more suitable to measure effects in algae. Also, growth rates and their inhibition can easily be compared between species, test durations and test conditions, which is not the case for biomass. After numerous discussions, the current test guidelines OECD TG 201, the EU-Method C3, the EC regulation for Classification and Labeling (EC regulation 1272/2008) and the PPR Opinion (EFSA Journal 461, 1-44, 2007) list growth rate as the most suitable endpoint of the algae inhibition test. Only the current Guidance Document on Aquatic Toxicology (SANCO/3268/2001 rev. 4) still states that "*As there is no clear evidence available to indicate which is the most relevant endpoint for the field situation the lower figure should be used in the risk assessment*". In order to avoid unnecessary delays in dossier reviews, toxicity-exposure-ratios in this assessment are built on the lower of the two values, the $E_bC_{50}$ or the $E_rC_{50}$ in case both values are available, unless justification is available.

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## IIIA 10.2.1 Toxicity exposure ratios for aquatic species

Aquatic organisms may be exposed to a plant protection product to some extent by spray drift, run-off or drainage from treated fields. The provided studies and data permit a risk assessment following exposure to the product under practical conditions.

**Predicted Environmental Concentrations in surface water bodies**

Predicted environmental concentrations for the active substances and their relevant metabolites were calculated in surface water ($PEC_{sw}$) and in sediment ($PEC_{sed}$) according to FOCUS surface water scenarios as described in detail in Point 9.7 (active substances) and 9.8 (metabolites).

Concentrations in groundwater are also considered, as groundwater might become surface water, leading to exposure of aquatic organisms. However, the PEC values for the active substance fenhexamid and the soil metabolite M24 are < 0.1 µg/L in groundwater for all relevant FOCUS scenarios and application rates (for details see Point 9.6), and thus not relevant for the risk assessment.

**Table 10.2.1- 1: Maximum $PEC_{sw}$ and $PEC_{sed}$ values for fenhexamid at FOCUS Steps 1 and 2**

| Crop | Step | Fenhexamid | | |
|---|---|---|---|---|
| | | $PEC_{sw, max}$ [µg/L] | $PEC_{sw, 21\ d\ TWA}$ [µg/L] | $PEC_{sed, max}$ [µg/kg] |
| Vine, late<br>2 × 0.8 kg/ha | 1 | 358.50 | 197.8 | 1630 |
| | 2 (N-EU Multi) | **25.86** | 10.68 | 66.85 |
| | 2 (S-EU Multi) | 25.86 | 10.70 | 67.03 |
| | 2 (N-EU Single) | 21.41 | 7.958 | 49.40 |
| | 2 (S-EU Single) | 21.41 | 7.978 | 49.58 |
| Strawberry (high rate)<br>3 × 1 kg/ha | 1 | 619.50 | 352.2 | 3060 |
| | 2 (N-EU Multi) | **11.88** | 5.246 | 33.08 |
| | 2 (S-EU Multi) | 11.88 | 5.270 | 33.30 |
| | 2 (N-EU Single) | 9.20 | 3.451 | 21.52 |
| | 2 (S-EU Single) | 9.20 | 3.476 | 21.74 |
| Strawberry (low rate)<br>4 × 0.75 kg/ha | 1 | 619.50 | 352.2 | 3060 |
| | 2 (N-EU Multi) | **9.145** | 4.119 | 26.01 |
| | 2 (S-EU Multi) | 9.145 | 4.138 | 26.18 |
| | 2 (N-EU Single) | 6.90 | 2.588 | 16.14 |
| | 2 (S-EU Single) | 6.90 | 2.607 | 16.30 |
| Tomato<br>3 × 0.75 kg/ha | 1 | 464.70 | 264.2 | 2300 |
| | 2 (N-EU Multi) | **8.913** | 3.934 | 24.81 |
| | 2 (S-EU Multi) | 8.913 | 3.953 | 24.98 |
| | 2 (N-EU Single) | 6.90 | 2.588 | 16.14 |
| | 2 (S-EU Single) | 6.90 | 2.607 | 16.30 |

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**Table 10.2.1- 2: Maximum $PEC_{sw}$ and $PEC_{sed}$ values for fenhexamid at FOCUS Step 3**

| | | Single application | | Multiple application | |
|---|---|---|---|---|---|
| Crop | Scenario | $PEC_{sw, max}$ [µg/L] | $PEC_{sed, max}$ [µg/kg] | $PEC_{sw, max}$ [µg/L] | $PEC_{sed, max}$ [µg/kg] |
| Vine (late) | D6 (ditch) | 13.72 | 14.27 | 14.07 | 16.96 |
| | R1 (pond) | 0.488 | 1.403 | 0.744 | 2.464 |
| | R1 (stream) | 10.06 | 1.417 | 8.879 | 1.374 |
| | R2 (stream) | 13.49 | 1.021 | 11.90 | 0.993 |
| | R3 (stream) | **14.19** | 3.092 | 12.52 | 2.851 |
| | R4 (stream) | 10.06 | 1.400 | 8.878 | 1.298 |
| Strawberry (high rate) | D6 (ditch) | 6.326 | 2.630 | 4.616 | 2.229 |
| | R2 (stream) | 5.617 | 0.930 | 4.075 | 0.905 |
| | R3 (stream) | 5.906 | 1.309 | 4.286 | 1.271 |
| | R4 (stream) | 4.190 | 1.953 | 3.044 | 2.209 |
| Strawberry (low rate) | D6 (ditch) | 4.747 | 1.994 | 3.195 | 1.565 |
| | R2 (stream) | 4.212 | 0.323 | 2.828 | 0.838 |
| | R3 (stream) | 4.430 | 0.988 | 2.974 | 1.126 |
| | R4 (stream) | 3.142 | 1.451 | 2.112 | 1.641 |
| Tomato | D6 (ditch) | 4.747 | 1.994 | 3.463 | 1.691 |
| | R2 (stream) | 4.212 | 0.323 | 3.055 | 0.843 |
| | R3 (stream) | 4.430 | 0.988 | 3.213 | 0.959 |
| | R4 (stream) | 3.142 | 1.451 | 2.282 | 1.649 |

**Table 10.2.1- 3: Maximum $PEC_{sw}$ and $PEC_{sed}$ of fenhexamid for all relevant scenarios at FOCUS Step 4 following application to vine with a 5 m buffer zone**

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

**Table 10.2.1- 4: Maximum $PEC_{sw}$ and $PEC_{sed}$ values for metabolites of fenhexamid at FOCUS Step 2**

| | | M24 | | M12 | | M39 | |
|---|---|---|---|---|---|---|---|
| Crop | FOCUS step | $PEC_{sw}$ [µg/L] | $PEC_{sed}$ [µg/kg] | $PEC_{sw}$ [µg/L] | $PEC_{sed}$ [µg/kg] | $PEC_{sw}$ [µg/L] | $PEC_{sed}$ [µg/kg] |
| Vine | 1 | 21.11 | 192.5 | 2.846 | < 0.001 | 2.861 | < 0.001 |
| | 2 (N-EU Multi) | 1.109 | 10.12 | 1.529 | 13.14 | 1.701 | 0.223 |
| | 2 (S-EU Multi) | **1.664** | 15.17 | **1.529** | 13.14 | **1.701** | 0.223 |
| | 2 (N-EU Single) | 0.598 | 5.455 | 1.423 | 7.782 | 1.430 | 0.186 |
| | 2 (S-EU Single) | 0.897 | 8.182 | 1.423 | 7.782 | 1.430 | 0.186 |
| Strawberry (high rate) | 1 | 39.58 | 361.0 | 1.834 | < 0.001 | 1.844 | < 0.001 |
| | 2 (N-EU Multi) | 2.036 | 18.57 | 0.639 | 6.926 | 0.791 | 0.104 |
| | 2 (S-EU Multi) | **3.054** | 27.85 | **0.639** | 6.926 | **0.791** | 0.104 |
| | 2 (N-EU Single) | 0.748 | 6.818 | 0.611 | 3.343 | 0.615 | 0.080 |
| | 2 (S-EU Single) | 1.121 | 10.23 | 0.611 | 3.343 | 0.615 | 0.080 |

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| Crop | FOCUS step | M24 | | M12 | | M39 | |
|---|---|---|---|---|---|---|---|
| | | **$PEC_{sw}$ [µg/L]** | **$PEC_{sed}$ [µg/kg]** | **$PEC_{sw}$ [µg/L]** | **$PEC_{sed}$ [µg/kg]** | **$PEC_{sw}$ [µg/L]** | **$PEC_{sed}$ [µg/kg]** |
| Strawberry (low rate) | 1 | 39.58 | 361.0 | 1.834 | < 0.001 | 1.844 | < 0.001 |
| | 2 (N-EU Multi) | 1.943 | 17.72 | 0.500 | 6.171 | 0.587 | 0.077 |
| | 2 (S-EU Multi) | **2.914** | 26.57 | **0.500** | 6.171 | **0.587** | 0.077 |
| | 2 (N-EU Single) | 0.561 | 5.114 | 0.458 | 2.507 | 0.461 | 0.060 |
| | 2 (S-EU Single) | 0.841 | 7.671 | 0.458 | 2.507 | 0.461 | 0.060 |
| Tomato | 1 | 29.68 | 270.7 | 1.375 | <0.001 | 1.383 | <0.001 |
| | 2 (N-EU Multi) | 1.527 | 13.93 | 0.479 | 5.195 | 0.594 | 0.078 |
| | 2 (S-EU Multi) | **2.291** | 20.89 | **0.479** | 5.195 | **0.594** | 0.078 |
| | 2 (N-EU Single) | 0.561 | 5.114 | 0.458 | 2.507 | 0.461 | 0.060 |
| | 2 (S-EU Single) | 0.841 | 7.671 | 0.458 | 2.507 | 0.461 | 0.060 |

For the Tier 1 risk assessment the worst case $PEC_{sw}$ FOCUS step 2 or Step 3 value (as marked in bold) resulting from each crop is used.

## Risk assessment

Based on the representative most sensitive endpoint values (Table 10.2- 1 and Table 10.2- 2) and the $PEC_{sw}$ values (Table 10.2.1- 1 to Table 10.2.1- 4, highest values selected as worst case), the TER-values have been calculated, based on the following equations:

$TER_a = LC_{50}$ or $EC_{50}$ / initial $PEC_{water}$
$TER_{lt} = E_rC_{50}$ / initial $PEC_{water}$
$TER_{lt}$ = chronic NOEC / long-term $PEC_{water}$
The risk is considered acceptable, if the $TER_a$ values for fish and invertebrates are >100, and the $TER_{lt}$ values >10.

## Summary of calculated TER values for aquatic organisms

**Table 10.2.1- 5: Summary of calculated TER values for aquatic organisms based on FOCUS Step 2 values (if not indicated otherwise) for the application of Fenhexamid WG 50**

| Compound | Appl. rate [g as/ha] | Organism | Time-scale | Distance [m] | TER | Trigger | Refined risk assessment |
|---|---|---|---|---|---|---|---|
| **Vine** | | | | | | | |
| Fenhexamid | 800 | Fish | acute | **Step 4:** 5 m | 120 | 100 | Yes |
| | | Fish | long-term | **Step 4:** 5 m | 9.8 - 178 | 10 | Yes |
| | | Invertebrates | acute | - | > 727 | 100 | No |
| | | Invertebrates | long-term | - | 39 | 10 | No |
| | | Sediment dweller | long-term | - | 441 [1)]<br>1492 [2)] | 10 | No |
| | | Green algae | long-term | - | 326 | 10 | No |
| | | Aquatic plants | long-term | - | > 89 | 10 | No |
| M24 | | Fish | acute | - | 1575 | 100 | No |
| | | Invertebrates | acute | | > 12019 | 100 | No |
| | | Green algae | long-term | - | 8534 | 10 | No |
| M12 | | Fish | acute | - | 2950 | 100 | No |
| | | Invertebrates | acute | - | 8241 | 100 | No |
| | | Green algae | long-term | - | > 16351 | 10 | No |

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| Compound | Appl. rate [g as/ha] | Organism | Time-scale | Distance [m] | TER | Trigger | Refined risk assessment |
|---|---|---|---|---|---|---|---|
| M39 | | Fish | acute | - | > 5879 | 100 | No |
| | | Invertebrates | acute | - | 81129 | 100 | No |
| | | Green algae | long-term | - | > 5879 | 10 | No |
| **Strawberry** (high rate) | | | | | | | |
| Fenhexamid | 1000 | Fish | acute | - | 104 | 100 | No |
| | | Fish | long-term | - | 16 [3)] | 10 | No |
| | | Invertebrates | acute | - | > 1582 | 100 | No |
| | | Invertebrates | long-term | - | 84 | 10 | No |
| | | Sediment dweller | long-term | - | 960 [1)]<br>3003 [2)] | 10 | No |
| | | Green algae | long-term | - | 710 | 10 | No |
| | | Aquatic plants | long-term | - | > 194 | 10 | No |
| M24 | | Fish | acute | - | 858 | 100 | No |
| | | Invertebrates | acute | - | > 6549 | 100 | No |
| | | Green algae | long-term | - | 4650 | 10 | No |
| M12 | | Fish | acute | - | 7058 | 100 | No |
| | | Invertebrates | acute | - | 19718 | 100 | No |
| | | Green algae | long-term | - | > 39124 | 10 | No |
| M39 | | Fish | acute | - | > 12642 | 100 | No |
| | | Invertebrates | acute | - | 174463 | 100 | No |
| | | Green algae | long-term | - | > 12642 | 10 | No |
| **Strawberry** (low rate) | | | | | | | |
| Fenhexamid | 750 | Fish | acute | - | 136 | 100 | No |
| | | Fish | long-term | - | 11 | 10 | No |
| | | Invertebrates | acute | - | > 2056 | 100 | No |
| | | Invertebrates | long-term | - | 109 | 10 | No |
| | | Sediment dweller | long-term | - | 1247 [1)]<br>3820 [2)] | 10 | No |
| | | Green algae | long-term | - | 922 | 10 | No |
| | | Aquatic plants | long-term | - | > 252 | 10 | No |
| M24 | | Fish | acute | - | 899 | 100 | No |
| | | Invertebrates | acute | - | > 6863 | 100 | No |
| | | Green algae | long-term | - | 4873 | 10 | No |
| M12 | | Fish | acute | - | 9020 | 100 | No |
| | | Invertebrates | acute | - | 25200 | 100 | No |
| | | Green algae | long-term | - | > 50000 | 10 | No |
| M39 | | Fish | acute | - | > 17036 | 100 | No |
| | | Invertebrates | acute | - | 235094 | 100 | No |
| | | Green algae | long-term | - | > 17036 | 10 | No |
| **Tomato** | | | | | | | |
| Fenhexamid | 750 | Fish | acute | - | 139 | 100 | No |
| | | Fish | long-term | - | 11 | 10 | No |
| | | Invertebrates | acute | - | > 2109 | 100 | No |
| | | Invertebrates | long-term | - | 112 | 10 | No |
| | | Sediment dweller | long-term | - | 1279 [1)]<br>4003 [2)] | 10 | No |
| | | Green algae | long-term | - | 946 | 10 | No |
| | | Aquatic plants | long-term | - | > 258 | 10 | No |
| M24 | | Fish | acute | - | 1144 | 100 | No |
| | | Invertebrates | acute | - | > 8730 | 100 | No |
| | | Green algae | long-term | - | 6198 | 10 | No |
| M12 | | Fish | acute | - | 9415 | 100 | No |
| | | Invertebrates | acute | - | 26305 | 100 | No |
| | | Green algae | long-term | - | > 52192 | 10 | No |

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| Compound | Appl. rate [g as/ha] | Organism | Time-scale | Distance [m] | TER | Trigger | Refined risk assessment |
|---|---|---|---|---|---|---|---|
| M39 | | Fish | acute | - | > 16835 | 100 | No |
| | | Invertebrates | acute | - | 232323 | 100 | No |
| | | Green algae | long-term | - | > 16835 | 10 | No |

1) Based on PECsw
2) Based on PECsed
3) TER based on FOCUS Step 3, D6 scenario as worst case

**Conclusion:**

For the use in strawberries and tomatoes, all TER values for fenhexamid and its metabolites meet the required trigger for acute and chronic risk based on FOCUS Step 2 and 3, indicating an acceptable risk to aquatic organisms for applications close to surface water bodies.
For the use in vine, all TER values are met at FOCUS Step 2 and 3 apart from acute and long-term risk of fish exposed to fenhexamid. Thus, to protect fish, a drift reducing buffer zone of 5 m is required for application in vine.
In conclusion, the risk for fish exposed to Fenhexamid WG 50 is acceptable for the use in strawberries and tomatoes without further mitigation measures and for the use in vine, when a 5 m buffer zone is applied.

