



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions  
**E1 - Plant health**

Benalaxyl  
SANCO/4351/2000 final  
13 February 2004

### Review report for the active substance **benalaxyl**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
**13 February 2004**  
in view of the inclusion of benalaxyl in Annex I of Directive 91/414/EEC

#### **1. Procedure followed for the re-evaluation process**

This review report has been established as a result of the re-evaluation of benalaxyl, made in the context of the work programme for review of existing active substances provided for in Article 8(2) 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.

Commission Regulation (EEC) No 3600/92<sup>(1)</sup> laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000<sup>(2)</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Benalaxyl is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, United Phosphorus Ltd on 26 July 1993 and ISAGRO S.p.A. on 22 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance benalaxyl in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94<sup>(3)</sup>, as last amended by Regulation (EC) No 2230/95<sup>(4)</sup>, designated Portugal as rapporteur Member State to carry out the assessment of benalaxyl on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for benalaxyl this deadline was 30 April 1995.

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<sup>1</sup> OJ No L 366, 15.12.1992, p.10.

<sup>2</sup> OJ No L 259, 13.10.2000, p.27.

<sup>3</sup> OJ No L 107, 28.04.1994, p.8.

<sup>4</sup> OJ No L 225, 22.09.1995, p.1.

Only ISAGRO S.p.A. submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore ISAGRO S.p.A. was considered to be the main data submitter. United Phosphorous Limited on a letter dated 23 December 1994 stated its intention not to support benalaxyl and did not submit a dossier. No information has furthermore been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Portugal submitted on 27 April 2000 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of benalaxyl in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on benalaxyl from ISAGRO S.p.A., on 18 July 2000.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 27 June 2000 as well as to ISAGRO S.p.A. being the main data submitter, on 25 August 2000.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from March to September 2001.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 16 November 2001 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review 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 the 15 Member States. This final examination took place from December 2001 to February 2004, and was finalised in the meeting of the Standing Committee on 13 February 2004.

The review did not reveal any open questions or concerns which would have required a consultation of the Scientific Committee on Plants.

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

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

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2004/58/EC<sup>5</sup> concerning the inclusion of benalaxyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing benalaxyl 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.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, 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 all operators having notified for this active substance under Article 4(1) of this Regulation.

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 to have 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 benalaxyl 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 benalaxyl containing plant protection product for which Member States will grant or review the authorisation.

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<sup>5</sup> OJ No L120, 24.4.2004, p.26.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main 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.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 1.4% of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

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 6 of this report.

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

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

As there is no FAO specification, the active substance shall comply with the specification of minimum purity, which is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter ISAGRO S.p.A., none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

#### **5. 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 were identified during the re-evaluation process. These endpoints are listed in Appendix II.

## **6. 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 benalaxyl**

On the basis of the proposed and supported uses (as listed in Appendix IV), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.

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

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

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for a field lysimeter study to provide further confidence on the possible leaching of metabolites of benalaxyl.

## **8. Information on studies with claimed data protection**

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

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

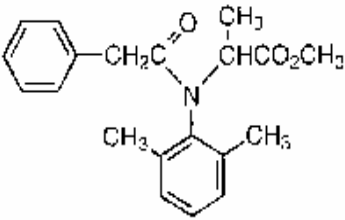
The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. 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 benalaxyl in Annex I of the Directive.



# APPENDIX I

## Identity, physical and chemical properties

### BENALAXYL

<b>Common name (ISO)</b>	Benalaxyl
<b>Chemical name (IUPAC)</b>	Methyl N-phenylacetyl-N-2, 6-xylol-DL-alaninate
<b>Chemical name (CA)</b>	Methyl N-(2, 6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate
<b>CIPAC No</b>	416
<b>CAS No</b>	71626-11-4
<b>EEC No</b>	275-728-7
<b>FAO SPECIFICATION</b>	Not available
<b>Minimum purity</b>	960 g/kg
<b>Molecular formula</b>	C <sub>20</sub> H <sub>23</sub> N O <sub>3</sub>
<b>Molecular mass</b>	325.4
<b>Structural formula</b>	

<b>Melting point</b>	76.8°C (994 g/kg)
<b>Boiling point</b>	Decomposition occurs at 250 °C
<b>Appearance</b>	Purified a. s. white microcrystalline solid Technical a.s. whitish microcrystalline solid
<b>Relative density</b>	1.181 g/cm <sup>3</sup> at 20°C (994g/kg)
<b>Vapour pressure</b>	5.72 × 10 <sup>-4</sup> Pa at 20°C 6.64 × 10 <sup>-4</sup> Pa at 25°C (calculated)
<b>Henry's law constant</b>	6.50 × 10 <sup>-3</sup> Pa. m <sup>3</sup> . mol <sup>-1</sup> at 20°C
<b>Solubility in water</b>	0.0286 g/l at 20°C The effect of pH on solubility is not required as the active substance does not form ions
<b>Solubility in organic solvents</b>	At 22°C n-Heptane: 19.4 g/l Xilene, 1,2-Dichloroethane, Methanol, Acetone, Ethyl acetate: >250 g/l
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	3.54 at 20°C and pH 6.1
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	At pH 4 and 7 → DT <sub>50</sub> > 1 year (room temperature) At pH 9 → DT <sub>50</sub> = 157 days (20°C) DT <sub>50</sub> = 86 days (25°C)
<b>Dissociation constant</b>	Dissociation in water does not occur
<b>Quantum yield of direct photo-transformation in water at λ &gt;290 nm</b>	Not required (No absorption at λ ≥ 290 nm)
<b>Flammability</b>	Not flammable
<b>Explosive properties</b>	Not explosive
<b>UV/VIS absorption (max.)</b>	λ <sub>max</sub> = 203nm No absorption at λ ≥ 290 nm
<b>Photostability in water (DT<sub>50</sub>)</b>	Not required (No absorption at λ ≥ 290 nm)

## APPENDIX II

### END POINTS AND RELATED INFORMATION

#### BENALAXYL

## 1 Toxicology and metabolism

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

Rate and extent of absorption:	Rapid, > 80% based on biliary and urinary excretion.
Distribution:	Widely distributed.
Potential for accumulation:	No potential for accumulation.
Rate and extent of excretion:	> 95% within 72 hours, mainly by faeces.
Toxicologically significant compounds:	Parent compound and 5 soil / groundwater metabolites: Parent compound and F4 - MAC 120µg/l M1 and F8 - MAC 3000µg/l M2 and F7 - MAC 2700µg/l
Metabolism in animals:	Extensive metabolism, mainly by oxidation and hydroxylation.

### Acute toxicity

Rat LD <sub>50</sub> oral:	4200 mg/kg bw (rats)
Rat LD <sub>50</sub> dermal:	> 2000 mg/kg bw (rabbit).
Rat LC <sub>50</sub> inhalation:	> 4.2 mg/l (nose only).
Skin irritation:	Not irritating.
Eye irritation:	Not irritating.
Skin sensitization (test method used and result):	Non-sensitiser (M & K).

### Short term toxicity

Target / critical effect:	Liver (hypertrophy and steatosis, rats and mice), testes (atrophy in dogs).
Lowest relevant oral NOAEL / NOEL:	90-d rat: 100 ppm (5.8 mg/kg bw/d) 1-yr dog: 200 ppm (6.5 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL:	No data, not required.
Lowest relevant inhalation NOAEL / NOEL:	No data, not required.

**Genotoxicity**

No genotoxic potential

**Long term toxicity and carcinogenicity**

Target / critical effect:

Liver toxicity (rats), increased mortality associated with amyloidosis (mice).

Lowest relevant NOAEL:

2-yr rat: 100 ppm (4.42 mg/kg bw/d)

Carcinogenicity:

No carcinogenic potential

**Reproductive toxicity**

Target / critical effect - Reproduction:

Decreased body weight gain and increased liver weight of pups at parental toxic dose levels.

Lowest relevant reproductive NOAEL / NOEL:

100 ppm (5.3 mg/kg bw/d)

Target / critical effect - Developmental toxicity:

Minor skeletal deviations at minimal materno toxicity.

Lowest relevant developmental NOAEL / NOEL:

12.5 mg/kg bw/d (rat)

**Delayed neurotoxicity**

No data, not required.

**Other toxicological studies**Rat LD<sub>50</sub> oral of soil and groundwater metabolite (methyl-N-malonyl-N-2,6-xylyl-DL-alaninate) compound A: > 2000 mg/kg bw.Rat LD<sub>50</sub> oral of soil and groundwater metabolite (N-malonyl-N-2,6-xylyl-DL-alanine) compound B: > 2000 mg/kg bw.

