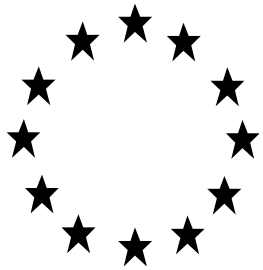
# Directive 98/8/EC concerning the placing of biocidal products on the market

***Inclusion of active substances in Annex I or IA to Directive 98/8/EC***

Assessment Report



# Fenpropimorph

# Product-type 8
# (Wood preservative)

20 February 2009

Annex I - Spain

# Fenpropimorph (PT 8)

## Assessment report

## Finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC

## CONTENTS

# 1. STATEMENT OF SUBJECT MATTER AND PURPOSE

## 1.1. Procedure followed

This assessment report has been established as a result of the evaluation of Fenpropimorph as product-type 8 (wood preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Fenpropimorph (CAS no. 67564-91-4) was notified as an existing active substance, by Dr. Wolman GmbH, hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 1451/2007 of 4 December 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Spain was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Fenpropimorph as an active substance in product-type 8 was 28 March 2004, in accordance with Article 9(2) of Regulation (EC) No 1451/2007.

On 24 March 2004, Spain competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 30 September 2004.

On 4 December 2006, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 11 January 2007. The competent authority report included a recommendation for the inclusion of Fenpropimorph in Annex I to the Directive for product-type 8.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 11 January 2007. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market, OJ L 123, 24.4.98, p.1

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly

On the basis of the final competent authority report, the Commission proposed the inclusion of Fenpropimorph in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 20 February 2009.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 20 February 2009.

### 1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include Fenpropimorph in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 8 that contain Fenpropimorph. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of the assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

### 1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that products containing Fenpropimorph for the product-type 8 will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

3 http://ec.europa.eu/comm/environment/biocides/index.htm

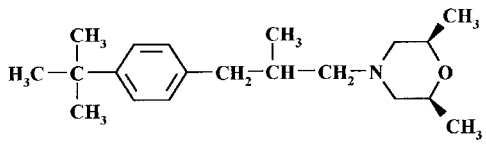
Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

# 2. OVERALL SUMMARY AND CONCLUSIONS

## 2.1. Presentation of the Active Substance

### *2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis*

Table 2.1 Identity of the active substance

| | |
|---|---|
| CAS-No. | 67564-91-4 |
| EINECS-No. | 266-719-9 |
| CIPAC- No. | 427 |
| IUPAC Name | (+/-)-cis-4-[3-(4-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine |
| Common name, synonyma | Fenpropimorph |
| Molecular formula | $C_{20}H_{33}NO$ |
| Structural formula |  |
| Molecular weight (g/mol) | 303.5 |

Fenpropimorph, manufactured with a minimum purity of 93 % w/w, is a colourless liquid with a faint aromatic odour at room temperature. Fenpropimorph is not considered highly flammable or explosive or oxidising. In conclusion, no hazard is identified for the physico-chemical properties of fenpropimorph.

The methods of analysis of active substance as manufactured have been validated and shown to be sufficiently specific, linear, accurate and precise, and the methods for analysis in environmental matrices, as appropriate for the assessed uses, have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

The identity, physico-chemical properties and analytical methods are listed in Appendix I of this assessment report. Moreover, a detailed description and discussion of these is presented in the Competent Authority Report.

### *2.1.2. Intended Uses and Efficacy*

Fenpropimorph is used for the preservation of wood products against wood discolouring and wood destroying fungi. It is intended for the temporary preventive protection of sawn timbers in areas with temperate or tropical climate and for the preservation of structural timber for interior and exterior use without ground contact (use classes 1, 2 and 3, taking into account the measures to risk mitigations).

The product is applied to the wood as a water-based formulation, via dipping in open dip tanks or using continuous flow dip tanks or spray-tunnels and it has industrial use only. Professional and non professional uses are not intended.

### *2.1.3. Classification and Labelling*

#### 2.1.3.1. Current classification

| | |
|---|---|
| Classification | as in Directive 67/548/EEC |
| Class of danger | Xn : harmful (Repr. Cat. 3)<br>N : dangerous for the environment |
| R-phrases | R22 : harmful if swallowed<br>R38 : irritating to skin<br>R 63 : possible risk of harm to the unborn child<br>R51/53 : toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment |
| S-phrases | S2 : Keep out of reach of children<br>S36/37 : Wear suitable protective clothing and gloves<br>S 46 : If swallowed, seek medical advice immediately and show this container or label<br>S61 : Avoid release to the environment. Refer to special instruction/safety data sheets |

#### 2.1.3.1. Proposal for the classification and labelling of the active substance

| | |
|---|---|
| Classification | as in Directive 67/548/EEC |
| Class of danger |  Xn : harmful (Repr. Cat. 3)<br>  N : dangerous for the environment |
| R-phrases | R22: harmful if swallowed<br>R38 : irritating to skin<br>R 63 : possible risk of harm to the unborn child<br>R51/53 : toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment |
| S-phrases | S2 : Keep out of reach of children<br>S36/37 : Wear suitable protective clothing and gloves<br>S 46 : If swallowed, seek medical advice immediately and show this container or label<br>S61: Avoid release to the environment. Refer to special instruction/safety data sheets |

**Justification for the proposal**

On basis of study results presented in the dossier, the Spanish Competent Authorities support the current classification and labelling of the active substance fenpropimorph on Annex I to Directive 67/548/EEC.

2.1.3.1. Proposal for the classification and labelling of the formulation

| | |
|---|---|
| Classification | as in Directive 67/548/EEC and Directive 1999/45/EC |
| Class of danger | C: Corrosive<br>T: Toxic (Repr. Cat. 2)<br>N: Dangerous for the environment |
| R-phrases | R22 Harmful if swallowed<br>R34 Causes burns<br>R60 May impair fertility<br>R61 May cause harm to the unborn child<br>R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment |
| S-phrases | S2: Keep out of reach of children<br>S13: Keep away from food, drink and animal feeding stuffs<br>S29: Do not empty into drains<br>S36/37/39: Wear suitable protective clothing, gloves and eye/face protection<br>S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label when possible)<br>S61: Avoid release to the environment. Refer to special instruction/safety data |

**Justification for the proposal**

Spanish Competent Authority suggests the classification and labelling of the biocidal product according to Directive 67/548/EEC and Directive 99/45/EC. One active substance of the biocidal product, boric acid, was included in the 30$^{th}$ draft proposal to adapting to technical progress the Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances:

Toxic (Repr. Cat. 2)

R60: May impair fertility
R61: May cause harm to the unborn child

Thus, classification and labelling of boric acid has been considered in the classification of the biocidal product WOLSIN FL 35.

## 2.2. Summary of the Risk Assessment

### *2.2.1. Human Health Risk Assessment*

#### 2.2.1.1. Hazard identification

Acute toxicity

Acute toxicity studies were carried out in rats and mice. Regarding acute toxicity of the active substance, fenpropimorph showed a moderate acute toxicity by both oral and inhalation routes of exposure, being females more sensitive than males. On the other hand, fenpropimorph is of low acute toxicity by the dermal route. Therefore, based on the acute toxicity studies with the active substance, fenpropimorph is considered to be classified as Xn R22.

Irritation

In animal studies, fenpropimorph is a skin irritant, but is not an eye irritant. Thus, fenpropimorph is considered to be classified as Xi R38. Nevertheless, the product formulation, Wolsin FL-35, caused irreversible damage in skin and eye; hence it meets the criteria for classification as corrosive (C R34).

Sensitisation

Skin sensitisation studies with either fenpropimorph or Wolsin F L-35 in Guinea pigs were negative.

Repeated dose toxicity

The repeated dose toxicity of fenpropimorph has been adequately assessed by means of oral, dermal and inhalation studies in rats, mice and dogs. Mortality and clinical signs attributed to fenpropimorph were noted only in sub-acute toxicity studies. The liver was considered as a target organ of fenpropimorph toxicity in repeated dose studies. In fact, increased liver weights were observed in rats, mice and dogs after repeated exposure of fenpropimorph. Liver damage was also determined by means of biochemical parameters including serum alanine aminotransferase, aspartate aminotransferase and alkaline phosphatase activities. Additionally, serum cholinesterase activity reduction was observed in sub-acute, sub-chronic and chronic toxicity studies performed in rats, which could indicate functional disturbance of liver activity. With regard of histopathological findings, centrilobular hepatocyte enlargement was noted in a 6-week mouse study and in a combined chronic toxicity/carcinogenicity study performed in rats. Following a postexposure period, no substance-related findings were observed in 28-day stop-dose rats, 90-day stop-dose rats, and 95-week stop-dose mice. Following repeated dermal exposure, substance-related effects were observed only in skin.

Genotoxicity

In vitro and in vivo studies did not find mutagenic or genotoxic effects which could be attributed to the active substance. Thus, fenpropimorph is considered to be non-genotoxic. Ingredients of the biocidal product, Wolsin FL-35, were considered non-genotoxic.

Carcinogenicity

In addition, carcinogenicity was investigated in rat and mouse well-conducted studies. It can be concluded that fenpropimorph is not considered as a carcinogen. Ingredients of the biocidal product, Wolsin FL-35, were considered non- carcinogen.

Reproduction (development/fertility)

In relation to reproductive toxicity, fenpropimorph did not affect fertility. However, it cause developmental toxicity, and thus it is considered to be classified as Xn R63. On the other hand, one active substance of the biocidal product, boric acid, was classified as Toxic(Repr. Cat. 2) with R60/61.

Neurotoxicity

Fenpropimorph did not cause neurotoxic effects after acute (gavage) oral feeding exposure in Wistar rats. Effects on parameters of a functional observational battery were observed in Wistar rats after subchronic oral feeding.

#### 2.2.1.1. Effects assessment

**The relevant NOAEL** value for **short-term exposure scenarios** was **NOAEL = 15 mg/kg bw/day** on the basis of skeleton malformations (position anomalies of fore and hind limbs) and embryo-/fetotoxicity derived from the three developmental studies performed in rabbits**.**

**For medium-term exposure scenarios, the relevant NOAEL** was **0.7 mg/kg bw/day** on the basis of absolute (males) and relative (males and females) liver weights deduced from a 90-day rat study.

**For long-term exposure scenarios, the relevant NOAEL** was **0.3 mg/kg bw/day** on the basis of increased liver weights, altered hepatocytes and plasma cholinesterase activity decrease derived from the combined chronic toxicity/carcinogenicity study.

**Relevant AOELs, NOAELs and assessment factors derived from effect assessment**

| **Scenarios** | **AOEL** | **NOAEL** | **Study** | **Total assessment factor** |
|---|---|---|---|---|
| | mg/kg bw(/day) | mg/kg bw/day | | |
| Acute | 0.15 | 15 | Developmental rabbit studies (combined data of 3 studies) | 100 |
| Medium-term | 0.007 | 0.7 | Subchronic rat study | 100 |
| Chronic | 0.003 | 0.3 | Combined chronic toxicity | 100 |

| | | | | |
|---|---|---|---|---|
| | | | / carcinogenicity rat study | |

2.2.1.1. Exposure assessment

The product is intended for an industrial use only, therefore, the primary exposure has been assessed for an industrial operator applying Wolsin FL-35 by dipping, using the models from the TNsG. The tasks considered are mixing and loading, application and post application of Wolsin FL-35; and cleaning the dipping tank after use. The application of fenpropimorph as wood preservative (PT8) in an industrial environment can result in direct exposure via skin contact or via inhalation, but the oral ingestion is not considered as a potential direct route. The exposure has been estimated using the models provided in the TNsG, which are: Mixing and loading model 7 (for the mixing and loading task), Dipping model 1 (for the application task) and Handling model 1 (for the cleaning task). The estimated systemic doses of fenpropimorph, considering that used gloves are worn but that there is not respiratory protection, are 0.00080243 mg a.i./kg bw/day for the mixing and loading task, 0.002266987 mg a.i./kg bw/day for the application by dipping including the handling of wet treated wood and 0.002014795 mg a.i./kg bw/day for the cleaning of the tank.

Secondary exposure has been also assessed through different acute and chronic scenarios for adults (sanding treated wood, cleaning work ware at home), infants (chewing wood off-cut, playing on weathered treated wooden structure and mouthing) and children (playing on playground structure outdoors). All the scenarios presented involve skin contact but some of them also include inhalation (processing of treated wood, for example) and oral exposure (infants chewing preserved timber off-cuts). The systemic dose of a professional sanding treated wood, which is considered a chronic scenario, is 0.00003405 mg a.i./kg bw/day, while the same for an amateur is 0.00001505 mg a.i./kg bw/day, and it is considered an acute scenario. An adult cleaning at home the work clothes (chronic phase) has a systemic exposure of 0.0003075 mg a.i./kg bw/week. The secondary exposure of infants may occur with a sort exposure period (acute phase) by chewing preserved timber off-cuts, and the corresponding oral dose is 0.00223 mg/kg bw/day. The chronic scenarios for children and infants involve a systemic dose of 0.00001296 mg a.i./kg bw/day for children and 0.00002592 mg a.i./kg bw/day for infants playing on playground structure outdoors, and 0.00011232 mg a.i./kg bw/day for infants playing on weathered treated wooden structure and mouthing.

Finally, the potential for combined exposure for the different groups of risk has been calculated adding the indirect exposure to each user. The results are 0.0025835 mg a.i./kg bw/day for an industrial operator that it is also secondarily exposed to fenpropimorph by sanding treated wood and cleaning work wear; and 0.0000491mg a.i./kg bw/day for population secondarily exposed, not directly involved in the use and application of the wood preservative, but in contact with treated wood.