## IIIA 10.2.1.1 $TER_A$ for fish

**Table 10.2.1.1- 1: $TER_A$ calculations for fish based on maximum $PEC_{sw}$ values according to FOCUS Step 2**

| Compound | Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | |
| Fenhexamid | *O. mykiss* | $LC_{50}$ | 1240 | 25.86 | **48** | 100 |
| M24 | *O. mykiss* | $LC_{50}$ | 2620 | 1.664 | 1575 | 100 |
| M12 | *O. mykiss* | $LC_{50}$ | 4510 | 1.529 | 2950 | 100 |
| M39 | *O. mykiss* | $LC_{50}$ | > 10000 | 1.701 | > 5879 | 100 |
| **Crop: Strawberry** (high rate) | | | | | | |
| Fenhexamid | *O. mykiss* | $LC_{50}$ | 1240 | 11.88 | 104 | 100 |
| M24 | *O. mykiss* | $LC_{50}$ | 2620 | 3.054 | 858 | 100 |
| M12 | *O. mykiss* | $LC_{50}$ | 4510 | 0.639 | 7058 | 100 |
| M39 | *O. mykiss* | $LC_{50}$ | > 10000 | 0.791 | > 12642 | 100 |
| **Crop: Strawberry** (low rate) | | | | | | |
| Fenhexamid | *O. mykiss* | $LC_{50}$ | 1240 | 9.145 | 136 | 100 |
| M24 | *O. mykiss* | $LC_{50}$ | 2620 | 2.914 | 899 | 100 |
| M12 | *O. mykiss* | $LC_{50}$ | 4510 | 0.500 | 9020 | 100 |
| M39 | *O. mykiss* | $LC_{50}$ | > 10000 | 0.587 | > 17036 | 100 |
| **Crop: Tomato** | | | | | | |
| Fenhexamid | *O. mykiss* | $LC_{50}$ | 1240 | 8.913 | 139 | 100 |
| M24 | *O. mykiss* | $LC_{50}$ | 2620 | 2.291 | 1144 | 100 |
| M12 | *O. mykiss* | $LC_{50}$ | 4510 | 0.479 | 9415 | 100 |
| M39 | *O. mykiss* | $LC_{50}$ | > 10000 | 0.594 | > 16835 | 100 |

**Bold values** do not meet the trigger

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The worst case acute TER values for fenhexamid applied in strawberries and tomatoes and for fenhexamid metabolites in all three mentioned crops are above the trigger of 100 and there is no need for a refined risk assessment.
However, the worst case acute TER value for fenhexamid for the application in vine does not meet the trigger based on worst-case FOCUS Step 2 PEC values. Therefore, in the next step TER values are calculated based on more realistic FOCUS Step 3 PEC values:

**Table 10.2.1.1- 2: $TER_A$ calculations for fish based on maximum $PEC_{sw}$ values according to FOCUS Step 3**

| Compound | Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | |
| Fenhexamid | *O. mykiss* | $LC_{50}$ | 1240 | 14.19 [1)] | **87** | 100 |

[1)] R3 (stream) as worst-case scenario covering all other FOCUS scenarios; **bold values** do not meet the trigger

The worst case acute TER value for fenhexamid for the application in vine does not meet the trigger based on worst-case FOCUS Step 3 PEC values. Therefore a refined risk assessment based on FOCUS Step 4 values is presented in the following.

**Refined risk assessment for fenhexamid**

The exposure of non-target aquatic organisms can be significantly reduced by mitigation measures, such as a buffer zone. These are taken into account for FOCUS Step 4 PEC values.
The following TER calculations for fenhexamid are based on the respective worst-case scenario from FOCUS Step 4 calculations:

**Table 10.2.1.1- 3: $TER_A$ calculations for fish based on maximum $PEC_{sw}$ values according to FOCUS Step 4**

| Compound | Species | Endpoint [µg/L] | | FOCUS scenario | Buffer | $PEC_{sw,max}$ [µg/L] | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | | | |
| Fenhexamid | *O. mykiss* | $LC_{50}$ | 1240 | R3, stream [1)] | 5 m buffer no drift reduction | 10.34 | 120 | 100 |

[1)] worst-case scenario covering all other FOCUS scenarios

Taking into account a 5 m buffer zone, the trigger is met.

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## IIIA 10.2.1.2 $TER_{LT}$ for fish

**Table 10.2.1.2- 1: $TER_{LT}$ calculation for fish based on maximum $PEC_{sw}$ values according to FOCUS Step 2**

| Compound | Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | |
| Fenhexamid | *O. mykiss* | NOEC | 101 | 25.86 | **3.9** | 10 |
| **Crop: Strawberry** (high rate) | | | | | | |
| Fenhexamid | *O. mykiss* | NOEC | 101 | 11.88 | **8.5** | 10 |
| **Crop: Strawberry** (low rate) | | | | | | |
| Fenhexamid | *O. mykiss* | NOEC | 101 | 9.145 | 11 | 10 |
| **Crop: Tomato** | | | | | | |
| Fenhexamid | *O. mykiss* | NOEC | 101 | 8.913 | 11 | 10 |

**Bold values** do not meet the trigger

The worst case long-term TER values for fenhexamid applied in strawberries (low rate) and tomatoes are above the trigger of 10 and there is no need for a refined risk assessment.
However, the worst case acute TER values for fenhexamid for the application in vine and strawberries (high rate) do not meet the trigger based on worst-case FOCUS Step 2 PEC values. Therefore, in the next step TER values are calculated based on more realistic FOCUS Step 3 PEC values:

**Table 10.2.1.2- 2: $TER_{LT}$ calculations for fish based on maximum $PEC_{sw}$ values according to FOCUS Step 3**

| Endpoint [µg/L] | | Scenario | Single application | | Multiple application | |
|---|---|---|---|---|---|---|
| | | | $PEC_{sw}$ [µg/L] | TER | $PEC_{sw}$ [µg/L] | TER |
| **Crop: Vine** | | | | | | |
| NOEC | 101 | D6 | 13.72 | **7.4** | 10.07 | **7.2** |
| | | R1 | 0.488 | 207 | 0.744 | 136 |
| | | R1 | 10.06 | 10 | 8.879 | 11 |
| | | R2 | 13.49 | **7.5** | 11.90 | **8.5** |
| | | R3 | 14.19 | **7.1** | 12.51 | **8.1** |
| | | R4 | 10.06 | 10 | 8.871 | 11 |
| **Crop: Strawberry** (high rate) | | | | | | |
| NOEC | 101 | D6 | 6.326 | 16 | 4.616 | 22 |
| | | R2 | 5.617 | 18 | 4.075 | 25 |
| | | R3 | 5.906 | 17 | 4.286 | 24 |
| | | R4 | 4.190 | 24 | 3.044 | 33 |

**Bold values** do not meet the trigger

The worst case acute TER values for fenhexamid for the application in strawberries are above the trigger of 10 and there is no need for a refined risk assessment. For the application in vine the trigger is not met for FOCUS Step 3 scenarios D6, R2 and R3. Therefore a refined risk assessment based on FOCUS Step 4 values is presented below.

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**Refined long-term risk assessment for fenhexamid based on FOCUS Step 4**

The exposure of non-target aquatic organisms can be significantly reduced by mitigation measures, such as a buffer zone. These are taken into account for FOCUS Step 4 PEC values.

The following TER calculations for fenhexamid are based on the respective worst-case scenario from FOCUS Step 4 calculations for the use in vine.

**Table 10.2.1.2- 3: $TER_{LT}$ calculations for fish based on maximum $PEC_{sw}$ values according to FOCUS Step 4 for the use in vine**

| | | | Single application | | Multiple application | |
|---|---|---|---|---|---|---|
| **Endpoint [µg/L]** | **Buffer [m]** | **Scenario** | **$PEC_{sw}$ [µg/L]** | **TER** | **$PEC_{sw}$ [µg/L]** | **TER** |
| NOEC 101 | 5 no drift reduction | D6 (ditch) | 8.297 | 12.2 | 8.469 | 11.9 |
| | | R1 (pond) | 0.567 | 178 | 0.865 | 117 |
| | | R1 (stream) | 7.333 | 13.8 | 6.452 | 15.7 |
| | | R2 (stream) | 9.829 | 10.3 | 8.649 | 11.7 |
| | | R3 (stream) | 10.34 | **9.8** | 9.095 | 11.1 |
| | | R4 (stream) | 7.332 | 13.8 | 6.451 | 15.7 |

**Bold values** do not meet the trigger

The TER of 9.8 obtained for the FOCUS Step 4 scenario R3 (single application) is just slightly below the trigger value of 10. All other scenarios are above the trigger of 10. Therefore, the long-term risk to fish is considered to be acceptable when a buffer zone of 5 m is applied for the use in vine.

**Conclusion**

The long term risk to fish exposed to Fenhexamid WG50 is acceptable for the use in strawberry and tomato without further mitigation measures and for the use in vine, when a 5 m buffer zone is applied.

## IIIA 10.2.1.3 $TER_A$ for Daphnia

**Table 10.2.1.3-1: $TER_A$ calculation for *Daphnia* based on max. $PEC_{sw}$ values according to FOCUS Step 2**

| **Compound** | **Species** | **Endpoint [µg/L]** | | **$PEC_{sw,max}$ [µg/L]** | **$TER_A$** | **Trigger** |
|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | |
| Fenhexamid | *D. magna* | $EC_{50}$ | > 18800 | 25.86 | > 727 | 100 |
| M24 | *D. magna* | $EC_{50}$ | > 20000 | 1.664 | > 12019 | 100 |
| M12 | *D. magna* | $EC_{50}$ | 12600 | 1.529 | 8241 | 100 |
| M39 | *D. magna* | $EC_{50}$ | 138000 | 1.701 | 81129 | 100 |
| **Crop: Strawberry** (high rate) | | | | | | |
| Fenhexamid | *D. magna* | $EC_{50}$ | > 18800 | 11.88 | > 1582 | 100 |
| M24 | *D. magna* | $EC_{50}$ | > 20000 | 3.054 | > 6549 | 100 |
| M12 | *D. magna* | $EC_{50}$ | 12600 | 0.639 | 19718 | 100 |
| M39 | *D. magna* | $EC_{50}$ | 138000 | 0.791 | 174463 | 100 |

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| Compound | Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| **Crop: Strawberry** (low rate) | | | | | | |
| Fenhexamid | *D. magna* | $EC_{50}$ | > 18800 | 9.145 | > 2056 | 100 |
| M24 | *D. magna* | $EC_{50}$ | > 20000 | 2.914 | > 6863 | 100 |
| M12 | *D. magna* | $EC_{50}$ | 12600 | 0.500 | 25200 | 100 |
| M39 | *D. magna* | $EC_{50}$ | 138000 | 0.587 | 235094 | 100 |
| **Crop: Tomato** | | | | | | |
| Fenhexamid | *D. magna* | $EC_{50}$ | > 18800 | 8.913 | > 2109 | 100 |
| M24 | *D. magna* | $EC_{50}$ | > 20000 | 2.291 | > 8730 | 100 |
| M12 | *D. magna* | $EC_{50}$ | 12600 | 0.479 | 26305 | 100 |
| M39 | *D. magna* | $EC_{50}$ | 138000 | 0.594 | 232323 | 100 |

The worst case TER values for fenhexamid meet the required trigger, indicating an acceptable acute risk to daphnids for application of Fenhexamid WG 50.

## IIIA 10.2.1.4 $TER_{LT}$ for Daphnia

**Table 10.2.1.4- 1: $TER_{LT}$ calculation for Daphnia based on max. $PEC_{sw}$ values according to FOCUS Step 2**

| Compound | Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | |
| Fenhexamid | *D. magna* | NOEC | 1000 | 25.86 | 39 | 10 |
| **Crop: Strawberry** (high rate) | | | | | | |
| Fenhexamid | *D. magna* | NOEC | 1000 | 11.88 | 84 | 10 |
| **Crop: Strawberry** (low rate) | | | | | | |
| Fenhexamid | *D. magna* | NOEC | 1000 | 9.145 | 109 | 10 |
| **Crop: Tomato** | | | | | | |
| Fenhexamid | *D. magna* | NOEC | 1000 | 8.913 | 112 | 10 |

The worst case TER values for fenhexamid meet the required trigger, indicating an acceptable long-term risk to daphnids for application of Fenhexamid WG 50.

## IIIA 10.2.1.5 $TER_A$ for an aquatic insect species

No specific studies on the acute toxicity of fenhexamid to aquatic insect species were conducted. However, chronic studies addressing long-term effects on the sediment dwelling insect *Chironomus riparius* were performed with the active substance fenhexamid (please refer to Point 10.2.1.6 of this dossier).

