EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare, international questions ${\bf E1}$ - Plant health

Picolinafen SANCO/1418/2001-rev. 5 18 April 2002

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DRAFT

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 $1999/555/EC^{1}$ of 2 July 1999 that these requirements were satisfied.

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.

¹ OJ No L210, 10.08 1999, p.22.

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 ../../00 EEC concerning the inclusion of picolinafen in Annex I to Directive 91/414/EEC, 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 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	AC 900001 (AC 900,001)	
(for new actives only)	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	<mark>970 g/kg</mark>	
Molecular formula	$C_{19}H_{12}F_4N_2O_2$	
Molecular mass	376.3	
Structural formula		
	CF ₃	
	CONTRACTOR	

Melting point	Melting range: 107.2 - 10	7.6 ℃ (PAS 98.7 %)
Boiling point	No defined boiling point of	bservable,
	decomposition at > 230 ℃ (PAS 98.7 %)	
Appearance	fine crystalline white to chalky solid with musty	
	smell (PAS 98.7 %)	
Relative density	1.45 g/cm [°] (PAS 98.7 %)	
Vapour pressure	1.7 · 10⁻′ Pa (20 °C, extra	apolated, PAS 99.5 %)
Henry's law constant	$1.6 \cdot 10^{-3} \text{ Pa m}^3 \text{ mol}^{-1}$ (20)	°C)
Solubility in water	pH 5 buffer:3.8 · 10 ⁻⁵ g/l	
	pH 7 buffer:4.7 \cdot 10 ⁻⁵ g/l	
	pH 9 buffer:3.8 · 10 ⁻⁵ g/l	
	DI water:3.9 · 10 ⁻³ g/l	
	(at 20 °C:)	
Solubility in organic solvents	<u>TAS (97.8 %), 20 ℃</u>	
	acetone: 557 g/l	
	dichloromethane:	764 g/l
	ethyl acetate:	464 g/l
	n-nexane:	3.8 g/l
	methanol:	30.4 g/l
Dertition on officient (los D.)		203 g/i
Partition co-efficient (log Pow)	Dimeter	
	DI Water	5.37
	pH 5 buller	0.30 5.40
	pH 7 buller	5.45
Hydrolytic stability (DT)	Stable at pH 4 7 and 9 (5	5.00 5 d 50 ℃)
Dissociation constant	No dissociation botwoon pH 2 12	
	$\frac{140 \text{ dissociation between } p = 2 - 12}{0.14 \text{ do}^{-6}}$	
transformation in water at s >290	2.14 10	
nm		
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	[I mol ⁻¹ cm ⁻¹] (shoulder)
	290 nm: ϵ =13000 [l mol ⁻¹ cm ⁻¹]	
Photostability in water (DT ₅₀)	Xe-lamp (λ > 290 nm), continuous irradiation (7 d)	
	pH 5 buffer: 25 d (23 °C)	
	pH 7 buffer: 31 d (23 ℃)	
	pH 9 buffer: 23 d (23 ℃)	

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

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NOEL:

Genotoxicity

No genotoxic potential

Long term toxicity and carcinogenicity

Tar

Low

Car

Г al off

get / critical effect:	Red blood cells, spleen (hemolysis); liver (hypertrophy)
vest relevant NOAEL:	2yr rat: 50 ppm (2.4 mg/kg bw/d)
rcinogenicity:	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

Medical data

Summary

ADI:

AOEL systemic:

ARfD (acute reference dose):

Dermal absorption

Value	Study	Safety factor
0.014 mg/kg bw	1yr dog	100
0.03 mg/kg bw/d	90d + 1y dog, 60% absorption	100
<mark>0.05 mg/kg bw/d</mark>	<mark>developmental</mark> rabbit	<mark>100</mark>

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:

Non-extractable residues after 100 days:

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

Supplemental studies

Anaerobic:

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

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

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)

 DT_{50} : 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:

Remarks:

stable to photolysis (DT₅₀: 30.2 days)