2.2.1.1. Risk characterisation

The application of fenpropimorph as wood preservative (PT8) in an industrial environment can result in direct exposure via skin contact or via inhalation, but the oral ingestion is not considered as a potential direct route for exposure during the use of wood preservatives. Based on a NOAEL value of 0.3 mg/kg bw/day, the risk assessment gives margins of exposure above

100. Therefore, the exposure as a result of the application of fenpropimorph as wood preservative (PT8) in an industrial environment is considered to be within the acceptable range.

Table 2.2.1.3.1. Summary of risk assessment for industrial use

| TASK | Total systemic dose (mg/kg bw/day) | MOE |
|---|---|---|
| Mixing and loading | 0.00080243 | 374 |
| Application: Dipping (including mixing/loading and handling) | 0.002266987 | 132 |
| Cleaning | 0.002014795 | 149 |

Regarding the indirect exposure as a result of use, secondary exposure scenarios have been assessed to represent worst cases for all of the relevant exposure routes: dermal (adults sanding treated wood; adults cleaning work wear at home; children playing on preserved wood), oral (infants chewing preserved timber off-cuts) and inhalation (sanding of treated wood). The relevant NOAEL value for long-term exposure was considered to be 0.3 mg/kg bw/day on the basis of increased liver weights and plasma cholinesterase activity decrease derived from the combined chronic toxicity/carcinogenicity study and hence, the risk assessment is based on this NOAEL value.

Table 2.2.1.3.2. Summary of risk assessment for indirect exposure as a result of use

| Use of the active substance in biocidal product | | | | Total potential systemic exposure (mg a.i./kg bw/day) | MOE |
|---|---|---|---|---|---|
| Acute scenario | Intended exposure | Adult sanding treated wood: amateurs | | 0.00001505 | 996678 |
| | Unintended exposure | Infants chewing preserved timber off-cuts | | 0.00223 | 6726 |
| Chronic scenario | Intended exposure | Adult sanding treated wood: professionals | | 0.00003405 | 8810 |
| | Unintended exposure | Adults cleaning work wear | | 0.0003075 | 975 |
| | | Childs playing on preserved timber | Children | 0.00001296 | 23148 |
| | | | Infants | 0.00002592 | 11574 |
| | | Infants playing on weathered treated wooden structure and mouthing | | 0.00011232 | 2671 |

Margins of exposure above the margin of safety, i.e. 100, for both short-term and long-term exposure scenarios were calculated. Therefore, the risk for indirect exposure as a result of use is considered to be within the acceptable range.

Concerning the potential for combined exposure for the different groups of risk, it has been calculated adding the indirect exposure to each user. For an industrial user, the estimated worst total systemic exposure corresponds to continuous flow dipping. An amateur application is not intended for this product. Therefore, to estimate the combined exposure of an industrial user it has to be only considered the potential secondary exposure as a result of the contact to the residues in air or in surfaces in places where the wood preservative has been used. This includes the amateur sanding of treated wood and the cleaning of work wear tasks that may be carried out by the same person after his or her working activity at the industrial plant. Adding up all this figures, a MOE of 116 is calculated.

On the other hand, it has to be estimated the combined exposure of population secondarily exposed, not directly involved in the use and application of the wood preservative, but in contact with treated wood (for example, an industrial worker sanding treated wood as an amateur and cleaning work wear at home), and it gives a MOE of 305499.

Table 2.2.1.3.3. Comparisons of NOAEL and total potential systemic exposure

| User | NOAEL (mg/kg bw/day) | Total potential systemic exposure (mg/kg bw/day) | MOE |
|---|---|---|---|
| Industrial | 0.3 | 0.0025835 | 116 |
| Professional | 15 | 0.0000491 | 305499 |

Margins of exposure above 100 for both industrial and professional users were calculated. Therefore, the exposure for the potential for combined exposure is considered to be within the acceptable range.

## 2.2.2. Environmental Risk Assessment

Fenpropimorph is a systemic fungicide of the family of “morpholine” used as active substance for the manufacture of wood preservatives due to its protective effect against blue-stain, moulds and basidiomycetes of wood. The manufacturing process for wood preservatives is a simple mixing process of fenpropimorph with the formulation additives on an industrial scale. The wood preservative called Wolsin FL-35 is the generic formulation used for the evaluation. Wolsin FL-35 is intended for the temporary, preventive protection of freshly sawn timbers in areas with temperate or tropical climate, and for the preservation of structural timber for interior and exterior use without permanent soil/water contact (protection of wood in Use Classes 1, 2 and 3): uses such as roofing, wooden construction, windows, etc. The impregnation of wood is only made by means of industrial application processes (preventive treatments).

Fenpropimorph is released to the environment during application processes of wood preservative, during the storage of the treated wood and during the useful life of wooden construction (fence, house, etc).

The fate and behaviour of fenpropimorph in the environment as well as the impact on non-target organisms is reflected in this document.

### 2.2.2.1. Fate and distribution in the environment

#### 2.2.2.1.1. Fate and behaviour in air

Fenpropimorph may displace into the atmosphere from other environmental compartments via volatilization. Nevertheless, to reach the troposphere it is expected to be degraded quickly by photochemical processes since its half-life in air is estimated to be 2.8 h.

The aerial concentration measurements of fenpropimorph carried near the treatment industrial tank during the application processes of Wolsin FL-35 on wood are below 1 μg/$m^3$ (*see reference report: Doc. III-B 6.6*).

#### 2.2.2.1.2. Fate and behaviour in aquatic compartment (incl. Sediment)

Fenpropimorph is hydrolytically stable in water at 25ºC in the pH range from 3 to 9. Besides, it is also photolytically stable at that same temperature at pH 5 under artificial sunlight (≥ 290 nm).

When fenpropimorph reaches aquatic compartment, quickly disappears from the water phase by adsorption into the sediment where may be oxidized to the metabolite BF 421-2, which due to its weaker adsorption and solubility is released from the sediment to water phase. In tested water-sediment systems after 100 days of incubation in the dark, BF 421-2 was detected in the water phases up to 23% initial applied radioactivity and in the sediment up to 8% TAR. Fenpropimorph did not undergo significantly mineralization and the major compound detected in sediment and water was the parent compound. Mineralization occurred within 100 days and ranged from 6 to 8% TAR. Therefore, although its disappearance from the water phase is rapid, considering its slow primary degradation observed in the total systems, the formation of a moderate to high plateau of bound residues (20-37% TAR) together with limited metabolism and negligible ultimate degradation indicate fenpropimorph can be regarded as persistent substance in the aquatic compartment.

The amount of fenpropimorph bound to sediment essentially depends on the organic matter content that characterizes the sediment (and also clay content and cationic exchange capacity). Hence, the adsorption capacity of fenpropimorph is greater in sediments with high organic matter and clay contents and with elevated cationic exchange capacity.

#### 2.2.2.1.3. Fate and behaviour in soil

Fenpropimorph once incorporated into soil, it undergoes degradative processes under aerobic conditions in microbially active soils. As a first step in degradation, the molecule undergoes the oxidation of several of its carbon atoms. In the dark the degradation products BF 421-2, BF 421-7, BF 421-8 and BF 421-10 are the first appearing compounds, whereas under the influence of light BF 421-13 and BF 421-15 were formed. Thus, the aerobic degradation of fenpropimorph in the dark seems to consist mainly in progressive oxidation of tert-butyl group,

methylpropyl group and opening of the morpholine moiety to give BF 421-2 (the acid), BF 421-7 (the hydroxypropilamine) and BF 421-8 (the hydroxyethylamine). No metabolite above 10% TAR could be detected in any of the studies.

Concurrent with the decline of fenpropimorph in soil there is a high formation of bound residues. Under aerobic laboratory conditions 54% TAR after 90 days and 44% TAR after 360 days. Furthermore, fenpropimorph is slowly mineralized in soil. The rates of mineralization ranged from a minimum of 45.55% after 149 days (laboratory test at 20ºC) to maximum of 36% after 12 weeks (laboratory test at 22ºC). $CO_2$ was released from different parts of the labelled molecule.

Its half-life in soil varies several-fold according to the soil type, temperature, moisture levels and application rates. High incubation temperature and moisture, in addition to small application rate accelerate the degradation process. Fenpropimorph was degraded in soil under laboratory conditions with $DT_{50}$ values at 12ºC that ranged from 26.55 to 216.19 days under standard conditions. Under outdoor field conditions its $DT_{50}$ values ranged from 10 to 90 days. In some of the degradation studies, a somewhat slower degradation of fenpropimorph occurred after an initial fast decrease in concentration. The $DT_{90}$ values in some of the field studies were > 365 days.

Under anaerobic laboratory conditions the degradation i.e. metabolism of fenpropimorph is insignificant with negligible amounts of both $CO_2$ and bound residues. No metabolite above 5% TAR could be detected in the studies, so fenpropimorph can be regarded as a persistent substance under anaerobic conditions.

Adsorption/desorption studies characterize to fenpropimorph as a compound with high adsorption capacity to soil. This binding capacity essentially depends on the organic matter percentage (the minimum $K_{oc}$ value estimated in the tests was 2772 L/kg), and also to a lesser extent of clay content and cationic exchange capacity that characterize to soils. Thus, it can be expected:

- Once incorporated into the soil, fenpropimorph is bound tightly to the soil particles of the first centimetres maintaining nearly immobile on this layer.
- The amount of fenpropimorph adsorbed is greater in acid soils with high organic matter and clay content and with elevated cationic exchange capacity.

## 2.2.2.2. Effects assessment

### 2.2.2.2.1. Effects on aquatic organisms

The key toxicity tests of fenpropimorph for estimation of $PNEC_{water}$ are summarized in the following table (effects on sediment-dwelling organisms are discussed in the next section).

**Summary of (key) toxicity tests of fenpropimorph for aqueous phase**

| Guideline / Test method | Species | Endpoint / Type of test | Exposure | | Results (mg/L) | | Related to conc[1] |
|---|---|---|---|---|---|---|---|
| | | | Design | Durat. | NOEC | $L(E)C_{50}$ | |
| OECD 210 | *O. mykiss* | Hatching, survival, growth | Flow-through | 94 d | 0.00016 | - | Nominal |
| OECD 202, part 2 | *D. magna* | Reproduction, immobilization | Semi-static | 21 d | 0.032 (0.024 a.s.) | 0.11 (0.083 a.s.) | Nominal |
| OECD 201 | *P. subscapitata* | Growth rate, biomass | Static | 72 h | 0.058[2] 0.005[2] | > 1 0.327 | Nominal |

[1]Concentrations were measured in all tests. If deviation of measured concentration from nominal value < 20%, effects were related to nominal concentrations.
[2]$EC_{10}$

The chronic NOECs of fenpropimorph for three trophic levels (fish, invertebrates and algae) are summarized in the above table. From the results of the early life stage test performed on Rainbow trout (*Oncorhynchus mykiss)* it is deduced that by far the most sensitive taxonomic group are fish.

Long-term effects of fenpropimorph on invertebrates were assessed with a reproduction toxicity test on *Daphnia magna.* However, this study was not considered valid because it did not fulfil one of the validity criteria for invertebrate reproduction test according to OECD Guideline 211. As a consequence of this and in order to make up for lack of chronic data in aquatic invertebrates, the endpoints of actived ingredient in daphnia were replaced by the results of a test performed on *Daphnia magna* with the formulation Corbel (containing fenpropimorph as a.i.). The NOEC of reproduction in this test was estimated to be 0.032 mg Corbel/L equivalent to 0.024 mg a.i./L.

Concerning the PNEC, it was selected the lowest endpoint available to its estimation. This endpoint corresponded with the NOEC estimated from early life stage test performed on Rainbout trout. The PNEC for aqueous phase organisms was estimated to be 0.016 µg/L, as the TGD recommends that “a safety factor of 10 must be applied to the lowest endpoint when chronic data for three trophic levels are available”.

In environmental studies a major metabolite, BF 421-2 (fenpropimorphic acid) was identified in aquatic test systems at significant concentrations. Therefore, BF 421-2 was subjected to ecotoxicological studies on aquatic organisms. This metabolite has acute toxicity values on *O.*

*mykiss*, *D. magna*, and *P. subcapita*, lower than the active substance. All $L(E)C_{50}$ values were >100 mg/L. Therefore, the metabolite may be considered to be ecotoxicologically non-relevant.

### 2.2.2.2.2. Effects on sediment organisms

*Assessment using the equilibrium partitioning method (EPM)*

The concentration of the substance in sediment-dwelling organisms was predicted using the equilibrium partitioning method.

$$PNEC_{sediment} = \frac{PNEC_{water} \cdot K_{susp\text{-}water} \cdot 1000}{RHO_{susp}} = 0.002079 \ mg/kg$$

It is important to emphasize that the formula of the EPM only considers uptake via the water phase, assuming partitioning equilibrium between water and suspended matter. The partition coefficient for suspended matter is calculated from the $K_{oc}$ value, and the fraction of the organic carbon in the suspended matter. However, uptake may also occur via other exposure pathways like ingestion of sediment and direct contact with sediment. This may become important, especially for adsorbing chemicals that are bound organic matter (substances with log $K_{ow}$ > 3) and/or clay of sediment (ionized substances: e.g. cationic substances are generally known to adsorb strongly). For these compounds the total uptake may be underestimated.

Fenpropimorph has at pH 7 a log $K_{ow}$ = 4.5 and a min. $K_{oc}$ > 2772 L/Kg. Furthermore, at pH values < 8 this substance is ionized (positively charged).

