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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Picolinafen

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

Review report for the active substance **picolinafen**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 19 April 2002 in view of the inclusion of picolinafen 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 picolinafen, 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 German authorities received on 10 May 1999 an application from BASF (formerly Cyanamid), hereafter referred to as the applicant, for the inclusion of the active substance picolinafen in Annex I to the Directive. German authorities indicated to the Commission on 3 June 1999 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 picolinafen was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on Plant Health in the meeting of the working group 'legislation' thereof on 10 June 1999, 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 1999/555/EC¹ of 2 July 1999 that these requirements were satisfied.

¹ OJ No L210, 10.08 1999, p.22.

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 Germany, as rapporteur Member State would carry out the detailed examination of the dossier and report the conclusions of the 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.

Germany submitted to the Commission on 21 December 2000 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 picolinafen in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States on 15 November 2000 as well as to BASF being the sole applicant on 21 December 2000.

Further discussion between the Rapporteur Member State and the United Kingdom acting as Co-rapporteur Member State were organised, to review the draft assessment report and the comments received thereon 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 report of this peer review (i.e. the Reporting Table) was circulated, for further consultation, to Member States and the sole applicant on 30 August 2001.

The dossier, revised draft assessment report and the peer review report (i.e. Reporting Table) including in particular an outline resumé of the remaining technical questions, were referred to the Standing Committee on Plant 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 October 2002 to December 2002, and was finalised in the meeting of the Standing Committee on 19 April 2002.

The present review report contains the conclusions of this final examination; given the importance of the revised draft assessment report, the peer review report (i.e. Reporting Table) and the comments and clarifications submitted after the revision of the draft assessment report 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.

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

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 2002/64/EC of 18 July 2002 concerning the inclusion of picolinafen in Annex I to Directive 91/414/EEC² and to assist the Member States in decisions on individual plant protection products containing picolinafen 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 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 picolinafen 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 picolinafen containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the following uses which were proposed and supported by the sole submitter:

- herbicide in winter cereals with a application rate up to 0.1 kg a.s./ha

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

² OJ L 189 18.07.2002 p45

requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of picolinafen in foodstuffs

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) for a 60 kg adult is 11 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

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 picolinafen are given in Appendix I.

The active substance shall have a minimum purity of >970 g/kg technical product.

The review has established that for the active substance notified by the applicant (BASF), 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 picolinafen

On the basis of the proposed and supported uses (max. application rate of 0.1 kg a.s./ha), the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Particular attention should be paid to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

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 picolinafen in Annex I.

When granting authorisations Member States may also require additional information to ensure protection of surface water bodies. Also a refined assessment of dermal absorption may be required to ensure protection of operators.

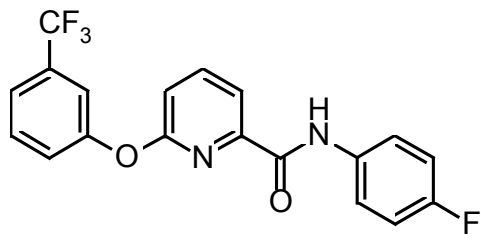
9. Updating of this review report

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 picolinafen in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

PICOLINAFEN

Common name (ISO)	picolinafen (ISO, proposed)
Development Code (for new actives only)	AC 900001 (AC 900,001) CL 900001 (CL 900,001) WL 161616 BAS 700 H
Chemical name (IUPAC)	4'-Fluoro-6-[(α,α,α -trifluoro-m-tolyl)oxy]picolinanilide
Chemical name (CA)	N-(4-Fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]-2-pyridinecarboxamide
CIPAC No	639
CAS No	137641-05-5
EEC No	not assigned
FAO SPECIFICATION	not available
Minimum purity	970 g/kg
Molecular formula	C ₁₉ H ₁₂ F ₄ N ₂ O ₂
Molecular mass	376.3
Structural formula	