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## IIIA 10.2.1.6 $TER_{LT}$ for an aquatic insect species

**Table 10.2.1.6- 1: $TER_{LT}$ calculations for *C. riparius* based on max. $PEC_{sw}$ values according to FOCUS Step 2**

| Compound | Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | |
| Fenhexamid | *C. riparius* | $EC_{15}$ | 11400 | 25.86 | 441 | 10 |
| | *C. riparius* | NOEC | 100000 µg/kg | 67.03 µg/kg [1)] | 1492 | 10 |
| **Crop: Strawberry** (high rate) | | | | | | |
| Fenhexamid | *C. riparius* | $EC_{15}$ | 11400 | 11.88 | 960 | 10 |
| | *C. riparius* | NOEC | 100000 µg/kg | 33.30 µg/kg [1)] | 3003 | 10 |
| **Crop: Strawberry** (low rate) | | | | | | |
| Fenhexamid | *C. riparius* | $EC_{15}$ | 11400 | 9.145 | 1247 | 10 |
| | *C. riparius* | NOEC | 100000 µg/kg | 26.18 µg/kg [1)] | 3820 | 10 |
| **Crop: Tomato** | | | | | | |
| Fenhexamid | *C. riparius* | $EC_{15}$ | 11400 | 8.913 | 1279 | 10 |
| | *C. riparius* | NOEC | 100000 µg/kg | 24.98 µg/kg [1)] | 4003 | 10 |

[1)] $PEC_{sed}$ max.

The worst case TER values for fenhexamid meet the required trigger, indicating an acceptable long-term risk to aquatic insects for application of Fenhexamid WG 50.

## IIIA 10.2.1.7 $TER_A$ for an aquatic crustacean species

No studies on aquatic crustaceans other than daphnids are required since the product is not an insecticide and the active substances do not show an insecticidal mode of action. The risk for these organisms is covered by the aquatic risk assessment provided in this dossier.

## IIIA 10.2.1.8 $TER_{LT}$ for an aquatic crustacean species

Please refer to point IIIA 10.2.1.7.

## IIIA 10.2.1.9 $TER_A$ for an aquatic gastropod mollusc species

No studies on aquatic gastropod molluscs are deemed necessary according to current requirements. The risk for these organisms is covered by the aquatic risk assessment provided in this dossier.

## IIIA 10.2.1.10 $TER_{LT}$ for an aquatic gastropod mollusc species

Please refer to point IIIA 10.2.1.9.

## IIIA 10.2.1.11 $TER_{LT}$ for algae

The risk assessment for algae and higher aquatic plants is conducted together. Details of any higher aquatic plant study if necessary are summarised in section 10.8.2.

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**Table 10.2.1.11- 1: $TER_{LT}$ calculations for algae based on FOCUS Step 2**

| Compound | Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | |
| Fenhexamid | *S. capricornutum* | $E_rC_{50}$ | 8430 | 25.86 | 326 | 10 |
| M24 | *P. subcapitata* | $E_rC_{50}$ | 14200 | 1.664 | 8534 | 10 |
| M12 | *P. subcapitata* | $E_rC_{50}$ | > 25000 | 1.529 | > 16351 | 10 |
| M39 | *P. subcapitata* | $E_rC_{50}$ | > 10000 | 1.701 | > 5879 | 10 |
| **Crop: Strawberry** (high rate) | | | | | | |
| Fenhexamid | *S. capricornutum* | $E_rC_{50}$ | 8430 | 11.88 | 710 | 10 |
| M24 | *P. subcapitata* | $E_rC_{50}$ | > 14200 | 3.054 | 4650 | 10 |
| M12 | *P. subcapitata* | $E_rC_{50}$ | > 25000 | 0.639 | > 39124 | 10 |
| M39 | *P. subcapitata* | $E_rC_{50}$ | > 10000 | 0.791 | > 12642 | 10 |
| **Crop: Strawberry** (low rate) | | | | | | |
| Fenhexamid | *S. capricornutum* | $E_rC_{50}$ | 8430 | 9.145 | 922 | 10 |
| M24 | *P. subcapitata* | $E_rC_{50}$ | 14200 | 2.914 | 4873 | 10 |
| M12 | *P. subcapitata* | $E_rC_{50}$ | > 25000 | 0.500 | > 50000 | 10 |
| M39 | *P. subcapitata* | $E_rC_{50}$ | > 10000 | 0.587 | > 17036 | 10 |
| **Crop: Tomato** | | | | | | |
| Fenhexamid | *S. capricornutum* | $E_rC_{50}$ | 8430 | 8.913 | 946 | 10 |
| M24 | *P. subcapitata* | $E_rC_{50}$ | 14200 | 2.291 | 6198 | 10 |
| M12 | *P. subcapitata* | $E_rC_{50}$ | > 25000 | 0.479 | > 52192 | 10 |
| M39 | *P. subcapitata* | $E_rC_{50}$ | > 10000 | 0.594 | > 16835 | 10 |

The worst case TER values for fenhexamid meet the required triggers, indicating acceptable long-term risk to algae for application of Fenhexamid WG 50.

**TER for aquatic plants**

TER calculations for *Lemna* are presented in the following table:

**Table 10.2.1.11- 2: $TER_{LT}$ calculations for higher aquatic plants based on FOCUS Step 2**

| Compound | Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| **Crop: Vine** | | | | | | |
| Fenhexamid | *Lemna gibba* | $EC_{50}$ | > 2300 | 25.86 | > 89 | 10 |
| **Crop: Strawberry** (high rate) | | | | | | |
| Fenhexamid | *Lemna gibba* | $EC_{50}$ | > 2300 | 11.88 | > 194 | 10 |
| **Crop: Strawberry** (low rate) | | | | | | |
| Fenhexamid | *Lemna gibba* | $EC_{50}$ | > 2300 | 9.145 | > 252 | 10 |
| **Crop: Tomato** | | | | | | |
| Fenhexamid | *Lemna gibba* | $EC_{50}$ | > 2300 | 8.913 | > 258 | 10 |

The worst case TER values for fenhexamid meet the required triggers, indicating acceptable long-term

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risk to aquatic plants for application of Fenhexamid WG 50.

## IIIA 10.2.2 Acute toxicity (aquatic) of the preparation

## IIIA 10.2.2.1 Fish acute toxicity $LC_{50}$, freshwater, cold-water species

| **Report:** | **KIIIA 10.2.2.1/01; [redacted] 1996** |
|---|---|
| Title: | KBR 2738 WG 50-Acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) in a semi-static test. |
| Document No: | **M-006209-01-1** (Report No: DOM95042) |
| Guidelines: | OECD Guideline No. 203 "OECD-Guideline for Testing of Chemicals", "Fish, Acute Toxicity Test", updated and adopted version of July 17, 1992 |
| GLP | Yes (certified laboratory) |

**Material and methods:**
Fenhexamid WG 50, purity: 49 %, Specification: (Batch No.: 0222 based on 04258/0214, Development No.: 170928), rainbow trout (*Oncorhynchus mykiss*/ lot F3/ 96): 10 fish per test concentration (mean body length 4.7 cm, mean body weight 1.2 g) for 96 h under semistatic conditions to nominal concentrations of 0.94, 1.88, 3.75, 7.50 and 15.0 mg test substance / L.

**Findings:** Toxicity to fish:

| | |
|---|---|
| Test substance | WG 50 |
| Test object | Rainbow Trout |
| Exposure | 96h, semi-static |
| $LC_{50}$ (mg a.i./L) | 1.30 |
| lowest tested. conc. with effect (LOEC) mg a.i./L | 0.92 |
| highest tested conc. without effect (NOEC) mg a.i./L | 0.46 |
| Threshold effect concentration, TEC (mean LOEC-NOEC) mg a.i./L | 0.65 |

**Observations:**
The results in summary are provided in the Table above. Nominal test substance concentrations ranged from 0.94 to 15.0 mg/L. Analytical data showed mean measured levels from 91-96 % of nominal, so nominal values were used in reporting. The 96-hour $LC_{50}$, NOEC and LOEC values were 2.66, 0.94 and 1.88 mg test substance/L, equivalent to 1.30, 0.46 and 0.92 mg a.i./L respectively.

**Conclusion:**
The $EC_{50}$ has been calculated as 2.66 mg product/L (corresponding to 1.30 mg a.s./L).

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## IIIA 10.2.2.2 Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna

| | |
|---|---|
| **Report:** | **KIIIA 10.2.2.2/01; [redacted] 1995** |
| Title: | Acute toxicity of KBR 2738 WG 50 to waterfleas (*Daphnia magna*) |
| Document No: | **M-006218-01-1** (Report No: HBF/DM 144) |
| Guidelines: | OECD 202 and EPA FIFRA 72-2 |
| GLP | Yes (certified laboratory) |

**Material and Methods:**
KBR 2738 WG 50, purit: 49.6 %, Specification (Batch No.: 0222 according to 4528/0214); first instars of *Daphnia magna* (< 24 h old) in a static test system were exposed for 48 h to nominal concentrations ranging from 2.02 to 202 mg formulation/L.

**Findings:** Toxicity to waterfleas

| | |
|---|---|
| Test substance | WG 50 |
| Test object | *Daphnia magna* |
| Exposure | 48, static |
| $EC_{50}$ mg a.i./L | 105 |
| Lowest tested conc. With effect (LOEC) mg a.i./L | 32 |
| Highest tested conc. Without toxic effect (NOEC) mg a.i./L | 18 |
| Threshold effect concentration, TEC (mean LOEC-NOEC) mg a.i./L | 24 |

**Observations:**
The results in summary are provided in the Table above. Analytical data showed measured levels from 103 - 111 % of the nominal. Nominal values were therefore appropriate for use in reporting. The 48-hour $EC_{50}$ value for *Daphnia magna* exposed to Fenhexamid WG 50 was 211 mg/L test substance, equivalent to 105 mg a.i./L.
The NOEC and LOEC values were 36 and 65 mg/l test substance, equivalent to 18 and 32 mg a.i./L.
In comparison to the $EC_{50}$ and NOEC values found in a similar test on waterfleas but using KBR 2738 technical a.i. (> 18.8 and 10.1 mg a.i./l resp.; Annex II, chapter 8.2.4) there is very close agreement with the values from the 50 WG study.

**Conclusion:**
The $EC_{50}$ has been calculated as 211 mg product/L (corresponding to 105 mg a.s./L).

## IIIA 10.2.2.3 Effects on algal growth and growth rate

| | |
|---|---|
| **Report:** | **KIIIA 10.2.2.3/01; [redacted] 1999** |
| Title: | KBR 2738 WG 50 – Influence on the Growth of Green Alga, *Selenastrum capricornutum* |
| Document No: | **M-006205-01-1** (Report No: DOM 98086) |

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| | |
|---|---|
| Guidelines: | OECD 201, EEC 79/831/E, ISO 8692, ASTM-Guideline E 1218-90 |
| GLP | Yes (certified laboratory) |

**Material and methods:**
KBR 2738 WG 50: a.i. content, 50.3 %. Name of sample: 50 WG 04258/0272, Batch No.: 299840001. *Selenastrum capricornutum* was exposed under static conditions (shake cultures) for 72 h. The following concentrations of nominal: 1.0, 2.0, 4.0, 8.0, 16.0 and 32.0 mg product/L were tested. Analytical determinations of KBR 2738 WG revealed that all measured concentrations from day 0 and day 3 ranged from 76 to 105 % (average: 99 %) of nominal. Calculations are based on nominal values.

**Findings:** Effects on algal average growth rate

| Test substance | KBR 2738 WG 50 |
|---|---|
| Test object | *Selenastrum capricornutum* |
| Exposure | 72h, static |
| $E_rC_{50}$ mg product/L | 36.30 |
| Lowest tested concentration with effect (LOEC) in mg product/L | 8.00 |
| Highest tested concentration without adverse effect (NOEC) in mg product/L | 4.00 |
| Threshold effect concentration, TEC (geometric mean LOEC – NOEC) in mg product/L | 5.66 |

**Conclusion:**
The $E_rC_{50}$ has been calculated as 36.3 mg product/L (18.26 mg a.s./L).

## IIIA 10.2.2.4 Marine or estuarine organisms acute toxicity $LC_{50}/EC_{50}$

According to the current data requirements, no studies on marine or estuarine organisms are necessary. The potential risk for these organisms is covered by the aquatic risk assessment provided in this dossier.

## IIIA 10.2.2.5 Marine sediment invertebrates, acute toxicity $LC_{50}/EC_{50}$

According to the current data requirements, no studies on marine or estuarine organisms are necessary. The potential risk for these organisms is covered by the aquatic risk assessment provided in this dossier.

## IIIA 10.2.3 Microcosm or mesocosm study

No microcosm or mesocosm studies were performed with the formulated product. Based on the toxicity data and application rate of the product, the risk assessment (TER calculations) presented above indicates acceptable risk to aquatic organisms. Therefore, microcosm or mesocosm studies with the formulated product are not deemed necessary.

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### IIIA 10.2.4 Residue data in fish (long term)

The steady state bioconcentration factor for fenhexamid in a laboratory study with Bluegill sunfish was determined to be in the range of 132 - 185 for whole fish (mean 159, see IIA 8.2.6.1/01 (EU point IIA, 8.2.3/01)). When exposure ceases, the radioactivity is depurated with a half-life of less than 1 day. Additionally, it was considered that the BCFs obtained may have been overestimated because all calculations referred to total radioactivity (including parent compound and metabolites). This was confirmed by a residue analysis. The BCF for the parent compound in whole fish was estimated to be about 80 (IIA 8.2.6.1/02 (EU point IIA, 8.2.3/02)).
Therefore, a study on bio-accumulation of the formulated product in fish is not considered necessary.

### IIIA 10.2.5 Chronic fish toxicity data

Chronic studies with the formulated product were not considered necessary, as the relevant information can be obtained from studies with the active ingredient.

#### IIIA 10.2.5.1 Chronic toxicity (28 day exposure) to juvenile fish

See statement provided under Point IIIA 10.2.5.

#### IIIA 10.2.5.2 Fish early life stage toxicity test

See statement provided under Point IIIA 10.2.5.

#### IIIA 10.2.5.3 Fish life cycle test

See statement provided under Point IIIA 10.2.5.

### IIIA 10.2.6 Chronic toxicity to aquatic invertebrates

Chronic studies with the formulated product were not considered necessary, as the relevant information can be obtained from studies with the active substances.

#### IIIA 10.2.6.1 Chronic toxicity to Daphnia magna (21-day)

See statement provided under Point IIIA 10.2.6.

#### IIIA 10.2.6.2 Chronic toxicity for a representative species of aquatic insects

See statement provided under Point IIIA 10.2.6.

#### IIIA 10.2.6.3 Chronic toxicity for a representative species of aquatic gastropod molluscs

See statement provided under Point IIIA 10.2.6.

### IIIA 10.2.7 Accumulation in aquatic non-target organisms

Based on the information given under Point IIIA 10.2.4, considerable accumulation of residues of the product and/or metabolites in aquatic organisms is unlikely to occur.

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## IIIA 10.3 Effects on terrestrial vertebrates other than birds

**Toxicity of the active substance**
The summary of the toxicity profile of the active substance fenhexamid to mammals is provided in the following.