*Assessment based on the toxicity test*

**Effects of fenpropimorph on sediment-dwelling organisms**

| Guideline/ Test method | Species | Endpoint/ Type of test | Exposure | | Results (mg/L) | | Reference |
|---|---|---|---|---|---|---|---|
| | | | Design | Duration | $LC_{50}$ | NOEC | |
| BBA/IVA protocol | *C. riparius* | Mortality and emergence | Static | 20 d | - | 0.125 | A 7.4.3.5.1 |

The calculation for derivation of PNEC for sediment-dwelling organisms with this approach is based on chronic NOEC (nominal concentration) estimated from *Chironomus riparus* toxicity test using spiked water although in the study Fenpropimorph was not detected in the water column at the end of the test (i.e. the concentration of fenpropimorph was not maintained > 80 of initial concentration during the test) and no concentration was measured in the sediment. However, fenpropimorph migrates quickly from water to the sediment (due to its high adsorption capacity to be an ionizable substance with min. $k_{oc}$ > 2772 L/kg) and is stable in aquatic compartment because neither is biodegraded ostensibly nor undergoes hydrolysis. Therefore, it may be assumed reasonably that the vast majority of fenpropimorph spiked water finally ended up in the sediment afterwards a short period of time. The rest of fenpropimorph

could be bound to food because during the test the larvae were regularly fed with fish food extract according to the feeding strategy for *Chironomus sp.* (collector-gatherer that feeds mainly on material deposited on submerged substrate see section 6.3.3 of TGD).

Therefore, taking into account that fenpropimorph stayed in the medium test, the highest concentration of tested (0.125 mg a.i./L) was regarded as a suitable endpoint for the derivation of a tentative $PNEC_{sediment}$ expressed as a concentration in water because this nominal concentration caused no effects on emergence and survival either of the chironomids larvae. Thus, the tentative PNEC for sediment-dwelling organisms was estimated to be 0.00125 mg a.i./L since the TGD recommends to apply a 100 safety factor when there is one available NOEC. As this PNEC is expressed as concentration in water, it cannot be compared with the $PNEC_{sediment}$ calculated from the equilibrium partitioning method. Nevertheless, this tentative PNEC is clearly higher than the PNEC for aquatic organisms, and therefore confirms that the risk for aquatic organisms also covers the risk for sediment-dwelling organisms.

### 2.2.2.2.3. Effects on sewage treatment plant micro-organisms

PNEC value for micro-organisms of sewage treatment plant (STP) is estimated to be 50 mg fenpropimorph/L. This PNEC value was derived from NOEC of the respiration inhibition test applying it a safety factor of 10 as the TGD recommends.

**Effects of fenpropimorph on microbial activity (aquatic)**

| Guideline/ Test method | Species/ Inoculum | Endpoint/ Type of test | Exposure | | Results (mg/L) | | | Reference |
|---|---|---|---|---|---|---|---|---|
| | | | Design | Duration | NOEC | $EC_{20}$ | $EC_{50}$ | |
| OECD 209 | Activated sludge | Respiration inhibition test | - | 180 min | 500 | 960 | > 1000 | A 7.4.1.4 |

#### 2.2.2.2.4. Effects on terrestrial organisms

The key toxicity tests of fenpropimorph for estimation of $PNEC_{terrestrial\ organisms}$ are summarized in the following table.

**Summary of (Key) toxicity tests of fenpropimorph for terrestrial compartment**

| Guideline / Test method | Species | Endpoint / Type of test | Duration | NOEC | Remarks | Reference |
|---|---|---|---|---|---|---|
| BBA VI 1-1 | Soil microflora | Soil respiration | 28 d | 9 mg a.s./$kg_{wwt}$ | Test done with Corbel | A 7.5.1.1/01 |
| BBA VI 1-1 | Soil microflora | Soil nitrification | 28 d | 9 mg a.s./$kg_{wwt}$ | Test done with Corbel | A 7.5.1.1/02 |
| OECD 222 | *E. fetida* | Reproduction, mortality | 56 d | 6.28 mg a.s./$kg_{wwt}$ | Test done with BAS 421 12F | A 7.5.1.2/01 |
| Extrapolation from OECD 208 | Vascular plants | Biomass | Depending on test crop specie | 8.25-150 mg a.i/$kg_{dwt}$ | - | Section 8.2.3.1, Doc. II |

According to TGD (*section: 6.3.4, page 191*), microbial processes are regarded as short-term test. However, a NOEC from these tests can be considered as long-term results for microbial. Therefore, the concentration of 9 mg fenpropimorph/kg wet soil can be considered as a long-term toxicity data (i.e. a chronic NOEC).

Regarding the toxicity of fenpropimorph for vascular plants, the results of the conversion from NOEC based on foliar application to soil concentration (*see section 8.2.3.1 of Doc. II*) confirm that this taxonomic group is not the most sensitive.

Thus, the PNEC for terrestrial organisms is estimated to be 0.628 mg a.s./$kg_{wwt}$ because the TGD recommends to apply a safety factor of 10 to the lowest endpoint when chronic data for three species of three trophic levels (primary producers, consumers and decomposers) are available.

#### 2.2.2.2.5. Non compartment specific effects relevant to food chain (secondary poisoning)

No specific data has been submitted. However, fenpropimorph has a $BCF_{fish}$ > 1000 L/kg what entails that an initial assessment of the secondary poisoning through the aquatic food chain must be done in order to rule out or not if fenpropimorph can move up into the higher levels of the trophic chain.

### 2.2.2.3. PBT assessment

A substance must be regarded as a PBT substance if fulfils the combined set of criteria of identification summarized in the Table 30 of TGD (section 4.4, Page 164). The combined set of criteria is based on inherent properties:

- Persistence (P)
- Bioaccumulation (B)
- Toxicity (T)

When it is clear that the P criterion is fulfilled a stepwise approach should be followed to elucidate the B criterion, eventually followed by clarifying the T criterion.

Persistence: the P criterion

Fenpropimorph seems not to fulfil the P criterion for soil since its half-life for most soils is below 120 d. Under outdoor field conditions its $DT_{50}$ values ranged from 10 to 90 days and under laboratory conditions there was only one soil with a $DT_{50}$ value at 12ºC above the cut-off value (Neuhofen soil: half-life about 216 days).

However, fenpropimorph can be regarded as a persistent substance in aquatic compartment (sediment-water systems) since although disappears from the water phase rapidly to bound to sediment (its the residence times in water phase in these systems are < 3.4 d) it was observed a slow primary degradation in the total system, the formation of a moderate to high plateau of bound residues (20-37% TAR) and limited metabolism and negligible ultimate degradation (6-8% TAR).

Bioaccumulation: the B criterion

The assessment of the (potential for) bioaccumulation in the context of PBT or vPvB evaluation makes use of measured bioconcentration factor. For the case of fenpropimorph the measured BCF for fish is about 1200. So, fenpropimorph does not fulfil the B criterion due to its BCF is below cut-off values proposed in the TGD (BCF > 2,000 for PBT assessment and > 5,000 for vPvB assessment).

Toxicity: the T criterion

Fenpropimorph fulfils the T criterion because the most sensitive specie (*O. mykiss*) has a chronic NOEC (0.00016 mg/L) much lower than cut-off value proposed in the TGD (NOEC < 0.01 mg/L).

**Conclusion:**

Fenpropimorph must not be regarded as a PBT or vPvB substance because does not fulfil the B criteria.

### 2.2.2.4. Exposure assessment

The estimation of the PECs in air, surface water, and soil was made according to the proposed OECD Emission Scenarios Document (ESD) for Wood Preservatives. For the calculation of PECs in sediment, groundwater and secondary poisoning the recommendations given by the TGD (part II) were followed.

Sewage treatment plants (STPs)

The environmental concentrations of fenpropimorph in STPs were derived considering the potential emissions produced during industrial product application and during the storage of treated wood prior to shipment. The facility drain is assumed to drain into the public sewage treatment plant.

Also, it was taken into consideration the possible releases from treated wood-in-service after rain events. It was assumed that in the case of noise barrier, leachate resulting from rainfall was collected in the gutter and sewer and finally entered a municipal sewage treatment plant (STP).

Water

Potential routes of entry for fenpropimorph into surface waters are:

- The effluents from sewage treatment plants because in ESD is assumed that the industrial treatment plants drain into the STPs.
- Run-off water from unpaved storage.
- Emissions from wood-in-service after rain events. The possible emissions from treated wood-in-service (Use Class 3 Wood) to aquatic compartment could be only originated from the noise barrier since it may be connected to a public sewage treatment plant (STP).

For industrial Scenarios, therefore, Predicted Environmental Concentrations (PECs) in surface water were calculated considering two emission sources:

- Emission via sewage treatment plant (STP).
- Direct emission by run-off from unpaved storage sites.

The direct emissions by run-off from storages sites were added to the potential releases to surface water from sewage treatment plants (STPs). The values of PECs in water are shown in **the section 2.2.2.5.2 of this document.**

Sediment

Two different approaches were used in this compartment, one of them was used the Equilibrium Partitioning Method (EQM) in order to estimate the PECs in sediment and the other was utilized the PECs in water jointly with toxicity data available on sediment organisms to estimate the risk characterization. For further details see **the section 2.2.2.5.3 of this document.**

Air

Taking into account the half-life of fenpropimorph in atmosphere is very short (2.8 hours) and that the aerial concentration measurements near the treatment tank are < 1 $\mu g/m^3$ (*see reference report: Doc. III-B 6.6*), **it can be concluded PECs in air are negligible, independently of figures that can be estimated according to ESD.**

Soil

Fenpropimorph can be reached to terrestrial compartment by:

- **Direct emissions**: via leaching out of industrially treated wood at storage stage and pre-treated wood-in-service.

- **Indirect emissions:** via the application of sewage sludge to agriculture soils and/or grassland. The concentration of fenpropimorph in sludge depends on emission to facility drain from industrial treatment plants in the different processes of application and emissions from pre-treated wood-in-service (noise barrier).

*Direct Emissions:*

The predicted environmental concentrations of fenpropimorph in soil were calculated according to OECD ESD. For the estimation of PECs in soil, leaching data of fenpropimorph from treated wood were used.

In a first tier estimation, removal processes from the receiving compartment due to degradation, volatilisation, and leaching to groundwater (from soil) was ignored. The predicted environmental concentrations were calculated for several sizes of the receiving soil and two assessment periods: 30 days (TIME1) and 5475 days (TIME2). As the leaching rate from wood will be high just after application, to fall to a lower more constant rate after a few days or weeks, two time spans may be distinguished: a short-time span just after application, to estimate soil concentrations after short-time high leaching rates (30 days), and a longer time span to estimate the long-term soil concentration (1 year or longer).

For a second tier, the removal processes were taken into account. The rate constant for removal only included biotic degradation in soil. No refinement for the losses in soil in the storage area has been made since it is assumed (according to ESD) a periodic renewal of stored wood in the storage area, and hence it can be considered that the release rate is continuous. Nevertheless, for wood-in-service it is assumed that the losses to soil via leaching dependent of frequency of precipitations.

*Indirect emissions:*

The predicted environmental concentrations of fenpropimorph in agriculture soil and grassland were calculated according to section 2.3.8.5 of TGD after the application of sewage sludge.The concentration will be high just after the application of sewage sludge, and then will diminish with the time due to removal processes. Therefore, for exposure of endpoints, the concentration in soil needs to be averaged over a certain time period. Different average times should be averaged:

- A period of 30 days after application of sludge for the ecosystem.
- A period of 180 days to determine biomagnification effects and indirect exposure to man.

The values of PECs in soil due to direct emissions as well as indirect releases are shown in **the section 2.2.2.5.4 of this document.**

Groundwater

The values of PECs in groundwater are shown in **the section 2.2.2.5.5 of this document.**

Non compartment specific effects relevant to food chain (secondary poisoning)

See **the section 2.2.2.5.6 of this document.**

## 2.2.2.5. Risk characterisation

### 2.2.2.5.1. Sewage treatment plant micro-organisms (STP)

The risk characterization for micro-organisms of STPs is shown in the following table.

**Table 2.2.2.5.1.1. PEC/PNEC ratios for STP in an exposure situation**

| Exposure Scenario | PEC [µg/L] | PNEC [µg/L] | PEC/PNEC |
|---|---|---|---|
| Dipping processes | 23.1028 | 50000 | $4.62 \cdot 10^{-4}$ |
| Automated spraying processes: Small plants | 4.6206 | | $9.24 \cdot 10^{-5}$ |
| Automated spraying processes: Big plants | 46.2056 | | $9.24 \cdot 10^{-4}$ |
| Noise barrier | 4.2229 | | $8.45 \cdot 10^{-5}$ |

**Conclusion:**

No risk is expected to micro-organisms of STPs since all PEC/PNEC ratios are < 1.

### 2.2.2.5.2. Aquatic organisms

The risk characterization for aquatic organisms is shown in the following table taking into account the different scenarios.

**Table 2.2.2.5.2.1. PEC/PNEC ratios for the surface water in an exposure situation**

| Exposure Scenario | $PEC_{surface\ water}$* [µg/L] | PNEC [µg/L] | PEC/PNEC |
|---|---|---|---|
| Dipping processes | 4.0552 | 0.016 | **253.45** |
| Automated spraying processes: Small plants | 1.1251 | | **70.3188** |
| Automated spraying processes: Big plants | 11.2505 | | **703.1563** |
| Noise barrier | 0.4223 | | **26.3938** |

*Calculated adding $Clocal_{surface\ water}$ of Run-off and via STP

**Conclusion:**

Based on the calculated PEC/PNEC ratios for the different scenarios, it is concluded that exists a potential risk for aquatic organisms (fish, aquatic invertebrates and algae) to be exposed to fenpropimorph as wood preservative since all PEC/PNEC ratios are greater than one. Therefore, in order to avoid it further actions have to be taken (e.g. at the product authorisation stage risk mitigation measures should be required to reach PEC/PNEC ≤ 1).

