



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain  
Unit D.3 - Chemicals, contaminants and pesticides

Bifenazate

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**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT  
THE VIEWS OF THE COMMISSION SERVICES**

Review report for the active substance **bifenazate**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 June 2005 in view of the inclusion of bifenazate in Annex I of Directive 91/414/EEC.

**1. Procedure followed for the evaluation process**

This review report has been established as a result of the evaluation of the new active substance bifenazate, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the Dutch authorities received on 3 July 2001 an application from Crompton Europe Ltd., hereafter referred to as the applicant, for the inclusion of the active substance bifenazate in Annex I to the Directive. The Dutch authorities indicated to the Commission on 23 July 2001 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on bifenazate was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 09 October 2001, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 2002/268/EC<sup>1</sup> of 08 April 2002 that these requirements were satisfied.

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<sup>1</sup> OJ No L 92, 09.04.2002, p.34.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that The Netherlands would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

The Netherlands submitted to the Commission on 03 April 2003 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of bifentazate in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Crompton Europe LTD being the sole applicant on 09 April 2003.

For bifentazate no peer review was organised.

The dossier and draft assessment report, were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final examination took place from November 2004 to June 2005, and was finalised in the meeting of the Standing Committee on 3 June 2005.

The present review report contains the conclusions of this final examination; given the importance of the draft assessment report and the comments and clarifications submitted as basic information for the final examination process, these documents are considered respectively as background documents A, and C to this review report and are part of it.

The review did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants or the Panel on Plant Health, Plant Protection Products and their Residues of the European Food Safety Authority.

## **2. Purposes of this review report**

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2005/58/EC<sup>2</sup> concerning the inclusion of bifentazate in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing bifentazate they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

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<sup>2</sup> OJ No L 246, 22.09.2005, p. 17-19

In parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the applicant.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated possession of regulatory access to the information on which this review report is based.

### **3. Overall conclusion in the context of Directive 91/414/EEC**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing bifentazate will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each bifentazate containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the sole data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC. This is particularly the case for uses outside of greenhouses.

### **4. Specific conclusions which are highlighted in this evaluation**

#### **4.1 Residues of bifentazate in foodstuffs**

For Bifentazate, only uses as a plant protection product on ornamentals in glasshouses have been supported by sufficient data. Since there is no exposure of foodstuffs to be expected, a risk for consumers can be excluded.

#### **4.2 Exposure of operators, workers and bystanders**

The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require, however, confirmation for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

### **4.3 Ecotoxicology**

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 7 of this report.

## **5. Identity and Physical/chemical properties**

The main identity and the physical/chemical properties of bifenazate are given in Appendix I.

The active substance shall have a minimum purity of 950 g/kg technical product.

The review has established that for the active substance notified by the applicant (Crompton Europe LTD), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

## **6. Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints as identified during the evaluation process are listed in Appendix II.

## **7. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing bifenazate**

On the basis of the proposed and supported uses, no particular issues have been identified as requiring short term attention from the Member States.

## **8. List of studies to be generated**

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of bifenazate in Annex I.

Some endpoints however may require the generation or submission of additional studies to be submitted at Member State level in order to support national authorisations for the use under certain vulnerable conditions or to support extensions of the use pattern beyond the uses described under Point 3 above.

This may particular be the case for reproduction studies for birds and studies on the toxicity of bifenazate and some of its metabolites to aquatic organisms and sediment dwellers.

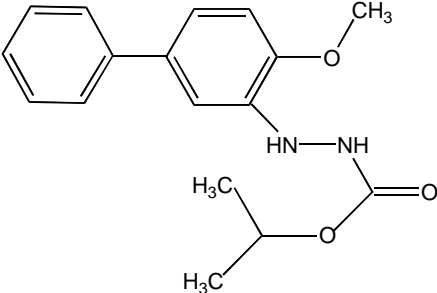
## **9. Updating of this review report**

The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for bifenazate in Annex I of the Directive.