Melting point	Melting range: 107.2 - 107.6 °C (PAS 98.7 %)	
Boiling point	No defined boiling point observable, decomposition at > 230 °C (PAS 98.7 %)	
Appearance	fine crystalline white to chalky solid with musty smell (PAS 98.7 %)	
Relative density	1.45 g/cm ³ (PAS 98.7 %)	
Vapour pressure	1.7 · 10 ⁻⁷ Pa (20 °C, extrapolated, PAS 99.5 %)	
Henry's law constant	1.6 · 10 ⁻³ Pa m ³ mol ⁻¹ (20 °C)	
Solubility in water	pH 5 buffer: 3.8 · 10 ⁻⁵ g/l pH 7 buffer: 4.7 · 10 ⁻⁵ g/l pH 9 buffer: 3.8 · 10 ⁻⁵ g/l DI water: 3.9 · 10 ⁻⁵ g/l (at 20°C:)	
Solubility in organic solvents	<u>TAS (97.8 %), 20 °C</u> acetone: 557 g/l dichloromethane: 764 g/l ethyl acetate: 464 g/l n-hexane: 3.8 g/l methanol: 30.4 g/l toluene: 263 g/l	
Partition co-efficient (log P_{ow})	solvent	log P _{ow}
	DI water	5.37
	pH 5 buffer	5.36
	pH 7 buffer	5.43
	pH 9 buffer	5.36
Hydrolytic stability (DT₅₀)	Stable at pH 4, 7 and 9 (5 d, 50 °C)	
Dissociation constant	No dissociation between pH 2 – 12	
Quantum yield of direct photo-transformation in water at ε >290 nm	2.14 · 10 ⁻⁶	
Flammability	not highly flammable	
Explosive properties	not explosive	
UV/VIS absorption (max.)	202 nm: ε=39500 [l mol ⁻¹ cm ⁻¹] 230 nm: ε=14600 [l mol ⁻¹ cm ⁻¹] (shoulder) 290 nm: ε=13000 [l mol ⁻¹ cm ⁻¹]	
Photostability in water (DT₅₀)	Xe-lamp (λ > 290 nm), continuous irradiation (7 d) pH 5 buffer: 25 d (23 °C) pH 7 buffer: 31 d (23 °C) pH 9 buffer: 23 d (23 °C)	

APPENDIX II

END POINTS AND RELATED INFORMATION

PICOLINAFEN

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapidly absorbed (60% based on urinary and biliary excretion within 48 h for males at low dose)
Distribution:	Widely distributed
Potential for accumulation:	No evidence for accumulation (<0.5% after 7 days: highest residues of the aniline-label in blood and spleen)
Rate and extent of excretion:	Rapidly excreted, ca. 88% within 48 h via urine (48/62% for males/females) and feces
Toxicologically significant compounds:	Parent compound and metabolites
Metabolism in animals:	Extensively metabolised (>87%) by hydrolytic cleavage (to substituted picolinic acid and <i>p</i> -fluoroaniline), oxidation, acetylation, and subsequent glucuronide and sulfate conjugations

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 4000 mg/kg bw
Rat LC ₅₀ inhalation:	> 5.9 mg/L (4 h, dust, nose only)
Skin irritation:	Non-irritating
Eye irritation:	Non-irritating
Skin sensitization (test method used and result):	Non-sensitizer (M & K)

Short term toxicity

Target / critical effect:	Red blood cells, spleen, liver (hemolysis); thyroid (hypertrophy, dog)
Lowest relevant oral NOAEL / NOEL:	90d overall dog (90 d + 1yr study): 150 ppm (5.2 mg/kg bw/d) 1yr dog: 50 ppm (1.4 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL:	28d rat: 50 mg/kg bw/d
Lowest relevant inhalation NOAEL /	No data - not required

NOEL:

Genotoxicity

No genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:

Red blood cells, spleen (hemolysis); liver (hypertrophy)

Lowest relevant NOAEL:

2yr rat: 50 ppm (2.4 mg/kg bw/d)

Carcinogenicity:

No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:

No effects on reproduction

Lowest relevant reproductive NOAEL / NOEL:

2gen rat: > 500 ppm (43 mg/kg bw/d)

Target / critical effect - Developmental toxicity:

Increased resorption rate; decreased fetal body weights at maternal toxic doses (rabbit)

Lowest relevant developmental NOAEL / NOEL:

Rabbit: 5 mg/kg bw/d

Delayed neurotoxicity

No data - not required

Other toxicological studies

No data - not required

Medical data

Limited; new compound

Summary

	Value	Study	Safety factor
ADI:	0.014 mg/kg bw	1yr dog	100
AOEL systemic:	0.03 mg/kg bw/d	90d + 1y dog, 60% absorption	100
ARfD (acute reference dose):	0.05 mg/kg bw/d	developmental rabbit	100