### 2.2.2.5.3. Sediment organisms

*Risk characterization using the equilibrium partitioning method (EPM)*

The risk characterization for sediment-dwelling organisms is shown in the following table for the different scenarios using the equilibrium partitioning method (EPM).

**Table 2.2.2.5.3.1. PEC/PNEC ratios for the sediment in an exposure situation using the equilibrium partitioning method (EPM)**

| Exposure Scenario | $PEC_{sediment}$ [mg/kg] | $PNEC_{sediment}$ [mg/kg] | PEC/PNEC |
|---|---|---|---|
| Dipping processes | 0.5271 | 0.0021 | **253.5354** |
| Automated spraying processes: Small plants | 0.1462 | | **70.3223** |
| Automated spraying processes: Big plants | 1.4623 | | **703.3670** |
| Noise barrier | 0.0549 | | **26.4069** |

**Conclusion:**

PEC/PNEC ratios for the different scenarios are the same as those of risk characterization to surface water due to the equilibrium partitioning method (EPM) was used for the estimation of $PNEC_{sediment}$ and also for the derivation of $PEC_{sediment}$.

*Risk characterization using the toxicity test performed on sediment-dwelling organisms*

The PNEC for sediment-dwelling organisms was derived from a chronic toxicity test on quironomids. This test was conducted using spiked water, so the PNEC had the same units as NOEC of the test i.e. it was expressed as a concentration in water. Thus, to keep the coherence in units for the risk characterization was necessary to compare the $PEC_{water}$ with aforementioned PNEC.

**Table 2.2.2.5.3.2. PEC/PNEC ratios for the sediment in an exposure situation**

| Exposure Scenario | $PEC_{surface\ water}$ [µg/L] | $PNEC_{sediment}$ [µg/L] | PEC/PNEC |
|---|---|---|---|
| Dipping processes | 4.0552 | 1.25 | **3.2442** |
| Automated spraying processes: Small plants | 1.1251 | | 0.9001 |
| Automated spraying processes: Big plants | 11.2505 | | **9.0004** |
| Noise barrier | 0.4223 | | 0.3378 |

**Conclusion:**

A risk for sediment-dwelling organisms is expected when wood is treated by means of the industrial treatments either by dipping or automated spraying (at large scale), since their PEC/PNEC ratios are greater than one (figures highlighted in bold). The PEC/PNEC ratios are much lower than the calculated for aquatic compartment, so the risk for sediment compartment is covered by the risk for aquatic phase. Therefore, adopting suitable measures of risk mitigation for surface water it is possible to control the emissions that reach to sediment and hence the risk for sediment-dwelling organisms.

### 2.2.2.5.4. Terrestrial organisms

The risk characterization for this compartment was conducted taking into account that fenpropimorph can be reached to soil by direct and/or indirect emissions (see section 2.2.2.4. of this document).

*Direct Emissions*

For the estimation of PECs in soil, leaching data of fenpropimorph from treated wood were used.

In a first tier estimation, removal processes from soil due to degradation, volatilisation, leaching to groundwater (from soil) was ignored. The predicted environmental concentrations were calculated for several sizes of the receiving soil and two different assessment periods: 30 days (TIME1) and 5475 days (TIME2).

**Table 2.2.2.5.4.1. PEC/PNEC ratios for different sizes of the soil receiving and assessment periods without taking into account the removal processes**

| Exposure Scenario | | Size of the soil receiving | $PEC_{soil}$ [$mg/kg_{wwt}$] | PNEC [$mg/kg_{wwt}$] | PEC/PNEC |
|---|---|---|---|---|---|
| Dipping processes | 30 d storage | 10 cm depth/10 cm horizontal | 11.5985 | 0.628 | **18.4690** |
| | | 20 cm depth/20 cm horizontal | 5.7993 | | **9.2345** |
| | | 30 cm depth/30 cm horizontal | 3.8662 | | **6.1563** |
| | | 40 cm depth/40 cm horizontal | 2.8996 | | **4.6172** |
| | | 50 cm depth/50 cm horizontal | 2.3197 | | **3.6938** |
| | 5475 d storage | 10 cm depth/10 cm horizontal | 2116.7 | | **3370.5917** |
| | | 20 cm depth/20 cm horizontal | 1058.4 | | **1685.2959** |
| | | 30 cm depth/30 cm horizontal | 705.6 | | **1123.5306** |
| | | 40 cm depth/40 cm horizontal | 529.2 | | **842.6479** |
| | | 50 cm depth/50 cm horizontal | 423.3 | | **674.1183** |
| Automated Spraying processes: Small plants | 30 d storage | 10 cm depth/10 cm horizontal | 38.3868 | | **61.1254** |
| | | 20 cm depth/20 cm horizontal | 19.1934 | | **30.5627** |
| | | 30 cm depth/30 cm horizontal | 12.7959 | | **20.3751** |
| | | 40 cm depth/40 cm horizontal | 9.5967 | | **15.2814** |
| | | 50 cm depth/50 cm horizontal | 7.6774 | | **12.2251** |
| | 5475 d storage | 10 cm depth/10 cm horizontal | 7005.6 | | **11155.3894** |
| | | 20 cm depth/20 cm horizontal | 3502.8 | | **5577.6947** |
| | | 30 cm depth/30 cm horizontal | 2335.2 | | **3718.4631** |
| | | 40 cm depth/40 cm horizontal | 1751.4 | | **2788.8474** |
| | | 50 cm depth/50 cm horizontal | 1401.1 | | **2231.0779** |
| Automated Spraying processes: Big plants | 30 d storage | 10 cm depth/10 cm horizontal | 38.3868 | | **61.1254** |
| | | 20 cm depth/20 cm horizontal | 19.1934 | | **30.5627** |
| | | 30 cm depth/30 cm horizontal | 12.7959 | | **20.3751** |
| | | 40 cm depth/40 cm horizontal | 9.5967 | | **15.2814** |
| | | 50 cm depth/50 cm horizontal | 7.6774 | | **12.2251** |
| | 5475 d storage | 10 cm depth/10 cm horizontal | 7005.6 | | **11155.3894** |
| | | 20 cm depth/20 cm horizontal | 3502.8 | | **5577.6947** |
| | | 30 cm depth/30 cm horizontal | 2335.2 | | **3718.4631** |
| | | 40 cm depth/40 cm horizontal | 1751.4 | | **2788.8474** |
| | | 50 cm depth/50 cm horizontal | 1401.1 | | **2231.0779** |
| Fence | 30 d service life-time | 10 cm depth/10 cm horizontal | 24.0588 | | **38.3102** |
| | | 20 cm depth/20 cm horizontal | 6.0147 | | **9.5776** |
| | | 30 cm depth/30 cm horizontal | 2.6732 | | **4.2567** |
| | | 40 cm depth/40 cm horizontal | 1.5038 | | **2.3944** |
| | | 50 cm depth/50 cm horizontal | 0.9624 | | **1.5324** |

| | | | | | |
|---|---|---|---|---|---|
| | **5475 d service life-time** | 10 cm depth/10 cm horizontal | 30.9412 | | **49.2694** |
| | | 20 cm depth/20 cm horizontal | 7.7353 | | **12.3173** |
| | | 30 cm depth/30 cm horizontal | 3.4379 | | **5.4744** |
| | | 40 cm depth/40 cm horizontal | 1.9338 | | **3.0793** |
| | | 50 cm depth/50 cm horizontal | 1.2376 | | **1.9708** |
| **House** | **30 d service life-time** | 10 cm depth/10 cm horizontal | 30.0736 | | **47.8878** |
| | | 20 cm depth/20 cm horizontal | 7.5184 | | **11.9719** |
| | | 30 cm depth/30 cm horizontal | 3.2687 | | **5.1939** |
| | | 40 cm depth/40 cm horizontal | 1.8204 | | **2.8988** |
| | | 50 cm depth/50 cm horizontal | 1.1567 | | **1.8418** |
| | **5475 d service life-time** | 10 cm depth/10 cm horizontal | 38.6765 | | **61.5867** |
| | | 20 cm depth/20 cm horizontal | 9.6691 | | **15.3967** |
| | | 30 cm depth/30 cm horizontal | 4.1948 | | **6.6797** |
| | | 40 cm depth/40 cm horizontal | 2.3412 | | **3.7280** |
| | | 50 cm depth/50 cm horizontal | 1.4876 | | **2.3687** |
| **Noise barrier** | **30 d service life-time** | 10 cm depth/10 cm horizontal | 10.8265 | | **17.2396** |
| | | 20 cm depth/20 cm horizontal | 2.7066 | | **4.3099** |
| | | 30 cm depth/30 cm horizontal | 1.2029 | | **1.9155** |
| | | 40 cm depth/40 cm horizontal | 0.6767 | | **1.0775** |
| | | 50 cm depth/50 cm horizontal | 0.4331 | | **0.6896** |
| | **5475 d service life-time** | 10 cm depth/10 cm horizontal | 13.9235 | | **22.1712** |
| | | 20 cm depth/20 cm horizontal | 3.4809 | | **5.5428** |
| | | 30 cm depth/30 cm horizontal | 1.5471 | | **2.4635** |
| | | 40 cm depth/40 cm horizontal | 0.8702 | | **1.3857** |
| | | 50 cm depth/50 cm horizontal | 0.5569 | | **0.8868** |

For a second tier, the removal processes was taken into account. The rate constant for removal only included biotic degradation in soil.

No refinement for the losses in soil in the storage area has been made since it is assumed (according to ESD) a periodic renewal of stored wood in the storage area, and hence it can be considered that the release rate is continuous. Nevertheless, for wood in-service it is assumed that the losses to soil via leaching dependent of frequency of precipitations. The average concentration of fenpropimorph over a certain period of time can be calculated considering the first order biodegradation rate of the chemical in the top soil.

**Table 2.2.2.5.4.2. PEC/PNEC ratios for the soil (adjacent to wood in-service) for TIME1 and TIME2 considering biotic degradation processes**

| Exposure Scenario | | Size of the soil receiving | $PEC_{soil}$ [$mg/kg_{wwt}$] | PNEC [$mg/kg_{wwt}$] | PEC/PNEC |
|---|---|---|---|---|---|
| Fence | 30 d service life-time | 10 cm depth/10 cm horizontal | 11.1543 | 0.628 | **17.7616** |
| | | 20 cm depth/20 cm horizontal | 2.7886 | | **4.4404** |
| | | 30 cm depth/30 cm horizontal | 1.2394 | | **1.9735** |
| | | 40 cm depth/40 cm horizontal | 0.6971 | | **1.1101** |
| | | 50 cm depth/50 cm horizontal | 0.4462 | | 0.7105 |
| | 5475 d service life-time | 10 cm depth/10 cm horizontal | 0.7165 | | **1.1410** |
| | | 20 cm depth/20 cm horizontal | 0.1791 | | 0.2852 |
| | | 30 cm depth/30 cm horizontal | 0.0796 | | 0.1268 |
| | | 40 cm depth/40 cm horizontal | 0.0448 | | 0.0713 |
| | | 50 cm depth/50 cm horizontal | 0.0287 | | 0.0456 |
| House | 30 d service life-time | 10 cm depth/10 cm horizontal | 13.9428 | | **22.2019** |
| | | 20 cm depth/20 cm horizontal | 3.4857 | | **5.5505** |
| | | 30 cm depth/30 cm horizontal | 1.5155 | | **2.4080** |
| | | 40 cm depth/40 cm horizontal | 0.8439 | | **1.3439** |
| | | 50 cm depth/50 cm horizontal | 0.5363 | | 0.8539 |
| | 5475 d service life-time | 10 cm depth/10 cm horizontal | 0.8957 | | **1.4262** |
| | | 20 cm depth/20 cm horizontal | 0.2239 | | 0.3566 |
| | | 30 cm depth/30 cm horizontal | 0.0971 | | 0.1547 |
| | | 40 cm depth/40 cm horizontal | 0.0542 | | 0.0863 |
| | | 50 cm depth/50 cm horizontal | 0.0344 | | 0.0549 |
| Noise barrier | 30 d service life-time | 10 cm depth/10 cm horizontal | 5.0194 | | **7.9927** |
| | | 20 cm depth/20 cm horizontal | 1.2549 | | **1.9982** |
| | | 30 cm depth/30 cm horizontal | 0.5577 | | 0.8881 |
| | | 40 cm depth/40 cm horizontal | 0.3137 | | 0.4995 |
| | | 50 cm depth/50 cm horizontal | 0.2008 | | 0.3197 |
| | 5475 d service life-time | 10 cm depth/10 cm horizontal | 0.3224 | | 0.5134 |
| | | 20 cm depth/20 cm horizontal | 0.0806 | | 0.1284 |
| | | 30 cm depth/30 cm horizontal | 0.0358 | | 0.0570 |
| | | 40 cm depth/40 cm horizontal | 0.0202 | | 0.0321 |
| | | 50 cm depth/50 cm horizontal | 0.0129 | | 0.0205 |

*Indirect emissions*

The predicted environmental concentrations of fenpropimorph in agriculture soils and grassland after the application of sewage sludge are defined as the averaged concentration over a certain time period t.