Genotoxicity of the two metabolites, including in vitro (compound A and B) and in vivo (compound A) studies: negative

90 days oral in rats for the metabolite A and B  
NOEL compound A 1000 mg/kg bw/day; NOEL compound B 900 mg/kg bw/day

Toxicological data of met. A (M1) are applicable to F8, of met. B (M2) to F7 and of parent compound to F4.

**Medical data**

Observation of workers involved in the production of a.s. didn't demonstrate any toxic effects.

## Summary

	Value	Study	Safety factor
ADI:	0.04 mg/kg bw/d	2-year, rat	100
AOEL systemic:	0.06 mg/kg bw/d	90 day, rat	100
AOEL inhalation:	Not relevant	---	---
AOEL dermal:	Not relevant	---	---
ARfD (acute reference dose):	Not established - not necessary.		

## Dermal absorption

No data, 10% default value used for calculations.

## 2 Fate and behaviour in the environment

### 2.1 Fate and behaviour in soil

#### Route of degradation

##### Aerobic:

Mineralization after 100 days:

benalaxyl: CO<sub>2</sub> was not detected throughout the studies methyl-N-(2, 6-xylyl)-N-malonyl alaninate (comp. A - M1):  
máx. 25% (100 DAT)  
N-(2, 6-xylyl)-N-malonyl alanine (comp. B – M2):  
máx. 26% (100 DAT)

Non-extractable residues after 100 days:

benalaxyl: 18.8% (133 d)  
compound A (M1) : 16.6% (100d)  
compound B (M2) : 15.7% (100d)

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

compound A (M1) max. 31% at 133 DAT;  
compound B (M2) max. 34.1% at 98 DAT;  
benalaxyl acid max. 4.9% at 28 DAT.

#### Supplemental studies

##### Anaerobic:

Anaerobic degradation followed the same pattern as observed under aerobic conditions although much slower; the main degradation product was compound A max. 50.73% at 203DAT; non-extractable residues after 120d represented 4.93% with a maximum of 26.3% by day 203 (end of the study).

##### Soil photolysis:

No data. Not considered necessary

##### Remarks:

none

## Rate of degradation

### Laboratory studies

DT<sub>50</sub>lab (20 °C, aerobic):

Benalaxyl: 36 – 85 d (at 5 mg/Kg, 22°C) and 77 – 100 d (at 50 mg/Kg, 22°C), reg. analysis Compound A (M1) 49 - 90d ( $r^2 > 0.98$ ) reg. analysis Compound B (M2) 66 - 118d ( $r^2 > 0.95$ ) reg. analysis
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DT<sub>90</sub>lab (20 °C, aerobic):

No data.

DT<sub>50</sub>lab (10 °C, aerobic):

198 d (estimate, Arrh. eq.)

DT<sub>50</sub>lab (20 °C, anaerobic):

160 d (graphic interpol.)

### Field studies (country or region)

DT<sub>50f</sub> from soil dissipation studies:

DT <sub>50f</sub> : Italy 49d (n = 1), benalaxyl remained confined to the upper 10 cm layer. Germany 20 - 98 d (n = 4),
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DT<sub>90f</sub> from soil dissipation studies:DT<sub>90f</sub>: Germany 67 - 326 d (n = 4),

Soil accumulation studies:

The a.s. is not expected to accumulate in soil. Compound A (M1) and compound B (M2) are not expected to accumulate in soil based on the calculation of the accumulation potential for these metabolites. After consecutive applications during 5 years according to maximum GAP a plateau is reached during the 3 <sup>rd</sup> 4 <sup>th</sup> year (after 4 applications) at a level 1.06 times greater than what is estimated just after the 4 <sup>th</sup> application in the 1 <sup>st</sup> year.
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Soil residue studies:

residue trials conducted on rotational crops tomato, lettuce, tobacco, carrot and wheat in concrete pots filled with silt loam soil (2.3% o.c.) and benalaxyl application at a rate of 2.25 Kg a.s./ha indicated that benalaxyl was mostly found in the 0 – 6 cm soil profile at max. levels of 0.5 to 0.9 mg a.s./Kg soil. Compound A (M1) reached maximums (0 – 18 cm) of 0.3 to 0.7 mg/Kg soil and Compound B (M2) was seldomly found at levels above 0.1 mg/Kg soil.
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### Remarks:

e.g. effect of soil pH on degradation rate

none
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**Adsorption/desorption**

Benalaxyl:

 $K_f / K_{oc}$  $K_d$ 

Compound A (M1)

Compound B (M2)

pH dependence:

soil	pH	org. C	Koc (dm <sup>3</sup> /kg)
sandy loam I	4.6	1.8	2728
sandy loam II	5.8	1.5	7173
sandy loam III	7.8	1.1	5094
Kd = 49.1 - 107.6			
Loamy sand	3.38	14.42	151
Silty clay	6.61	1.35	521
Silt Loam	5.58	2.13	455
Kd = 7.03 - 21.7			
Kfads = 8.4 - 18.1			
Loamy sand	3.38	14.42	80
Silty clay	6.61	1.35	127
Silt Loam	5.58	2.13	756
Kd = 1.22 - 12.28			
Kfads = 1.2 - 12.28			
no pH dependence			

**Mobility****Laboratory studies:**

Column leaching:

Three formulations of benalaxyl were tested (GALBEN OE 20, GALBEN 25 WP and GALBEN 5 GR) on standard soils (BBA 2.1, BBA 2.2 and BBA 2.3). In all the studies less than 2% of the applied amount (corresponding to levels below the LOD - 25.6 µg/l) were found in the soil leachates.

Aged residue leaching:

30 d ageing benalaxyl was applied to silty loam soil. 86% AR was found in the soil columns with more than 70% AR in the upper 0-15 cm soil; 14% AR was found in leachate and was characterised as compound A (7.86%AR), compound B (5.56% AR) and benalaxyl acid with 0.29% AR.

**Field studies:**

Lysimeter/Field leaching studies:

Two lysimeters (I and II) with undisturbed sandy soil monoliths were installed in Switzerland. The lysimeters were treated 4 times with <sup>14</sup>C-benalaxyl formulated as GALBEN M 8 – 65 at a rate of 0.240 Kg a.s./ha , starting on May 30, at 12 days interval, on tomatoes. Common agronomic practice was followed throughout the study. (For details see Addendum 8).

Results are available for the first 273 days of the study.

The leachate collected during the first experimental period contained 10% and 8.3% AR, respectively for Lysimeter I and II, corresponding to 9.5 and 7.9 mg a.s. equivalents. Mean concentrations amounted to 18.43 µg a.s. equiv./L and 14.33 µg a.s./equiv./L

Analysis of leachates showed the presence of 8 radioactive fractions. Among these M1 and M2 were positively identified at mean levels of, respectively, 4.68 and 7.83 µg a.s.equiv./L in Lysimeter I and of 4.87 and 4.53 µg a.s. equiv./L in Lysimeter II, respectively. Maximum detected values were of 8.28 µg a.s.equiv./L for M1 (Nov. 2002) and 20.31 µg a.s. equiv./L for M2 (Jan. 2003).

A follow up of the lysimeter study was also submitted with results from the remaining study period to complete 1 year (sampling data until June 2003). The metabolic profile of the major radioactive fractions that remained unidentified from the first interim report was also submitted.

The updated levels of radioactivity detected in leachates of Lys. I and II indicated mean (1 year) levels of M1 and M2 of, respectively, 4.69 and 8.18 µg a.s. equiv./L. in Lys. I and of 4.81 and 5.19 µg a.s. equiv./L.

Mean levels of radioactive fractions identified above 0.1 µg/L were of 2.05 and 1.74 µg a.s. equiv./L for F4, 0.96 and 0.99 µg a.s. equiv./L for F7 and 1.70 and 1.24 µg a.s. equiv./L for F8, respectively in Lys. I and Lys. II.

**Remarks:**

none

## 2.2 Fate and behaviour in water

### Abiotic degradation

Hydrolytic degradation:

pH 4 : stable (50°C and 70°C)  
pH 7 : stable (50°C and 70°C)  
pH 9 : DT50 = 55d (50°C) and 19hr (70°C)  
DT50 = 157d (20°C) and 86d (25°C)

Major metabolites:

Main hydrolysis product at pH 9 is benalaxyl acid

Photolytic degradation:

Italy: June-August (45°28'N, 3°10'W)  
At the end of the study (64days) 60% AR was still present as benalaxyl. Stable

Major metabolites:

none.