Dermal absorption

25 % (based on comparison of oral and dermal toxicity)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

aniline label: 17.4 % (61 d) (n=1)
pyridine label: 22.8 - 43.0 % (100 d) (n=4)

Non-extractable residues after 100 days:

aniline label: 43.9 % (61 d), max. 65 % (134 d);
pyridine label: 21.2 % (100 d), max. 22.7 (60 d)
(n=1)

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

CL 153815 (range 23.9 (14 d) – 43.6 % (30 d),
max. 54 %), end of study: 1.4 - 4.9 % (150 d, 122
d), (n=4)

Supplemental studies

Anaerobic:

DT₅₀: 6 – 7 days (2nd order)
DT₉₀: 58 – 73 days (2nd order)
CL 7693 (range 0 - 8 %, max. 8 %, day 120)
CL 153815 (range 35 - 88 %, max. 88 %, day 63)

Soil photolysis:

stable to photolysis (DT₅₀: 30.2 days)

Remarks:

None

Rate of degradation

Laboratory studies

DT_{50lab} (20 °C, aerobic):

DT_{50lab} (20°C, aerobic):
1-14 d (n=4), r²= >0.95 ($\sqrt{1}$ st order),
recalculation by 1st order:
Speyer 2.2 (aniline-¹⁴C): 46 d (r²= 0.9574)
Speyer 2.2 (pyridine-¹⁴C): 50 d (r²= 0.8198)
Engelstadt/Benz: 51d (r²= 0.4937)
Ingelheim/Moers: 47 d (r²= 0.5475)
Kloppenheim/Untere Gewann: 46 d (r²= 0.5656)
CL 153815 (20°C, aerobic): 30-77 days (n=4),
r²= >0.96

DT_{90lab} (20 °C, aerobic):

DT_{90lab} (20°C, aerobic): 34-149 d (n=4), r²=>0.95
($\sqrt{1}$ st order)

DT_{50lab} (10 °C, aerobic):

DT_{50lab} (8°C, aerobic): pyridine label, 7 d ($\sqrt{1}$ st
order), n=1, r²= >0.95

DT_{50lab} (20 °C, anaerobic):DT_{50lab} (20°C, anaerobic): aniline label, 7 d ($\sqrt{1}$ st order), $r^2=0.98$, $n=1$, pyridine label, 6 d, $r^2=0.99$, $n=1$ (2nd order)**Field studies (country or region)**DT_{50f} from soil dissipation studies:DT_{50f}: 9-64 d (n=8), average 30 d (1st order)
locations: 4 in Germany, 3 in France, 1 in UK
CL 153815: 19-107 d (N=8)DT_{90f} from soil dissipation studies:DT_{90f}: 56-212 d (n=8) average, 107 d

Soil accumulation studies:

DT₅₀ is < 3 months and DT₉₀ is < 1 yr., picolinafen is not expected to accumulate in the soil

Soil residue studies:

not required

Remarks:

e.g. effect of soil pH on degradation rate

None

Adsorption/desorptionK_f / K_{oc}:Picolinafen
K_d: 248 - 764 l/kg , K_{oc}: 15,000 - 31,800 l/kg
(n = 4)K_d:CL 153815
K_d: 6.3 - 16.2 l/kg, K_{oc}: 160 - 783, mean 440 kg/l
(n = 4)

pH dependence:

Yes. Stronger binding was observed in acidic soils.

Mobility**Laboratory studies:**

Column leaching:

column leaching study with picolinafen 750 g ai/kg WG formulation showed <0.1 % applied radioactivity in leachate (~200 mm percolate).

