

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Pyridate

7576/VI/97-final

22 March 2001

Review report for the active substance **pyridate**

Finalised in the Standing Committee on Plant Health at its meeting on December 12, 2000
in view of the inclusion of pyridate 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 pyridate, 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⁽¹⁾ 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 1972/99⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. pyridate 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, Stefes Agro GmbH on 20 July 1993, Syngenta (former Novartis, former Sandoz, former Agrolinz) on 26 July 1993 and AgriChem on 15 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance pyridate 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⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Austria as rapporteur Member State to carry out the assessment of pyridate on the basis of the dossier submitted by the notifier. 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 pyridate this deadline was 30 April 1995.

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.09.1999, p.41.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Sandoz AG (now Syngenta) submitted a dossier to the rapporteur Member State. The dossier was considered as complete. Information has furthermore been submitted by the Austrian Umweltbundesamt .

AgriChem and Stefes Agro GmbH have withdrawn their notification 27 September 1994 and 19 January 1995 respectively.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Austria submitted on 18 November 1996 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 pyridate 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 pyridate from Syngenta on 7 January 1997.

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 as well as to Syngenta being the main data submitter, on 11 February 1997.

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 April to July 1997.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 30 July 1997 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 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 December 1998 to September 2000, and was finalised in the meeting of the Standing Committee on December 12, 2000.

The present review report contains the conclusions of this 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.

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The Committee was asked in particular to comment on the suitability of the three-generation study in rats as a basis for the estimation of the AOEL for pyridate. The Committee concluded that the three generation study in rats is suitable for the estimation of the AOEL. The report of this Committee was formally adopted on 13 July 2000 (SCP/PYRID/002-Final⁵).

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 2001/21/EC concerning the inclusion of pyridate in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing pyridate 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 pyridate 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 pyridate 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 main data submitter:

⁵ Opinion of the scientific Committee on Plants regarding the inclusion of pyridate in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

- herbicide against dicotyle weeds in cereals, fodder plants and vegetables.

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 2.3 % 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 pyridate are given in Appendix I. The active substance shall comply with the specification mentioned in the inclusion Directive and there seem not to be reasons for deviating from that specification.

The review has established that for the active substance notified by the main data submitter Syngenta 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 as identified during the re-evaluation process 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 pyridate

On the basis of the proposed and supported uses, 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:

- The risk of groundwater contamination by pyridate and / or its degradation products needs to be carefully assessed.
- Particular attention should be paid to the impact on aquatic organisms and where appropriate the conditions of authorisation should include risk mitigation measures.

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 pyridate in Annex I under the current inclusion conditions. However, some endpoints 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.

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.

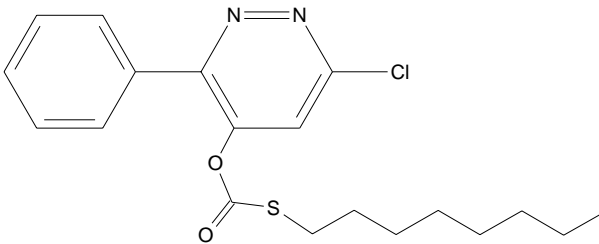
9. Updating of this review report

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 Plant Health, in connection with any amendment of the inclusion conditions for pyridate in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

PYRIDATE

Common name (ISO)	Pyridate
Chemical name (IUPAC)	6-chloro-3-phenylpyridazin-4-yl S-octyl thiocarbonate
Chemical name (CA)	O-(6-chloro-3-phenyl-4-pyridazinyl) S-octyl carbonothioate
CIPAC No	447
CAS No	55512-33.9
EEC No	259-686-7
FAO SPECIFICATION	Not available.
Minimum purity	The active substance as manufactured shall have a specified minimum purity of at least 900 g/kg
Molecular formula	$C_{19}H_{23}ClN_2O_2S$
Molecular mass	378.9
Structural formula	