### Biological degradation

Readily biodegradable:

No

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:

17 days (Pond) and 58 days (River) ( $r^2 = 0.96$ )  
57 days (Pond) and 190 days (River) ( $r^2 = 0.96$ )  
118 days (Pond) and 166 days (River)  
228 days (Pond) and 309 days (River)

Distribution in water / sediment systems  
(active substance)

Pond: 0 h until day 2, main portion in water phase, then benalaxyl remains adsorbed to the sediment with 53% at the end of the study (100d). River 0 h until day 30, main portion in water phase. At day 100, 25.8% in water phase and 43% adsorbed to the sediment.

Distribution in water / sediment systems  
(metabolites)

Compound A were preferentially in water with a maximum of 7.3% AR at day 100; methyl-N-phenylacetyl-N-(2-carboxy-6-methyl)phenyl DL-alaninate and benalaxyl acid were preferentially in the sediment with maximums of 1.38% AR and 5.38% AR, respectively at day 100.

Accumulation in water and/or sediment:

no accumulation expected based on the findings

### Degradation in the saturated zone

no data

Remarks:

none

## 2.3 Fate and behaviour in air

### Volatility

Vapour pressure:

5.72 x 10 <sup>-4</sup> Pa at 20°C
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Henry's law constant:

6.50 x 10 <sup>-3</sup> Pa m <sup>3</sup> mol <sup>-1</sup> at 20°C
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### Photolytic degradation

Direct photolysis in air:

no data submitted. Not relevant
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Photochemical oxidative degradation in air

DT<sub>50</sub>:

DT50: 4.174 h and 12.523 h, assuming OH-radical concentrations of 1.5 x 10 <sup>6</sup> /cm <sup>3</sup> and 0.5 x 10 <sup>6</sup> /cm <sup>3</sup> (Atkinson estimation)
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Volatilisation:

from plant surfaces: no data Not relevant from soil: no data. Not relevant
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**Remarks:**

none
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### 3 Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals:	mouse: LD50 = 680* rat: LD50 = 4200
Acute toxicity to birds:	LD50 = 4600; 3700*; > 4500; > 5000
Dietary toxicity to birds:	LC50 > 5000 ppm*
Reproductive toxicity to birds:	NOEC = 1000 ppm*
Short term oral toxicity to mammals:	100 ppm (90 d, rat study)

\* value used for TERacute calculations

#### Aquatic Organisms

	Group/ Test species	Test substance	Endpoint	Toxicity mg/
Acute toxicity fish:	fish	a.s.	LC50	3.75
	fish	compound A	LC50	> 100
	fish	compound B	LC50	> 100
	fish	GALBEN M 8-65	LC50	0.81
Long term toxicity fish:	fish	a.s.	NOEC	0.49
Bioaccumulation fish:	No, BCF = 57			
Acute toxicity invertebrate:	<i>D. magna</i>	a.s.	EC50	0.59
	<i>D. magna</i>	compound A	LC50	> 100
	<i>D. magna</i>	compound B	LC50	> 100
	<i>D. magna</i>	GALBEN M 8-65	EC50	0.26
Chronic toxicity invertebrate:	<i>D. magna</i>	a.s.	NOEC	0.03
	<i>D. magna</i>	GALBEN M 8-65	NOEC	0,0332
Acute toxicity algae:	Green alga	a.s.	EC50	2.4
	Green alga	compound A	EC50	62.5
	Green alga	compound B	EC50	64.5
	Green alga	GALBEN M 8-65	EC50	3.7
Chronic toxicity sediment dwelling organism:	<i>C. riparius</i>	a.s.	NOEC	3.13

## Honeybees

Acute oral toxicity:

>100 µg a.s./bee  
> 255 µg GALBEN M/bee

Acute contact toxicity:

BBA test with a.s.. A maximum of 7% mortality after 7 days exposure to max. conc. of 0.032% a.s. on paper.  
BBA test with GALBEN M. A maximum of 3% mortality after 72 h exposure to max. conc. of 6mg form./ml

## Other arthropod species

<i>Test species</i>	stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect
<i>P. persimilis</i>	adult	lab. a.s.	0.16 and 0.48	mortality	0%
<i>T. pyri</i>	adult	ext.-lab. GALBEN M 8-65	4 x 0.240 (max. rate) and 4 x 0.018 (drift rate)	mortality reproduction	(max. rate): 75.3% at 1DA4T 17.2% at 7DA4T 1% at 14DA4T (drift rate): -2.5% at 1DA4T 4.0% at 7DA4T 9.3% at 14DA4T no effects on reproduction
<i>T. pyri</i>	adult	field GALBEN M	4 x 0.200	mortality reproduction	7DA1T: E = 44% 7DA3T: E = 61.1% 7DA4T: E = 68% at 28DA4T numbers were still below controls; at 56DA4T recovery was aparent with numbers below but not statistically significant from controls
<i>P. cupreus</i>	adult	lab. GALBEN M 8-65	0.240	food consumption	13.6%

<i>T. cacaoeciae</i>	pupae adult	lab. GALBEN M 8-65	0.240	parasitisation efficiency	91% 99.9%
<i>T. cacaoeciae</i>	adult	ex-lab. GALBEN M 8-65	0.08 and 2.0	Parasitisation efficiency	0% and > 44%
<i>T. cacaoeciae</i>	Adult	ex-lab. GALBEN M 8-65	4 x 0.240 (max. rate) and 4 x 0.018 (drift rate)	Parasitisation efficiency	(max. rate): 14.0 at 1DA4T -16.9% at 7DA4T -25.5% at 14DA4T (drift rate): 24.4% at 1DA4T 4.2% at 7DA4T 5.9% at 14 DA4T
<i>Crysoperla carnea</i>	larvae	ex-lab. GALBEN M 8-65	0.240 and 0.480	mortality and fecundity	maximum of - 2.2% for both appl. rates; no effects on fecundity or fertility
<i>S. corollae</i>	larvae	lab. GALBEN M 8-65	0.240	reproduction (fecundity and larval hatching rate)	61.4%

## Earthworms

Acute toxicity:

benalaxyl:  
LC50 = 180 mg as/kg soil (*Dendroboena rubida*)  
M1 (Compound A):  
LC50 (14 days) > 1000 mg/Kg substrate (*E. foetida*)  
M2 (Compound B):  
LC50 (14 days) > 1000 mg/Kg substrate (*E. foetida*)

Reproductive toxicity:

benalaxyl:  
NOEC (28 days) = 36.4 mg a.s./Kg substrate (*E. foetida*)  
M1 (Compound A):  
NOEC (28 days) = 50 mg/Kg substrate (*E. foetida*)  
NOEC (28 days) = 62.5 mg/Kg substrate (*Folsomia candida*)  
M2 (Compound B):  
NOEC (28 days) = 250 mg/Kg substrate (*E. foetida*)  
NOEC (28 days) = 125 mg/Kg substrate (*Folsomia candida*)

## Soil micro-organisms

Nitrogen mineralization:

benalaxyl: no prolonged adverse effects at soil concentrations up to 1.65 mg a.s./kg  
M1: no prolonged adverse effects at soil concentrations up to 0.5 mg/kg  
M2: no prolonged adverse effects at soil concentrations up to 0.5 mg/kg

Carbon mineralization:

benalaxyl: no prolonged adverse effects at soil concentrations up to 1.65 mg a.s./kg  
M1: no prolonged adverse effects at soil concentrations up to 0.5 mg/kg  
M2: no prolonged adverse effects at soil concentrations up to 0.5 mg/kg

**APPENDIX IIIA****BENALAXYL**

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion.