**Toxicity of fenhexamid to mammals**
A summary of the toxicity of fenhexamid to mammals is provided in the following table:

**Table 10.3- 1: Toxicity of fenhexamid to mammals (selected studies)**

| Test species | Test design | Ecotoxicological endpoint | | Reference |
|---|---|---|---|---|
| Fenhexamid | | | | |
| Rat | acute, oral | $LD_{50}$ | > 5000 mg a.s./kg bw | [redacted] (1991)<br>20640<br>M-010368-01-1<br>IIA 5.2.1 |
| Rat | Two-generation study | $NOAEL_{reproduction\ and\ pup}$ | 76.6 mg a.s./kg bw/day 1)<br>(500 mg/kg feed) | [redacted] (1996)<br>BC8008<br>M-010252-02-1<br>IIA 5.6.1 |

**Justification of the endpoint proposal for wild mammal reproduction risk assessment:**

The EU list of endpoints for fenhexamid (EFSA review report 6497/VI/99-rev.2,(19.10.2000) refers to two "short-term oral toxicity" studies conducted with dogs, reporting a NOAEL of 500 ppm (18 mg/kg bw/d) in the 1-year study and a NOAEL of 1000 ppm (33 mg/kg bw/d) in the 90-d study.
These effects are not considered appropriate for use in $TER_{LT}$ calculation for wild mammals under the EFSA GD 2009, for reasons summarised below:

The entry in the EU list of endpoints for fenhexamid is based on the most sensitive parameter in dog toxicity studies, which was the incidence of "Heinz bodies". "Heinz bodies" are small round inclusions in erythrocytes, which are associated to the inner surface of the erythrocyte membrane. They develop as a consequence of long lasting oxidative stress to the cell by means of drugs, chemicals or toxins, especially basic amines.

In toxicological studies with fenhexamid, such formation of "Heinz bodies" was only observed in longer lasting studies in dogs (after ≥ 7 weeks), but not in mice, rats or rabbits, even at markedly higher doses or after longer exposures.

In the field, if any then only negligible exposure of dogs would be expected. Under EFSA GD (2009), the most critical wild mammal long-term risk assessments are usually conducted for herbivorous mammals (which are best represented by the rodents and rabbits used in the toxicological studies). The exposure of such wild mammals to fenhexamid in the field is not long-lasting (eg, mean $DT_{50}$ = 4.7 days on ground vegetation, [redacted] 2010, KIIIA 10.3.3/01, M-384914-01-1), and rodents or rabbits did not present Heinz bodies in the studies with fenhexamid.

Thus, the occurrence of effects on "Heinz bodies" in species represented by the critical generic focal species scenarios is unlikely in the field. Furthermore, the wild mammal risk assessment should be based on an endpoint more clearly related to population sustainability.

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It is therefore appropriate to propose for the $TER_{LT}$ calculation for wild mammals an endpoint from the more relevant studies including reproductive parameter, i.e. the developmental toxicity (DT) studies with rat and rabbit, and the reproduction study in rat.

The endpoints of potential relevance from these studies are presented in the table below.

**Table 10.3- 2: Toxicological endpoints including reproductive parameters**

| **Study** (overview) | **LOAEL** | **NOAEL** |
|---|---|---|
| **Rat reproduction** (Monograph p 65) | pub bodyweight reduced by 6-11% over lactation days 7-21 at 5000 ppm | 500 ppm = 76 mg/kg bw/d (dose during lactation) |
| **Rat DT** (Monograph p 158) | Very slight maternal toxicity 1000 mg/kg bw/d (limit test) | Considered acceptable without need for NOAEL quantification |
| **Rabbit DT** (Monograph p 159) | Food consumption ↓, maternal weight gain ↓, placental weight ↓ at 300 mg/kg bw/d | 100 mg/kg bw/d |

Based on these results it is proposed to consider the NOAEL of 76.6 mg/kg bw/d (achieved dose by females at 500 ppm) during lactation as a conservative Tier 1 estimate for the wild mammal $TER_{LT}$ calculations.

**Toxicity of the formulated product**

The acute oral toxicity of the formulated product was determined in a study on rats

**Table 10.3- 3: Mammalian toxicity data of the formulated product Fenhexamid WG 50**

| Test species | Test design | Ecotoxicological endpoint | | Reference |
|---|---|---|---|---|
| Rat | acute, oral | $LD_{50}$ | > 2000 mg a.s./kg bw | [redacted] (1995)<br>24227<br>M-010213-01-1<br>KIIIA 10.3.2.1/01 |

For the risk assessment of fenhexamid the acute endpoint has been chosen from the study with the active substance for the following reason:

The formulation was tested at a limit dose of 2000 mg/kg bw, and the $LD_{50}$ was set at > 2000 mg/kg bw. However, the study with active ingredient shows that the compound is clearly less toxic than the tested limit dose in the study with the formulation.

**Metabolites**

Please refer to remarks for birds, point 10.1

**Risk Assessment for mammals**

The risk assessment procedure for wild mammals follows the same principles as described in detail under point 10.1 for birds, i.e. EFSA Guidance Document on Risk Assessment for Birds & Mammals (2009).

**Mammalian generic focal species for Tier 1 risk assessment**

According to EFSA (2009) the following generic focal species have to be addressed in Tier 1 risk assessment.

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**Table 10.3- 4: Relevant generic mammalian focal species for Tier 1 risk assessment**

| Crop | Growth stage (BBCH) | Generic focal species | Representative species | Shortcut value (SV) For long-erm RA based on $RUD_m$ | Shortcut value (SV) For acute RA based on $RUD_{90}$ |
|---|---|---|---|---|---|
| Vineyard | ≥ 40 | Large herbivorous mammal "lagomorph" | Brown hare | 3.3 | 8.1 |
| | ≥ 20 | Small insectivorous mammal "shrew" | Common shrew | 1.9 | 5.4 |
| | ≥ 40 | Small herbivorous mammal "vole" | Common vole | 21.7 | 40.9 |
| | ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse | 2.3 | 5.2 |
| Strawberries | ≥ 20 | Small insectivorous mammal "shrew" | Common shrew | 1.9 | 5.4 |
| | ≥ 40 | Small herbivorous mammal "vole" | Common vole | 28.9 | 54.6 |
| | ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit | 5.7 | 14.0 |
| | ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse | 3.1 | 6.9 |
| Fruiting vegetables | Fruit stage 71-89 | Frugivorous mammal "rat" | Brown rat | 9.3 [1)] | 22.3 [1)] |
| | ≥ 20 | Small insectivorous mammal "shrew" | Common shrew | 1.9 | 5.4 |
| | ≥ 50 | Small herbivorous mammal "vole" | Common vole | 21.7 | 40.9 |
| | ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse | 2.3 | 5.2 |

[1)] Shortcut value based on RUD unit specified for tomato according to EFSA (2009) Appendix F, Table 1 ($RUD_m$ = 12.8, $RUD_{90}$ = 30.6) and an FIR/bw for rat = 0.73 instead of RUD unit specified for gourds ($RUD_m$ = 34.3, $RUD_{90}$ = 61.5)

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## IIIA 10.3.1 Toxicity exposure ratios for terrestrial vertebrates other than birds

### Summary of calculated TER values for mammals

**Table 10.3.1- 1 Summary of all TER calculations as given under points 10.3.1.1**

| Active substance | Crop | Generic focal species | $SV_{90}$ | $TER_A$ | Refinement |
|---|---|---|---|---|---|
| Fenhexamid | Vine (2 × 0.8 kg/a.s./ha) | Large herbivorous mammal “lagomorph” | 8.1 | > 594 | No |
| | | Small insectivorous mammal “shrew” | 5.4 | > 890 | No |
| | | Small herbivorous mammal “vole” | 40.9 | > 118 | No |
| | | Small omnivorous mammal “mouse” | 5.2 | > 925 | No |
| | Strawberry (3 × 1.0 kg a.s./ha) [1)] | Small insectivorous mammal “shrew” | 5.4 | > 579 | No |
| | | Small herbivorous mammal “vole” | 54.6 | > 57 | No |
| | | Large herbivorous mammal “lagomorph” | 14.0 | > 223 | No |
| | | Small omnivorous mammal “mouse” | 6.9 | > 453 | No |
| | Fruiting vegetables (Tomato) (3 × 0.75 kg a.s./ha) | Frugivorous mammal "rat" | 22.3 [2)] | > 187 | No |
| | | Small insectivorous mammal “shrew” | 5.4 | > 772 | No |
| | | Small herbivorous mammal “vole” | 40.9 | > 102 | No |
| | | Small omnivorous mammal “mouse” | 5.2 | > 801 | No |

[1)] worst case, covering lower rate of 4 × 0.75 kg a.s./ha

[2)] Shortcut value based on RUD unit specified for tomato according to Appendix F, Table1 ($RUD_{90}$ = 30.6) and an FIR/bw for rat = 0.73 instead of RUD unit specified for gourds ($RUD_{90}$ = 61.5)

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**Table 10.3.1- 2 Summary of all TER calculations as given under points 10.3.1.3**

| Active substance | Crop | Generic focal species | $SV_m$ | $TER_{LT}$ | Refinement |
|---|---|---|---|---|---|
| Fenhexamid | Vine (2 × 0.8 kg/a.s./ha) | Large herbivorous mammal "lagomorph" | 33 | 36 | No |
| | | Small insectivorous mammal "shrew" | 1.9 | 63 | No |
| | | Small herbivorous mammal "vole" | 21.7 | 5.6 | No |
| | | Small omnivorous mammal "mouse" | 2.3 | 52 | No |
| | Strawberry (3 × 1.0 kg a.s./ha) 1) | Small insectivorous mammal "shrew" | 1.9 | 38 | No |
| | | Small herbivorous mammal "vole" | 28.9 | 3.3 - 6.3 | Yes |
| | | Large herbivorous mammal "lagomorph" | 5.7 | 13 | No |
| | | Small omnivorous mammal "mouse" | 3.1 | 23 | No |
| | Fruiting vegetables (Tomato) (3 × 0.75 kg a.s./ha) | Frugivorous mammal "rat" | 9.3  2) | 10 | No |
| | | Small insectivorous mammal "shrew" | 1.9 | 51 | No |
| | | Small herbivorous mammal "vole" | 21.7 | 5.9 | Yes |
| | | Small omnivorous mammal "mouse" | 2.3 | 42 | No |

1) worst case, covering lower rate of 4 × 0.75 kg a.s./ha

2) Shortcut value based on RUD unit specified for tomato according to EFSA (2009) Appendix F, Table 1 ($RUD_m$ = 12.8) and an FIR/bw for rat = 0.73 instead of RUD unit specified for gourds ($RUD_m$ = 34.3)

**Conclusion:**
According to the presented risk assessment, an unacceptable risk to mammals from dietary exposure after use of Fenhexamid WG 50 as described in this dossier can be excluded.

## IIIA 10.3.1.1 Acute toxicity exposure ratio ($TER_A$)

### Tier 1 acute toxicity exposure ratio for mammals

The tier 1 risk assessment has been performed for grapes for an application rate of 2 × 0.8 kg fenhexamid/ha at a minimum application interval of 11 days, for strawberries for an application rate of 3 × 1.0 kg/ha at a minimum application interval of 7 days covering the lower rate of 4 × 0.75 kg/ha and for tomatoes for an application rate of 3 × 0.75 kg fenhexamid/ha at a minimum application interval of 7 days.

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**Table 10.3.1.1- 1: Tier 1 acute TER calculation for mammals**

| Crop | Generic focal species | $LD_{50}$ [mg/kg bw] | DDD: Appl. rate [kg/ha] | DDD: $SV_{90}$ | DDD: $MAF_{90}$ | DDD | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|---|---|
| **Fenhexamid** | | | | | | | | |
| Vine | Large herbivorous mammal “lagomorph” | > 5000 | 0.8 | 8.1 | 1.3 | 8.4 | > 594 | 10 |
| Vine | Small insectivorous mammal “shrew” | > 5000 | 0.8 | 5.4 | 1.3 | 5.6 | > 890 | 10 |
| Vine | Small herbivorous mammal “vole” | > 5000 | 0.8 | 40.9 | 1.3 | 42.5 | > 118 | 10 |
| Vine | Small omnivorous mammal “mouse” | > 5000 | 0.8 | 5.2 | 1.3 | 5.4 | > 925 | 10 |
| Strawberry | Small insectivorous mammal “shrew” | > 5000 | 1.0 | 5.4 | 1.6 | 8.6 | > 579 | 10 |
| Strawberry | Small herbivorous mammal “vole” | > 5000 | 1.0 | 54.6 | 1.6 | 87.4 | > 57 | 10 |
| Strawberry | Large herbivorous mammal “lagomorph” | > 5000 | 1.0 | 14.0 | 1.6 | 22.4 | > 223 | 10 |
| Strawberry | Small omnivorous mammal “mouse” | > 5000 | 1.0 | 6.9 | 1.6 | 11.0 | > 453 | 10 |
| Fruiting vegetables (tomato) | Frugivorous mammal "rat" | > 5000 | 0.75 | 22.3 | 1.6 | 26.8 | > 187 | 10 |
| Fruiting vegetables (tomato) | Small insectivorous mammal “shrew” | > 5000 | 0.75 | 5.4 | 1.6 | 6.5 | > 772 | 10 |
| Fruiting vegetables (tomato) | Small herbivorous mammal “vole” | > 5000 | 0.75 | 40.9 | 1.6 | 49.1 | > 102 | 10 |
| Fruiting vegetables (tomato) | Small omnivorous mammal “mouse” | > 5000 | 0.75 | 5.2 | 1.6 | 6.2 | > 801 | 10 |

All TER values are above the trigger of 10 for acute exposure. Accordingly an unacceptable acute risk to mammals from the use of Fenhexamid WG 50 according to the use pattern can be excluded.

## IIIA 10.3.1.2 Short-term toxicity exposure ratio ($TER_{ST}$)

Not required under Directive 91/414/EEC.

## IIIA 10.3.1.3 Long-term toxicity exposure ratio ($TER_{LT}$)

**Tier 1 reproductive/long-term toxicity exposure ratio for mammals**

The tier 1 risk assessment has been performed for grapes for an application rate of 2 × 0.8 kg fenhexamid/ha at a minimum application interval of 11 days, for strawberries for an application rate of 3 × 1.0 kg/ha at a minimum application interval of 7 days covering the lower rate of 4 × 0.75 kg/ha and for tomatoes for an application rate of 3 × 0.75 kg fenhexamid/ha at a minimum application interval of 7 days.