None

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

DT _{50lab} (20°C, aerobic):	
1-14 d (n=4), r² = >0.95 (√1 st or	der),
recalculation by 1 st order:	
Speyer 2.2 (aniline- 14 C): Speyer 2.2 (pyridine- 14 C): Engelstadt/Benz: Ingelheim/Moers: Kloppenheim/Untere Gewann: CL 153815 (20°C, aerobic): 30 r^2 = >0.96	46 d (r^2 = 0.9574) 50 d (r^2 = 0.8198) 51d (r^2 = 0.4937) 47 d (r^2 = 0.5475) 46 d (r^2 = 0.5656) -77 days (n=4),
DT_{90lab} (20°C, aerobic): 34-149 ($\sqrt{1^{st} order}$)	d (n=4), r ² =>0.95
DT_{50lab} (8°C, aerobic): pyridine order), n=1, r ² = >0.95	label, 7 d (√1 st

DT₉₀lab (20 °C, aerobic):

DT₅₀lab (10 °C, aerobic):

APPENDIX II END POINTS AND RELATED INFORMATION 2. Fate and behaviour in the environment 4 April 2002

DT₅₀lab (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 (2^{nd} order)

 DT_{50f} : 9-64 d (n=8), average 30 d (1st order)

DT_{90f}: 56-212 d (n=8) average, 107 d

is not expected to accumulate in the soil

CL 153815: 19-107 d (N=8)

not required

None

soils.

locations: 4 in Germany, 3 in France, 1 in UK

 DT_{50} is < 3 months and DT_{90} is < 1 yr., picolinafen

Field studies (country or region)

 DT_{50f} from soil dissipation studies:

DT_{90f} from soil dissipation studies: Soil accumulation studies:

Soil residue studies:

Remarks:

e.g. effect of soil pH on degradation rate

Adsorption/desorption

K_f / K_{oc}:

K_d:

pH dependence:

Mobility

Laboratory studies:

Column leaching:

Aged residue leaching:

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

not required. Field studies showed no picolinafen

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

Field studies:

Lysimeter/Field leaching studies:

Remarks:

None

in depth below 10 cm

Picolinafen
k _d : 248 - 764 l/kg , K _{OC} : 15,000 - 31,800 l/kg (n = 4)
CL 153815
$k_{d}\!\!:6.3$ - 16.2 l/kg, $K_{OC}\!\!:160$ - 783, mean 440 kg/ $(n=4)$
Yes. Stronger binding was observed in acidic

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation: Major metabolites: Photolytic degradation:

Stable at pH 4, 7 and 9 (5 d, 50 $^{\circ}$ C)	
none	
Xe-lamp (λ > 290 nm), continuous irradiation	
(7 d), DT ₅₀ :	
pH 5 buffer: 25 d (23 ℃)	
pH 7 buffer: 31 d (23 ℃)	
pH 9 buffer: 23 d (23 ℃)	
none	

Major metabolites:

Biological degradation

Readily biodegradable:	No
Water/sediment study:	Mineralization: 2.5 % AR after 100 d Non-extractable residues: 64 – 83 % AR after 100 d
DT ₅₀ water:	et et
DT water	DT_{50} water: 1.1 – 1.4 d (sqrt 1 st order, 1 st or
	DT_{90} water: 4.5 - 12.1 (1 st order, sqrt 1 st order,
DT ₅₀ whole system:	n = 2)
DT ₉₀ whole system:	DT_{50} whole system: 6.2 d (1 st order, n = 2)
	DT_{90} whole system: 20.5 d (1 st order, n = 2)
Distribution in water / sediment systems	
(active substance)	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
Distribution in water / sediment systems	
(metabolites)	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 % AB (day 62)
Accumulation in water and/or sediment:	(main part as bound residues)

Degradation in the saturated zone not measured, not required

Remarks:

None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

Henry's law constant:

1.7 · 10 ⁻⁷ Pa (20 ℃, extrapolated, PAS 99.5 %)	
1.6 · 10 ⁻³ Pa m ³ mol ⁻¹ (20 °C)	