**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**

<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>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA, 2.1.1; 2.2; 2.3.1; 2.3.2; 2.5.1; 2.6; 2.8/01	Costantini, G.	1995	Benalaxyl purified active substance: Physical and chemical properties of the purified active substance Source: BIOLAB Project report n° 94/1087.B Company file No. 108 GLP. Unpublished	
IIA, 2.1.2; 2.1.3/01	Saldi, S.	1995	Boiling point determination of benalaxyl purified active substance Source: EniChem I.G.D. Project report n° 030/95 Company file n°: 110 GLP. Unpublished	
IIA, 2.7; 2.11.2; 2.13; 2.14; 2.15/01	Costantini, G.	1995	Benalaxyl technical active substance: Physical and chemical properties of the technical active substance Source: BIOLAB Project report n° 94/1087.C Company file No. 109 GLP. Unpublished	

<sup>6</sup> Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

<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>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA, 2.10/01	Mechthild, A.	1996	Benalaxyl: Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions Source: :SCC Scscientific Consulting Company Project report n°: 165-005 Company file n°: 139 Not GLP. Unpublished	
IIA, 2.11.1/01	Jonas, W.	1993	Flammability (Solids) test substance: Benalaxyl. Source: NATEC Project report n°: NA 91 9628/2 Company file n°: 102 GLP. Unpublished	
IIA, 2.5.1/M1	Costantini, G. Camevali, E. Pelizzoli, R. Vecchi, C.	1997	Chemical characterization and assay determination of Methyl-N-malonyl-N-2,6-xylyl-DL-alaninate Source: BIOLAB Project report n°: 97/8281-1 Company file: 151 GLP. Unpublished	
IIA 2.5.1/M2	Costantini, G. Camevali, E. Pelizzoli, R. Vecchi, C.	1997	Chemical characterization and assay determination of N-malonyl-N-2,6-xylyl-DL-alaninate Source: BIOLAB Project report n°: 97/8281-2 Company file: 156 GLP. Unpublished	
IIA 2.6/M1	Costantini, G. Magnani, C	1997	Methyl-N-malonyl-N-2,6-xylyl-DL-alaninate water solubility determination Source: BIOLAB Project report n°: 97/8282-1 Company file: 149 GLP. Unpublished	
IIA 2.6/M2	Costantini, G. Magnani, C	1997	N-malonyl-N-2,6-xylyl-DL-alaninate water solubility determination Source: ISAGRO Project report n°: 97/8282-3 Company file: 154 GLP. Unpublished	
IIA 2.8/M1	Costantini, G. Magnani, C	1997	Methyl-N-malonyl-N-2,6-xylyl-DL-alaninate Partition coefficient determination Source: BIOLAB Project report n°: 97/8282-2 Company file: 150 GLP. Unpublished	

<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>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA 2.8/M2	Costantini, G. Magnani, C	1997	N-malonyl-N-2,6-xylyl-DL-alaninate Partition coefficient determination Source: BIOLAB Project report n°: 97/8282-4 Company file: 155 GLP. Unpublished	
IIA 2.9.4/M1- M2	Brekelmans, M.J.C.	1997	Determination of the dissociation constant(s) of N-malonyl-N-2,6-xylyl- DL-alaninate and Methyl-N-malonyl-N- 2,6-xylyl-DL-alaninate. Source: NOTOX Project report n°: 201961 and 201972 Company file: 140 Not GLP. Unpublished	
IIA, 4.1.2/01	Costantini, G.	1996	Benalaxyl technical active substance - Method set up and validation for Acetamide Derivative and GC/1 – GC/2 diastereomeres determination. Source: BIOLAB Report n°: 96/137 Company file n°.106/1 GLP, Unpublished	
IIA, 4.1.2/02	Costantini, G.	1996	Acetamide Derivative – Chemical characterization and purity determination. Source: BIOLAB Report n°: 96/136 Company file n°.106/2 GLP, Unpublished	
IIA, 4.1.2/03	Costantini, G.	1996	GC/1 and GC/2 diastereomers – Preparation, chemical characterization and purity determination. Source: BIOLAB Report n°: 95/18307 Company file n°.106/3 GLP, Unpublished	
IIA, 4.2.1/02	Zini, G.	1999	Validation of a method for residues of benalaxyl in drinking water, vegetal crops and food of animal origin Source: ISAGRO RICERCA Study n°: 2259 Company file n°: 171 GLP, Unpublished	

<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>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA, 4.2.2/01	Birkinbine, B.A.	1988	Determination of Benalaxyl (Galben) and its main degradation products in selected soil from Blacksburg, Virginia, and Keystone, Florida. Source: Hazleton Laboratories America, Inc. Report: HLA 6012-174 Company file n°: 79/1 GLP, Unpublished	
IIA, 4.2.2/03	Zini, G.	1998	Validation of a method for residues of benalaxyl in sediment. Source: ISAGRO RICERCA Study n°: 2231 Company file n°: 164 GLP, Unpublished	
IIA, 4.2.2/04	Wende, S.	2001	Residue analysis of benalaxyl and three metabolites in soil – Method validation Source: GAB – IFU Report n°: 20011331/01 – RVS Company file n° 195 GLP, Unpublished	
IIA, 4.2.3/01	Zini, G.	1990	Determination of benalaxyl in water at 0,1µg/l (ppb) Source: AGRIMONT Company file n°: 84/1 Not GLP, Unpublished	
IIA, 4.2.3/02	Zini, G	1998	Validation of a method for residues of benalaxyl in water. Source: ISAGRO RICERCA Study n°: 2228 Company file n°: 163 GLP, Unpublished	
IIA 4.2.3/04	Wende, S	2001	Residue analysis of benalaxyl and three metabolites in drinking water – Method validation Source: GAB-IFU Report n° 20011331/01-RVW Company file n°: 196 GLP, Unpublished	
IIA, 4.2.4/01	Heintze, A.	2001	Set up and validation of an analytical method for the determination of benalaxyl in air Source: GAB-IFU Report n°: 20011331/01-CMLU Company file n°: 195 GLP, Unpublished	

**B.6 Toxicology and metabolism**

<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>	<b>Reports on previous use in granting national authorizations</b>
IIA, 5.1.1/03	Triolo, A.	1996	<sup>14</sup> C-Benalaxyl Preliminary pharmacokinetic study in the rat after single oral administration. Source: RBM Study n°: 950606 Company file n°: 111 GLP, Unpublished	
IIA, 5.1.1/04	Triolo, A.	1996	<sup>14</sup> C-Benalaxyl Blood pharmacokinetics, excretion and tissue distribution of radioactivity in the rat after a single oral administration. Source: RBM Study n°: 950607 Company file n°: 112 GLP, Unpublished	
IIA, 5.1.2/01	Triolo, A.	1996	<sup>14</sup> C-Benalaxyl Blood pharmacokinetics, excretion and tissue distribution of radioactivity in the rat after repeated oral administrations. Source: RBM Study n°: 950608 Company file n°: 113 GLP, Unpublished	
IIA, 5.1.3/01	Castoldi, F.C., Pizzingrilli, G.	1997	Profiling of radiolabelled metabolites of <sup>14</sup> C-Benalaxyl in urine and faeces of male rats after single and repeated oral administrations. Source: ISAGRO Ricerca Study n°: R/ABT.96.01 Company file n°: 113/1 GLP, Unpublished	
IIA, 5.2.5/02	Renoldi, A.	1999	Acute eye irritation study in New Zealand white rabbits treated with the test article Benalaxyl Tech. Source: RBM Study n°: 990862 Company file n°: 179 GLP, Unpublished	
IIA, 5.8/01	Ping Yu	1997	Acute oral toxicity study in rats treated with the test article Methyl-N-malonyl-N-2,6-xylyl-DL-alaninate. Source: RBM Study n°: 970683 Company file n°: 146 GLP, Unpublished	

<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>	<b>Reports on previous use in granting national authorizations</b>
IIA, 5.8/02	Ping Yu	1997	Acute oral toxicity study in rats treated with the test article N-malonyl-N-2,6-xylyl-DL-alanine. Source: RBM Study n°: 970684 Company file n°: 147 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>	<b>Reports on previous use in granting national authorizations</b>
IIA 6.3/03	Fabbrini, R.	1991a	Benalaxyl residue determination in tomato samples. Agrimont ISAGRO, Report No. 64 a GLP, Unpublished	
IIA 6.3/04	Fabbrini, R.	1991b	Benalaxyl residue determination in potato samples. Agrimont ISAGRO, Report No. 62 a GLP, Unpublished	
IIA 6.3/05	Fabbrini, R.	1993	Benalaxyl residue determination in grape samples. ISAGRO, Report No. 61 a GLP, Unpublished	
IIA 6.3/07	Pizzingrilli, G.F. Rizzo F.	1994	<sup>14</sup> C-GALBEN determination in potato plants: determination of <sup>14</sup> C-benalaxyl residues in potatoes ISAGRO, Report No. 105 GLP, Unpublished	
IIA 6.3/08	Zini, G.	1993a	Analysis of benalaxyl residues in vine (grape). ISAGRO, Report No. 61 b GLP, Unpublished	
IIA 6.3/09	Zini, G.	1993b	Analysis of benalaxyl residues in vine (grape). ISAGRO, Report No. 61 c GLP, Unpublished	
IIA 6.3/10	Zini, G.	1993c	Analysis of benalaxyl residues in strawberries ISAGRO, Report No. 94/5a GLP, Unpublished	