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**Table 10.3.1.3- 1: Tier 1 long-term TER calculation for mammals**

| Crop | Generic focal species | NO(A)EL [mg/kg bw/d] | DDD Appl. Rate [kg/ha] | DDD $SV_m$ | DDD $MAF_m$ | DDD $f_{twa}$ | DDD | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|---|---|---|
| **Fenhexamid** | | | | | | | | | |
| Grape | Large herbivorous mammal "lagomorph" | 76.6 | 0.8 | 3.3 | 1.5 | 0.53 | 2.1 | 36 | 5 |
| | Small insectivorous mammal "shrew" | | | 1.9 | | | 1.2 | 63 | |
| | Small herbivorous mammal "vole" | | | 21.7 | | | 13.8 | 5.6 | |
| | Small omnivorous mammal "mouse" | | | 2.3 | | | 1.5 | 52 | |
| Strawberry | Small insectivorous mammal "shrew" | 76.6 | 1.0 | 1.9 | 2.0 | 0.53 | 2.0 | 38 | 5 |
| | Small herbivorous mammal "vole" | | | 28.9 | | | 30.6 | **2.5** | |
| | Large herbivorous mammal "lagomorph" | | | 5.7 | | | 6.0 | 13 | |
| | Small omnivorous mammal "mouse" | | | 3.1 | | | 3.3 | 23 | |
| Fruiting vegetables (tomato) | Frugivorous mammal "rat" | 76.6 | 0.75 | 9.3 | 2.0 | 0.53 | 7.4 | 10 | 5 |
| | Small insectivorous mammal | | | 1.9 | | | 1.5 | 51 | |
| | Small herbivorous mammal "vole" | | | 21.7 | | | 17.3 | **4.4** | |
| | Small omnivorous mammal "mouse" | | | 2.3 | | | 1.8 | 42 | |

**Bold values:** TER does not meet the trigger

All TER values are above the trigger of 5 for the long-term exposure apart from the vole scenario for application in strawberries and tomatoes. Thus, a refined risk assessment is needed for the vole scenario.

**Refined risk assessment for small herbivorous mammal**

A refined risk assessment is triggered for exposure of small herbivorous mammals ("vole") to fenhexamid in strawberries and fruiting vegetables (tomatoes), where Tier 1 $TER_{LT}$ values of 2.5 and 4.4 were obtained.

- **Resilience and potential for recovery of vole populations**

The Joint Working Group on the Guidance Document on Risk Assessment for Birds & Mammals (SANCO 10997/2009) raised the question on the "need for the vole scenario… given the resilience of the vole populations"; i.e. well-known fact that voles are able to recover after large population breakdowns, or despite eradication programs with targeted rodenticide use. This implies that the level of protection required for this scenario may be low, so that the achieved Tier 1 $TER_{LT}$ values (10.3.1.3- 1) may be considered acceptable.

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- **Exposure of voles in strawberry and tomato fields**

The available information about the relevance of row vegetable fields as habitat for voles suggests very limited concern for exposure and risk at the local population level. The optimum habitat of common voles (*Microtus arvalis*) comprises large open, dry, uniform grassy areas. Originally confined to small-scaled habitats such as riparian vegetation, steppes and natural grassland, voles successfully colonized some agricultural habitats when crops and grassland replaced the natural vegetation.
Annual crops are considered to comprise secondary vole habitats. They are characterized by periods of immigration of voles during mass occurrences in prime habitats alternating with multi-annual periods of almost complete non-existence. The common vole may colonize crops when the plants provide sufficient cover, and is forced to retreat at harvest time. A permanent survival of voles on arable land with annual crops is not feasible where seasonal agricultural operations (harvest, ploughing) prove detrimental to their populations (eg, [redacted] 2003 [2]).

Similarly, in a review on the biology of the field vole presented in the Danish Guidance Document Pesticide Risk Assessment for Birds and Mammals (August, 2010) it is pointed out that the field vole can be found in farmland where it mainly occurs in set-aside and permanent grassland while numbers in cereal fields are low.
In several studies the captures of field voles in arable crops are few (e.g. [redacted] 1991a; [redacted] 1995a, [redacted] 2003) and the time spent in this habitat is probably low.

In conclusion, permanently vegetated prime habitats are the source for any colonisation voles of other (secondary / sub-optimal) habitats, e.g. annual field crops. The prime habitats that generally are of smaller scale compared to surrounding secondary habitats are essential for the survival of local populations and serve as donor habitats for secondary habitats in years of mass occurrences in the prime habitats.

Therefore, if considering the vole as a relevant focal species at all, protection of voles in the off-field habitat seems to be the key protection goal. To predict realistic exposure of voles in the off-field, primarily spray drift after the application should be taken into account. A refined TER calculation can be based on a drift factor of 7.23% (82$^{nd}$ percentile for 2 applications in vine), 2.01% (3 applications in field crops, 77$^{th}$ percentile) or 1.85% (4 applications in field crops, 74$^{th}$ percentile) applied to the intended application rate. It is obvious that the TER values would increase by a factor of >> 10 when these drift rates are considerd, thus a quantitative risk assessment is not deemed necessary.

- **Refined $DT_{50}$ in the exposure assessment of herbivorous mammals**

Residue decline data of fenhexamid after application on grassy ground vegetation are reported and evaluated for derivation of $DT_{50}$. The mean $DT_{50}$ over all trials is 4.7 days ([redacted] 2010, KIIIA 10.3.3/01, M-384914-01-1). Considering that $DT_{50}$ and the different time intervals, different refined MAFs and a refined 21-d $f_{TWA}$ are calculated with a moving-time window calculator (Tab.

[2] [redacted] (2003) Short-term effects of farming practices on populations of common voles. Agriculture, Ecosystems & Environment 95: 321-325, M-414511-01-1

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10.3.1.3-2).

**Table 10.3.1.3- 2: Refined long-term TER calculation for voles exposed to fenhexamid in strawberry and tomato fields calculated with the measured residue decline $DT_{50}$ = 4.7 d of fenhexamid**

| **Crop** | Strawberry high rate | | Strawberry low rate | | | Tomato |
|---|---|---|---|---|---|---|
| **Application rate [kg a.s./ha]** | 3 × 1.0 | | 4 × 0.75 | | | 3 × 0.75 |
| **Interval** | 7 d | 14 d | 7 d | 10 d | 14 d | 7 d |
| **MAF** | 1.48 | 1.14 | 1.53 | 1.29 | 1.14 | 1.48 |
| **21-d $f_{TWA}$** | 0.54 | 0.49 | 0.59 | 0.53 | 0.49 | 0.54 |
| **$SV_m$** | 28.9 | | | | | 21.7 |
| **DDD [mg a.s./kg bw/d]** | 23.1 | 16.1 | 19.6 | 14.8 | 12.1 | 13.0 |
| **PT** | 1.0 | | | | | |
| **NOAEL [mg a.s./kg bw/d]** | 76.6 | | | | | |
| **$TER_{LT}$** | 3.3 | 4.7 | 3.9 | 5.2 | 6.3 | 5.9 |

Based on the measured $DT_{50}$ of 4.7 days, the refined $TER_{LT}$ values were 3.3 - 6.3 calculated for the use in strawberry and 5.9 for the use in tomato, indicating an acceptable risk.

**Overall conclusion**

Taking into account the high resilience and potential for recovery of vole species, the low relevance of row vegetable fields as habitat for vole populations and a more realistic residue decline of the active substance, the risk for small herbivorous mammals from the use of Fenhexamid WG 50 is low and acceptable.

**Long-term risk assessment for mammals drinking contaminated water**

For further details, reference is made to Point 10.1.1 of this dossier. However, according to EFSA Guidance Document for Birds and Mammals (2009), unlike for birds the scenario of pools formed in leaf axils is not relevant for mammals. Therefore the risk assessment for mammals is limited to the scenario of puddles formed on the ground after application.

The acute risk from water in puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil is covered by the long-term risk assessment.

**Table 10.1.2- 3: Evaluation of potential concern for exposure of mammals drinking water (escape clause)**

| **Compound** | **Koc [L/kg]** | **Application rate* $MAF_m$ [g a.s./ha]** [1] | **NO(A)EL [mg a.s./ kg bw/d]** | **Ratio (Application rate* MAF) / NO(A)EL** | **"Escape clause" No concern if ratio** | **Conclusion** |
|---|---|---|---|---|---|---|
| Fenhexamid | 517 | 1000 × 2.0 | 76.6 | 26.1 | **≤ 3000** | No concern |

[1] Critical GAP for application in strawberry (high rate) used as worst case approach.

This evaluation confirms that the risk for mammals from drinking water that may contain residues from the use of Fenhexamid WG 50 is acceptable.

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## IIIA 10.3.2 Effects on terrestrial vertebrates other than birds

### IIIA 10.3.2.1 Acute oral toxicity of the preparation

| **Report:** | **KIIIA 10.3.2.1/01; [redacted] 1995, also filed under KIIIA 7.1.1/01** |
|---|---|
| Title: | KBR 2738 50 WG 04258/0214 - Study for acute oral toxicity in rats |
| Document No | **M-010213-01-1** (24227) |
| Guidelines: | OECD 401; US-EPA FIFRA §81-1; Directive 67/548/EEC, Annex V, Part B.1 |
| GLP: | Yes (certified laboratory) |

A study conducted for purposes of labelling and classification has been summarised in Annex III, point 7.1 (KIIIA 7.1.1/01) of this dossier, and is not repeated here. The study was conducted according to OECD 401 shwoing that Fenhexamid WG 50 is of low toxicity to rats after acute oral administration at a dose of 2000 mg/kg bw.
The $LD_{50}$ is > 2000 mg/kg body weight.

### IIIA 10.3.2.2 Acceptance of bait, granules or treated seed

Not applicable for spray application.

### IIIA 10.3.2.3 Effects of secondary poisoning

Fenhexamid (log $P_{OW}$ = 3.52) will be evaluated for potential effects of secondary poisoning of mammals. For details please refer to IIIA 10.1.9.

**Risk assessment for bioaccumulation and food chain behaviour for mammals**

The risk assessment procedure for wild mammals follows the same principles as described in detail under Point 10.1.9 for birds, i.e. EFSA Guidance Document on Risk Assessment for Birds & Mammals (2009).

**Mammalian generic focal species for Tier 1 risk assessment**

According to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) the following generic focal species have to be addressed in the Tier 1 risk assessment.

**Table 10.3.2.3- 1: Mammalian generic focal species for the Tier 1 risk assessment of secondary poisoning**

| Generic focal species | Body weight [g] | Example | FIR/bw |
|---|---|---|---|
| Earthworm eater | 100 | Common shrew | 1.28 |
| Fish eater | 1000 | Otter | 0.142 |

**Long-term TER calculation for earthworm-eating mammals**

The risk assessment has been performed for application in strawberries (high rate). This is a worst-case covering all other uses according to the intended GAP.

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**Table 10.3.2.3- 2: Tier 1 long-term TER calculation for earthworm eating mammals**

| Compound | Fenhexamid | Origin of value |
|---|---|---|
| $PEC_{worm}$ [mg/kg] | 0.53 | Table 10.1.9- 2 |
| **DDD calculation:** | | |
| FIR/bw | 1.28 | Default |
| DDD [mg/kg bw/d] | 0.67 | |
| **$TER_{LT}$ calculation:** | | |
| NO(A)EL [mg/kg bw/d] | 76.6 | IIIA 10.3 |
| $TER_{LT}$ | 114 | |
| Trigger | 5 | |
| Refined risk assessment required? | No | |

The TER value for the use in strawberries (high rate) as worst case scenario is above the trigger of 5. Accordingly an unacceptable risk to earthworm eating mammals from the use of Fenhexamid WG 50 according to the proposed use pattern can be excluded.

**Long-term toxicity exposure ratio for fish-eating mammals**

The risk assessment has been performed for application in vine. This is a worst-case covering all other uses according to the intended GAP.

**Table 10.3.2.3- 3: Tier 1 long-term TER calculation for fish-eating birds**

| Compound | Fenhexamid | Origin of value |
|---|---|---|
| $PEC_{fish}$ [mg/kg] | 0.86 | Table 10.1.9- 3 |
| **DDD calculation:** | | |
| FIR/bw | 0.142 | Default |
| DDD [mg/kg bw/d] | 0.12 | |
| **TER calculation:** | | |
| NO(A)EL [mg/kg bw/d] | 76.6 | IIIA 10.3 |
| $TER_{LT}$ | 630 | |
| Trigger | 5 | |
| Refined risk assessment required? | No | |

The TER value for the use in vine as worst case scenario is above the trigger of 5. Accordingly an unacceptable risk to fish eating mammals from the use of Fenhexamid WG 50 according to the proposed use pattern can be excluded.

## IIIA 10.3.3 Supervised cage or field trials or other appropriate studies

| **Report:** | **KIIIA 10.3.3/01; [redacted] 2010** |
|---|---|
| Title: | Determination of the residues of fenhexamid in/on Grass after Spraying of Fenhexamid WG 50 in the Field in France (North), Italy, Spain, United Kingdom |
| Document No: | **M-384914-01-1** (Report-No: 09-2041) |
| Guidelines: | The study was especially designed to generate residue decline data on grass for use in ecotoxicological risk assessments; its methodology is based on EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed, and the EC guidance working document 7029/VI/95 rev. 5 (1997-07-22). |

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| | |
|---|---|
| GLP | Yes (certified laboratory) |

**Material and methods:**

Test item: Fenhexamid WG 50% w/w; Batch-no.: EM20003983; FAR No. 01445-00; content (a.s.) Fenhexamid (KBR 2738) nominal 50% (actual 51.2%).

The aim of this study was to generate $DT_{50}$ values for dissipation of Fenhexamid from grass, for use in exposure assessments on birds and wild mammals that may feed on such ground vegetation in the field.

The study was conducted in four different regions of Europe (France, Italy, Spain, United Kingdom). At each study site, three ground spray applications were scheduled in weekly intervals with the Fenhexamid WG 50% w/w applied at a nominal rate of 1.5 kg product/ha (water application rate: 200 L/ha). The application was performed on established grass of various heights with a Knapsack sprayer. After each application, and frequently between the applications until one week after the third application, samples of typically 1-2 kg green plant material were collected from the treated area and subjected to residue analysis. $DT_{50}$ values were calculated assuming first order kinetics (SFO).

**Information about the Analytical Methods**

| Active Substance | Analytes | Method Number | Limit of Quantitation [mg/kg] | Measurement Principle |
|---|---|---|---|---|
| fenhexamid | fenhexamid | 01180 | 0.05 | HPLC-MS/MS |

**Findings:**

The mean of the concurrent recoveries were for all matrices and for all fortification levels, within the acceptable range of 70 – 110%.