Aged residue leaching:

leachates contained 0 - 0.09 % of applied radioactivity (~200 mm percolate)

Field studies:

Lysimeter/Field leaching studies:

not required. Field studies showed no picolinafen in depth below 10 cm

Remarks:

None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

Major metabolites:

Photolytic degradation:

Major metabolites:

Stable at pH 4, 7 and 9 (5 d, 50 °C)
none
Xe-lamp ($\lambda > 290$ nm), continuous irradiation (7 d), DT ₅₀ : pH 5 buffer: 25 d (23 °C) pH 7 buffer: 31 d (23 °C) pH 9 buffer: 23 d (23 °C)
none

Biological degradation

Readily biodegradable:

Water/sediment study:

DT₅₀ water:DT₉₀ water:DT₅₀ whole system:DT₉₀ whole system:Distribution in water / sediment systems
(active substance)Distribution in water / sediment systems
(metabolites)

Accumulation in water and/or sediment:

No
Mineralization: 2.5 % AR after 100 d Non-extractable residues: 64 – 83 % AR after 100 d
DT ₅₀ water: 1.1 – 1.4 d (sqrt 1 st order, 1 st order, n = 2) DT ₉₀ water: 4.5 - 12.1 (1 st order, sqrt 1 st order, n = 2) DT ₅₀ whole system: 6.2 d (1 st order, n = 2) DT ₉₀ whole system: 20.5 d (1 st order, n = 2)
Water: 22.7 – 52.2 % AR (day 0 sample), 0 % AR after 30 d; sediment: max. 39 – 68.6 % AR (day 0 sample), 0 – 1.9 % AR after 100 d
Metabolite CL 153815 Water: max. 31.5 – 41.4 % AR (day 7), 0 – 9.3 % AR after 100 d; Sediment: max. 83.1 % AR (day 100) and 47.9 % AR (day 62)
Metabolite CL 153815 accumulates in sediment (main part as bound residues)

Degradation in the saturated zone

Remarks:

not measured, not required

None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

$1.7 \cdot 10^{-7}$ Pa (20 °C, extrapolated, PAS 99.5 %)

Henry's law constant:

$1.6 \cdot 10^{-3}$ Pa m ³ mol ⁻¹ (20 °C)

Photolytic degradation

Direct photolysis in air:

No data

Photochemical oxidative degradation in air
DT₅₀:

Calculation according to Atkinson's method (AOPWin 1.89): $t_{1/2} = 1.0$ d ($C_{OH} = 0.5 \cdot 10^6$ cm ⁻³ , 24 h day)

Volatilisation:

from plant surfaces: ≤ 10 % within 24 h

Remarks:

None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

LD₅₀ >5000 mg/kg bw (rat)

Acute toxicity to birds:

LD₅₀ >2250 mg/kg bw (bobwhite and mallard duck)

Dietary toxicity to birds:

LC₅₀ >5314 ppm (bobwhite and mallard duck)

Reproductive toxicity to birds:

NOEL 864 ppm (bobwhite and mallard duck)

Long term toxicity to mammals:

NOEL 50 ppm (rat, multi-gen. study)

Aquatic Organisms

Acute toxicity fish:

O. mykiss mortality (LC₅₀) > 0.68

Long term toxicity fish:

O. mykiss mortality, growth, behaviour (NOEC) 0.0064

Bioaccumulation fish:

fish Bioaccumulation BCF = 580
Level of residues (%) in organisms after the 14 day depuration phase: < 5 %

Acute toxicity invertebrate:

D. magna mortality (EC₅₀) > 0.45

Chronic toxicity invertebrate:

D. magna mortality, growth, reproduction (NOEC) 0.007

Acute toxicity algae:

Ankyra judayi biomass (EC₅₀) 0.000025

Chronic toxicity sediment dwelling organism:

Chironomus riparius development (NOEC) 0.18

Chronic toxicity aquatic plants:

Lemna gibba fronds (EC₅₀) 0.057

Microcosm or mesocosm tests

A test over 116 d in a glasshouse was conducted. Algae, plants and invertebrates were tested. Conclusions can only be reached for a few species. Effects on algae and plants were observed but recovery occurred up to a concentration of 0.18 µg/L. This concentration is relevant for the risk assessment.

Honeybees

Acute oral toxicity:

LD₅₀ > 200 µg as/bee

Acute contact toxicity:

LD₅₀ > 200µg as/bee

Other arthropod species

Test species

*T. pyri**A. rhopalosiphi**P. cupreus**Pardosa spp.*

% Effect

Fertility: 10 %

Fertility: 10 %

Food uptake: 0 %

Food uptake: + 1 %

Earthworms

Acute toxicity:

LC₅₀ > 1000 mg as/kgLC₅₀ 476.5 mg metabolite/kg

Reproductive toxicity:

NOEC 0.5 kg as/ha (corresponds to 0.665 mg as/kg)