<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>	<b>Reports on previous use in granting national authorizations</b>
IIA 6.3/11	Zini, G.	1993d	Analysis of benalaxyl residues in tomatoes ISAGRO, Report No. 64 b GLP, Unpublished	
IIA 6.3/12	Zini, G.	1993e	Analysis of benalaxyl and chlorothalonil residues in tomatoes ISAGRO, Report No. 64 c GLP, Unpublished	
IIA 6.3/13	Zini, G.	1993f	Analysis of benalaxyl residues in potatoes ISAGRO, Report No. 62 b GLP, Unpublished	
IIA 6.3/14	Zini, G.	1993g	Analysis of benalaxyl residues in tomatoes. ISAGRO, Report No. 64d GLP, Unpublished	
IIA 6.3/15	Zini, G.	1993h	Analysis of benalaxyl and chlorothalonil residues in tobacco (dried leaves). ISAGRO, Report No. 70 a GLP, Unpublished	
IIA 6.3/16	Zini, G.	1994a	Analysis of benalaxyl residues in tomatoes ISAGRO, Report No. 64 f GLP, Unpublished	
IIA 6.3/17	Zini, G.	1994b	Analysis of benalaxyl residues in vine (grape). ISAGRO, Report No. 61 f GLP, Unpublished	
IIA 6.3/18	Zini, G.	1994c	Analysis of benalaxyl residues in vine (grape). ISAGRO, Report No. 61 g GLP, Unpublished	
IIA 6.3/19	Zini, G.	1994d	Analysis of benalaxyl residues in tomatoes. ISAGRO, Report No. 64 e GLP, Unpublished	
IIA 6.3/20	Zini, G.	1995a	Analysis of benalaxyl residues in vine (grape). ISAGRO, Report No. 61 i GLP, Unpublished	
IIA 6.3/21	Zini, G	1996a	Analysis of benalaxyl residues in melon, watermelon and in lettuce. ISAGRO, Report No. 66.a GLP, UnpublishedN	
IIA 6.3/22	Zini, G	1996b	Analysis of benalaxyl residues in melon, watermelon and in lettuce. ISAGRO, Report No.94/3a GLP, Unpublished	

<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>	<b>Reports on previous use in granting national authorizations</b>
IIA 6.3/23	Zini, G	1996c	Analysis of benalaxyl residues in lettuce. ISAGRO, Report No.94/3.B GLP, Unpublished	
IIA 6.3/24	Zini, G.	1996d	Stability of benalaxyl in grape (bunches) ISAGRO, Report No. 61.0 GLP, Unpublished	
IIA 6.3/25	Zini, G.	1996e	Stability of benalaxyl in potatoes ISAGRO, Report No. 62. c GLP, Unpublished	
IIA 6.3/26	Zini, G.	1996f	Stability of benalaxyl in tomatoes ISAGRO, Report No. 64. h GLP, Unpublished	
IIA 6.3/27	Zini, G	1997a	Analysis of benalaxyl residues in lettuce. ISAGRO, Report No. 94/3d GLP, Unpublished	
IIA 6.3/28	Zini, G	1997b	Analysis of benalaxyl in lettuce. ISAGRO, Report No.94/3f GLP, Unpublished	
IIA 6.3/29	Zini, G.	1997c	Analysis of benalaxyl and mancozeb residues in Watermelon ISAGRO, Report No.66/b GLP, Unpublished	
IIA 6.3/30	Zini, G	1997d	Analysis of benalaxyl and mancozeb residues in lettuce. ISAGRO, Report No.94/3e GLP, Unpublished	
IIA 6.3/31	Zini, G.	1997e	Analysis of benalaxyl and mancozeb residues in lettuce. ISAGRO, Report No.94/3c GLP, Unpublished	
IIA 6.3/32	Zini, G	1998a	Benalaxyl residues in melon. Field trial in Isola S. António - Sale (Alessandria -Italy), 1996 ISAGRO, Report No.66/c GLP, Unpublished	
IIA 6.3/33	Zini, G	1998b	Benalaxyl residues in lettuce. Two field trials in Valencia area (Spain), 1997 ISAGRO, Report No.94/3h GLP, Unpublished	
IIA 6.3/34	Zini, G	1998c	Benalaxyl residues in melon. Field trial in Valencia area (Spain), 1997 ISAGRO, Report No.66 e GLP, Unpublished	

<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>	<b>Reports on previous use in granting national authorizations</b>
IIA 6.3/35	Zini, G	1998d	Benalaxyl residues in lettuce. Field trial in Sallerano Sul Lambro (Lodi-Italy), 1996 ISAGRO, Report No. 94/3g GLP, Unpublished	
IIA 6.3/36	Zini, G	1998e	Benalaxyl residues in melon. Two field trials in Valencia area (Spain), 1997 ISAGRO, Report No.66 f GLP, Unpublished	
IIA 6.3/37	Zini, G	1998f	Benalaxyl residues in watermelon. Field trial in Alluvioni Cambió - Sale (Alessandria - Italy), 1996 ISAGRO, Report No. 66.d GLP, Unpublished	
IIA 6.3/38	Zini, G	1998g	Stability of benalaxyl in grape (must and marc) stored at 20°C, in the dark ISAGRO, Report No 61r GLP, Unpublished	
IIA 6.3/39	Zini, G	1999a	Benalaxyl residues in melon. Field trial in Badia Polesine (Rovigo -Italy), 1998 ISAGRO, Report No.66.H GLP, Unpublished	
IIA 6.3/40	Zini, G.	1999b	Benalaxyl residues in melon. Field trial in San Martino Spino (Modena-Italy), 1998 ISAGRO, Report No.66/I GLP, Unpublished	
IIA 6.5/01	Zini, G.	1992	Benalaxyl residue determination in grape and must samples. / Benalaxyl residue determination in wine samples. ISAGRO, Report No. 61 h GLP, Unpublished	
IIA 6.5/02	Zini, G.	1993	Analysis of benalaxyl residues in wine. ISAGRO, Report No. 61 d GLP, Unpublished	
IIA 6.5/03	Zini, G.	1994	Analysis of benalaxyl residues in vine (grapes, must and wine). ISAGRO, Report No. 61 e GLP, Unpublished	
IIA 6.5/04	Zini, G.	1995a	Analysis of benalaxyl residues in grape (bunch, marc, juice, must and wine) ISAGRO, Report No. 61.L GLP, Unpublished	
IIA 6.5/05	Zini, G.	1995b	Analysis of benalaxyl residues in grape (bunch, marc, juice, must and wine) ISAGRO, Report No. 61.M GLP, Unpublished	

**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>	<b>Reports on previous use in granting national authorizations</b>
IIA,7.1.2/01M1	Scacchi, A., Soddu, R., Pizzingrilli, G.	2002a	Adsorption-desorption of <sup>14</sup> C-methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate (M1) in soil. ISAGRO Ricerca Srl. Report No. MEF.01.10 GLP, Unpublished	
IIA,7.1.2/02M2	Scacchi, A., Pizzingrilli, G.	2002	Adsorption-desorption of <sup>14</sup> C-N-malonyl-N-(2,6-xylyl)-DL-alanine (M2) in soil. ISAGRO Ricerca Srl. Report No. MEF.01.11 GLP, Unpublished	
IIA, 7.1.1./03	A. Scacchi, G. Pizzingrilli	1997	Aerobic degradation of <sup>14</sup> C-methyl-N-malonyl-N-(2,6-xylyl)alaninate in three German standard soils. ISAGRO RICERCA. Study No. R/ABT.97.03 Company file no 143 Generated by: ISAGRO GLP. Unpublished	
IIA, 7.1.1./04	A. Scacchi, G. Pizzingrilli	1997	Aerobic degradation of <sup>14</sup> C-N-malonyl-N-(2,6-xylyl)alanine in three German standard soils. ISAGRO RICERCA. Study No. R/ABT.97.04 Generated by: ISAGRO Submitted by: ISAGRO Company file No.145 GLP, unpublished	
IIA, 7.1.3.1./02	W. Jonas	1993	Assessment of residues in soil samples generated during a field trial active ingredient (parent compound): Benalaxyl. NATEC Institut Report NA 91 9719 + Final report field study on Benalaxyl. NATEC Institut Report NA 91 9180 Enichem Deutschland ISAGRO Company file No.101 + 101/a GLP, Unpublished	
IIA, 7.4.3.1.	J. Hertl	1999	Ready Biodegradability of Benalaxyl tech. in a manometric respiratory test. IBACON – Project: 7201160 ISAGRO Company file No.97/1 GLP, Unpublished	