**Application and Residue Summary in Grass in Northern Europe (N-EU)**

| Location Trial No. | Application | Portion Analysed | Application No. | DALT | Residues [mg/kg] fenhexamid | $DT_{50}$ [days] appl. | trial | N-EU |
|---|---|---|---|---|---|---|---|---|
| [redacted] 09-2041-01 | 3x 1.5 kg/ha Fenhexamid WG 50 (3x 0.75 kg a.s./ha) | green material | 1 | -13 | 55 | 7.9 | 6.2 | 4.9 |
| | | | | -12 | 62 | | | |
| | | | | -11 | 47 | | | |
| | | | | -10 | 41 | | | |
| | | | | -8 | 18 | | | |
| | | | | -6 | 7.8 | | | |
| | | | 2 | -6 | 56 | 7.5 | | |
| | | | | -5 | 52 | | | |
| | | | | -4 | 49 | | | |
| | | | | -3 | 20 | | | |
| | | | | -1 | 14 | | | |
| | | | | -0 | 12 | | | |
| | | | 3 | 0 | 41 | 3.2. | | |
| | | | | 1 | 34 | | | |
| | | | | 2 | 32 | | | |
| | | | | 3 | 17 | | | |
| | | | | 6 | 6.1 | | | |
| | | | | 7 | 4.3 | | | |
| | | | | 13 | 1.4 | | | |

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| Location Trial No. | Application | Portion Analysed | Application No. | DALT | Residues [mg/kg] fenhexamid | DT50 [days] appl. | DT50 [days] trial | DT50 [days] N-EU |
|---|---|---|---|---|---|---|---|---|
| [redacted] 09-2041-02 | 3x 1.5 kg/ha Fenhexamid WG 50 (3x 0.75 kg a.s./ha) | green material | 1 | -14 | 44 | 5.0 | 3.7 | |
| | | | | -13 | 42 | | | |
| | | | | -12 | 37 | | | |
| | | | | -11 | 40 | | | |
| | | | | -9 | 26 | | | |
| | | | | -7 | 7.9 | | | |
| | | | 2 | -7 | 43 | 3.9 | | |
| | | | | -6 | 5.0 | | | |
| | | | | -5 | 3.1 | | | |
| | | | | -4 | 1.9 | | | |
| | | | | -2 | 2.1 | | | |
| | | | | -0 | 1.6 | | | |
| | | | 3 | 0 | 44 | 2.1 | | |
| | | | | 1 | 35 | | | |
| | | | | 2 | 31 | | | |
| | | | | 3 | 29 | | | |
| | | | | 5 | 24 | | | |
| | | | | 7 | 20 | | | |
| | | | | 15 | 8.4 | | | |

DALT = Days After Last Treatment, " - " = Days Before Last Treatment
a.s. = Active Substance

**Application and Residue Summary in Grass in Southern Europe (S-EU)**

| Location Trial No. | Application | Portion Analysed | Application No. | DALT | Residues [mg/kg] fenhexamid | DT50 [days] appl. | DT50 [days] trial | DT50 [days] S-EU |
|---|---|---|---|---|---|---|---|---|
| [redacted] 09-2041-03 | 3x 1.5 kg/ha Fenhexamid WG 50 (3x 0.75 kg a.s./ha) | green material | 1 | -14 | 46 | 4.3 | 3.9 | 4.5 |
| | | | | -13 | 8.7 | | | |
| | | | | -12 | 6.4 | | | |
| | | | | -11 | 5.1 | | | |
| | | | | -9 | 3.3 | | | |
| | | | | -7 | 2.2 | | | |
| | | | 2 | -7 | 51 | 3.7 | | |
| | | | | -6 | 45 | | | |
| | | | | -5 | 39 | | | |
| | | | | -4 | 29 | | | |
| | | | | -2 | 28 | | | |
| | | | | -0 | 25 | | | |
| | | | 3 | 0 | 54 | 3.6 | | |
| | | | | 1 | 53 | | | |
| | | | | 2 | 54 | | | |
| | | | | 3 | 50 | | | |
| | | | | 5 | 48 | | | |
| | | | | 7 | 39 | | | |
| | | | | 14 | 3.8 | | | |

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| Location Trial No. | Application | Portion Analysed | Application No. | DALT | Residues [mg/kg] fenhexamid | $DT_{50}$ [days] appl. | trial | S-EU |
|---|---|---|---|---|---|---|---|---|
| [redacted] 09-2041-04 | 3x 1.5 kg/ha Fenhexamid WG 50 (3x 0.75 kg a.s./ha) | green material | 1 | -14 | 50 | 7.9 | 5.0 | |
| | | | | -13 | 47 | | | |
| | | | | -12 | 46 | | | |
| | | | | -11 | 41 | | | |
| | | | | -10 | 3.6 | | | |
| | | | | -7 | 3.0 | | | |
| | | | 2 | -7 | 49 | 3.4 | | |
| | | | | -6 | 55 | | | |
| | | | | -5 | 41 | | | |
| | | | | -4 | 41 | | | |
| | | | | -3 | 39 | | | |
| | | | | -0 | 28 | | | |
| | | | 3 | 0 | 86 | 3.8 | | |
| | | | | 1 | 35 | | | |
| | | | | 2 | 32 | | | |
| | | | | 3 | 33 | | | |
| | | | | 4 | 28 | | | |
| | | | | 7 | 17 | | | |
| | | | | 14 | 7.3 | | | |

DALT = Days After Last Treatment, " - " = Days Before Last Treatment
a.s. = Active Substance

**Conclusion:**
The aim of this study was to generate $DT_{50}$ values for dissipation of Fenhexamid from grass, for use in exposure assessments on birds and wild mammals that may feed on such ground vegetation in the field. The mean $DT_{50}$ was 4.9 days for trials conducted in Northern Europe (UK, northern France) and 4.5 days for trials conducted in Southern Europe (Italy, Spain). The overall mean $DT_{50}$ was 4.7 days.

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## IIIA 10.4 Effects on bees

Studies on effects on bees are available for the product Fenhexamid WG 50 and the active ingredient fenhexamid. The results are summarised in the following table.

**Table 10.4- 1: Acute toxicity to honey bees**

| Test species | Test design | Ecotoxicological endpoint | Reference |
|---|---|---|---|
| **Fenhexamid** | | | |
| Honey bee | acute, 48 h oral<br>acute, 48 h contact | $LD_{50}$ **> 102.1** µg a.s./bee<br>$LD_{50}$ > 200 µg a.s./bee | [redacted] (1995)<br>94124/01-BLEU<br>M-006350-01-1<br>IIA, 8.7.1/01<br>(EU point IIA, 8.3.1.1/01) |
| Honey bee | acute, 48 h oral<br>acute, 48 h contact | $LD_{50}$ > 189 µg a.s./bee<br>$LD_{50}$ **> 188** µg a.s./bee | [redacted] (1995)<br>951048058<br>M-006340-01-1<br>IIA, 8.7.1/02<br>(EU point IIA, 8.3.1.1/02) |
| Fenhexamid WG 50 | | | |
| Honey bee | acute, 48 h oral<br>acute, 48 h contact | $LD_{50}$ **> 106.7** µg a.s./bee<br>$LD_{50}$ **> 100** µg a.s./bee | [redacted] (2009)<br>EBKBL021<br>M-360877-01-1<br>KIIIA 10.4.2.1/01 |

**Bold values**: Endpoints considered relevant for risk assessment

### IIIA 10.4.1 Hazard Quotients for bees

An indication of hazard (Hazard Quotient $Q_H$) can be derived according to the EPPO risk assessment scheme, by calculating the ratio between the maxiumum single application rate (expressed in g or mL/ha) and the lowest laboratory contact and oral $LD_{50}$ (expressed in µg/bee).

$Q_{HO}$ and $Q_{HC}$ resp. = Application rate [g or mL/ha] / $LD_{50}$ oral or $LD_{50}$ contact [µg/bee]

$Q_H$ values can be calculated using data from the studies performed with each of the active ingredients and with the formulation. $Q_H$ values higher than 50 are assumed to reflect levels of concern which trigger higher tiered tests for clarification of the risk to honey bees.

#### IIIA 10.4.1.1 Oral exposure $Q_{HO}$

**Table 10.4.1.1- 1: Hazard quotients for bees – oral exposure**

| Crop | Exposure route | $LD_{50}$ [µg/bee] | Application rate [g a.s./ha] | Hazard quotient $Q_{HO}$ | Trigger | Refined risk assessment |
|---|---|---|---|---|---|---|
| **Fenhexamid WG 50** | | | | | | |
| Strawberries (high rate) [1] | Oral | > 106.7 | 1000 | < 9.4 | 50 | No |
| Fenhexamid | | | | | | |
| Strawberries (high rate) [1] | oral | > 102.1 | 1000 | < 10 | 50 | No |

[1] Critical GAP for strawberries (high rate) as worst case approach that covers all intended application.

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The hazard quotient for oral exposure is below the trigger of concern ($Q_{HO}$ < 50). Therefore, no unacceptable risk to bees is expected using Fenhexamid WG 50 according to the proposed use pattern.

## IIIA 10.4.1.2 Contact exposure $Q_{HC}$

**Table 10.4.1.2- 1: Hazard quotients for bees – contact exposure**

| Crop | Exposure route | $LD_{50}$ [µg/bee] | Application rate [g a.s./ha] | Hazard quotient $Q_{HC}$ | Trigger | Refined risk assessment |
|---|---|---|---|---|---|---|
| **Fenhexamid WG 50** | | | | | | |
| Strawberries (high rate) [1] | contact | > 100 | 1000 | < 1 | 50 | No |
| **Fenhexamid** | | | | | | |
| Strawberries (high rate) [1] | contact | > 188 | 1000 | < 11 | 50 | No |

1) Critical GAP for strawberries (high rate) as worst case approach that covers all intended application.

The hazard quotient for contact exposure is below the trigger of concern ($Q_{HC}$ < 50). Therefore, no unacceptable risk to bees is expected using Fenhexamid WG 50 according to the proposed use pattern.

**Conclusion:**

No major acute risk was shown with the active ingredient on bees in oral and contact conditions of exposure. Based on the low toxicity of the active ingredient and the fact that the product contains only one active ingredient it can be concluded that the risk is considered acceptable for the proposed use of the product.

## IIIA 10.4.2 Acute toxicity of the preparation to bees

### IIIA 10.4.2.1 Acute oral toxicity

| | |
|---|---|
| **Report:** | **KIIIA 10.4.2.1/01; [redacted] 2009** |
| Title: | Effects of fenhexamid WG 50 W (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory |
| Document No: | **M-360877-01-1** (Report-No: EBKBL021) |
| Guidelines: | OECD Guideline 213 and 214 (1998) |
| GLP | Yes (certified laboratory) |

**Objective:** Honey bees (*A. mellifera*) can be affected by pesticide residues as a result of indirect contact on plant surfaces, via oral intake of contaminated food or water, via inhalation of vapour or by direct overspray in the course of an application in the field according to normal agricultural practice. If the proposed use pattern of fenhexamid WG 50 W indicates such a possible exposure of honey bees, acute contact and oral toxicity data is necessary for the registration of the pesticide use in question. This study provides:

- the acute toxicity levels of the test item to honey bees;
- toxicity information comparable to expected residues from standard rates, for assessment of the potential hazard to honey bees;
- information to support precautionary label statements;

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• information to indicate the need for further testing e.g. semi-field or field studies.

**Material and methods:** Test item: Fenhexamid WG 50 W (Specification: Batch ID.: EM20002826, Sample Description: FAR01338-00, Specification No.: 102000007271), content: 49.7% w/w analytical.
Test organism: Honey bee (*Apis mellifera* L.), female worker bees, obtained from a healthy and queen-right colony, bred by IBACON, collected on the morning of use.
Under laboratory conditions *Apis mellifera* (50 worker bees per dose; 10 individuals in 5 replicates per test item dose level, controls and reference item doses) were exposed for 48 hours to a single dose of 100.0 µg a.i. per bee for topical application (contact) and feeding (oral value based on the actual intake of the test item) with a single dose of 200.0 µg product per bee.

Oral toxicity study
Aqueous stock solutions of the test item and reference item were prepared in such a way that they had the respective target concentration of the test item once they were subsequently mixed with sugar syrup at a ratio of 1 + 1. After mixing of these test solutions with ready-to-use sugar syrup (composition of the sugar component: 30 % saccharose, 31 % glucose, 39 % fructose) the final concentration of sugar syrup in the test item solutions offered to the bees was 50 %.
For the controls water and sugar syrup was used at the same ratio (1 + 1).
The treated food was offered in syringes, which were weighed before and after introduction into the cages (duration of uptake was 45 minutes for the test item treatments). After a maximum of 45 minutes, the food uptake was complete, weighed and replaced by ones containing fresh, untreated food.
The target dose levels (e.g. 100.0 µg a.i./bee nominal) would have been obtained if 20 mg/bee of the treated food was ingested, hi practice, higher (or lower) dose levels were obtained as the bees had a higher or lower uptake of the test solutions than the nominal 20 mg/bee.
The measured dose level was 106.7 µg a.i./bee.
The test was conducted in darkness, temperature was 25-26°C and humidity between 47 and 74%.
Biological observations including mortality and behavioural changes were recorded at 4, 24 and 48 hours after dosing. Results are based on measured concentrations of the a.i. per bee.

Contact toxicity study
A single 5 µL droplet of fenhexamid WG 50 W in an appropriate carrier (tap water + 0.5 % Adhäsit) was placed on the dorsal bee thorax.
For the control one 5 µL droplet of tap water containing 0.5 % Adhäsit was used.
The reference item was also applied in 5 µL tap water (dimethoate made up in tap water containing 0.5 % Adhäsit).
A 5 µL droplet was chosen in deviation to the guideline recommendation of a 1 µL droplet, since a higher volume ensured a more reliable dispersion of the test item.
The test was conducted in darkness, temperature was 25°C and humidity between 52 and 67%. Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application. Results are based on nominal concentrations of the product per bee.

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**Findings:** The results can be considered as valid, as all validity criteria of the test were met: control mortality is 0% in the oral and in the contact test, $LD_{50}$ (24 h) of the toxic standard in the oral test equals 0.16 µg a.i./bee, the $LD_{50}$ (24 h) of the toxic standard in the contact test equals 0.18 µg/bee.
A summary of effects of the test item on mortality and behavioural abnormalities of the bees is given below for both tests:

**Mortality and behavioural abnormalities of the bees in the oral toxicity test**

| ingested dosage [µg a.i./bee] | after 4 hours | | after 24 hours | | after 48 hours | |
|---|---|---|---|---|---|---|
| | mortality (mean %) | behavioural abnormalities (mean %) | mortality (mean %) | behavioural abnormalities (mean %) | mortality (mean %) | behavioural abnormalities (mean %) |
| test item 106.7 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| water control | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| reference item | | | | | | |
| 0.33 | 40.0 | 48.0 | 96.0 | 0.0 | 96.0 | 0.0 |
| 0.16 | 14.0 | 6.0 | 50.0 | 4.0 | 60.0 | 0.0 |
| 0.08 | 0.0 | 0.0 | 2.0 | 4.0 | 6.0 | 0.0 |
| 0.06 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

results are averages from five replicates (ten bees each) per dosage / control

**Mortality and behavioural abnormalities of the bees in the contact toxicity test**

| Dose [µg a.i./bee] | after 4 hours | | after 24 hours | | after 48 hours | |
|---|---|---|---|---|---|---|
| | mortality (mean %) | behavioural abnormalities (mean %) | mortality (mean %) | behavioural abnormalities (mean %) | mortality (mean %) | behavioural abnormalities (mean %) |
| test item 100.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| water control | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| reference item | | | | | | |
| 0.30 | 4.0 | 18.0 | 92.0 | 6.0 | 94.0 | 0.0 |
| 0.20 | 4.0 | 0.0 | 70.0 | 2.0 | 80.0 | 0.0 |
| 0.15 | 2.0 | 0.0 | 22.0 | 6.0 | 46.0 | 2.0 |
| 0.10 | 0.0 | 0.0 | 2.0 | 0.0 | 2.0 | 0.0 |

results are averages from five replicates (ten bees each) per dosage / control

**Observations:** At the end of the contact toxicity test (48 hours after application), there was no mortality at 100.0 µg a.i./bee. No mortality occurred in the control (water + 0.5 % Adhasit).
In the oral toxicity test the maximum nominal test level of fenhexamid WG 50 W (100.0 µg a.i./bee) corresponded to an actual intake of 106.7 µg a.i./bee. This dose level led to no mortality after 48 hours. No mortality occurred in the control (50 % sugar solution). No test item induced behavioural effects were observed at any time.