Melting point	26.5 – 27.8 °C
Boiling point	Decomposition from 250°C without boiling.
Appearance	White crystalline solid (Pyridate purified, purity > 98.9%) Dark-brown oily liquid (Pyridate technical, purity > 90.5%)
Relative density	1.28
Vapour pressure	9.98x10 ⁻⁷ Pa at 25°C or 4.8x10 ⁻⁷ Pa at 20°C CL 9673: 5.72 x 10 ⁻⁸ Pa at 25°C
Henry's law constant	1.21 x 10 ⁻⁴ Pa m ³ mol ⁻¹ at 20°C CL 9673: 2.9 x 10 ⁻⁸ Pa m ³ mol ⁻¹ at 20°C (pH7)
Solubility in water	pH 3 : 0.37 mg/l
	pH 7 : 1.49 mg/l (hydrolysis) at 20°C in buffer system
	CL 9673: 59.8 mg/l at pH 4 (20°C) 120.6 mg/l at pH 5.5 (20°C) 1638.2 mg/l at pH 7.0 (20°C)
Solubility in organic solvents	Acetone, cyclohexanone, ethyl acetate, N-methylpyrrolidine, kerosine, xylene: > 900g/100 ml
Partition co-efficient (log P_{ow})	CL 9673: pH 5: 1.85 (22°C)
	pH 6: 1.37 (22°C)
	pH 7: 0.50 (22°C)
Hydrolytic stability (DT₅₀)	pH 4 : 117 hours (25°C)
	pH 5: 89 hours (25°C)
	pH 7: 58.5 hours (25°C)
	pH 9: 6.2 hours (25°C)
Dissociation constant	N/A
Quantum yield of direct photo-transformation in water at ε >290 nm	CL 9673: 1.70 x 10 ⁻⁴ at pH 7
Flammability	N/A
Explosive properties	Not explosive.
UV/VIS absorption (max.)	295 nm, 246 nm, 204 nm
Photostability in water (DT₅₀)	3.5 d at pH 5 1.8 d at pH 7.3 2.2 d at pH 9.2

APPENDIX II

END POINTS AND RELATED INFORMATION

PYRIDATE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	oral > 80% within 24 hours, rat (single and repeated dose of 20 mg/kg bw); at higher dose (200 mg/kg bw) lower absorption rate (70%)
Distribution:	widely; higher residues in liver and kidney
Potential for accumulation:	No signs of accumulation.
Rate and extent of excretion:	> 90% within 96 hours, most via urine
Toxicologically significant compounds:	CL 9673 (main metabolite) and glucuronides of CL 9673
Metabolism in animals:	Cleavage of the ester bond and conjugation

Acute toxicity

Rat LD ₅₀ oral:	> 2000 mg/kg bw
Rat LD ₅₀ dermal:	> 2000 mg/kg bw
Rat LC ₅₀ inhalation:	> 4.37 mg/l air
Skin irritation:	Irritant.
Eye irritation:	Not irritant.
Skin sensitization (test method used and result):	Sensitizing in the Maximization test as well as in the Buehler test.

Short term toxicity

Target / critical effect:	Clinical (neurotoxic) symptoms, minimale degenerative myelopathy at high dosage; decreased enzyme activity (ALT); dog studies
Lowest relevant oral NOAEL / NOEL:	30 mg/kg bw/d (52 weeks dog study; in reality this study is comparable to a 3 month study with preapplication)
Lowest relevant dermal NOAEL / NOEL:	not allocated
Lowest relevant inhalation NOAEL / NOEL:	not allocated

Genotoxicity

Negative.

Long term toxicity and carcinogenicity

Target / critical effect:	Decreased body weight.
Lowest relevant NOAEL:	400 ppm equivalent to 18 mg/kg bw/d (long term toxicity study in rats)
Carcinogenicity:	Negative.

Reproductive toxicity

Target / critical effect - Reproduction:	Increased kidney weight (Parents F ₁ and F ₂). Decreased thyroid weight (parental males (F ₂). No reproductive effects.
Lowest relevant reproductive NOAEL / NOEL:	NOEL 3.6 mg/kg bw/d
Target / critical effect - Developmental toxicity:	Embryotoxic only at maternal toxic doses.
Lowest relevant developmental NOAEL / NOEL:	NOEL 150 mg/kg bw/d; rabbit

Delayed neurotoxicity

Clinical (neurotoxic) symptoms, minimal degenerative myelopathy at high dosage (dog studies).

Other toxicological studies

Metabolite CL9673: acute oral LD ₅₀ 1420 mg/kg bw; not sensitizing; no point mutations.
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Medical data

No cases of poisoning reported.

Summary

	Value	Study	Safety factor
ADI:	0.036 mg/kg bw/d	multigeneration study in rats	100
AOEL systemic:	0.036 mg/kg bw/d	multigeneration study in rats	100
AOEL inhalation:	not allocated	-	-
AOEL dermal:	not allocated	-	-
ARfD (acute reference dose):	not allocated	-	-

Dermal absorption

Not required; assumed 10% dermal absorption rate on the properties of the molecule.