<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>	<b>Reports on previous use in granting national authorizations</b>
IIA, 7.4.3.2./0 1	A. Scacchi, G. Pizzingrilli	1997	[14C-U-Aniline Ring] benalaxyl: Degradation and Retention in Water- Sediment Systems ISAGRO RICERCA study No. R/ABT96.03 ISAGRO Company file No. 116 GLP, Unpublished	
IIA, 7.7./01	M. Anthe	1996	Benalaxyl: Estimation of the rate of photochemical transformation in the atmosphere under trpospheric conditions. SCC Project No. 165-005 ISAGRO Company file No. 139 GLP, Unpublished	

**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>	<b>Reports on previous use in granting national authorizations</b>
IIA 8.2/01	Rodgers, M.H., Cameron, D.M., Fischer, E.	2001	Assessment to Determine the Effects on Reproduction in the Bobwhite quail HLS-Report AGR 121/003916 Company file no 189 ISAGRO, Milano, Italy GLP, Unpublished	
IIA, 8.2.1.1./0 5	T.L. Hamaker	1994	Bluegill sunfish 96 hour static acute toxicity test with GALBEN. Environmental Research & Technology Inc., Farmoplant Report no. B941-100 ISAGRO Company file No. 42 GLP, Unpublished	
IIA, 8.2.1.1./0 6	M. Bogers	1997	96-hour acute toxicity study in rainbow trout with Methyl-N-malanoyl- N-2,6-xylyl-DL-alaninate (static) NOTOX Project 211005 ISAGRO Company file No. 159 GLP, Unpublished	

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	Reports on previous use in granting national authorizations
IIA, 8.2.1.1./0 7	M. Bogers	1997	96-hour acute toxicity study in rainbow trout with N-malanoyl-N-2,6-xylyl-DL-alanine (static) NOTOX Project 210994 ISAGRO Company file No. 160 GLP, Unpublished	
IIA, 8.2.2.1./0 1	W. Jonas	1992	Benalaxyl prolonged toxicity test on the Rainbow Trout ( <i>Oncorhynchus mykiss</i> ). NATEC Institut Report NA 91 9628 Enichem Deutschland Company file no 100 GLP, Unpublished	
IIA, 8.2.5.1./0 1	W. Jonas	1993	Benalaxyl reproduction test on <i>Daphnia magna</i> . Here: Acute Immobilisation test on <i>Daphnia magna</i> . Addendum to the study Report NA 90 9455 Enichem Deutschland ISAGRO Company file No. 99/1 GLP, Unpublished	
IIA, 8.2.5.1./0 2	P. Gnemi,G. Zanolo, P. Zaninelli	1997	Methyl-N-malanoyl-N-2,6-xylyl-DL-alaninate: Acute immobilization study in <i>Daphnia magna</i> . RBM Exp. No. 970568 ISAGRO Company file No. 152 GLP, Unpublished	
IIA, 8.2.5.1./0 3	P. Gnemi,G. Zanolo, P. Zaninelli	1997	N-malanoyl-N-2,6-xylyl-DL-alanine: Acute immobilization study in <i>Daphnia magna</i> . RBM Exp. No. 970570 ISAGRO Company file No. 157 GLP, Unpublished	
IIA, 8.2.6.1./0 1	W. Jonas	1992	Benalaxyl reproduction test on <i>Daphnia magna</i> . Report NA 90 9455 Enichem Deutschland ISAGRO Company file No. 99 GLP, Unpublished	

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	Reports on previous use in granting national authorizations
IIA, 8.2.8.1./0 2	P. Gnemi, G. Zanolo, P. Zaninelli	1997	Methyl-N-malanoyl-N-2,6-xylyl-DL- alaninate: Algal growth inhibition study. RBM Exp. No. 970569 Submitted by: ISAGRO Company file No. 153 GLP, Unpublished	
IIA, 8.2.6.2./0 1 IIIA, 9.2.3.2./0 1	M. Knoch	1996	Assessment of toxic effects of GALBEN M 8 - 65 on <i>Daphnia magna</i> using the 21 Day reproduction test (OECD 202.2). GAB IFU study code 95192/02-ARDm ISAGRO Company file: GM 039 GLP, Unpublished	
IIA, 8.2.8.2./0 1 IIIA, 9.2.4./01	D. Dengler	1996	Testing of toxic effects of GALBEN M 8 - 65 on the single cell green alga <i>Scenedesmus subspicatus</i> GAB IFU study code 95192/01-AASs Submitted by ISAGRO Company file: GM 037	
IIA, 8.4.1.2./0 1 IIIA, 9.3.1/01	R. Petto, H.E. Knoell	1992	Toxicity testing of GALBEN M 8-65 to honey bees ( <i>Apis mellifera</i> L.) (Hymenoptera, Apidae) in laboratory. RCC Umweltchemie GmbH & Co. Project 250942 Enichem Deutschland ISAGRO Company file: GM17 GLP, Unpublished	
IIA, 8.4.9.2./0 1 IIIA, 9.3.2./01	U. Decker, P. Althaus, L. Ullmann	1992	The effects of GALBEN M 8-65 on Imagines of <i>Poecilus cupreus</i> L. (Coleoptera: carabidae) in the laboratory. RESEARCH & CONSULTING COMPANY AG Project RCC 307923 Enichem Deutschland ISAGRO Company file: GM15 GLP, Unpublished	

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	Reports on previous use in granting national authorizations
IIIA 9.3.2./02 IIA, 8.4.9.2./0 2	R. Petto, H.E. Knoell	1992	Effects of GALBEN M 8-65 on <i>Trichogramma cacoeciae</i> Marchal (Hymenoptera, Trichogrammatidae) in laboratory. RCC Umweltchemie GmbH & Co. Project 250931 Enichem Deutschland ISAGRO Company file: GM16 GLP, Unpublished	
IIA, 8.4.9.2./0 3 IIIA, 9.3.2./03	U. Decker, T. Porricello, H. Becker	1992	The effects of of Larval and Pupal exposure to GALBEN M 8-65 on <i>Syrphus corollae</i> Fabr. (syn.: <i>Eupeodes corollae</i> (Diptera: Syrphidae) in the laboratory. RESEARCH & CONSULTING COMPANY AG Project RCC 307934 Enichem Deutschland ISAGRO Company file: GM18 GLP, Unpublished	
IIA, 8.3.2/07 IIIA,10.5.1 /06	Moll, M., Butzler, R.	2002	Effects of GALBEN M 8-65 on adults of the parasitoid <i>Trichogramma</i> <i>cacoeciae</i> under extended laboratory conditions (aged residue test). IBACON report n° 10852026 Company file n° GM 104 GLP, Unpublished	
IIA, 8.3.2/08 IIIA,10.5.1 /07	Schwiening, S.	2002	Effects of GALBEN M 8-65 on the predatory mite <i>Typhlodromus pyri</i> under extended laboratory conditions (aged residue test) IBACON Report n° 9102062 Company file n° GM 105 GLP, Unpublished	
IIA, 8.03.02/0 9	Drexler, A.	2001a	Effects of GALBEN M 8-65 on the Lacewing <i>Chrysoperla carnea</i> - Extended Laboratory Study. IBACON Report No.10851047 GLP, Unpublished	
IIA, 8.03.02/1 1	Drexler, A.	2001b	Effects of use of GALBEN M 8-65 on predatory mites in grape vine yards (field experiment). IBACON Report No. 9101064 Company file No GM103 GLP, Unpublished	