**Table 2.2.2.5.4.3. PEC/PNEC ratios for agriculture soils and grassland in an exposure situation**

| Exposure Scenario | | Avg. time (d) | $PEC_{soil}$ [$mg/kg_{wwt}$] | PNEC [$mg/kg_{wwt}$] | PEC/PNEC |
|---|---|---|---|---|---|
| Dipping-STP sludge | Agriculture | 30 | $2.98 \cdot 10^{-2}$ | 0.628 | 0.0476 |
| Dipping-STP sludge | Agriculture | 180 | $1.80 \cdot 10^{-2}$ | | 0.0289 |
| Dipping-STP sludge | Grassland | 180 | $7.21 \cdot 10^{-3}$ | | 0.0115 |
| A. Spraying (Small plants)-STP sludge | Agriculture | 30 | $5.95 \cdot 10^{-3}$ | | 0.0095 |
| A. Spraying (Small plants)-STP sludge | Agriculture | 180 | $3.61 \cdot 10^{-3}$ | | 0.0058 |
| A. Spraying (Big plants)-STP sludge | Agriculture | 30 | $5.95 \cdot 10^{-2}$ | | 0.0953 |
| A. Spraying (Big plants)-STP sludge | Agriculture | 180 | $3.61 \cdot 10^{-2}$ | | 0.0575 |
| A. Spraying (Small plants)-STP sludge | Grassland | 180 | $1.44 \cdot 10^{-3}$ | | 0.0023 |
| A. Spraying (Big plants)-STP sludge | Grassland | 180 | $1.44 \cdot 10^{-2}$ | | 0.0231 |
| Noise barrier-STP sludge | Agriculture | 30 | $5.43 \cdot 10^{-3}$ | | 0.0086 |
| Noise barrier-STP sludge | Agriculture | 180 | $3.29 \cdot 10^{-3}$ | | 0.0052 |
| Noise barrier-STP sludge | Grassland | 180 | $1.32 \cdot 10^{-3}$ | | 0.0021 |

**Conclusion:**

Fenpropimorph as active substance of wood preservatives poses a potential risk to soil organisms when from industrial treatment plants it is released to soil, since PEC/PNEC ratios for these scenarios are greater than one (figures highlighted in bold in the Table 2.2.2.5.4.1). Therefore, in order to avoid the risk further actions have to be taken (e.g. at the product authorisation stage risk mitigation measures should be required to reach PEC/PNEC $\leq 1$).

Instead of fenpropimorph does not pose a risk to soil organisms when it is released to soils from treated wood-in-service (see Table 2.2.2.5.4.2) or via application of sewage sludge (see Table 2.2.2.5.4.3).

These conclusions are based on assuming by default a distance of 50 cm depth and 50 horizontal for every scenario in order to define the size of receiving soil compartment. These dimensions agreed during 23rd CA meeting.

### 2.2.2.5.5. Groundwater

The concentration in groundwater was calculated for indirect exposure of humans through drinking water.

For fenpropimorph a first approach for the estimation of the PECs in groundwater was performed as the TGD recommends from the concentration in soil porewater using the partitioning equation. In several of proposed scenarios the concentration estimated of fenpropimorph in groundwater exceeds the pesticides drinking water standard of 0.1 µg/L (EU Drinking Water Directive, 98/83/EC). Nevertheless, it should be borne in mind that the concentration in porewater is a worst-case assumption to neglect transformation (case of direct emissions) and dilution in deeper soil layers.

On one hand the scenarios included the direct emissions to soil from treated wood (produced during storage stage in industrial on-site assuming treated timber is stored on bare earth) and on

the other hand indirect emissions to soil due to the application of sewage sludge contaminated with fenpropimorph.

However, according to agreement of TMI06 (considering the use of treated timber) a groundwater assessment should only be necessary for the house scenario, as this can be considered worst-case for soil exposure. Since, for the industrial on-site storage scenario (where treated timber is assumed to be stored on bare earth) a groundwater assessment is only considered to be necessary where there is no risk identified for the soil compartment for the industrial scenario. In the case of fenpropimorph was identified a risk for soil, so risk mitigation measures will be required to prevent losses to soil (i.e. impermeable hard standing and recovery of leachate), which will by default prevent exposure to the groundwater compartment.

Therefore, taking into account the aforementioned a groundwater assessment for house scenario was performed following the guidance proposed by UK CA, i.e. the assessment of groundwater contamination resulting from the application to and leaching from houses treated with wood preservatives. In order to do the assessment, the simulation model FOCUS-PELMO 3.3.2 was utilized and was assumed as a realistic worst-case a density of 35 houses per hectare.

Nine realistic worst-case scenarios have been defined, which collectively represent agricultural use in the EU. It was accepted at TMII06 that not all scenarios have to be shown to meet the <0.1 µg/l drinking water limit for pesticides. However, for each scenario the concentration of fepropimorph estimated in groundwater was much less than 0.1 µg/l.

**Table 2.2.2.5.5.1. The 80$^{th}$ percentile of the predicted annual concentrations of fenpropimorph as biocide (35 houses ha$^{-1}$) for the winter cereals scenarios (worst-case) calculated using the simulation model FOCUS-PELMO 3.3.2**

| Model | Scenario | $PEC_{groundwater}$ [µg/l] |
|---|---|---|
| FOCUS-PELMO | Châteaudun | < 0.001 |
| | Hamburg | < 0.001 |
| | Jokioinen | < 0.001 |
| | Kremsmünster | < 0.001 |
| | Okehampton | < 0.001 |
| | Piacenza | < 0.001 |
| | Porto | < 0.001 |
| | Seville | < 0.001 |
| | Thiva | < 0.001 |

The results of this simulation are in accordance with those of the simulation PELMO that are included in DAR in plant protection (although the agricultural application rate, 0.75 kg a.s./ha, is much higher than application rate as biocide) and with monitoring data collected by RMS of this evaluation (Germany). There were only 3 cases in which it were detected concentrations of fenpropimorph > 0.1 µg/L in groundwater samples (from 784 groundwater sampling points on 5 Federal States investigated between 1999 and 2002).

**Table 2.2.2.5.5.2. Groundwater monitoring data from Germany (1999 – 2002)**

| Year | Federal States number | Sampling points total | Number of sampling points | | | |
|---|---|---|---|---|---|---|
| | | | n > LOQ* | < 0.1 µg/L | > 0.1 and < 1.0 µg/L | > 1.0 µg/L |
| 1999 | 4 | 253 | 0 | 0 | 0 | 0 |
| 2000 | 5 | 263 | 0 | 0 | 0 | 0 |
| 2001 | 5 | 86 | 0 | 0 | 0 | 0 |
| 2002 | 3 | 182 | 4 | 1 | 3 | 0 |

*LOQ: limit of quantification

## 2.2.2.5.6. Non compartment specific effects relevant to food chain (secondary poisoning)

### 2.2.2.5.6.1. Assessment of secondary poisoning via the aquatic food chain

The secondary poisoning through food chain in the predators of fish was assessed because bioconcentration factor of fenpropimorph was found to be higher than 1000 L/kg in whole fish. The results of this assessment are shown in the following Tables.

**Table 2.2.2.5.6.1.1. PEC/PNEC ratios for Birds predator in an exposure situation**

| Exposure Scenario | $PECoral_{predator}$ [$mg/kg_{diet}$] | PNEC [$mg/kg_{diet}$] | PEC/PNEC |
|---|---|---|---|
| Dipping processes | 4.5499 | 11.1 | 0.4099 |
| Automated spraying processes: Small plants | 1.2624 | | 0.1137 |
| Automated spraying processes: Big plants | 12.6231 | | **1.1372** |
| Noise barrier | 0.4738 | | 0.0427 |

**Table 2.2.2.5.6.1.2. PEC/PNEC ratios for Mammals predator in an exposure situation**

| Exposure Scenario | $PECoral_{predator}$ [$mg/kg_{diet}$] | PNEC [$mg/kg_{diet}$] | PEC/PNEC |
|---|---|---|---|
| Dipping processes | 4.5499 | 10.67 | 0.4264 |
| Automated spraying processes: Small plants | 1.2624 | | 0.1183 |
| Automated spraying processes: Big plants | 12.6231 | | **1.1830** |
| Noise barrier | 0.4738 | | 0.0444 |

## Conclusion:

Fenpropimorph poses potential risk to fish-predator (birds and mammals) when as active ingredient of wood preservatives is applied by means of automated spraying processes at large scale.

However, adopting suitable measures of risk mitigation for surface water should be avoided the risk for eating-fish predators (birds and mammals).

*Remark: When the risk characterization was done comparing the PECoral$_{predator}$ values and PNEC expressed as dose (i.e. mg/kg$_{b.w.}$) the following results were obtained:*

- *The ratios estimated were higher than the above mentioned (see Tables* 2.2.2.5.6.1.1/2*).*
- *An additional risk was identified to fish-predator: exposure scenario for dipping processes.*

### 2.2.2.5.6.2. Assessment of secondary poisoning via the terrestrial food chain

*Due to direct emissions of fenpropimorph to storage soils and adjacent soils to treated wooden structures*

**Table 2.2.2.5.6.2.1. PEC/PNEC ratios for Birds predator in an exposure situation**

| Exposure Scenario | PECoral$_{predator}$ [mg/kg$_{diet}$] | PNEC [mg/kg$_{diet}$] | PEC/PNEC |
|---|---|---|---|
| Dipping processes | 323.0175 | 11.1 | **29.1007** |
| Automated spraying processes: Small plants | 1069.0663 | | **96.3123** |
| Automated spraying processes: Big plants | 1069.0663 | | **96.3123** |
| Fence | 670.0351 | | **60.3635** |
| House | 837.5438 | | **75.4544** |
| Noise barrier | 301.51578 | | **27.1636** |

**Table 2.2.2.6.2.2. PEC/PNEC ratios for Mammas predator in an exposure situation**

| Exposure Scenario | PECoral$_{predator}$ [mg/kg$_{diet}$] | PNEC [mg/kg$_{diet}$] | PEC/PNEC |
|---|---|---|---|
| Dipping processes | 323.0175 | 10.67 | **30.2734** |
| Automated spraying processes: Small plants | 1069.0663 | | **100.1937** |
| Automated spraying processes: Big plants | 1069.0663 | | **100.1937** |
| Fence | 670.0351 | | **62.7962** |
| House | 837.5438 | | **78.4952** |
| Noise barrier | 301.51578 | | **28.2583** |

*Due to indirect emissions to agriculture soils and grassland (application of sewage sludge contaminated with fenpropimorph)*

**Table 2.2.2.5.6.2.3. PEC/PNEC ratios for Birds predator in an exposure situation**

| Exposure Scenario | | Avg. time (d) | $PECoral_{predator}$ (mg/kg diet) | PNEC [$mg/kg_{diet}$] | PEC/PNEC |
|---|---|---|---|---|---|
| Dipping-STP sludge | Agriculture | 30 | 0.8331 | 11.1 | 0.0751 |
| Dipping-STP sludge | Agriculture | 180 | 0.5048 | | 0.0455 |
| Dipping-STP sludge | Grassland | 180 | 0.2019 | | 0.0182 |
| A. Spraying (Small plants)-STP sludge | Agriculture | 30 | 0.1666 | | 0.0150 |
| A. Spraying (Small plants)-STP sludge | Agriculture | 180 | 0.1010 | | 0.0091 |
| A. Spraying (Big plants)-STP sludge | Agriculture | 30 | 1.6662 | | 0.1501 |
| A. Spraying (Big plants)-STP sludge | Agriculture | 180 | 1.0097 | | 0.0910 |
| A. Spraying (Small plants)-STP sludge | Grassland | 180 | 0.0404 | | 0.0036 |
| A. Spraying (Big plants)-STP sludge | Grassland | 180 | 0.4039 | | 0.0364 |
| Noise barrier-STP sludge | Agriculture | 30 | 0.1511 | | 0.0136 |
| Noise barrier-STP sludge | Agriculture | 180 | 0.0916 | | 0.0083 |
| Noise barrier-STP sludge | Grassland | 180 | 0.0366 | | 0.0033 |

**Table 2.2.2.5.6.2.4. PEC/PNEC ratios for Mammas predator in an exposure situation**

| Exposure Scenario | | Avg. time (d) | $PECoral_{predator}$ (mg/kg diet) | PNEC [$mg/kg_{diet}$] | PEC/PNEC |
|---|---|---|---|---|---|
| Dipping-STP sludge | Agriculture | 30 | 0.8331 | 10.67 | 0.0781 |
| Dipping-STP sludge | Agriculture | 180 | 0.5048 | | 0.0473 |
| Dipping-STP sludge | Grassland | 180 | 0.2019 | | 0.0189 |
| A. Spraying (Small plants)-STP sludge | Agriculture | 30 | 0.1666 | | 0.0156 |
| A. Spraying (Small plants)-STP sludge | Agriculture | 180 | 0.1010 | | 0.0095 |
| A. Spraying (Big plants)-STP sludge | Agriculture | 30 | 1.6662 | | 0.1562 |
| A. Spraying (Big plants)-STP sludge | Agriculture | 180 | 1.0097 | | 0.0946 |
| A. Spraying (Small plants)-STP sludge | Grassland | 180 | 0.0404 | | 0.0038 |
| A. Spraying (Big plants)-STP sludge | Grassland | 180 | 0.4039 | | 0.0379 |
| Noise barrier-STP sludge | Agriculture | 30 | 0.1511 | | 0.0142 |
| Noise barrier-STP sludge | Agriculture | 180 | 0.0916 | | 0.0086 |
| Noise barrier-STP sludge | Grassland | 180 | 0.0366 | | 0.0034 |

## Conclusion:

Although it is identified a potential risk for earthworm-predator (birds and mammals) in some scenarios (especially important for direct emissions), these results must be always interpreted with much caution (like a first estimation or screening) because they were derived at request of ECB from a model (Q)SAR not valid for ionizable substances like fenpropimorph, assuming as worst-case that this substance does not undergo ionisation i.e. choosing for the calculation of (Q)SAR the lowest pH value in which fenpropimorph is not ionized. Even so, the RMS keeps considering that this (Q)SAR should not be used for this chemical and that the approach may not to be ecologically relevant due to pH value chosen (pH = 9). So, the RMS proposes taking into account the current level of scientific knowledge to conduct a semi-quantitative estimation of bioaccumulation (and its relevance) based on the mammalian toxicokinetic data. However, this approach has not been incorporated into the TGD yet.