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**Conclusion:**

**Toxicity to Honey Bees; laboratory tests**

| **Test Item** | Fenhexamid WG 50 W | |
|---|---|---|
| **Test object** | *Apis mellifera* | |
| **Application rate (µg a.i./bee)** | 106.7 | 100.0 |
| **Exposure** | oral (sugar solution) | contact<br>(solution in Adhäsit (0.5 %)/water) |
| **$LD_{50}$ µg product/bee** | >106.7 | > 100.0 |

The toxicity of fenhexamid WG 50 W was tested in both an acute contact and an oral toxicity test on honey bees.
The $LD_{50}$ (48 h) value was > 100.0 µg a.i./bee in the contact toxicity test.
The $LD_{50}$ (48 h) value was > 106.7 µg a.i./bee in the oral toxicity test.

## IIIA 10.4.2.2 Acute contact toxicity

Please refer to point Point 10.4.2.1.

## IIIA 10.4.3 Effects on bees of residues on crops

In view of the findings reported under 10.4.1 and 10.4.2, and based on the requirements of Directive 91/414/EEC (Annex III, Point 10), no further studies are required. The $Q_{HC}$ value is <50.

## IIIA 10.4.4 Cage tests

Please refer to point Point 10.4.3.

## IIIA 10.4.5 Field tests

Please refer to point Point 10.4.3.

## IIIA 10.4.6 Investigation of special effects

Please refer to point Point 10.4.3.

### IIIA 10.4.6.1 Larval toxicity

Please refer to point Point 10.4.3.

### IIIA 10.4.6.2 Long residual effects

Please refer to point Point 10.4.3.

### IIIA 10.4.6.3 Disorienting effects on bees

Please refer to point Point 10.4.3.

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## IIIA 10.4.7 Tunnel tests - effects of feeding on contaminated honey dew or flowers

Please refer to point Point 10.4.3.

## IIIA 10.5 Effects on arthropods other than bees

Toxicity tests on non-target arthropods have been carried out with Fenhexamid WG 50 on the two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi*. Further studies have been conducted on two additional ground/leaf dwelling arthropods, as represented by *Coccinella septempunctata* and *Aleochara bilineata*. A summary of the results is provided in Table 10.5-1.

**Table 10.5- 1: Effects of Fenhexamid WG 50 on Non-Target Arthropods in Laboratory Studies**

| Test species | Test design | Ecotoxicological endpoint | | Reference |
|---|---|---|---|---|
| *Aphidius rhopalosiphi* | WG 50, laboratory, spray deposits on glass plates. | $LR_{50}$ [kg a.s./ha] > 2 | | [redacted] (1995)<br>BAY-95-1<br>M-006379-01-1<br>IIA 8.8.1.1/01<br>(EU point IIA, 8.3.2/02) |
| | | Corr. Mortality [%] | Effect on Reproduction[A] [%] | |
| | 0.3 kg a.s./ha | 0 | -9.2 | |
| | 1 kg a.s./ha | 0 | 13.7 | |
| | 2 kg a.s./ha | 0 | 5.9 | |
| *Aphidius rhopalosiphi* | WG 50, laborator, spray deposits on glass plates. | $LR_{50}$ [kg a.s./ha] > 5 | | [redacted] (2009)<br>CW08/069<br>M-327444-01-1<br>IIA 8.8.1.1/02 |
| | | Corr. Mortality [%] | Effect on Reproduction[A] [%] | |
| | 0.5 kg a.s./ha | 1.7 | -77.3 | |
| | 0.9 kg a.s./ha | 1.7 | -13.9 | |
| | 1.6 kg a.s./ha | 1.7 | 13.4 | |
| | 2.8 kg a.s./ha | 1.7 | -17.5 | |
| | 5 kg a.s./ha | 3.3 | -33.0 | |
| *Typhlodromus pyri* | WG 50, laboratory, spray deposits on glass plates. | $LR_{50}$ [kg a.s./ha] > 2 | | [redacted] (1995)<br>95-001-1022<br>M-006380-01-1<br>IIA 8.8.1.2/01<br>(EU point IIA, 8.3.2/01) |
| | | Corr. Mortality [%] | Effect on Reproduction[A] [%] | |
| | 1 kg a.s./ha | 0 | -51.3 | |
| | 2 kg a.s./ha | 1 | -57.5 | |
| *Typhlodromus pyri* | WG 50, laboratory, spray deposits on glass plates. | $LR_{50}$ [kg a.s./ha] > 5 | | [redacted] (2009)<br>CW08/068<br>M-327443-01-1<br>IIA 8.8.1.2/02 |
| | | Corr. Mortality[B] [%] | Effect on Reproduction[A] [%] | |
| | 0.5 kg a.s./ha | 5.2 | -11.5 | |
| | 0.9 kg a.s./ha | 3.1 | 6.3 | |
| | 1.6 kg a.s./ha | 4.1 | -21.2 | |
| | 2.8 kg a.s./ha | 6.2 | -16.5 | |
| | 5 kg a.s./ha | 1 | -3.2 | |
| *Aleochara bilineata* | WG 50, laboratory, spray deposits on quartz sand. | $LR_{50}$ [kg a.s./ha] > 2 | | [redacted] (1996)<br>SXR/AL 30<br>M-006378-01-1<br>IIA 8.8.1.3/01<br>(EU point IIA, 8.3.2/04) |
| | | Corr. Mortality [%] | Effect on Reproduction[A] [%] | |
| | 0.750 kg a.s./ha | 0 | -11 | |
| | 2 kg a.s./ha | 0 | -8 | |

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| Test species | Test design | Ecotoxicological endpoint | | | Reference |
|---|---|---|---|---|---|
| *Coccinella septempunctata* | WG 50, laboratory spray deposits on glass plates. | $LR_{50}$ [kg a.s./ha] > 2 | | | [redacted] (1996)<br>SXR/CS 10<br>M-006377-01-1<br>IIA 8.8.1.4/01<br>(EU point IIA, 8.3.2/03) |
| | | Corr. Mortality[B] [%] | Eggs/Female Day | Hatching [%] | |
| | Control | - | 525.9 | 65 | |
| | 0.3 kg a.s./ha | -5.0 | 499.8 | 57 | |
| | 0.6 kg a.s./ha | 2.4 | 641.3 | 63 | |
| | 2 kg a.s./ha | 5.2 | 733.3 | 60 | |

[A] A negative value indicates a higher reproduction rate in the treatment than in the control
[B] A negative value indicates a higher mortality in the control than in the treatment

It has been demonstrated by laboratory studies that Fenhexamid WG 50 (tested up to 2.5 kg a.s./ha) has no negative impact on representatives of the four major functional arthropod groups: ground-dwelling arthropods (as represented by *Aleochara bilineata*), foliage-dwelling arthropods (as represented by *Coccinella septempunctata*), predatory mites (as represented by *Typhlodromus pyri*), and parasitoids (as represented by *Aphidius rhopalosiphi*).

**Risk assessment procedures**

The risk assessment was performed according to Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and to the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2, [redacted] et al. 2000[3]).

**In-field hazard quotient (HQ) for tier 1 risk assessment**

The following equation is used to calculate the TER (Toxicity Exposure Ratio) value for the in-field exposure scenario:

In-field HQ = max. single application rate * MAF / $LR_{50}$

The risk is considered acceptable if the calculated HQ is < 2.

Fenhexamid is intended to be applied at the following conditions:

Maximum application rates: 2 × 800 g a.s./ha in grapes
3 × 1000 g a.s./ha in strawberries (high rate)
4 × 750 g a.s./ha in strawberries (low rate)
3 × 750 g a.s./ha in tomatoes

Therefore the following multiple application factors (MAF) were used for the risk assessment

MAF (multiple application factor): 2.7 (4 applications)
2.3 (3 applications)
1.7 (2 applications)

[3] [redacted] et al.: Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods; ESCORT 2 workshop (European Standard Characteristics Of Non-Target Arthropod Regulatory Testing), [redacted], March 21-23, 2000, [redacted] publication August 2001

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**Table 10.5- 2: HQ for the indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* for the in-field scenario**

| Crop | Appl. rate [g a.s./ha] | MAF | $LR_{50}$ / $ER_{50}$ [g a.s./ha] | HQ | Trigger | Refined risk assessment |
|---|---|---|---|---|---|---|
| Grapes | 800 | 1.7 | > 5000 | < 0.27 | 2 | No |
| Strawberries (high rate) | 1000 | 2.3 | | < 0.46 | 2 | No |
| Strawberries (low rate) | 750 | 2.7 | | < 0.41 | 2 | No |
| Tomatoes | 750 | 2.3 | | < 0.35 | 2 | No |

**Conclusion:** The in-field HQ values are below the trigger of concern, indicating an acceptable risk for non-target arthropods.
This conclusion is further supported by the results of laboratory studies with *Coccinella septempunctata* and *Aleochara bilineata.* For both species no unacceptable adverse effects (> 50%) could be observed up to the highest rate tested (2 kg a.s./ha).

**Off-field hazard quotient (HQ) tier 1 risk assessment**
The following equation was used to calculate the hazard quotient (HQ) for the off-field scenario:

Off-field HQ = max. single application rate * MAF * (drift factor/VDF)*correction factor / $LR_{50}$.

MAF = multiple application factor
Drift factor = 7.23%, (82nd percentile for 2 applications in vine, according to ESCORT2)
2.01%, (77th percentile for 3 applications in field crops, according to ESCORT2)
1.85%, (74th percentile for 4 applications in field crops, according to ESCORT2)
VDF = Vegetation distribution factor
Vegetation distribution factor = 10
Correction factor = 10 (tier 1 tests, *Aphidius* + *Typhlodromus*)

The risk is considered acceptable if the calculated HQ is < 2.

**Table 10.5- 3: HQ for the indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* for the off-field scenario**

| Crop | Appl. rate [g a.s./ha] | MAF | Drift [%] | VDF | Correction factor | $LR_{50}$ / $ER_{50}$ [L/ha] | HQ | Trigger |
|---|---|---|---|---|---|---|---|---|
| Grapes | 800 | 1.7 | 7.23 | 10 | 10 | > 5000 | < 0.02 | 2 |
| Strawberries (high rate) | 1000 | 2.3 | 2.01 | 10 | 10 | | < 0.01 | 2 |
| Strawberries (low rate) | 750 | 2.7 | 1.85 | 10 | 10 | | < 0.01 | 2 |
| Tomatoes | 750 | 2.3 | 2.01 | 10 | 10 | | < 0.01 | 2 |

**Conclusion:** The off-field HQs are below the trigger of concern, indicating an acceptable risk for non-target arthropods.
This conclusion is further supported by the results of laboratory studies with *Coccinella septempunctata* and *Aleochara bilineata.* For both species no unacceptable adverse effects (> 50%) could be observed up to the highest rate tested (2 kg a.s./ha).

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## IIIA 10.5.1 Effects on sensitive species already tested, artificial substrates

Formulation studies on non target arthropods using artificial substrate carried out with the lead formulation Fenhexamid WG 50 are summarised in the Tier II summary document on the active substance Annex II, point IIA 8.8.1 (EU point IIA 8.3.2).

## IIIA 10.5.2 Effects on non-target terrestrial arthropods in ext. laboratory tests

In view of the findings reported above, and based on the current requirements, no semi-field studies with the preparation have been conducted.

## IIIA 10.5.3 Effects on non-target terrestrial arthropods in semi-field tests

In view of the findings reported above, and based on the current requirements, no semi-field studies with the preparation have been conducted.

## IIIA 10.5.4 Field tests on arthropods species

In view of the findings reported above, and based on the current requirements, no semi-field studies with the preparation have been conducted.

## IIIA 10.6 Effects on earthworms and other soil macro-organisms

The summary of the toxicity of Fenhexamid WG 50, the active substance fenhexamid and the fenhexamid soil metabolite M 24 is provided in Table 10.6- 1.

**Table 10.6- 1: Effect on soil macro-organisms – earthworms**

| Test species | Test design | Ecotoxicological endpoint | | | Reference |
|---|---|---|---|---|---|
| **Fenhexamid** | | | | | |
| *Eisenia fetida* | acute, 14 d (10 % peat in test soil) | $LC_{50}$ | > 1000 | mg a.s./kg dws | [redacted] (1995) HBF/Rg 210 M-006331-01-1 IIA 8.9.1/01 (EU point IIA, 8.4.1/01) |
| **Fenhexamid WG 50** | | | | | |
| *Eisenia fetida* | chronic, 56 d (10 % peat in test soil) | NOEC | ≥ 5<br>≥ 19.8 | g a.s./ha<br>mg a.s./kg dws [1)] | [redacted] (1999) HBF/Rg 316 M-024530-01-1 IIA 8.9.2/01 |
| **M24** | | | | | |
| *Eisenia fetida* | chronic, 56 d (5% peat in test soil) | NOEC | ≥ 100 | mg p.m./kg dws | [redacted] (2012) 121048007S M-422055-01-1 IIA 8.9.2/02 |

dws = dry weight soil
p.m. = pure metabolite
1) conversion carried out as follows: endpoint [mg/m²] × soil surface of test vessel [m²] / dry weight of soil in test vessel [kg d.wt.s]; with soil surface of test vessel = 0.0198 m², d.wt.s. in test vessel = 0.5 kg

### Metabolites

From the studies on the route of degradation in soil it can be concluded that fenhexamid was rapidly

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degraded in soil to the final degradation product $CO_2$. 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. For further details please refer to IIIA, Point 9.4.
An earthworm reproduction study has been performed with this soil metabolite of fenhexamid.

**Exposure in soil**
Predicted environmental concentrations in soil ($PEC_{soil}$) values were calculated for the active substance fenhexamid and its metabolite as described in detail in Point 9.4 and Point 9.5 of this dossier. A soil layer of 5 cm with a bulk density of 1.5 g/cm³, and conservative $DT_{50}$ values of 2.99 and 75 days for fenhexamid and its metabolite M24 respectively, were considered. This calculation for initial PECs in soil is a first approach to simulate exposure of soil micro- or macro-organisms. The $PEC_{soil}$ values used for the risk assessment are presented in Table 10.6- 2.