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

19 - 26 %

Non-extractable residues after 100 days:

52 - 60 %

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

CL 9673 (6-chloro-3-phenyl-pyridazin-4-ol):
3 - 88 % (maximum day 3)

Supplemental studies

Anaerobic:

Aerobically and anaerobically the same DT50 rate of ca. 0.3 days was found.
CL 9673 stable under anaerobic conditions

Soil photolysis:

Pyridate: 2.9 days (dark controls: 17 d)
CL 9673: 16 days (dark controls: stable over 31 days)

Remarks:

Pyridate does not absorb light at wavelengths >290 nm, is rapidly hydrolysed to CL 9673 even in air dried soil.
CL 9673 is further degraded. CO₂ and several minor products and soil-bound residues are formed

Rate of degradation

Laboratory studies

DT_{50lab} (20 °C, aerobic):

0.2 - 1 days (1st order)
0.03 days (2nd order)
0.5 days at 55 % MWC (1st order)

DT_{90lab} (20 °C, aerobic):

2.3 - 11 days (1st order)
2.7 days (2nd order)
5 days at 55 % MWC (1st order)

DT_{50lab} (10 °C, aerobic):

DT_{50lab} (7°C, aerobic): after 32 days 2.6 % AR were left as a.i.

DT_{50lab} (20 °C, anaerobic):

0.3 days (1st order)

Supplemental studies with the main metabolite CL 9673:

DT_{50lab} (18-23° C, aerobic):

15 - 55 days(1st order)
19 days (1.5 order) and 55 % MWC

DT_{90lab} (18-23° C, aerobic):

47 - 183 days (1st order)
88 days (1.5 order) and 55 % MWC

DT_{50lab} (7° C, aerobic):

150 d

Field studies (country or region)

DT_{50f} from soil dissipation studies:

USA
Pyridate: 1.5 - 7.7 days
CL9673: 30 - 60 days
CL 9673-O-methyl: appears sporadically at low levels

Switzerland
Pyridate: <1day
CL 9673: <14 days

Austria
CL 9673: 14-18 days

DT_{90f} from soil dissipation studies:

Switzerland
Pyridate: <1 day
CL 9673: <45 days

Austria
CL 9673: 35-50 days

Soil accumulation studies:

not required

Soil residue studies:

Applicationrate: 1.1-1.6 kg a.i./ha (emulsifiable concentrate)

Pyridate:0.07 - 0.75 mg/kg (day 0)
CL9673: 0.18 - 0.53 mg/kg (day 0)

Remarks:

e.g. effect of soil pH on degradation rate

None.

Adsorption/desorption

Active metabolite CL 9673:

K_f / K_{oc} :

K_d

pH dependence:

K_{oc} : 20 – 188

0.5 – 3.5

The adsorption of CL 9673 increased with increasing content of the organic matter and decreasing pH.

Mobility

Laboratory studies:

Column leaching:

Aged residue leaching:

Not required

Radioactivity in leachate: 3 - 65 % AR

No Pyridate or CL 9673-O-methyl was detected in the percolation water.

Only ^{14}C -CL 9673 was identified in the leachates. Other metabolites did not exceed 1 % of applied radioactivity.

Field studies:

Lysimeter/Field leaching studies:

Lysimeterstudy 1 (Germany): orthic luvisol soil and a loamy sand; total precipitation over 2 years: 1613.6 mm and 1635.1 mm; total leachates: 26% and 27.8%; application rates: 1x1.31 and 1x1.26 kg as/ha for the two soils respectively.

Lysimeterstudy 2 (Germany): soil "Borstel"; precipitation: 1022.6 mm (year 1) and 1032.0 mm (year 2); leachates: Lysimeter 1: 446.1 + 490.8 l, Lysimeter 2: 348.2 + 426.6 l (1st + 2nd year); application rate: 1x1.26 kg as/ha (Lysimeter 1) and 1x1.22 kg as/ha (Lysimeter 2) as Lentagran WP; cropping: maize/winter wheat/winter rape.

The results of the two lysimeter studies were very similar:

Total radioactivity in the leachate: 0.1 - 0.3 % of applied radiocarbon (up to 60 % CO_2).

Pyridate or metabolites CL 9673 or CL 9673-O-methyl were not found in the percolation water.