# APPENDIX I

## Identity, physical and chemical properties

### BIFENAZATE

<b>Common name (ISO)</b>	bifenazate
<b>Development Code (for new actives only)</b>	D2341
<b>Chemical name (IUPAC)</b>	Isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinoformate
<b>Chemical name (CA)</b>	1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate
<b>CIPAC No</b>	736
<b>CAS No</b>	149877-41-8
<b>EEC No</b>	02-06-1590-00
<b>FAO SPECIFICATION</b>	No FAO specification established
<b>Minimum purity</b>	950 g/kg
<b>Molecular formula</b>	$C_{17}H_{20}N_2O_3$
<b>Molecular mass</b>	300.4
<b>Structural formula</b>	

<b>Melting point</b>	123 - 125 °C (99.7%)
<b>Boiling point</b>	Decomposition before boiling
<b>Appearance</b>	White crystalline solid (99.7%)
<b>Relative density</b>	density : 1.19 g/cm <sup>3</sup> (99.7%)
<b>Vapour pressure</b>	at 25 °C < 1.33 x 10 <sup>-5</sup> Pa (99.5%)
<b>Henry's law constant</b>	at 20 °C < 1.01 x 10 <sup>-3</sup> Pa m <sup>3</sup> mole <sup>-1</sup>
<b>Solubility in water</b>	pH (neutral): 2.06 mg/L at 20 °C pH_5____: 2.07 mg/l at 20 °C
<b>Solubility in organic solvents</b>	at 20 °C, technical substance: ethyl acetate: 113 g/L toluene: 26.2 g/L methanol: 50.7 g/L acetonitrile: 111 g/L hexane: 0.232 g/L 1-octanol: 9.54 g/L acetone: 210.7 g/L 1,2-dichloroethane: 189.8 g/L dichloromethane: 331.8 g/L
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	log Pow 3.4 (HPLC method, non-buffered, temp. 40 °C)
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	pH 4: DT <sub>50</sub> = 9.1 days (25 °C) pH 7: DT <sub>50</sub> = 0.8 days (25 °C) pH 9: DT <sub>50</sub> = 0.08 days (25 °C)
<b>Dissociation constant</b>	pKa = 12.94
<b>Quantum yield of direct photo-transformation in water at λ &gt;290 nm</b>	1.48 x 10 <sup>-2</sup> moles/einstein
<b>Flammability</b>	Non flammable
<b>Explosive properties</b>	Non explosive
<b>UV/VIS absorption (max.)</b>	Neutral: λ206 nm with ε = 27686 L/mol.cm; λ232 nm with ε = 25058 L/mol.cm; λ264nm with ε = 12413 L/mol.cm. At 290 nm a shoulder is present with λ290 nm with ε = 6186 L/mol.cm.
<b>Photostability in water (DT<sub>50</sub>)</b>	At pH 5 at 25 °C. DT <sub>50</sub> was 17 hours.

## APPENDIX II

### END POINTS AND RELATED INFORMATION

#### BIFENAZATE

### 1 Toxicology and metabolism

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

Rate and extent of absorption:	Oral: at least 28% at single low dose (10 mg/kg bw), based on radiolabel recovered from urine, cage wash, tissues and residual carcass, 168 h after administration. Twenty-four hours after administration absorption was at least 22%.
Distribution:	Mainly to liver, kidneys, whole blood and red blood cells
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	75% in 24 h, 90% in 96 h; mostly in faeces
Toxicologically significant compounds:	Parent compound and metabolites. Quantitatively most important metabolites <sup>3</sup> in rats: 4-hydroxybiphenyl, 4,4'-biphenol
Metabolism in animals:	Extensively metabolised in a network of pathways including a/o the following steps: dehydrogenation, hydroxylation, conjugation with glucuronic acid or sulphate and elimination of the hydrazine carboxylic acid moiety.

#### Acute toxicity

Rat LD <sub>50</sub> oral:	> 5000 mg/kg bw
Rat LD <sub>50</sub> dermal:	> 5000 mg/kg bw
Rat LC <sub>50</sub> inhalation:	> 4.4 mg/l
Skin irritation:	Not irritating
Eye irritation:	Not irritating
Skin sensitization (test method used and result):	Sensitising to skin (Maximisation test)

<sup>3</sup> Representing 5% or more of the administered dose recovered from urine, either conjugated and/or as native compound.