**Table 10.6- 2: Maximum $PEC_{soil}$ values**

| Crop | Fenhexamid | | M24 |
|---|---|---|---|
| | **$PEC_{soil,max}$ [mg/kg]** | **$PEC_{soil}$ (twa, 21 d) [mg/kg]** | **$PEC_{soil,max}$ [mg/kg]** |
| Grapes | 0.320 | 0.065 | 0.039 |
| Strawberry (high rate) [1)] | 0.659 | 0.134 | 0.132 |
| Strawberry (low rate) [1)] | 0.498 | 0.101 | 0.128 |
| Tomatoes | 0.247 | 0.050 | 0.049 |

[1)] The risk assessment is conducted worst case for the high application rate in strawberries, covering the intended lower rate.

## IIIA 10.6.1 Toxicity exposure ratios for earthworms, $TER_A$ and $TER_{LT}$

The risk assessment procedure follows current regulatory requirements and the Guidance Document on Terrestrial Ecotoxicology.

Based on most sensitive endpoints (see Table 10.6- 1) the TER values are calculated using the following equations:

$TER_A = LC_{50} / PEC_{soil}$
$TER_{LT}$ = chronic NOEC / $PEC_{soil}$

The risk is considered acceptable, if the $TER_A$ is > 10 and the $TER_{LT}$ is > 5.

For lipophilic substances (log $P_{OW}$ > 2) the Terrestrial Guidance Document recommends to apply an additional assessment factor of 2 for the ecotoxicological endpoints ($LC_{50}$, NOEC), if the study was conducted in artificial soil with a high content of organic matter (i.e. 10% peat), to consider the possible sorption of these compounds to the organic matter.

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**Table 10.6.1- 1: TER calculations for earthworms**

| Compound test design | Endpoint [mg/kg soil] | | $PEC_{max}$ [mg/kg soil] | $TER_A$ / $TER_{LT}$ | Trigger | Refined risk assessment? |
|---|---|---|---|---|---|---|
| **Grapes** | | | | | | |
| Fenhexamid, acute | $LC_{50}$ | > 500[1] | 0.320 | > 1563 | 10 | No |
| Fenhexamid WG 50, chronic | NOEC | ≥ 9.9[1] | 0.320 | ≥ 31 | 5 | No |
| M24, chronic | NOEC | ≥ 100 | 0.039 | ≥ 2564 | 5 | No |
| **Strawberry** (high rate covering low rate) | | | | | | |
| Fenhexamid, acute | $LC_{50}$ | > 500[1] | 0.659 | > 759 | 10 | No |
| Fenhexamid WG 50, chronic | NOEC | ≥ 9.9[1] | 0.659 | ≥ 15 | 5 | No |
| M24, chronic | NOEC | ≥ 100 | 0.132 | ≥ 758 | 5 | No |
| **Tomato** | | | | | | |
| Fenhexamid, acute | $LC_{50}$ | > 500[1] | 0.247 | > 2024 | 10 | No |
| Fenhexamid WG 50, chronic | NOEC | ≥ 9.9[1] | 0.247 | ≥ 40 | 5 | No |
| M24, chronic | NOEC | ≥ 100 | 0.049 | ≥ 2041 | 5 | No |

[1] Study endpoint divided by factor 2

**Conclusion:**
The TER values are above the trigger of concern, indicating no unacceptable risk for earthworms from the application of Fenhexamid WG 50 according to the intended GAP.

## IIIA 10.6.2 Acute toxicity to earthworms

No acute study with Fenhexamid WG 50 was conducted. The risk assessment is conducted with the endpoint received from the study with the active substance fenhexamid.

## IIIA 10.6.3 Sublethal effects on earthworms

A formulation study on sublethal effects on earthworms carried out with the lead formulation Fenhexamid WG 50 is summarized in the Tier II summary document on the active substance Annex II, point 8.9.

## IIIA 10.6.4 Field tests (effects on earthworms)

Considering the findings reported above no further studies are required.

## IIIA 10.6.5 Residue content of earthworms

According to the current regulatory requirements a log $P_{ow}$ > 3 is used to indicate that there might be a potential for bioaccumulation. For information on the residue content of earthworms please refer to IIIA 10.1.9.

## IIIA 10.6.6 Effects on other soil non-target macro-organisms

Considering the low risk for earthworms (see point 10.6.1), no further studies were necessary.

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## IIIA 10.6.7 Effects on organic matter breakdown

A study on the organic matter breakdown is not required based on the $DT_{90}$ value of the active substance and acceptable TER values for earthworms, soil macro-organisms and soil micro-organisms.

## IIIA 10.7 Effects on soil microbial activity

Studies are available for the product Fenhexamid WG 50 and the active ingredient fenhexamid. The results are summarised in the following table.

**Table 10.7- 1: Effects on soil non-target micro-organisms**

| Test design | | Ecotoxicological endpoint | | | Reference |
|---|---|---|---|---|---|
| **Fenhexamid WG 50** | | | | | |
| N-cycle | 28 d | no influence | 26.80<br>20.1 | mg/kg dws<br>kg product/ha | [redacted] (2009)<br>FRM-N-131/09<br>M-359659-01-1<br>IIA 8.10.1/02 |
| **Fenhexamid** | | | | | |
| C-cycle | 28 d | no influence | 10 | kg a.s./ha | [redacted] (1995a)<br>AJO/126094<br>M-006374-01-1<br>IIA 8.10.2/01 (EU point IIA, 8.5/01) |
| N-cycle | 42 d | no influence | 10 | kg a.s./ha | [redacted] (1995b)<br>AJO/126194<br>M-006371-01-1<br>IIA 8.10.1/01 (EU point IIA, 8.5/02) |

**Risk assessment**
According to current regulatory requirements the risk is acceptable, if the effect of the recommended application rate of a compound/product on nitrogen or carbon mineralisation is < 25% after days. In no case, deviations from control exceeded 25% after 28 days, indicating low rik to soil micro-organisms.

Thus, no unacceptable risks to soil non-target micro-organisms is to be expected from the use of Fenhexamid WG 50, if the product is used according to the recommended use pattern.

## IIIA 10.7.1 Laboratory test to investigate impact on soil microbial activity

A formulation study on soil microbial activity carried out with the lead formulation Fenhexamid WG 50 is summarized in the Tier II summary document on the active substance Annex II, point 8.10.1.

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### IIIA 10.7.2 Further testing to investigate impact on soil microbial activity

Since laboratory testing has demonstrated that fenhexamid would not be expected to cause any significant effects on either soil microflora respiration or nitrogen transformation at concentrations above the maximum field rate, no additional testing has been performed.

### IIIA 10.8 Effects on non-target plants

### IIIA 10.8.1 Effects on non-target terrestrial plants

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.
In the case of a non-herbicide, screening results and/or Tier 1 studies give first information about the likelihood for terrestrial plant effects. The risk can be considered acceptable if there are no data indicating more than 50% phytotoxic effect at the maximum application rate.

Seedling emergence and vegetative vigour studies have been conducted with Fenhexamid WG 50 in a screening test following the OECD Non-Target Plant Testing Guideline Proposal. Each study involved 11 species tested at the maximum application rate of 5000 g a.s./ha.

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**Table IIIA 10.8- 1: Ecotoxicological endpoints for non-target terrestrial plants**

| Fenhexamid WG 50 | | | | |
|---|---|---|---|---|
| **Plant species** | **Seedling emergence (Tier 1)** | | **Vegetative vigour (Tier 1)** | |
| | Worst-case impact at 5000 g a.s./ha | Parameter | Worst-case impact at 5000 g a.s./ha | Parameter |
| Sugarbeet | 0 % | Phytotoxic effects (visual damage) | 30 % | Phytotoxic effects (visual damage) |
| Common amaranth | 0 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| Indian mallow | 0 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| Morningglory | 0 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| White mustard | 0 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| Cleavers | 30 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| Corn | 0 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| Black twitch | 0 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| Wild oat | 0 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| Cockspur | 0 % | Phytotoxic effects (visual damage) | 0 % | Phytotoxic effects (visual damage) |
| Green bristlegrass | 0 % | Phytotoxic effects (visual damage) | 30 % | Phytotoxic effects (visual damage) |
| Reference | [redacted] (1999)<br>DOM 99105<br>M-017075-01-1<br>IIA 10.8.12/01 | | | |

In the case of Fenhexamid WG 50, neither the seedling emergence nor the vegetative vigour studies showed phytotoxic effects ≥50% at the maximum rate of 5000 g a.s./ha.
Thus, no unacceptable risks to non-target terrestrial plants are to be expected from the use of Fenhexamid WG 50, when used according to the recommended GAP.

## IIIA 10.8.1.1 Seed germination

Please refer to Annex Point IIIA 10.8.1.2.

## IIIA 10.8.1.2 Vegetative vigour

Effects on vegetative vigour and seedling emergence have been caried out in an herbicidal screening test with the lead formulation Fenhexamid WG 50. The study is summarised in the Tier II summary document on the active substance Annex II, point IIA 8.12.

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### IIIA 10.8.1.3 Seedling emergence

Please refer to Annex Point IIIA 10.8.1.2.

### IIIA 10.8.1.4 Terrestrial field testing

Further studies were not considered necessary.

### IIIA 10.8.2 Effects on non-target aquatic plants

The toxicological spectrum of the active substances towards aquatic plants is presented under Annex Point IIIA 10.2. The risk assessment for *Lemna* is presented under IIIA 10.2.1.11.

### IIIA 10.8.2.1 Aquatic plant growth – Lemna

Due to the use of the product as a fungicide and since the product is not used as plant-growth regulator, tests on aquatic plants are not required. Nevertheless, a study with *Lemna gibba* has been conducted with the active substance fenhexamid. The results are summarised in Table 10.2- 1.

### IIIA 10.8.2.2 Aquatic field testing

The spectrum of the biological activity of the product is well represented by the results and the risk assessments in Point 10.2. Therefore, further studies are not considered necessary.

### IIIA 10.9 Effects on other non-target organisms believed to be at risk

The spectrum of the biological activity of the product is well represented by the results and the risk assessments in Point 10.2 to 10.8 of this dossier. Therefore, further data from biological primary screening or other preliminary tests are not considered relevant for the risk assessment.

### IIIA 10.9.1 Summary of preliminary data: biological activity & dose range finding

Not relevant. See statement provided under Point 10.9.

### IIIA 10.9.2 Assessment of relevance to potential impact on non-target species

Not relevant. See statement provided under Point 10.9.

### IIIA 10.10 Other/special studies

The spectrum of the biological activity of the product is well represented by the results and the risk assessments in Point 10.2 to 10.8 of this dossier. Therefore, further data from biological primary screening or other preliminary tests are not considered relevant for the risk assessment.

### IIIA 10.10.1 Other/special studies - laboratory studies

Not relevant. See statement provided under Point 10.10.

### IIIA 10.10.2 Other/special studies - field studies

Not relevant. See statement provided under Point 10.10.

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## IIIA 10.11 Summary and evaluation of points IIIA 9 and IIIA 10.1 to 10.10

## IIIA 10.11.1 Predicted distribution and fate in the environment and time courses

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

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

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

In a phototransformation experiment with fenhexamid published in Chemosphere vol. 81, pp. 844-852 ([redacted]. 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.

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

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

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

**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.

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## IIIA 10.11.2 Non-target species at risk and extent of potential exposure

**Terrestrial Vertebrates**

The risk assessment showed that all toxicity-to-exposure-ratios (TER) for birds meet the a-priori acceptability criteria. Thus, an unacceptable risk to birds from dietary exposure after use of the product as described in this dossier is unlikely.

The risk assessment for mammals showed that all TER values are met for all scenarios apart from the vole scenario for application in strawberries and tomatoes where a refined risk assessment is conducted. Taking into account the high resilience and potential for recovery of vole species, the low relevance of row vegetable fields as habitat for vole populations and a more realistic residue decline of the active substance, the risk for small herbivorous mammals from the use of Fenhexamid WG 50 is low and acceptable.

It was also shown that no unacceptable risk to birds and mammals resulted from exposure via drinking water and from secondary poisoning via earthworms or fish is given.

The risk from metabolites to vertebrates is considered to be low.

**Aquatic Organisms**

For the use in strawberries and tomatoes, all TER values for fenhexamid and its metabolites meet the required trigger for acute and chronic risk based on FOCUS Step 2 and 3, indicating an acceptable risk to aquatic organisms for applications close to surface water bodies. Thus, for the use in strawberries and tomatoes, mitigation measures are not needed.

For the use in vine, all TER values are met for FOCUS Step 2 and 3 apart from acute and long-term risk of fish exposed to fenhexamid. Thus, to protect fish, a drift reducing buffer zone of 5 m is required for application in vine.

**Honey-Bees**

Tier 1 risk assessment showed that the hazard quotients (oral and contact) are below the EU-trigger value. Therefore the use of Fenhexamid WG 50 according to the proposed use pattern does not constitute an unacceptable risk towards bees.

**Terrestrial Non-Target Arthropods**

The risk assessment indicated that no adverse effects on non-target arthropods are to be expected in the in-field and off-field area from the use of Fenhexamid WG 50. This was demonstrated by studies with the product on the indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi*. Additional leaf- and soil-dwelling arthropod species were tested with Fenhexamid WG 50 and confirmed the results.

**Earthworms and other soil not-target macro-organisms**

As has been demonstrated by acute and chronic studies no unacceptable effects on earthworms are to be expected from Fenhexamid WG 50 following the application according to the proposed use pattern.

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**Non-target soil micro-organisms**

The risk consideration indicates that no adverse effects on soil micro-organisms are to be expected, when Fenhexamid WG 50 is applied according to the proposed use pattern.

**Terrestrial Non-Target Plants**

Screening studies with Fenhexamid WG 50 indicate that no adverse effects on non-target plants are to be expected from the use of Fenhexamid WG 50 according to the proposed use pattern.

## IIIA 10.11.3 Short and long term risks for non-target organisms

Please refer to point 10.11.2.

## IIIA 10.11.4 Risk of fish kills and fatalities in large vertebrates

According to the aquatic risk assessment provided under Point 10.2, application of the product according to the proposed use pattern and recommended mitigation measures will not result in unacceptable adverse effects for fish.
Based on the information presented under Points 10.1 and 10.3, it is most unlikely that unacceptable risks will occur in large vertebrates and terrestrial predators when the product is used in accordance with the label recommendations.

## IIIA 10.11.5 Precautions necessary to avoid or minimize contamination

No unacceptable risk to non-target organisms is to be expected from the application of the product when following the proposed risk mitigation for aquatic organisms, i.e. a 5 m buffer zone in vine.
Further information is given under Point 10.11.2 of this document.

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## 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 | |

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| 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 | |

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