Not more than 2 % of applied radiocarbon was found in the soil below 30 cm

Remarks:

None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

	22° C	25° C	50° C
pH4:	-	117 h	10.7 h
pH 5:	66.7 h	89 h	-
pH 7:	17.8 h	59 h	4.7 h
pH 9:	6.8 h	6.2 h	0.3 h

Relevant metabolites:

Photolytic degradation:

Hydrolytically stable.	
Pyridate: (Hydrol.)	pH 5: 3.5 d pH 7: 1.8 d pH 9: 2.2 d
Dark controls: Rapid degradation of Pyridate but increasing amounts of CL 9673 with time.	

Relevant metabolites:

CL 9673: (Calcul.)	pH 5: 3.7 d pH 7: 14.1 d pH 9: 9.5 d
Dark controls: Rapid degradation of Pyridate but increasing amounts of CL 9673 with time.	

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)

Not readily biodegradable	
DT ₅₀ water:	< 0.4 d
DT ₉₀ water:	not relevant
DT ₅₀ whole system:	<1 d
DT ₉₀ whole system:	not relevant
not detected in the water phase rapid adsorption by the sediment	
CL 9673: Max. concentration in water: 48-58 % AR (day 1-7) Amount at termination (day 84): 10 % AR	
Max. concentration in the sediment: 46.7 % AR (day 3) in one system and 44.4 % AR (day 30) in the other. Amount at termination (day 84): 25-27 % AR	
CL 9673-O-methyl: Max. in the sediment at termination (day 84): 9-12 % AR	

Accumulation in water and/or sediment:

Not required

Degradation in the saturated zone

Not required

Remarks:

None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

9.98x10⁻⁷ Pa at 25°C or 4.8x10⁻⁷ Pa at 20°C
CL 9673: 5.72 x 10⁻⁸ Pa at 25°C

Henry's law constant:

1.21 x 10⁻⁴ Pa m³ mol⁻¹ at 20°C
CL 9673: 2.9 x 10⁻⁸ Pa m³ mol⁻¹ at 20°C (pH7)

Photolytic degradation

Direct photolysis in air:

Not required

Photochemical oxidative degradation in air

DT₅₀: 18.2 hrsDT₅₀:

Volatilisation:

from plant surfaces: up to 13 % within 24 h
from soil: <20 % within 24 h

Remarks:

None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD ₅₀ = 3588 mg/kg bw (rat)
Acute toxicity to birds:	LD ₅₀ = 1269 mg/kg bw (bobwhite quail)
Dietary toxicity to birds:	LC ₅₀ > 5000 ppm (bobwhite quail)
Reproductive toxicity to birds:	NOEC > 640 ppm (mallard duck)
Short term oral toxicity to mammals:	NOAEL / NOEL: 30 mg/kg bw/d (dog, 52 weeks)
Long term oral toxicity to mammals:	NOAEL: 400 ppm equivalent to 18 mg/kg bw/d (rat, 2 years)

Aquatic Organisms

Pyridate

Acute toxicity fish:	LC ₅₀ (96 h) > 1.2 mg/l (rainbow trout)
Long term toxicity fish:	NOEC(21 days) = 0.08 mg/l (rainbow trout)
Bioaccumulation fish:	BCF 116 (whole fish)
Acute toxicity invertebrate:	LC ₅₀ (48 h) = 0.83 mg/l (<i>daphnia magna</i>)
Chronic toxicity invertebrate:	NOEC (21 d) = 0.01 mg/l (<i>daphnia magna</i>)
Acute toxicity algae:	EC ₅₀ (96 h) > 2.0 mg/l (<i>anabaena flos-aquae</i>)
Chronic toxicity sediment dwelling organism:	Not required
Acute toxicity aquatic plants:	EC ₅₀ (7 d) > 2.0 mg/l (<i>lemna gibba</i>)

Metabolite CL 9673

Acute toxicity fish:	LC ₅₀ (96 h) > 20 mg/l (rainbow trout)
Long term toxicity fish:	NOEC (21 days) = 20 mg/l (rainbow trout)
Acute toxicity invertebrate:	LC ₅₀ (48 h) = 26.1 mg/l (<i>daphnia magna</i>)
Chronic toxicity invertebrate:	NOEC (21 d) = 5 mg/l (<i>daphnia magna</i>)
Acute toxicity algae:	EC ₅₀ (96 h) = 4.93 mg/l (<i>S. capricornutum</i>)

Honeybees

Acute oral toxicity:	> 100 µg Lentagran (45 % a.s.) / bee
Acute contact toxicity:	> 100 µg a.s. / bee