**Short term toxicity**

Target / critical effect:	Spleen and haematological parameters
Lowest relevant oral NOAEL / NOEL:	90-d dog: 40 mg/kg food (0.9 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL:	21-d rat: 80 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL:	No data – not required

**Genotoxicity**

No genotoxic potential
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**Long term toxicity and carcinogenicity**

Target / critical effect:	Spleen and haematological parameters
Lowest relevant NOAEL:	104-w rat: 20 mg/kg food (1 mg/kg bw/d)
Carcinogenicity:	No carcinogenic potential

**Reproductive toxicity**

Target / critical effect - Reproduction:	No reproductive toxicity
Lowest relevant reproductive NOAEL / NOEL:	≥200 mg/kg food (≥15.0 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	No developmental toxicity or teratogenicity
Lowest relevant developmental NOAEL / NOEL:	Rabbit: ≥200 mg/kg food (≥15.0 mg/kg bw/d)

**Delayed neurotoxicity**

acute neurotoxicity NOAEL: No data – not required semi-chronic neurotoxicity NOAEL: No evidence of neurotoxicity (90d oral rat)
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**Other toxicological studies**

No evidence of cholinergic toxicity was found in a 2-w oral toxicity study on cholinergic toxicity in rats
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**Medical data**

No concern
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**Summary**

	Value	Study	Safety factor
ADI:	0.01 mg/kg bw/d	90-d + 12-m oral dog, 104-w oral rat	100
AOEL (semichronic, systemic, oral route)	0.0028 mg/kg bw/d	90-d + 12-m oral dog	100
AOEL (chronic, systemic, oral route)	0.0028 mg/kg bw/d	104-w oral rat	100

AOEL inhalation:

Not applicable

AOEL dermal:

Not applicable

ARfD (acute reference dose):

Not necessary

### **Dermal absorption**

0.4% (suspension concentrate) and 2.7% (spray dilution) from *in vivo* and *in vitro* rat study

## 2 Fate and behaviour in the environment

### 2.1 Fate and behaviour in soil

#### Route of degradation

##### Aerobic:

Mineralization after 100 days:

15.2-23.0% after 119 days

Non-extractable residues after 100 days:

64.0-67.3% after 119 days

Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)

D2341-diazene (D3598): 92% (25 °C)  
4-methoxybiphenyl (D1989): 31% (20 °C)

#### Supplemental studies

##### Anaerobic:

non-extractable residue: maximum 58.7% of AR after 121 days  
mineralisation: 2.7% of AR after 121 days  
D3598: 35.5% of AR in water; <10% of AR in soil  
D1989: 14.5% of AR in water; 15.5% of AR in soil

##### Soil photolysis:

non-extractable residue: maximum 60.5% of AR in dark controls and 41.1% of AR in light exposed samples after 3 days (end of study)  
mineralisation: not measured  
D3598: 77.5% of AR in dark controls and 84.3% of AR in light exposed samples (2 hours)  
D1989: 22.1% of AR in dark controls and 11.2% of AR in light exposed samples (3 days)

##### Remarks:

none

**Rate of degradation****Laboratory studies**DT<sub>50lab</sub> (20 °C, aerobic):

<b>bifenazate</b>	
DT <sub>50, lab</sub> (25°C, aerobic):	<0.5 h (1 soil)
DT <sub>50, lab</sub> (20°C, aerobic):	<1 d (4 soils)
<b>D3598</b> (applied as parent)	
DT <sub>50, lab</sub> (25°C, aerobic):	9.3 h (8 single time points)
DT <sub>50, lab</sub> (20°C, aerobic):	0.53 d (8 dupl. time points; r <sup>2</sup> =0.965)
	0.34 d (8 dupl. time points; r <sup>2</sup> =0.995)
	0.52 d (8 dupl. time points; r <sup>2</sup> =0.974)
	0.47 d (8 dupl. time points; r <sup>2</sup> =0.991)
	average 0.5 d
<b>D1989</b> (applied as parent)	
DT <sub>50, lab</sub> (20°C, aerobic):	5.2 d (7 dupl. time points; r <sup>2</sup> =0.885)
	2.1 d (7 dupl. time points; r <sup>2</sup> =0.981)
	6.0 d (7 dupl. time points; r <sup>2</sup> =0.884)
	8.5 d (7 dupl. time points; r <sup>2</sup> =0.997)
	average 5.5 d