<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>	<b>Reports on previous use in granting national authorizations</b>
IIA, 8.03.02/1 3M1	Meister, A.	2002b	Effects of N-malonyl-N-(2,6-xylyl)-DL-alanine on reproduction of the Collembola Folsomia candida in artificial soil IBACON Report No: 12293016 Company file No 219 GLP, Unpublished	
IIA, 8.03.02/1 4M2	Meister, A.	2002c	Effects of methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate on reproduction of the Collembola Folsomia candida in artificial soil. IBACON Report No: 12283016 Company file No 220 GLP, Unpublished	
IIA, 8.04.01/0 4M1	Luhrs, U.	2001a	Acute toxicity (14 days) of methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate to the earthworm Eisenia fetida in artificial soil IBACON Report No.12281021 Company file No 197 GLP, Unpublished	
IIA, 8.04.01/0 5M2	Luhrs, U.	2001b	Acute toxicity (14 days) of N-malonyl-N-(2,6-xylyl)-DL-alanine to the earthworm Eisenia fetida in artificial soil. IBACON Report No.1229102 Company file No 198 GLP, Unpublished	
IIA, 8.04.02/0 2	Luhrs, U.	2002a	Revised version No. 1. Effects of Benalaxyl technical on reproduction and growth of earthworms Eisenia fetida in artificial soil. IBACON Report No: 12371022 Company file No 202 GLP, Unpublished	
IIA, 8.04.02/0 3M1	Luhrs, U.	2002b	Effects of methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate on reproduction and growth of earthworms Eisenia fetida in artificial soil. IBACON Report No: 12282022. Company file No 212 GLP, Unpublished	
IIA, 8.04.02/0 4M2	Luhrs, U.	2002c	Effects of N-malonyl-N-(2,6-xylyl)-DL-alanine on reproduction and growth of earthworms Eisenia fetida in artificial soil. IBACON Report No: 12292022 Company file No 218 GLP, Unpublished	

<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>	<b>Reports on previous use in granting national authorizations</b>
IIA, 8.05/03M 1	Volkel, W.	2002a	The effects of methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate (soil metabolite of benalaxyl) on soil respiration and nitrification. RCC Report No: 7841173 Company file n° 213 GLP, Unpublished	
IIA, 8.05/04M 2	Volkel, W.	2002b	The effects of N-malonyl-N-(2,6-xylyl)-DL-alanine (soil metabolite of benalaxyl) on soil respiration and nitrification. RCC Report No: 841174 Company file n° 214 GLP, Unpublished	

**APPENDIX IIIB****BENALAXYL**

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**

<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, 1.11/02	Costantini, G.	2001	Quantitative determination of the active substance (benalaxyl) and impurities (acetamide derivative and GC/1-GC/2 diastereoisomers) in five batches of Benalaxyl Technical grade Source: BIOLAB Project report n° AM0044 Company file n°: 187 GLP, Unpublished CONFIDENTIAL
IIA, 1.11/03	Fenizi, V Borgatti, C	2002	Benalaxyl technical – Five batches analysis Source: ISAGRO Ricerca Study n°: FR 00128 Company file n°: 226 GLP, Unpublished CONFIDENTIAL
IIA, 4.2.2/04	Wende, S.	2001	Residue analysis of benalaxyl and three metabolites in soil – Method validation Source: GAB - IFU Report n°: 20011331/01-RVS Company file n°.195 GLP, Unpublished
IIA, 4.2.3/04	Wende, S.	2001	Residue analysis of benalaxyl and three metabolites in drinking water – Method validation Source: GAB - IFU Report n°: 20011331/01-RVW Company file n°.196 GLP, Unpublished
IIA, 4.2.4/01	Heintze, A.	2001	Set up and validation of an analytical method for the determination of benalaxyl in air Source: GAB - IFU Report n°: 20011331/01- CMLU Company file n°.195 GLP, Unpublished

**B.6 Toxicology and metabolism**

<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, 5.1.5	Kemp, L.	2001	[ <sup>14</sup> C]-benalaxyl - Biliary excretion study in the rat. Source: Huntingdon Life Sciences Study n°: IGA 001/012155 Company file n°: 188 GLP, Unpublished
IIA, 5.2.3/02	Dotti, A.	2000	Benalaxyl Tech. 4-hour acute inhalation toxicity study in the rat. Source: RBM Study n°: 990864 Company file n°: 180 GLP, Unpublished
IIA, 5.4.1/02	Wollny, H.E.	2002	<i>Salmonella Thyphimurium</i> reverse mutation assay with benalaxyl. Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR Project 709401 GLP, Unpublished
IIA, 5.4.1/09	Schulz, M	2002	<i>In vitro</i> chromosome aberration test in Chinese Hamster Ovary (CHO) cells with benalaxyl. Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR 709404 GLP, Unpublished
IIA, 5.4.2/02	Golzio, L.	2000	Micronucleus induction in bone marrow cells of rats treated by intraperitoneal route with the test article Benalaxyl Tech. Source: RBM Study n°: 990863 Company file n°: 181 GLP, Unpublished
IIA, 5.5/04	Maltoni, C.	2000	Carcinogenicity study in the mouse: Data on historical controls – Swiss mice. Attachment to the Final Report – Study No BT 5004: Evaluation of Chronic Toxicity and Oncogenic Potential of GALBEN® (CAS No. 71626-11-49 IN Swiss Mice(Oral Dosing Study) No GLP, Unpublished
IIA, 5.5/05	Millar, P.M.	2001	BT 5004: Evaluation of chronic toxicity and oncogenic potential of Galben© (CAS No. 71626-11-4) in Swiss mice (oral dosing study). Pathology Peer Review of Urinary Bladder Tumours. Source: P.M. Millar 22 Inverleith Gardens, Edinburgh. GLP, Unpublished
IIA, 5.5/06	Millar, P.M.	2001	BT 5004: Evaluation of chronic toxicity and oncogenic potential of Galben© (CAS No. 71626-11-4) in Swiss mice (oral dosing study). Report of the Pathology Working Group on Urinary Bladder Tumours. Source: P.M. Millar 22 Inverleith Gardens, Edinburgh No GLP, Unpublished

<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, 5.8.2/01	Wollny, H.E.	2002	<i>Salmonella Thyphimurium</i> reverse mutation assay with methyl-N-malonyl-N-(2,6-xylyl)-D,L-alaninate Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR Project 709402 GLP, Unpublished
IIA, 5.8.2/02	Wollny, H.E.	2002	Cell mutation assay at the Thymidine kinase locus (TK <sup>+/+</sup> ) in mouse lymphoma L5178Y cells with methyl-N-malonyl-N-(2,6-xylyl)-D,L-alaninate. Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR Project 709407 GLP, Unpublished
IIA, 5.8.2/03	Schulz, M.	2002	<i>In vitro</i> chromosome aberration test in Chinese Hamster Ovary (CHO) cells with methyl-N-malonyl-N-(2,6-xylyl)-D,L-alaninate. Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR 709405 GLP, Unpublished
IIA, 5.8.2/04	Pritchard, L. and Knights, S.	2002	Compound A - M1: <i>In vitro</i> mammalian chromosome aberration test in human lymphocytes. Source: Huntingdon Life Science Ltd. Study n°: IGA 023/023175 GLP, Unpublished
IIA, 5.8.2/05	Honarvar, N.	2002	Micronucleus assay in bone marrow cells of the mouse with methyl-N-malonyl-N-(2,6-xylyl)-D,L-alaninate. Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR 736600 GLP, Unpublished
IIA, 5.8.2/06	Wollny, H.E.	2002	<i>Salmonella Thyphimurium</i> reverse mutation assay with N-malonyl-N-(2,6-xylyl)-D,L-alanine. Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR Project 709403 GLP, Unpublished
IIA, 5.8.2/07	Wollny, H.E.	2002	Cell mutation assay at the Thymidine kinase locus (TK <sup>+/+</sup> ) in mouse lymphoma L5178Y cells with N-malonyl-N-(2,6-xylyl)-D,L-alanine. Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR 709408 GLP, Unpublished
IIA, 5.8.2/08	Schulz, M.	2002	<i>In vitro</i> chromosome aberration test in Chinese Hamster Ovary (CHO) cells with N-malonyl-N-(2,6-xylyl)-D,L-alanine. Source: RCC Cytotest Cell Research GMBH Study n°: RCC-CCR 709406 GLP, Unpublished

<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, 5.8.3/01	Kumar, Santhosh D.P.	2003	Repeated dose (90-days) oral toxicity study with methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate (compound A-M1) in Wistar rats Rallis Research Centre Report No TOXI-3383/02 (080/1-A-M1/90-OR) GLP Unpublished.
IIA, 5.8.3/02	Stanley, Abrahaman	2003	Repeated dose (90-days) oral toxicity study with N-malonyl-N-(2,6-xylyl)-DL-alanine (compound B-M2) in Wistar rats Rallis Research Centre Report No TOXI-3402/02 (080/2-B-M2/90-OR) 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>