### *2.2.3. Listing of endpoints*

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

# 3. PROPOSAL FOR THE DECISION

## 3.1. Background to the Proposed Decision

The overall conclusion from the human health evaluation of fenpropimorph for use in product type 8 (wood preservatives) is that the use concentration of active substance in biocidal products should not contain more than 0.216% w/w. In this case, fenpropimorph will not present an unacceptable risk to humans during the proposed normal use. This conclusion relies on the fact that industrial uses will be applying the basic principles of good practice and using appropriate and obligatory PPE.

The results of the secondary exposure risk assessment demonstrate that adult, children and infants will not be exposed to unacceptable levels of fenpropimorph during the realistic worst-case scenarios presented.

Regarding the environmental risk assessment, fenpropimorph has shown risk for soil and aquatic compartments. Proper risk mitigation measures must therefore be taken. The inclusion of fenpropimorph in Annex I of Directive 98/8/EC as a wood preservative (product-type 8) is only recommended if the requirements and specific provisions indicated below are adopted.

## 3.2. Proposed Decision regarding Inclusion in Annex I

It is recommended that fenpropimorph is included in Annex I to Directive 98/8/EC as an active substance for use in product-type 8 (wood preservatives), subject to the following specific provisions:

The active substance fenpropimorph, as manufactured, shall have a minimum purity of 930 g/kg.

When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.

Member States shall ensure that authorisations are subject to the following conditions:

1. In view of the assumptions made during the risk assessment, products authorised for industrial use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means.

2. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

## 3.3. Factors to be taken into account by Member States when authorising products

The evaluation of fenpropimorh has shown sufficient efficacy against wood destroying basidiomycetes. However, further efficacy data will be required to support product authorisation at the Member State level.

Products containing fenpropimorph may be used in the treatment of wood by dipping in open dip tanks or using continuous flow dip tanks or spray-tunnels by industrial users.

In case of persistent foaming, an available antifoaming agent can be added to the formulation.

In view of the identified environmental risks, the following risk mitigation measures should be adopted:

**Pre-treated timber held in storage:**

- All timber treated on an industrial site must be stored on hard standing exhibiting impermeable grounds. The leachate due to run-off must be collected and recycled into the impregnation process to prevent losses to soil (direct) and/or surface water (indirect via STP). In addition, feasible waste treatment options have to be proven when recycling to the impregnation tank is not practicable.

- Keep the treated timber on storage places covered by roofs.

**Application:**

- For industrial treatment processes, significant losses to the aquatic environment must be contained (e.g. no drain connections to storm drains or STP) and recycled/ or collected and treated the wastewater.

- Where emissions to water are possible and products (wooden structures) show a PEC/PNEC ratio higher than 1 (case of noise barrier), treated timber has to be protected with a topcoat[4].

4 Topcoat: Before accepting these measures the following point should be kept in mind: Scientific evidence (through testing) showing that such a coating will prevent the wood preservative from leaching through the coating, also in the long term. This evidence should be presented for preventive as well as curative treatments of the wood.

## 3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of fenpropimorph in Annex I to Directive 98/8/EC.

## 3.5. Updating this Assessment Report

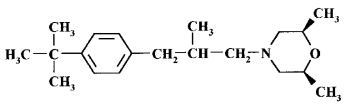
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of fenpropimorph in Annex I to the Directive.

# Appendix I: Listing of end points

## Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

| | |
|---|---|
| Active substance (ISO Common Name) | Fenpropimorph |
| Product-type | Fungicide |

**Identity**

| | |
|---|---|
| Chemical name (IUPAC) | (+/-)-cis-4-[3-(4-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine |
| Chemical name (CA) | Cis-4-(3-(4-(1,1-dimethylethyl)phenyl-2-methylpropyl)-2,6-dimethylmorpholine |
| CAS No | 67564-91-4 |
| EC No | 266-719-9 |
| CIPAC No. | 427 |
| Minimum purity of the active substance as manufactured (g/kg or g/l) | 930 g/kg |
| Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg) | There are no impurities of toxicological or ecotoxicological concern |
| Molecular formula | $C_{20}$ $H_{33}$ NO |
| Molecular mass | 303.5 |
| S |  |

**Physical and chemical properties**

| | |
|---|---|
| Melting point (state purity) | -47 – -41°C (99.6 %) |
| Boiling point (state purity) | No boiling point (99.6 %) |
| Temperature of decomposition | Approx. 310°C |
| Appearance (state purity) | Colourless liquid with faint aromatic odour (100%) |
| Relative density (state purity) | 0.934 at 20°C (99.2%) |
| Surface tension | 48.9 mN/m at 20°C |
| Vapour pressure (in Pa, state temperature) | $3.9 \cdot 10^{-3}$ at 20°C |
| Henry's law constant (Pa $m^3$ $mol^{-1}$) | 0.274 $Pa \cdot m^3 \cdot mol^{-1}$ |
| Solubility in water (g/l or mg/l, state temperature) | pH 4.4 : 7.3 g/l at 20°C<br>pH 7 : 4.32 mg/l at 20°C<br>pH 9 – 11: 3.53 mg/l at 20°C |
| Solubility in organic solvents (in g/l or mg/l, state temperature) | At 20 ºC (purity 99.2%):<br>acetone : 7604 g/L<br>ethyl acetate : 7780 g/L<br>n-octanol : 7705 g/L<br>dichloromethane : 7742 g/L<br>n-heptane : 7254 g/L<br>acetonitrile : 7727 g/L<br>iso-propanol : 8167 g/L<br>toluene : 7646 g/L<br>methanol : 7892 g/L<br>olive oil : 7789 g/L |
| Stability in organic solvents used in biocidal products including relevant breakdown products | The active substance as manufactured does not include an organic solvent |
| Partition coefficient (log $P_{OW}$) (state temperature) | pH 5 : 2.6 at 22°C<br>pH 7 : 4.1 at 22°C<br>pH 9 : 4.4 at 22 ºC |
| Hydrolytic stability ($DT_{50}$) (state pH and temperature) | pH 3 – 9 : stable, no hydrolysis products |
| Dissociation constant | pKb = 7.02 at 20°C |
| UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) | 203 nm 1.1 x 10000<br>219 nm 1.1 x 10000<br>242 nm 2.1 x 100<br>264 nm 4.2 x 100<br>270 nm 3.2 x 100<br>272 nm 4.2 x 100<br>290 nm baseline |
| Photostability ($DT_{50}$) (aqueous, sunlight, state pH) | Photolytically stable, no half-life calculated |
| Quantum yield of direct phototransformation in | Not relevant |

| | |
|---|---|
| water at Σ > 290 nm | |
| Oxidizing properties | The test substance has no oxidizing properties |
| Reactivity towards container material | No incompatibility with the used HDPE (High Density Polyethylene) containers. |
| Flammability | Auto-ignition temperature: 265 ºC (purity 96.6%) |
| Explosive properties | The test substance has no explosive properties |

**Classification and proposed labelling**

| | |
|---|---|
| with regard to physical/chemical data | - |
| with regard to toxicological data | Xn : harmful (Repr. Cat. 3)<br>R22: harmful if swallowed<br>R38 : irritating to skin<br>R 63 : possible risk of harm to the unborn child |
| with regard to fate and behaviour data | N: dangerous for the environment<br>R 53: may cause long-term adverse effects in the aquatic environment |
| with regard to ecotoxicological data | N: dangerous for the environment<br>R 51: toxic to aquatic organisms |

## Chapter 2: Methods of Analysis

**Analytical methods for the active substance**

| | |
|---|---|
| Technical active substance (principle of method) | GC with flame ionisation detection |
| Impurities in technical active substance (principle of method) | See confidential data and information |

**Analytical methods for residues**

| | |
|---|---|
| Soil (principle of method and LOQ) | LC-MS/MS (fenpropimorph and fenpropimorph acid)<br>LOQ: 0.01 mg/kg |
| Air (principle of method and LOQ) | Gas chromatography with nitrogen-phosphorus detection<br>LOQ: 0.5 µg /m³<br>LC-MS/MS (fenpropimorph and fenpropimorph acid)<br>LOQ: 0.093 µg/$m^3$ |
| Water (principle of method and LOQ) | GC with flame ionisation detection<br>LOQ: 0.05 µg/kg<br>LC-MS/MS (fenpropimorph and fenpropimorph acid)<br>LOQ: 0.05 µg/L (surface water and tap water) |
| Body fluids and tissues (principle of method and LOQ) | --- |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | GC with mass spectrometric detection<br>LOQ: 0.01 mg/kg in tomato, lemon, and wheat (grain) and 0.02 mg/kg in rapeseed. |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | HPLC with UV detection (fenpropimorph metabolite)<br>LOQ: 0.01 mg/kg (animal tissues, egg), 2 µg/L (milk) |

# Chapter 3: Impact on Human Health

**Absorption, distribution, metabolism and excretion in mammals**

| | |
|---|---|
| Rate and extent of oral absorption: | Rapidly absorbed from gastro-intestinal tract |
| Rate and extent of dermal absorption: | Dermal absorption of 3% |
| Distribution: | Liver, digestive tract, fat, kidney |
| Potential for accumulation: | No accumulation potential |
| Rate and extent of excretion: | Rapidly and nearly equally excreted via urine and faeces |
| Toxicologically significant metabolite(s) | None |

**Acute toxicity**

| | |
|---|---|
| Rat $LD_{50}$ oral | Males<br>2830 mg/kg<br>Females<br>1670 mg/kg |
| Rat $LD_{50}$ dermal | > 4000 mg/kg (rat) |
| Rat $LC_{50}$ inhalation | Males<br>3.7 mg/l<br>Females<br>2.2 – 2.4 mg/l |
| Skin irritation | Irritant (rabbit) |
| Eye irritation | Not irritating (rabbit). Not classified for this effect |
| Skin sensitization (test method used and result) | Not sensitizing (guinea pig). Not classified for this effect |

**Repeated dose toxicity**

| | |
|---|---|
| Oral | |
| Species / target / critical effect (short term) | Rabbit / developmental toxicity / embryo- and fetotoxicity and teratogenicity |
| Lowest relevant oral NOAEL | NOAEL = 15 mg/kg bw/day (prenatal developmental toxicity studies) |
| | |
| Species / target / critical effect (medium term) | Rat / liver / absolute (males) and relative (males and females) liver weights. Reduced serum cholinesterase activity was observed from 0.7 mg/kg bw/day |
| Lowest relevant NOAEL | NOAEL = 0.7 mg/kg bw/day (90-day study) |
| Species / target / critical effect (long term) | Rat / liver / increased liver weights, e altered hepatocytes functional disturbance of liver activity, reduced serum |

| | |
|---|---|
| | cholinesterase activity |
| Lowest relevant NOAEL | NOAEL = 0.3 mg/kg bw/day (combined chronic toxicity/carcinogenicity rat study) |
| Dermal | |
| Species/target/critical effect | Rat/liver/multifocal scale formation (this end point was not used for risk characterization since systemic effects were not observed) |
| Lowest relevant NOAEL (short term) | NOAEL = 2 mg/kg bw (28-day rat study) |
| Inhalation | |
| Species/target/critical effect | Rat/liver/increased both liver weights and alkaline phosphatase activity.<br>Reduced serum cholinesterase activity from 0.01 mg/L |
| Lowest relevant NOAEL (short term) | NOAEL = 0.01 mg/L (28-day rat study) |

| | |
|---|---|
| **Genotoxicity** | No evidence of genotoxic effects was noted |

**Carcinogenicity**

| | |
|---|---|
| Species/ target / critical effect | Tests were carried out in rats and mice. No oncogenic effects in rats and mice |

**Reproductive toxicity**

***Reproduction toxicity***

| | |
|---|---|
| Species/ Reproduction target / critical effect | |
| Parental NOAEL / LOAEL | 4 mg/kg bw/day |
| Reproductive NOAEL / LOAEL | 16 mg/kg bw/day (High dose did not showed effects) |
| Offspring NOAEL / LOAEL | 4 mg/kg bw/day |

***Developmental toxicity***

| | |
|---|---|
| Developmental toxicity study | |
| Developmental target/critical effect | Rabbit / skeleton malformations (position anomalies of fore and hind limbs) and embryo-/fetotoxicity |
| Relevant maternal NOAEL | 15 mg/kg bw/day (reduced both bw and bw gain) |
| Relevant developmental NOAEL | 15 mg/kg bw/day (anomalies and embryo-/fetotoxicity) |
| Two-generation study | |
| Developmental target/critical effect | Rat/ pups showed reduced body weight and impaired body weight change |
| Relevant maternal NOAEL | 4 mg/kg bw/day |
| Relevant developmental NOAEL | 4 mg/kg bw/day |