DT<sub>90lab</sub> (20 °C, aerobic):DT<sub>90, lab</sub> (20°C, aerobic): <1 d (extrapolated)DT<sub>50lab</sub> (10 °C, aerobic):

<b>bifenazate</b>	
DT <sub>50, lab</sub> (10°C, aerobic):	< 1 d (1 soil)
<b>D3598</b> (applied as parent)	
DT <sub>50, lab</sub> (10°C, aerobic):	1.3 d (8 single time points; r <sup>2</sup> =0.977)
<b>D1989</b> (applied as parent)	
DT <sub>50, lab</sub> (10°C, aerobic):	5.7 d (6 single time points; r <sup>2</sup> =0.997)
degradation in the saturated zone: not available	

DT<sub>50</sub>lab (20 °C, anaerobic):**bifenazate**DT<sub>50, lab</sub> (20°C, anaerobic):value in soil not applicable (bifenazate in soil  
max. 3.7% of AR)0.8 d in water (5 dupl. time points;  $r^2=0.802$ )0.8 d in system (7 dupl. time points;  $r^2=0.802$ )**D3598** (applied as parent)DT<sub>50, lab</sub> (20°C, anaerobic):value for soil not reliable ( $r^2<0.8$ )0.39 d in water (5 dupl. time points;  $r^2=0.924$ )0.8 d in system (7 dupl. time points;  $r^2=0.845$ )**D1989** (applied as parent)DT<sub>50, lab</sub> (20°C, anaerobic):58.2 d in soil (5 dupl. time points;  $r^2=0.866$ )1.73 d in water (5 dupl. time points;  $r^2=0.898$ )44.7 d in system (6 dupl. time points;  $r^2=0.863$ )**Field studies (country or region)**DT<sub>50f</sub> from soil dissipation studies:**bifenazate + D3598 combined**North Carolina, USA: 4.7 d (7 tripl. time points;  
 $r^2=0.724$ )Washington, USA: 6.8 d (8 tripl. time points;  
 $r^2=0.840$ )

average 6 d

max. residues D1989 0.03 mg/kg

DT<sub>90f</sub> from soil dissipation studies:

not available

Soil accumulation studies:

not available

Soil residue studies:

not available

**Remarks:**

e.g. effect of soil pH on degradation rate

none

## Adsorption/desorption

K<sub>f</sub> / K<sub>oc</sub>:K<sub>d</sub>:

pH dependence:

**bifenazate**K<sub>oc</sub>: 1778 L/kg  
corresponding K<sub>om</sub>: 1046 L/kg  
column leaching with artificial adsorbent**D3598**K<sub>oc</sub>: 8710 L/kg  
corresponding K<sub>om</sub>: 5124 L/kg  
column leaching with artificial adsorbent**D1989**K<sub>F</sub> (soil): 84, 77, and 83 L/kg  
corresponding K<sub>om</sub> values: 2296, 2330, and 2190  
L/kg (average 2272 L/kg)  
corresponding K<sub>oc</sub> values: 3905, 3962, and 3725  
L/kg (average 3864 L/kg)  
K<sub>F</sub> (sediment): 246 L/kg  
corresponding K<sub>om</sub> value: 3639 L/kg  
corresponding K<sub>oc</sub> value: 6189 L/kg  
no pH dependence

## Mobility

**Laboratory studies:**

Column leaching:

<0.1 to 0.2% of AR in leachate, possibly D1989  
bifenazate in soil extracts after 5 d of leaching  
max. 14.9% of AR; D1989 max. 26.1% of AR and  
D3598 max. 10.4% of AR

Aged residue leaching:

not available; in view of rapid degradation, non-  
aged column leaching is appropriate**Field studies:**

Lysimeter/Field leaching studies:

not available

**Remarks:**

none

## 2.2 Fate and behaviour in water

### Abiotic degradation

Hydrolytic degradation:

**bifenazate**

pH 4 (25°C): DT<sub>50</sub> 9.1 d

pH 7 (25°C): DT<sub>50</sub> 0.8 d

pH 9 (25°C): DT<sub>50</sub> 0.08 d

metabolites >10% of AR:

**D3598**

pH 4: 21.3% of AR (14 d)

pH 5: 27.3% of AR (10.d)

pH 7: 58.5% of AR (27 h)

pH 9: 23.5% of AR (1.8 h)

**D9472 (3,4-dihydroxy-[1,1'-biphenyl])**

pH 4: 83.5% of AR (30 d, end)

pH 5: 72.8% of AR (21 d)

pH 7: 43.4% of AR (48 h)

pH 9: 64.1% of AR (2.8 h)

9 minutes peak (MW 384 g/mol; C<sub>24</sub>H<sub>16</sub>O<sub>5</sub>):

pH 5: 14.4% of AR (14 d)

pH 7: 24.0% of AR (14 d)

**D3598 (applied as parent)**

pH 7 (25°C): DT<sub>50</sub> 1.2 d

pH 9 (25°C): DT<sub>50</sub> 0.02 d

Major metabolites:

D3598, D9472

Photolytic degradation:

**bifenazate**  
acetate buffer, pH 5, artificial sunlight, >290 nm  
(12:12 h), 25°C: DT<sub>50</sub> 20.3 h; quantum yield 0.0122  
moles/einstein

sodium citrate buffer, pH 5, artificial sunlight, >290  
nm (12:12 h), 25°C: DT<sub>50</sub> 21.1 h

natural water, pH 7, artificial sunlight, >290 nm  
(cont.), 25°C: DT<sub>50</sub> 0.83 h

metabolites >10% of AR:

D3598: 58.6% of AR after 36 h

D1989: 13.1% of AR after 54 h

D9472: 18.6% of AR after 36 h

D9963: 30.4% of AR after 150 h

unidentified: 18.0% of AR after 72 h

Major metabolites:

D3598; D1989; D9472; D9963; unidentified

**Biological degradation**

Readily biodegradable:

Water/sediment study:

DT<sub>50</sub> water:DT<sub>90</sub> water:DT<sub>50</sub> whole system:DT<sub>90</sub> whole system:

no
<p>DT<sub>50, water</sub> (aerobic; 20 °C):  <b>bifenazate</b>  &lt; 0.25 d (&gt;50% degradation within 0.25 d)  <b>D3598</b> (applied as parent):  sandy loam: &lt;1 d (&gt;50% degradation within 1 d)  clay loam: too few data points  <b>D9472</b> (applied as parent):  sandy loam: 10.5 d (6 dupl. time points;  r<sup>2</sup>=0.957)  clay loam: 3.2 d (5 dupl. time points, 1 single;  r<sup>2</sup>=0.967)  average: 6.9 d</p>
<p>DT<sub>90, water</sub> (aerobic; 20 °C):  <b>bifenazate</b>  &lt;7 d (no bifenazate present at t=7 d)  <b>D3598</b> (applied as parent)  &lt;7 d (&gt;90% degraded at t=7 d)  <b>D9472</b> (applied as parent)  34.6 d and 10.6 d (extrapolated from DT<sub>50</sub> value  assuming first order exponential decay: 3.3·DT<sub>50</sub>)</p>
<p>DT<sub>50, whole system</sub> (aerobic; 20 °C):  <b>bifenazate</b>  &lt; 0.25 d (&gt;50% degradation within 0.25 d)  <b>D3598</b> (applied as parent)  sandy loam: 3.4 d (7 single time points;  r<sup>2</sup>=0.833)  clay loam: 3.4 d (7 single time points;  r<sup>2</sup>=0.981)  average: 3.4 d  <b>D9472</b> (applied as parent)  sandy loam: 14.4 d (6 single time points;  r<sup>2</sup>=0.980)  clay loam: 5.3 d (5 single time points;  r<sup>2</sup>=0.908)  average: 9.9 d</p>
<p>DT<sub>50, whole system</sub> (anaerobic, 25 °C):  <b>bifenazate</b>  77 d (11 time points, r<sup>2</sup> 0.981; 116 d at 20 °C)</p>
<p>DT<sub>90, whole system</sub> (aerobic; 20 °C):  <b>bifenazate</b></p>