Soil micro-organisms

Nitrogen mineralisation:

Active substance picolinafen: Tolerable effects up to 502.5 g /ha (0.67 mg/kg soil)
Metabolite CL 153815: Tolerable effects up to 221 g / ha (0.3 mg/kg soil)

Carbon mineralisation :

Active substance picolinafen: Tolerable effects up to 502.5 g /ha (0.67 mg/kg soil)
Metabolite CL 153815: Tolerable effects up to 221 g / ha (0.3 mg/kg soil)

Effects on other soil non-target macro-organisms

Organic matter breakdown

In a test with leaves of *Castanea sativa* buried in a cereal field in 10 cm depth no adverse effects on litter breakdown were observed with 100 g as/ha after 6 month

Effects on other non-target organisms (flora and fauna)

Seedling emergence and vegetative vigour test

ED₅₀: 5-10 g as/ha (most sensitive species: *Beta vulgaris*, *Brassicae vulgaris*)

APPENDIX III**PICOLINAFEN**

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 BBA registration number
AIIA-2.7	Daum, A.	2001	Comparison between Picolinafen (BAS 700 H, Reg.No. 4004047) TGAI and PAI of solubilities in organic solvents (Reg.No. 4004047 identical with CL 900001) BASF, 2001/1019582 not relevant unpublished CHE2002-102
AIIIA-2.7.3	Goldsmith, A. E.	2000	Generation of Chemical and Physical Stability Data on a Batch of Picolinafen 750 g/kg WG – 104 week interim report BASF, RLG 4589 GLP, unpublished PHY2000-777
AIIA-4.1	Jones, M. T.	2001	Additional Information on the Validation of High Resolution Gas Chromatographic Method M-3437 to Assay for the Minor Components in BAS 700 H for the Support of World-Wide Registrations Technical Grade Active Ingredient BASF, APBR 1160 GLP, unpublished CHE2001-608

B.6 Toxicology and metabolism

None

B.7 Residue data

None

B.8 Environmental fate and behaviour

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 BBA registration number
AIIA-2.10, AIIA-7.2.2	Mangels, G.	2000	Picolinafen (AC 900001): Estimation of the Photochemical Oxidation Rate in the Atmosphere BASF, EXA 00-022 no GLP, unpublished LUF2001-79
AIIA- 7.1.1.2.2	Anonym	2000	Response for PSD's request for additional information on how an 82 day half-life was calculated for CL 153815 in the UK field dissipation study. BASF BOD2001-457
AIIA- 7.1.1.2.2	Mangels, G.	2001	Calculation of the Degradation Kinetics of CL 153815 (Soil Metabolite of BAS 700, Picolinafen) in Two Field Dissipation Studies (AR-620-015) (UK) and (AR-620-019) (FR) BASF Report Number EXA 01-029 non GLP, unpublished BOD2001-676
AIIIA-9.1.3	Mangels, G.	2001	Calculation of the Predicted Environmental Concentrations of CL 153815 in Soil from Applications of BAS 700 at 100 g/ha BASF Report Number EXA 01-036 non GLP, unpublished BOD2001-674
AIIIA-9.2.1	Mangels, G.	2001	Calculation of Predicted Environmental Concentrations of Picolinafen and Its Major Soil Metabolite, CL 153815, in Groundwater Following Applications of Picolinafen (BAS 700H) to Cereals in the United Kingdom BASF REPORT NO. EXA 01-010 no GLP (not relevant), unpublished BOD2001-458

B.9 Ecotoxicology

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 BBA registration number
AIIA-8.6, AIIIA-10.8	Brandt, A	1997	Greenhouse evaluation of the herbicidal activity of the picolinic acid metabolite of AC 900001, CL 153815, in comparison to the parent AC 900001 BASF, CFS 1997-119 GLP not relevant not published PFL2000-5
AIIA-8.6, AIIIA-10.8	Stalmans, H.	1999	Effects on other non-target organisms (Flora) with AC 900,001 (Farmer P. Debois) BASF, BE 99 HS 009 1/2 GLP not relevant not published PFL2000-6
AIIA-8.6, AIIIA-10.8	Stalmans, H.	1999	Effects on other non-target organisms (Flora) with AC 900,001 (Farmer L. Baes) BASF, BE99HS009 ½ GLP not relevant not published PFL2000-7
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