**Neurotoxicity**

| | |
|---|---|
| Acute neurotoxicity | No evidence of acute neurotoxicity |
| Repeated neurotoxicity | Effects on parameters of a functional observational battery were observed in Wistar rats after subchronic oral feeding |
| Delayed neurotoxicity | No evidence of delayed neurotoxicity |

**Other studies**

| | |
|---|---|
| ..... | |

**Medical data**

| | |
|---|---|
| ..... | |

| **Summary** | Value | Study | Safety factor |
|---|---|---|---|
| ADI (acceptable daily intake, external long-term reference dose) | Not relevant | Not relevant | Not relevant |
| AOEL (Operator/Worker Exposure) | | | |
| Acute AOEL | 0.15 mg/ kg bw | Developmental rabbit studies (combined data of 3 studies) | 100 |
| Medium-term AOEL | 0.007 mg/ kg bw/day | Subchronic rat study | 100 |
| Chronic AOEL | 0.003 mg/kg bw/day | Combined chronic toxicity/ carcinogenicity rat study | 100 |
| Drinking water limit | Not relevant | Not relevant | Not relevant |
| ARfD (acute reference dose) | Not relevant | Not relevant | Not relevant |

**Acceptable exposure scenarios (including method of calculation)**

| | |
|---|---|
| Industrial users | The application of fenpropimorph as wood preservative (PT8) in an industrial environment can result in direct exposure via skin contact or via inhalation; oral ingestion is not considered as a potential direct route of exposure. CA has estimated the exposure using the models provided in the TNsG, considering the continuous flow dipping process as a worst case between the industrial procedures. The task, associated models and corresponding total systemic doses (estimated considering that used gloves are worn but that there is not respiratory protection) are:<br>- Mixing and loading. **Mixing and loading model 7**: 0.00080243 mg/kg bw/day<br>- Application (including mixing/loading and handling). **Dipping model 1**: 0.002266987 mg/kg bw/day<br>- Cleaning the dipping tank. **Handling model 1**: 0.002014795 mg/kg bw/day |
| Professional users | Not applicable (only industrial use is intended) |
| Non-Professional users | Not applicable (only industrial use is intended) |
| Indirect exposure as a result of use | Secondary exposure scenarios have been assessed to represent worst cases for all of the relevant exposure routes:<br>- Acute scenarios: dermal (adults sanding treated wood as an amateur: 0.00001505 mg/kg bw/day), oral (infants chewing preserved timber off-cuts: 0.00223 mg/kg bw/day)<br>- Chronic scenarios: dermal (adults sanding treated wood as a professional: 0.00003405 mg/kg bw/day; adults cleaning work wear at home: 0.0003075 mg/kg bw/day; children and infants playing on preserved wood: 0.00001296 and 0.00002592 mg/kg bw/day, respectively), oral (infants playing on weathered treated wooden structure and mouthing: 0.00011232 mg/kg bw/day) and inhalation (adults sanding treated wood as a professional: 0.00003405 mg/kg bw/day). |

## Chapter 4: Fate and Behaviour in the Environment

**Route and rate of degradation in water**

| | |
|---|---|
| Hydrolysis of active substance and relevant metabolites ($DT_{50}$) (state pH and temperature) | Stable at pH 3, 5, 7 and 9. No hydrolysis products |
| Photolytic/photo-oxidative degradation of active substance and resulting relevant metabolites | Photolytically stable in water |
| Readily biodegradable (yes/no) | A higher tier water-sediment study was provided instead of the test on ready biodegradability. **From the results** |

| | |
|---|---|
| | **of this test it can be concluded that fenpropimorph can be regarded as persistent substance in the aquatic compartment.** |
| Biodegradation in seawater | Utilization in seawater is not intended |
| Non-extractable residues | The amounts of bound residues ranged from 20 and 37% TAR at the end of study. Fenpropimorph was the relevant residue in sediment |
| Distribution in water / sediment systems (active substance) | Fenpropimorph has low water solubility and a high adsorption coefficient that leads to a fast movement into the sediment. In the sediment fenpropimorph is oxidized to fenpropimorphic acid.<br><br>**Disappearance times** for fenpropimorph:<br><br>$DT_{50}$ (water) at 20ºC: 1.9-3.4 days; $DT_{50}$ (water) at 12ºC: 1.9-3.4 days<br><br>$DT_{50}$ (sediment) at 20ºC: 83.6 days; $DT_{50}$ (sediment) at 12ºC: 158.6 days<br><br>$DT_{50}$ (total system) at 20ºC: 18-54; $DT_{50}$ (total system) at 12ºC: 34.1-102.4 |
| Distribution in water / sediment systems (metabolites) | The main metabolite of fenpropimorph in water/sediment systems is fenpropimorphic acid (BF 421-2). This metabolite has a much better solubility in water and a weaker adsorption. Fenpropimorphic acid moves back to the water phase. It can further be metabolized and final mineralisation to $CO_2$ ranges from 6 to 8 % of the applied radioactivity. Fenpropimorphic acid is the major metabolite in water (a maximum of 23% TAR) and sediment (it never exceeded 10% TAR) |

**Route and rate of degradation in soil**

| | |
|---|---|
| Mineralization (aerobic) | Fenpropimorph is slowly mineralized in soil. The rates of mineralization ranged from a minimum of 45.55% after 149 days (laboratory test at 20ºC) to maximum of 36% after 12 weeks (laboratory test at 22ºC). $CO_2$ was released from different parts of the labelled molecule |
| Laboratory studies (range or median, with number of measurements, with regression coefficient) | $DT_{50lab}$ (20°C, aerobic): the values ranged from 14 to 114 days |
| | $DT_{90lab}$ (20°C, aerobic): the values ranged from 6 to 124 days |
| | $DT_{50lab}$ (12°C, aerobic): values range from 26.55 days to |

| | |
|---|---|
| | 216.19 days |
| | $DT_{50lab}$ (20°C, anaerobic): not calculated |
| | Degradation in the saturated zone: not calculated |
| Field studies (state location, range or median with number of measurements) | $DT_{50f}$: the values ranged from 10 to 90 days. **$DT_{50}$ value of 90 days was used in the evaluation because was regarded as a realistic worst-case** |
| | $DT_{90f}$: the values ranged from 35 to > 365 days |
| Anaerobic degradation | Mineralisation < 2% of total applied radioactivity. Amount of non-extractable residues are also very low. $DT_{50}$ > 120 days |
| Soil photolysis | $DT_{50}$~30 days<br><br>Fenpropimorph is stable in sterilized soil in the dark. Two metabolites are formed under the influence of light |
| Non-extractable residues | Aerobic degradation in soil: Under aerobic laboratory conditions 54% TAR after 90 days and 44% TAR after 360 day<br><br>Anaerobic degradation in soil: Amount of non-extractable residues are very low<br><br>Soil photolysis: 11.9% TAR at the end of test (30 days). |
| Relevant metabolites - name and/or code, % of applied a.i. (range and maximum) | Aerobic degradation in soil:<br>• Laboratory tests: BF 421-2 (main metabolite), BF 421-8 and BF 421-10<br>• Field study: BF 421-2 (main metabolite) and BF 421-7<br>Soil photolysis: BF 421-13 and BF 421-15<br><br>No metabolite > 10% of total applied radioactivity |
| Soil accumulation and plateau concentration | Accumulation studies are not required because only a few soils showed a slow degradation and the mean value of all studies is significantly shorter than 1 year. Furthermore, over the long period of agricultural use, no findings of accumulation have been reported |

**Adsorption/desorption**

| | |
|---|---|
| **Ka, Kd**<br><br>$Ka_{oc}$, $Kd_{oc}$ | Loamy sand:<br>pH = 7<br>$K_{oc}$ (ml/g) = 5943 (worst-case for sediment)<br>Desorption in $H_2O$ = 55.95 |

| | |
|---|---|
| pH dependence (yes / no) (if yes type of dependence) | Desorption in $CaSO_4$ solution = 48.33<br><br>Loamy sand:<br>pH = 7.2<br>$K_{oc}$ (ml/g)= 2772 (worst-case for water)<br>Desorption in $H_2O$ = 97.28<br>Desorption in $CaSO_4$ solution = 74.91<br><br>Sand:<br>pH = 7<br>$K_{oc}$ (ml/g) = 4432<br>Desorption in $H_2O$ = 24.15<br>Desorption in $CaSO_4$ solution= 15.17<br><br>$K_{oc}$ (arithmetic mean) = 4382 ml/g |

**Mobility in soil**

| | |
|---|---|
| Mobility in soil | --- |

**Fate and behaviour in air**

| | |
|---|---|
| Direct photolysis in air | --- |
| Quantum yield of direct photolysis at T >290 nm | --- |
| Photo-oxidative degradation in air | Latitude: --- Season: --- $DT_{50}$: 2.8 hours (calculated) |
| Volatilization | Volatilization potential |

**Monitoring data, if available**

| | |
|---|---|
| Soil (indicate location and type of study) | --- |
| Surface water (indicate location and type of study) | --- |
| Ground water (indicate location and type of study) | --- |
| Air (indicate location and type of study) | --- |

## Chapter 5: Effects on Non-target Species

**Toxicity data for aquatic species (most sensitive species of each group)**

| Species | Time-scale | Endpoint | Toxicity |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **Fish** | | | |
| Rainbow trout (*O. mykiss*) | 96 h | Mortality | $LC_{50}$ = 4.29 mg/l |
| Bluegill (*L. macrochirus*) | 96 h | Mortality | $LC_{50}$ = 2.23 mg/l |
| Rainbow trout (fenpropimorphic acid) | 96 h | Mortality | $LC_{50}$ > 100 mg/l |
| Rainbow trout | 21 days | Toxic signs | NOEC = 0.1 mg/l |
| Rainbow trout | 94 days | Mortality, body weight | **NOEC = 0.00016 mg/l (the lowest endpoint for water phase)** |
| Rainbow trout | 49 days | Body weight | NOEC = 0.003 mg/l (a.s.)* |
| Golden orf *(Leuciscus idus)* | 28 days | Mortality, body weight | NOEC ≥ 0.012 mg/l (a.s.)* |
| **Invertebrates** | | | |
| *Daphnia magna* | 48 h | Mobility | $LC_{50}$ = 2.24 mg/l |
| *Daphnia magna* (fenpropimorphic acid) | 48 h | Mobility | $LC_{50}$ > 100 mg/l |
| *Daphnia magna* | 21 days | Mobility | $LC_{50}$ = 0.083 mg/l (a.s.)*<br>NOEC = 0.024 mg/l (a.s.)* |
| **Algae** | | | |
| *Pseudokirchnerialla subscapitata* | 72 h | Growth rate<br>Biomass | $EC_{50}$ > 1 mg/l<br>$EC_{50}$ = 0.327 mg/l |
| *Pseudokirchnerialla subscapitata* (fenpropimorphic acid) | 72 h | Growth rate<br>Biomass | $EC_{50}$ > 100 mg/l<br>$EC_{50}$ > 100 mg/l |
| **Sediment-dwelling organisms** | | | |
| *Chironomus riparius* | 20 days | Mortality, emergence | **NOEC = 0.125 mg/l (key endpoint for sediment compartment)** |

*results obtained from a test conducted with a formulation containing as active ingredient fenpropimorph

| | | | |
|---|---|---|---|
| **Toxicity data for STP micro-organisms** | | | |
| Activated sludge (bacteria community) from the waste-water treatment plant | 3 h | $EC_{50}$ > 1000 mg/L<br>**NOEC = 500 mg/l (key endpoint for sewage microorganisms)**<br>(inhibition of microbial activity) | - |

**Effects on earthworms or other soil non-target organisms**

| | |
|---|---|
| Acute toxicity to …… *Eisenia foetida* (Annex IIIA, point XIII.3.2) | Endpoint: mortality, body weight, etc.<br>Duration: 14 days<br>$LC_{50}$ > 1000 mg/kg dry soil<br>NOEC for mortality, body weight: ≥ 1000 mg/kg dry soil |
| Reproductive toxicity to …… *Eisenia fetida* (Annex IIIA, point XIII.3.2) | Endpoint: reproduction, mortality, body weight, etc.<br>Duration: 28 days<br>**NOEC for reproduction: 6.28 mg/kg wet soil (the lowest endpoint for terrestrial compartment)*** |

*results obtained from a test conducted with a formulation containing as active ingredient fenpropimorph

**Effects on soil micro-organisms**

| | |
|---|---|
| Nitrogen mineralization | Only negligible effects on the N-turnover. No effects up to 9 mg a.i./Kg wet soil* |
| Carbon mineralization | Only negligible effects on the soil respiration rates. No effects up to 9 mg a.i./Kg wet soil* |

*results obtained from a test conducted with a formulation containing as active ingredient fenpropimorph

**Effect on terrestrial plants**

| | |
|---|---|
| Corn, carrot, oat, onion, cabbage, pea | Time-scale: 14 d<br>NOEC = 1687.5 g a.i./ha excepted to Corn:<br>NOEC for biomass = 562.5 g a.i./ha* |

*results obtained from a test conducted with a formulation containing as active ingredient fenpropimorph