Distribution in water / sediment systems (active substance)	<p>&lt;7 d (no bifenazate present at t=7 d)</p> <p><b>D3598</b> (applied as parent) 11.2 d (extrapolated from DT<sub>50</sub> value assuming first order exponential decay: 3.3·DT<sub>50</sub>)</p> <p><b>D9472</b> (applied as parent) 47.5 and 17.5 d (extrapolated from DT<sub>50</sub> value assuming first order exponential decay: 3.3·DT<sub>50</sub>)</p>
Distribution in water / sediment systems (metabolites)	<p>DT<sub>90, system</sub> (anaerobic, 25 °C):</p> <p><b>bifenazate</b> 254 d (extrapolated from DT<sub>50</sub> value assuming first order exponential decay: 3.3·DT<sub>50</sub>; 383 d at 20 °C)</p> <p>DT<sub>50, sediment</sub> (aerobic; 20 °C):</p> <p><b>bifenazate</b> not applicable (bifenazate in sediment max. 3.1% of AR)</p> <p><b>D3598</b> (applied as parent) sandy loam: not applicable (D3598 in sediment max. 4.6% of AR) clay loam: 10.1 d (; 6 dupl. time points; r<sup>2</sup>=0.824)</p> <p><b>D9472</b> (applied as parent) not applicable (D9472 in sediment max. 5.4% of AR)</p>
Accumulation in water and/or sediment:	<p>DT<sub>90, sediment</sub> (aerobic; 20 °C):</p> <p><b>bifenazate</b> not applicable</p> <p><b>D3598</b> (applied as parent) 33.3 d (extrapolated from DT<sub>50</sub> value assuming first order exponential decay: 3.3·DT<sub>50</sub>)</p> <p><b>D9472</b> (applied as parent) not applicable</p>
<b>Degradation in the saturated zone</b>	Not available; not required
<b>Remarks:</b>	None

## 2.3 Fate and behaviour in air

### Volatility

Vapour pressure:

at 25 °C < $1.33 \times 10^{-5}$ Pa (99.5%)
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Henry's law constant:

at 20 °C < $1.01 \times 10^{-3}$ Pa m <sup>3</sup> mole <sup>-1</sup>
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### Photolytic degradation

Direct photolysis in air:

Not available; not required
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Photochemical oxidative degradation in air

DT<sub>50</sub>:

Bifenazate has vapour pressure of $< 1.33 \cdot 10^{-5}$ Pa, and a Henry's law constant of $< 1.01 \times 10^{-3}$ Pa·m <sup>3</sup> ·mol <sup>-1</sup> (at 20 °C). Based on the information submitted it is considered that significant volatilisation of bifenazate is unlikely to occur. The gas phase oxidation half-life was estimated to be 37 minutes. Should bifenazate volatilise, then the compound will degrade quickly.
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Volatilisation:

from plant surfaces: not available
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from soil: not available
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Remarks:

None
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### 3 Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals:	LD <sub>50</sub> >5000 mg/kg bw
Acute toxicity to birds:	LD <sub>50</sub> 1036 mg/kg bw (bobwhite quail)
Dietary toxicity to birds:	LC <sub>50</sub> 686 mg/kg fd, 106 mg/kg bw-d (mallard duck)
Reproductive toxicity to birds:	NOEC 20 mg/kg fd, 2.1 mg/kg bw-d (mallard duck)
Short term oral toxicity to mammals:	No data available
Long term toxicity to mammals:	NOAEL 200mg/kg fd, 15 mg/kg bw-d

#### Aquatic Organisms

	Group	Test substance	Time-scale	Endpoint	Toxicity (mg as/L)
Acute toxicity fish:	<i>Lepomis macrochirus</i>	bifenazate technical	96 h	mortality, LC <sub>50</sub>	0.58
	<i>Oncorhynchus mykiss</i>	D3598 technical	96 h	mortality, LC <sub>50</sub>	0.044
	<i>Oncorhynchus mykiss</i>	D9472 technical	96h	mortality, LC <sub>50</sub>	0.21
Long term toxicity fish:	<i>Oncorhynchus mykiss</i>	bifenazate technical	87 d	ELS, NOEC	0.017
Bioaccumulation fish:	not available, but considered not necessary				
Acute toxicity invertebrate:	<i>Daphnia magna</i>	bifenazate technical	48 h	immobility, EC <sub>50</sub>	0.50
	<i>Crassostrea virginica</i>	bifenazate technical	96 h	Growth, EC <sub>50</sub>	0.42
	<i>Daphnia magna</i>	D3598 technical	48 h	immobility, EC <sub>50</sub>	0.051
	<i>Daphnia magna</i>	D9472 technical	48h	immobility, EC <sub>50</sub>	0.78
Chronic toxicity invertebrate:	<i>Daphnia magna</i>	bifenazate technical	21 d	reproduction, growth F1, NOEC	0.15