Other arthropod species

<i>Poecilus cupreus</i>	<p>0 – 3 % (adults, mortality, 1.37 kg a.s./ha, lab test with Lentagran 45 WP)</p> <p>0 % (adults, mortality, 0.9 kg a.s./ha, lab test with Lentagran 45 EC)</p>
<i>Aleochara bilineata</i>	<p>5.5 – 35 % (adult, mortality and reproduction, 1.37 kg a.s./ha, lab test with Lentagran 45 WP)</p> <p>10 % (adults, reduction of parasitism, 1.37 kg a.s./ha, semi-field test with Lentagran 45 WP)</p> <p>0-70 % (adults, mortality and reproduction, 0.91 kg a.s./ha, lab test with Lentagran 45 EC)</p> <p>2.4 % (adults, reduction of parasitism, 0.91 kg a.s./ha, semi-field test with Lentagran 45 EC)</p>
<i>Typhlodromus pyri</i>	<p>4.2 % (protonymphs, mortality, 0.91 kg a.s./ha, ext. Lab test with Lentagran 45 WP)</p> <p>-21.6 % (protonymphs, reduction in reproduction, 0.91 kg a.s./ha, ext. Lab test with Lentagran 45 WP)</p> <p>-8 % (protonymphs, mortality, 0.91 kg a.s./ha, ext. Lab test with Lentagran 45 EC)</p> <p>-63 % (protonymphs, reduction in reproduction, 0.91 kg a.s./ha, ext. Lab test with Lentagran 45 EC)</p>
<i>Aphidius rhopalosiphi</i>	<p>6.9 % (adults, mortality, 0.90 kg a.s./ha, ext. Lab test with Lentagran 45 WP)</p> <p>11 % (adults, reduction in reproduction, 0.90 kg a.s./ha, ext. Lab test with Lentagran 45 WP)</p> <p>10 % (adults, mortality, 0.90 kg a.s./ha, ext. Lab test with Lentagran 600 EC)</p> <p>15 % (adults, reduction in reproduction, 0.90 kg a.s./ha, ext. Lab test with Lentagran 600 EC)</p>
<i>Episyrphus balteatus</i>	<p>4 % (larvae, mortality and fecundity, 1.36 kg a.s./ha, lab test with Lentagran 45 WP)</p> <p>0 % (larvae, mortality, 1.31 kg a.s./ha, lab test with Lentagran 45 EC)</p>

Earthworms

Pyridate techn.

Acute toxicity:

LC50: 799 mg/kg (<i>Eisenia foetida</i>)
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Reproductive toxicity:

Not required

Metabolit CL 9673 techn.

Acute toxicity:

LC50: 348 mg/kg (<i>Eisenia foetida</i>)
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Reproductive toxicity:

Not required

Soil micro-organisms

Nitrogen mineralization:

WP: no effects up to 80 mg/kg (= 34.9 mg ai/kg; equiv. to 25.8 kg/ha) EC: no effects up to 20 mg/kg (= 8.9 mg ai/kg; equival. to 6.6 kg/ha)
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Carbon mineralization:

WP: no effects up to 64 mg/kg (= 28.8 mg ai/kg; equiv. to 21.6 kg/ha) EC: no effects up to 20 mg/kg (= 8.9 mg ai/kg; equival. to 6.6 kg/ha)
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APPENDIX III**PYRIDATE**

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 inclusion¹.

- 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	Reports² on previous use in granting national authorizations
IIA 2.1.1, IIA 2.1.2, IIA 2.1.3, IIA 2.5.1	Bates, M.	1996	Pyridate: Determination of Physico-Chemical Properties of the Purified Active Substance (Melting and Boiling Points, Ultra-violet/visible, Infra-red, Nuclear Magnetic Resonance and Mass Spectra). CORNING Hazleton, UK, Report No.: 252/197-1014 Sandoz Agro Ltd. Report No.: TDS BS 7245 GLP, unpublished	
IIA 2.2	Schneider, R.	1995 (b)	Relative density of pure Pyridate. Sandoz Agro Ltd. Report No.: BS 6493 Non-GLP, unpublished	

¹ List based on an analysis of the Rapporteur Member State.

² Entries concerning UK are based on information from UK at the date of finalisation of the present review report Other entries are based on information received from the Notifier. Neither the Commission nor the Member States are responsible for the completeness or validity of this information provided.