**Effects on terrestrial vertebrates**

| | |
|---|---|
| Acute toxicity to mammals | --- |
| Acute toxicity to birds | Species: bobwhite quail<br>Endpoint: mortality, body weight, food intake, etc<br>Duration: 14 d<br>$LC_{50}$ > 2000 mg/kg bw NOEC: 1000 mg/kg bw |
| Dietary toxicity to birds | Species: mallard duck<br>Endpoint: mortality, body weight, food intake, etc<br>Duration: 8 days<br>$LC_{50}$ = 5000 mg/kg diet NOEC: 1250 mg/kg diet<br><br>Species: bobwhite quail<br>Endpoint: mortality, body weight, food intake, etc<br>Duration: 8 d<br>$LC_{50}$ > 5000 mg/kg diet NOEC: 5000 mg/kg diet |
| Reproductive toxicity to birds | Species: bobwhite quail<br>Endpoint: mortality, reproduction, food intake, etc<br>Duration: 24 weeks<br>NOEC: 45 mg/kg diet<br><br>Species: bobwhite quail<br>Endpoint: mortality, reproduction, food intake, etc<br>Duration: 24 weeks<br>NOEC: 333 mg/kg diet |

**Effects on honeybees**

| | |
|---|---|
| Acute oral toxicity | $LD_{50}$ > 95,6 µg/bee |
| Acute contact toxicity | $LD_{50}$ > 100 µg/bee |

**Effects on other beneficial arthropods**

| | |
|---|---|
| Acute oral toxicity | --- |
| Acute contact toxicity | --- |
| Acute toxicity to …….. | --- |

**Bioconcentration**

| | |
|---|---|
| Bioconcentration factor (BCF) | $BCF_{kinetic}$ =1122 (worst-case)<br>$BCF_{ss}$ (arithmetic mean) = 1019<br>$BCF_{kinetic}$ (arithmetic mean) = 1080 |
| Depuration time ($DT_{50}$)<br>($DT_{90}$) | --- |
| Level of metabolites (%) in organisms accounting for > 10 % of residues | --- |
| Bioconcentration factor (BCF) | Species*: Lepomis macrochirus*<br>Time-scale: 28 d (exposure phase)<br>14 d (depuration phase)<br>Test system: flow-thr.<br>BCF (Whole fish): 942<br>BCF (Viscera): 1471<br>BCF (Edible tissues): 598 |
| Depuration time ($DT_{50}$)<br>($DT_{90}$) | 5.9 days |
| Level of metabolites (%) in organisms accounting for > 10% of residues | --- |
| Bioconcentration factor (BCF) | Species*: Lepomis macrochirus*<br>Time-scale: 28 d (exposure phase)<br>14 d (depuration phase)<br>Test system: flow-thr.<br>BCF (Whole fish): 1096<br>BCF (Viscera): 1842<br>BCF (Edible tissues): 616 |
| Depuration time ($DT_{50}$)<br>($DT_{90}$) | 4.8 days |
| Level of metabolites (%) in organisms accounting for > 10% of residues | --- |

# Chapter 6: Other End Points

# Appendix II: List of Intended Uses

Fenpropimorph is a liquid, water miscible wood preservative concentrate, with preventive efficacy against blue-stain, wood discolouring fungi and wood destroying basidiomycetes. It is only intended for industrial use and it is applied to the wood via dipping in open dip tanks, or using continuous flow dip tanks, or spray-tunnels. The continuous flow dipping process is considered the worst case, because it treats bigger amounts of wood in comparison to discontinuous batch processes. Furthermore, spray tunnel plants are considered closed system processes. The continuous flow dipping process can be subdivided into several activities, mixing and loading (5.8% a.i.), application (0.216% a.i,) and cleaning the dipping tank.

Professional and non-professional uses are not intended for this product.

# Appendix III: List of Studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

| Section No | Author(s) | Year | Title.<br>Source (where different from company)<br>Company, Report No. | GLP Y/N | Published Y/N | Data Protection Claimed (Yes/No) | Owner |
|---|---|---|---|---|---|---|---|
| A 2.6 | Ohnsorge U. | 1999 | Fenpropimorph TC, Description of the manufacturing process<br>BASF Aktiengesellschaft, Limburgerhof, Germany<br>BASF DocID # 1999/11148 | | N | Y | **BASF AG** |
| A 2.8/01 | Bross M | 1992 | Bestimmung von Verunreinigungen in Fenpropimorph techn. mittels Kapillar-GC, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1992/11856 | | N | Y | BASF AG |
| A 2.8/02 | Bross M. | 1992 | Analytical method CP No. 149/1: Determination of Fenpropimorph in techn. Fenpropimorph by capillary GC,<br>BASG AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1992/11989 | | N | Y | BASF AG |
| A 2.8/03 | Anonymous | 1997 | Data concerning the composition (specification) of the technical active ingredient Fenpropimorph,<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1997/1000161 | | N | Y | BASF AG |
| A 2.8/04 | Kaeser W | 1995 | Report on chemical composition: CGA 101031<br>Ciba-Geigy Limited, Basel, Switzerland<br>BASF DocID # 1995/1000445 | | N | Y | BASF AG |
| A 2.8/05 | Ciba-Geigy | 1992 | CGA 114900 (Fenpropidin): Bestimmung von CGA 289274,<br>Ciba-Geigy Limited, Basel, Switzerland<br>BASF DocID # 1992/1000408 | | N | Y | BASF AG |

| Section No | Author(s) | Year | Title.<br>Source (where different from company)<br>Company, Report No. | GLP Y/N | Published Y/N | Data Protection Claimed (Yes/No) | Owner |
|---|---|---|---|---|---|---|---|
| A 2.8/06 | Ohnsorge U. | 1999 | Fenpropimorph TC composition of the technical active ingredient,<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1999/11139 | | N | Y | BASF AG |
| A 3.1.1 | Daum A. | 1999 | Determination of the melting point and the appearance of Fenpropimorph (Reg.No.108406, BAS 421F),<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1999/11214 | Y | N | Y | BASF AG |
| A 3.1.2 | Daum A. | 1999 | Determination of the melting point and the appearance of Fenpropimorphe (Reg.No. 108406 BAS 421F),<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1999/11214 | Y | N | Y | BASF AG |
| A 3.1.3 | Kästel R. | 1994 | Physical and chemical properities report for Fenpropimorph,<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1994/10395 | Y | N | Y | BASF AG |
| A 3.2/01 | Kästel R. | 1994 | Physical and chemical properities report for Fenpropimorph,<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1994/10395 | Y | N | Y | BASF AG |
| A 3.2/02 | Kästel R | 2004 | Vapour pressure Fenpropimorph,<br>BASF AG, Agricultural centre Limburgerhof, Germany, BASF DocID 2004/1016297 | Y | N | Y | BASF AG |
| A 3.2.1 | Ohnsorge U. | 2004 | Henry's law constant for Fenpropimorph<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 2004/1031205 | | N | Y | BASF AG |
| A 3.4 | Türk W. | 1996 | Spectra of Fenpropimorph Reg.No. 108406<br>BASF AG, Agrarzentrum Limburgerhof,Limburgerhof, Germany<br>BASF DocID # 1996/10288 | Y | N | Y | BASF AG |

| Section No | Author(s) | Year | Title.<br>Source (where different from company)<br>Company, Report No. | GLP Y/N | Published Y/N | Data Protection Claimed (Yes/No) | Owner |
|---|---|---|---|---|---|---|---|
| A 3.5/01 | Redeker J. | 1988 | Solubility of Fenpropimorph in water,<br>BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1988/10222 | Y | N | Y | BASF AG |
| A 3.5/02 | Redeker J. | 1988 | Water solubility of Fenpropimorph in neutral range and at pH 9-11, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1988/10154 | Y | N | Y | BASF AG |
| A 3.5/03 | Redeker J. | 1988 | Water solubility of Fenpropimorph in neutral range and at pH 9-11, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1988/11302 | Y | N | Y | BASF AG |
| A 3.6 | Redeker J. | 1988 | Determination of the pKb value of Fenpropimorph in water, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1988/11671 | Y | N | Y | BASF AG |
| A 3.7 | Redeker J. | 1992 | Determination of the solubility of Fenpropimorph in organic solvents at 20°C, BASF AG, Agrarzentrum Limburgerhof, Germany<br>BASF DocID # 1992/11596 | Y | N | Y | BASF AG |
| A 3.9 | Keller W. | 1986 | Determination of the n-octanol water partition coefficient of Fenpropimorph (flask-shaking method),<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1986/10156 | | N | Y | BASF AG |
| A 3.9/02 | Ohnsorge U. | 2004 | Calculation of the pKa value of Fenpropimorph-hydrochloride and of pH dependent log POW values for Fenpropimorph | | N | Y | BASF AG |
| A 3.11 | Loeffler U. | 1999 | Evaluation of safety characteristics according to 92/69/EEC<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1999/11009 | | N | Y | BASF AG |

| Section No | Author(s) | Year | Title.<br>Source (where different from company)<br>Company, Report No. | GLP Y/N | Published Y/N | Data Protection Claimed (Yes/No) | Owner |
|---|---|---|---|---|---|---|---|
| A 3.12 | Kästel R. | 1994 | Physical and chemical properties report for Fenpropimorph (techn. active ingredient), BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1994/10392 | Y | N | Y | BASF AG |
| A 3.13/01 | Kästel R. | 1994 | Physical and chemical properties report of Fenpropimorph (techn. active ingredient), BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1994/10392 | Y | N | Y | BASF AG |
| A 3.13/02 | Kästel R. | 1994 | Physical and chemical properties report for Fenpropimorph (techn. active ingredient), BASF AG, Agrarzentrum Limburgerhof,<br>BASF DocID # 1994/10392 | Y | N | Y | BASF AG |
| A 3.14 | Kästel R. | 1994 | Physical and chemical properities report for Fenpropimorph (techn. active ingredient), BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1994/10392 | Y | N | Y | BASF AG |
| A 4.1 | Bross M. | 1992 | Analytical method CP No. 149/1: Determination of Fenpropimorph in techn. Fenpropimorph by capillary GC, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1992/11989 | | N | Y | BASF AG |
| A 4.2/01 | Zangmeister W | 2005 | Validation of analytical method 576 for determination of BAS 421 F (Fenpropimorph) and BF 421-2 (Fenpropimorph acid) in soil using LC/MS-MS, BASF Agricultural Center Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, 67114 Limburgerhof, Germany, BASF DocID 2005/1013248 | Y | N | Y | BASF AG |
| A 4.2/02 | Tribolet R. | 1992 | Fenpropimorph (CGA 101031): Sampling of air and determination of residues of parent compound by gas chromatography, Ciba-Geigy Limited, Basel, Switzerland<br>BASF DocID # 1992/11729 | | N | Y | BASF AG |

| Section No | Author(s) | Year | Title.<br>Source (where different from company)<br>Company, Report No. | GLP Y/N | Published Y/N | Data Protection Claimed (Yes/No) | Owner |
|---|---|---|---|---|---|---|---|
| A 4.2/03 | Tribolet R. | 1995 | Report on Special Study 124/95. Validation of method REM 167.02 in air. Validation by analysis of fortified specimens and determination of recoveries, Ciba-Geigy Limited, Basel, Switzerland<br>BASF DocID # 1995/10920 | Y | N | Y | BASF AG |
| A 4.2/04 | Zangmeister W. | 2000 | To Ciba-Geigy Method REM 167.02 (BASF Reg.Doc.# 1992/11729)<br>Confirmatory Method for Determation of BAS 421 F (108406)<br>Residues in Air using GC/MS, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 2000/1004091 | | N | Y | BASF AG |
| A 4.2/05 | Zangmeister W | 2005 | Validation of analytical method 577: Determination of Fenpropimorph (BAS 421 F) in air by HPLC/MS-MS, BASF Agricultural Center Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, 67114 Limburgerhof, Germany, BASF DocID 2005/1013247 | Y | N | Y | BASF AG |
| A 4.2/06 | Ziegler G. | 1999 | Validation of analytical method No. 454 - Determination of BAS 421 F (Fenpropimorph) in tap and surface water<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1999/11100 | Y | N | Y | BASF AG |
| A 4.2/07 | Ziegler G. | 1999 | Report amendment No. 1 to final report: Validation of analytical method No. 454: Determination of BAS 421 F (Fenpropimorph) in tap and surface water<br>BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany<br>BASF DocID # 1999/11298 | Y | N | Y | BASF AG |

| Section No | Author(s) | Year | Title. Source (where different from company) Company, Report No. | GLP Y/N | Published Y/N | Data Protection Claimed (Yes/No) | Owner |
|---|---|---|---|---|---|---|---|
| A 4.2/08 | Zangmeister W | 2005 | Validation of analytical method 465/2 for determination of BAS 421 F (Fenpropimorph) and BF 421-2 (Fenpropimorph acid) in water using LC/MS-MS, BASF AG, BASF Agricultural Center Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, 67114 Limburgerhof, Germany, BASF DocID 2005/1013249 | Y | N | Y | BASF AG |
| A 4.3 | Triblet, R. | 1995 | Fenpropimorph (GCA 101031). Determination of metabolite CGA 294975 by high performance liquid chromtography (HPCL). Animal tissues, egg and milk BASF DocID # 1995/11081 | Y | N | Y | BASF AG |
| A 4.3/01 | Weeren RD Pelz S. | 1999 | Validation of DFG method S 19 for the determination of Dimethenamid, Epoxiconazole, Fenpropimorph, Kresoxim-methyl, Metazachlor and Vinclozolin in various plant materials, Dr. Specht & Partner, Chemische Laboratorien GmbH, St. Anscharplatz 10, D-20354 Hamburg, Germany, Az.M8020/99, BASF Reg. Doc. 99/11462 | Y | N | Y | BASF AG |
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