Acute toxicity algae:

<i>Skeletonema costatum</i>	bifenazate technical	96 h	biomass, E <sub>b</sub> C <sub>50</sub>	0.30
<i>Skeletonema costatum</i>	bifenazate technical	96 h	Biomass, NOEC	0.20
<i>Selenastrum capricornutum</i>	D3598 technical	96 h	biomass, E <sub>b</sub> C <sub>50</sub>	0.83
<i>Scenedesmus subspicatus</i>	D9472 technical	96h	biomass, E <sub>b</sub> C <sub>50</sub>	0.71
Chronic toxicity sediment dwelling organism: not available, but considered not necessary				

## Honeybees

Acute oral toxicity:

LD<sub>50</sub> >98 µg/bee (480 g as/L SC)

Acute contact toxicity:

LD<sub>50</sub> 8.50 µg/bee (technical material)

## Other arthropod species

Test species	Stage	Test Substance	Dose (g as/ha)	Endpoint	Effect (%)
Laboratory tests					
<i>T. pyri</i>	protonymphs	bifenazate 480 SC	5	survival fecundity	0 n.s.
<i>T. pyri</i>	protonymphs	bifenazate 480 SC	10	survival fecundity	0 83
<i>T. pyri</i>	protonymphs	bifenazate 480 SC	25-400	survival	67-98
					LR <sub>50</sub> 23.8 g as/ha
<i>C. carnea</i>	larvae	bifenazate 480 SC	75	survival egg production egg hatching	5.4 5.6 0
<i>C. carnea</i>	larvae	bifenazate 480 SC	150	survival egg production egg hatching	0.6 11.7 5.5
<i>C. carnea</i>	larvae	bifenazate 480 SC	300	survival egg production egg	3.0 14.3 +0.50

				hatching	
<i>O. laevigatus</i>	larvae	bifenazate 480 SC	75	survival egg production egg hatching	+2.2 11.2 0.6
<i>O. laevigatus</i>	larvae	bifenazate 480 SC	150	survival egg production egg hatching	19.1 0.6 +2.2
<i>O. laevigatus</i>	larvae	bifenazate 480 SC	300	survival egg production egg hatching	+2.2 17.7 +2.8
<i>A. rhopalosiphi</i>	adults	bifenazate 480 SC	1	survival	21.4
<i>A. rhopalosiphi</i>	adults	bifenazate 480 SC	10 and 100	survival fecundity	7.1 and 21.4 21.4 and 16.1
<i>A. rhopalosiphi</i>	adults	bifenazate 480 SC	200-600	survival	42.9-57.1
					LR <sub>50</sub> 262 g as/ha
<i>P. cupreus</i>	adults	bifenazate 480 SC	75	survival food cons	0 1.7
<i>P. cupreus</i>	adults	bifenazate 480 SC	150	survival food cons	0 12
<i>P. cupreus</i>	adults	bifenazate 480 SC	300	survival food cons	0 -10
<i>Extended laboratory tests</i>					
<i>T. pyri</i>	protonymphs	bifenazate 480 SC	25	survival fecundity	2.4 33
<i>T. pyri</i>	protonymphs	bifenazate 480 SC	75	survival fecundity	2.4 52
<i>T. pyri</i>	protonymphs	bifenazate 480 SC	150	survival fecundity	-7.3 69
<i>T. pyri</i>	protonymphs	bifenazate 480 SC	300	survival fecundity	14.6 78
<i>T. pyri</i>	protonymphs	bifenazate 480 SC	600	survival fecundity	4.9 83
<i>E. formosa</i>	adults	bifenazate 480 SC	75	survival	0

<i>E. formosa</i>	adults	bifenazate 480 SC	150	survival	5.5
<i>E. formosa</i>	adults	bifenazate 480 SC	300	survival	2.6

Field or semi-field tests: field test to investigate the effect of bifentazate 480 SC on the population of predatory Phytoseiid mites in an apple orchard. At a dose of 0.480 kg a.i./ha no significant effects were found on predatory mites in these orchards.