Photolytic degradation

Direct photolysis in air:

Photochemical oxidative degradation in air DT_{50} :

Volatilisation:

No data
Calculation according to Atkinson's method (AOPWin 1.89): $t_{1/2} = 1.0 \text{ d} (C_{OH} = 0.5 \cdot 10^6 \text{ cm}^{-3}, 24 \text{ h day})$
from plant surfaces: \leq 10 % within 24 h

Remarks:

None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals: Acute toxicity to birds:

Dietary toxicity to birds: Reproductive toxicity to birds: Long term toxicity to mammals:

Aquatic Organisms

LD ₅₀ >5000 mg/kg bw (rat)
LD ₅₀ >2250 mg/kg bw (bobwhite and mallard duck)
LC_{50} >5314 ppm (bobwhite and mallard duck)
NOEL 864 ppm (bobwhite and mallard duck)
NOEL 50 ppm (rat, multi-gen. study)

	species	endpoint	Toxicity
			mg as/L
Acute toxicity fish:	O. mykiss	mortality (LC ₅₀)	> 0.68
Long term toxicity fish:	O. mykiss	mortality, growth, behaviour (NOEC)	0.0064
Bioaccumulation fish:	fish	Bioaccumula-	BCF = 580
		tion	Level of residues (%) in organisms after the 14 day depuration phase: < 5 %
Acute toxicity invertebrate:	D. magna	mortality (EC ₅₀)	> 0.45
Chronic toxicity invertebrate:	D. magna	mortality, growth, reproduction	0.007
	.		0 000005
Acute toxicity algae:	Ankyra judayi	biomass (EC ₅₀)	0.000025
Chronic toxicity sediment dwelling organism:	Chironomus	development	0.18
	riparius	(NOEC)	
Chronic toxicity aquatic plants:	Lemna gibba	fronds (EC ₅₀)	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 μ g/L. This concentration is relevant for the risk assessment.

Honeybees

Acute oral toxicity:	LD ₅₀ > 200 μg as/bee
Acute contact toxicity:	LD ₅₀ > 200µg as/bee

Other arthropod species

Test species	% Effect
T. pyri	Fertility: 10 %
A. rhopalosiphi	Fertility: 10 %
P. cupreus	Food uptake: 0 %
Pardosa spp.	Food uptake: + 1 %

 $LC_{50} > 1000 \text{ mg as/kg}$

LC₅₀ 476.5 mg metabolite/kg

NOEC 0.5 kg as/ha (corresponds to 0.665 mg

Earthworms

Acute toxicity:

Reproductive toxicity:

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)

as/kg)

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 Chromatograpic 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	Author(s)	Year	Title
point/			source (where different from company)
reference			company, report no.
number			GLP or GEP status (where relevant),
			published or not
			BBA registration number
AIIA-2.10,	Mangels, G.	2000	Picolinafen (AC 900001): Estimation of the Photochemical
AIIA-7.2.2			Oxidation Rate in the Atmosphere
			BASF, EXA 00-022
			no GLP,
			unpublished
			LUF2001-79
AllA-	Anonym	2000	Response for PSD's request for additional information on how
7.1.1.2.2			an 82 day half-life was calculated for CL 153815 in the UK
			field dissipation study.
			BASE
A 11 A	Mangala C	0001	BOD2001-457
AIIA-	Mangels, G.	2001	Calculation of the Degradation Kinetics of CL 153815 (Soli Metabolite of RAS 700, Displington) in Two Field Displication
1.1.1.2.2			Studion (AD 620.015) (LIK) and (AD 620.010) (ED)
			Sidules (AR-020-015) (OK) and (AR-020-019) (FR) BASE Papart Number EXA 01 020
			non GLP
			unnublished
			BOD2001-676
AIIIA-913	Mangels G	2001	Calculation of the Predicted Environmental Concentrations of
	mangele, en	200.	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
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B.9 Ecotoxicology

Annex	Author(s)	Year	Title
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