**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>
IIA, 7.1.2/01M 1	Scacchi, A., Soddu, R., Pizzingrilli, G.	2002a	Adsorption-desorption of <sup>14</sup> C-methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate (M1) in soil. ISAGRO Ricerca Srl. Report No. MEF.01.10 GLP, Unpublished
IIA, 7.1.2/02M 2	Scacchi, A., Pizzingrilli, G.	2002	Adsorption-desorption of <sup>14</sup> C-N-malonyl-N-(2,6-xylyl)-DL-alanine (M2) in soil. ISAGRO Ricerca Srl. Report No. MEF.01.11 GLP, Unpublished
IIA, 7.1.3.3/01	Diehl, M.	2003	First Interim Report – Benalaxyl: Mobility and Degradation in soil in Outdoor Lysimeters. RCC Report n° 841308 Company file n° 2311 GLP. Unpublished
IIA, 7.3/01	Gross, R	2001	Calculation of Predicted Environmental Concentrations and Estimation of the Accumulation Potential of Methyl-N-(2,6-xylyl)-N-malonyl-alaninate (Mono-acid, M1) and N-(2,6-xylyl)-N-malonyl-alanin (Bi-acid, M2) in soil SCC Project No. 165 021 ISAGRO, Milano, Italy GLP, unpublished

**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, 8.3.2/07 IIIA, 10.5.1/06	Moll, M., Butzler, R.	2002	Effects of GALBEN M 8-65 on adults of the parasitoid <i>Trichogramma cacoeciae</i> under extended laboratory conditions (aged residue test). IBACON report n° 10852026 Company file n° GM 104 GLP, Unpublished
IIA 8.2/01	Rodgers, M.H., Cameron, D.M., Fischer, E.	2001	Assessment to Determine the Effects on Reproduction in the Bobwhite quail HLS-Report AGR 121/003916 Company file no 189 ISAGRO, Milano, Italy GLP, Unpublished
IIA, 8.3.2/08 IIIA, 10.5.1/07	Schwiening, S.	2002	Effects of GALBEN M 8-65 on the predatory mite <i>Typhlodromus pyri</i> under extended laboratory conditions (aged residue test) IBACON Report n° 9102062 Company file n° GM 105 GLP, Unpublished
IIA, 8.3.2/09	Drexler, A.	2001 a	Effects of GALBEN M 8-65 on the Lacewing <i>Chrysoperla carnea</i> - Extended Laboratory Study. IBACON Report No.10851047 GLP, Unpublished
IIA, 8.3.2/11	Drexler, A.	2001 b	Effects of use of GALBEN M 8-65 on predatory mites in grape vine yards (field experiment). IBACON Report No. 9101064 Company file No GM103 GLP, Unpublished
IIA, 8.03.02/1 3M1	Meister, A.	2002 b	Effects of N-malonyl-N-(2,6-xylyl)-DL-alanine on reproduction of the <i>Collembola Folsomia candida</i> in artificial soil IBACON Report No: 12293016 Company file No 219 GLP, Unpublished
IIA, 8.03.02/1 4M2	Meister, A.	2002 c	Effects of methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate on reproduction of the <i>Collembola Folsomia candida</i> in artificial soil. IBACON Report No: 12283016 Company file No 220 GLP, Unpublished
IIA, 8.04.01/0 4M1	Luhrs, U.	2001 a	Acute toxicity (14 days) of methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate to the earthworm <i>Eisenia fetida</i> in artificial soil IBACON Report No.12281021 Company file No 197 GLP, Unpublished

<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, 8.04.01/0 5M2	Luhrs, U.	2001 b	Acute toxicity (14 days) of N-malonyl-N-(2,6-xylyl)-DL-alanine to the earthworm <i>Eisenia fetida</i> in artificial soil. IBACON Report No.1229102 Company file No 198 GLP, Unpublished
IIA, 8.04.02/0 2	Luhrs, U.	2002 a	Revised version No. 1. Effects of Benalaxyl technical on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil. IBACON Report No: 12371022 Company file No 202 GLP, Unpublished
IIA, 8.04.02/0 3M1	Luhrs, U.	2002 b	Effects of methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil. IBACON Report No: 12282022. Company file No 212 GLP, Unpublished
IIA, 8.04.02/0 4M2	Luhrs, U.	2002 c	Effects of N-malonyl-N-(2,6-xylyl)-DL-alanine on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil. IBACON Report No: 12292022 Company file No 218 GLP, Unpublished
IIA, 8.05/03M 1	Volkel, W.	2002 a	The effects of methyl-N-malonyl-N-(2,6-xylyl)-DL-alaninate (soil metabolite of benalaxyl) on soil respiration and nitrification. RCC Report No: 7841173 Company file n° 213 GLP, Unpublished
IIA, 8.05/04M 2	Volkel, W.	2002 b	The effects of N-malonyl-N-(2,6-xylyl)-DL-alanine (soil metabolite of benalaxyl) on soil respiration and nitrification. RCC Report No: 841174 Company file n° 214 GLP, Unpublished
IIIA, 10.8	Signorini, E.; Fossati, N.	1997	Biological Activity of Benalaxyl metabolites M1 and M2. Fungicidal Activity on <i>Phytophthora infestans</i> and <i>Pythium ultimum</i> (Laboratory study) ISAGRO RICERCA Report n° 1/FVT 97 Company file n° 142 Non GLP, Unpublished

## APPENDIX IV

## List of uses supported by available data

## BENALAXYL

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		
Grapes	N,S	GALBEN M	F	<i>Plasmopara viticola</i> (Downy mildew) <i>Guignardia bidwellii</i> (Black rot) <i>Pseudopeziza tracheiphyla</i> (Rot Brenner) <i>Phomopsis viticola</i> (Escoriose)	WP	8% <sup>1</sup>	"	Start application when favourable conditions for the disease occur, from cluster formation and not later than fruit setting	2-4	12-14	0,02	1000	0,2	42	
Tomato	N,S	GALBEN M	F	<i>Phytophthora infestans</i> (Late blight) <i>Phytophthora parasitica</i> (Foot rot)	WP	8% <sup>1</sup>	"	Start application when favourable conditions for disease occur.	4	12-14	0,024	1000	0,24	14	
Melon	S	GALBEN M	F	<i>Pseudoperonospora cubensis</i>	WP	8% <sup>1</sup>	"	from 6-8 leaves stage to the beginning of ripening (fruit size 5-10 cm)	2-3	7-15	0,02	1000	0,200	7	
Watermelon	S	GALBEN M	F	<i>Pseudoperonospora cubensis</i>	WP	8% <sup>1</sup>	"	from 6-8 leaves stage to the beginning of ripening (fruit size 5-10 cm)	2-3	7-15	0,02	1000	0,200	7	
Lettuce	S	GALBEN M	F	<i>Bremia lactucae</i> (Downy mildew)	WP	8% <sup>1</sup>	"	start at beginning of the spray season	2-3	10-15	0,02	1000	0,2	14	

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		
Potatoes	N	GALBEN M	F	<i>Phytophthora infestans</i> (Late blight)	WP	8% <sup>i</sup>	<sup>iii</sup>	start at beginning of the spray season when haulm growth is most rapid prior to the crop becoming infected	3-4	10-14	0,02-0,09	222-800	0,16-0,2	7-14	
Potatoes	S	GALBEN M	F	<i>Phytophthora infestans</i> (Late blight)	WP	8% <sup>i</sup>	<sup>ii</sup>	start at beginning of the spray season when haulm growth is most rapid prior to the crop becoming infected	4	10-14	0,024	1000	0,24	14	
Flowers and ornamental plants		GALBEN M	F	<i>Pythium</i> spp. <i>Phytophthora</i> spp. <i>Pseudoperonospora</i> spp. <i>Aphanomyces</i> spp.	WP	8% <sup>i</sup>	<sup>ii</sup>	Start at beginning of the spray season	-	-	0,024	1000	0,24	-	

- 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

<sup>i</sup> Wettable powder containing 65% mancozeb

<sup>ii</sup> High volume spraying - hydraulic tractor mounted field crop sprayer, portable sprayer or air-assisted fruit tree sprayer

<sup>iii</sup> Low volume spraying - hydraulic tractor mounted field crop sprayer, portable sprayer or air-assisted fruit tree sprayer