## Earthworms

Acute toxicity:

bifenazate: LC50 >429 mg/kg dry soil (10% OM), equivalent to >215 mg/kg for a soil with the standard average organic matter content (5.0%), which is used for risk assessment;  
metabolite D3598: LC50 = 185 mg/kg dry soil (10% OM) equivalent to 92.5 mg/kg for a soil with the standard average organic matter content (5.0%), which is used for risk assessment;  
metabolite D1989: LC50 = 87.2 mg/kg dry soil (10% OM) equivalent to 43.6 mg/kg for a soil with the standard average organic matter content (5.0%), which is used for risk assessment.

Reproductive toxicity:

No data provided, but not considered necessary

## Soil micro-organisms

Nitrogen mineralization:

<25% effect after 28 d on nitrification at 0.8 mg as/kg  
<25% effect after 28 d on N-mineralisation at 0.8 mg as/kg

Carbon mineralization:

<25% effect after 28 d on respiration at 0.8 mg as/kg

## APPENDIX III

### BIFENAZATE

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

#### B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 1.9	Osborn, D.J.	2004	Bifenazate proposed specifications/analytical method for organic impurities in technical material Crompton Europe limited Letter 15 January 2004 Not GLP, Unpublished.
IIA, 4.1.2	Riggs, A.S.	2003	Analytical method, determination of trace organic impurities in bifenazate technical material using high performance liquid chromatography Crompton Co. research laboratories, Canada Method nr: GRL-GM-1187 31 October 2003 (version 1.0) GLP, Unpublished
IIA, 4.1.2	Riggs, A.S.	2003 a	Validation of an analytical method for the impurities in technical bifenazate using HPLC with external standardization Crompton Co. research laboratories, Canada Study nr: GRL-12052 31 October 2003 GLP, Unpublished

#### B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA, 7.3/02	Roper, C.S., Crow, L.	2003	The <i>in vitro</i> percutaneous absorption of a suspension concentration formulation of radiolabelled bifenazate at two concentrations through rat and human skin. Inveresk Research, Scotland, Report No. 22574. GLP, Unpublished.

**B.7 Residue data**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
none			

**B.8 Environmental fate and behaviour**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
none			

**B.9 Ecotoxicology**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA, 8.4.1/02	Eyre, D. and D. Webster	2003	A laboratory study to determine the median lethal concentration (LC <sub>50</sub> ) of D3598 to the earthworm, <i>Eisenia fetida</i> June 26, 2003 Ecotox Limited, Tavistock, UK Report nr. ER-03-HMA478 GLP, Unpublished.
IIA, 8.4.1/03	Eyre, D. and D. Webster	2003	A laboratory study to determine the median lethal concentration (LC <sub>50</sub> ) of D1989 to the earthworm, <i>Eisenia fetida</i> June 27, 2003 Ecotox Limited, Tavistock, UK Report nr. ER-03-HMA479 GLP, Unpublished.
IIIA, 10.5.2/01	Lagrasse, S.	2003	A field study to evaluate the effect of bifenazate on Phytoseiid populations in an orchard (France) March 6, 2003 Promo-Vert S.A., Serres-Castet, France Report nr. 02 TYURL05 GLP, Unpublished.

## APPENDIX IV

## List of uses supported by available data

## BIFENAZATE

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
Ornamentals	NL	Floramite 240 SC	G	Mites	SC	240 g/l	HV Knapsack	Mature	1-4*	7 days*	0.0096	1000-1500	0.096-0.144	N/A	

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions

\* The GAP involves up to 4 applications in 2 spray-programmes. 1 spray programme is 2 applications with a seven-day interval followed by at least two other different acaricides. The minimum interval to the next spray-programme is 56 days.