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	Reports² on previous use in granting national authorizations
IIA 2.2	Füldner, H.H.	1998	Pyridate pure: Report on Density of Solids Generated by: Novartis Services AG Submitted by: Novartis Crop Protection AG Anal.Test. No.: PP-98/33P.DES, SAN 319/81 Date: 10.06.98 GLP, unpublished	
IIA 2.3.1	Landvoigt, W., Creeger, S. M.	1988	Volatility assessment of Pyridate and its major degradation product CL 9673. Chemserv / CHMR Report No.: 727 Non-GLP, unpublished	DE (05.1990)
IIA 2.3.1	Anonymous		Determination of vapor pressure using a modified Knudsen method. Chemie Linz AG Report No.: - Non-GLP, unpublished	DE (06.1981)
IIA 2.3.2	Krüger, B.	1995	Pyridate: Estimation of Henry's Law Constant of Pyridate and its main metabolite CL 9673. Agrolinz Melamin GmbH Report No.: 1228 Non-GLP, unpublished	
IIA 2.4.1	Schneider, R.	1988 (b)	Colour and appearance of technical Pyridate. Agrolinz Agrarchemikalien GmbH Report No.: Non-GLP, unpublished	DE (05.1990)
IIA 2.4.1	Schneider, R.	1988 (c)	Physical State of technical Pyridate. Agrolinz Agrarchemikalien GmbH Report No.: Non-GLP, unpublished	DE (05.1990)
IIA 2.4.1 IIA 2.4.2	Kettner, R.	1995 (a)	Appearance of Pyridate -physical state, odour and colour of purified Pyridate. Sandoz Agro Ltd. Report No.: BS 6457 Non-GLP, unpublished	
IIA 2.4.2	Schneider, R.	1988 (d)	Non-GLP, unpublished Odour of technical Pyridate. Agrolinz Agrarchemikalien GmbH Report No.: Non-GLP, unpublished	DE (05.1990)

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 ² on previous use in granting national authorizations
IIA 2.5.1	Herling, H.	1996	Pyridate – Determination of ¹ H-NMR-Spectrum. Spectral Service Laboratorium für Auftragsanalysen GmbH, Germany, Report No.: SSL00696 Sandoz Agro Ltd. Report No.: TDS BS 7246 GLP, unpublished	
IIA 2.6	Zohner, A.	1985 (b)	Water solubility of CL 9673, the hydrolyzation product of Pyridate at different pH-values. Chemie Linz AG Report No.: 835 Non-GLP, unpublished	DE (05.1990)
IIA 2.6	M. Wisson	1996	Solubility of Pyridate in water including effect of pH Generated and submitted by: Sandoz Agro Ltd. Company file No.: E 96-12, BS 9474 GLP, unpublished	
IIA 2.7	Schneider, R.	1988 (e)	Solubility of technical Pyridate in organic solvents. Agrolinz Agrarchemikalien GmbH Report No.: Non-GLP, unpublished	DE (05.1990)
IIA 2.9.1	Lutringer C.	1997	Pyridate: Hydrolysis as a Function of pH Generated by: Novartis Agro Europe Submitted by: Novartis Crop Protection AG Company file No.: E96-23, Desire SAN 319/7 December 17,1997 GLP, not published	DE (04.2000)
IIA 2.9.2	Van Dijk, A., Betschart, B.	1992	Photodegradation study of ¹⁴ C-Pyridate in water at pH 5, 7 and 9. RCC Umweltchemie AG Report No.: 287548 GLP, unpublished	
IIA 2.9.3	Werle, H.	1993	Direct phototransformation study CL 9673 -determination of quantum yield in water at pH 7. BioChem GmbH Report No.: 92 50 40 035 B GLP, unpublished	DE (01.1994)

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	Reports² on previous use in granting national authorizations
IIA 2.9.4	Schneider, R.	1989 (a)	Dissociation constant of technical Pyridate. Agrolinz Agrarchemikalien GmbH Report No.: Non-GLP, unpublished	DE (05.1990)
IIA 2.10	Ewald, G.	1993	Photochemical-oxidative degradation of Pyridate, theoretical calculation according to Atkinson. ECON GmbH Report No.: Non-GLP, unpublished	DE (05.1993)
IIA 2.11.2	Krips, H.J.	1995	Determination of Auto-Ignition Temperature (Liquids) - Pyridate Technical. NOTOX B. V., Report No.: 157106 1995oz Agro Ltd. Report No.: TDS BS 6741995 GLP, unpublished	
IIA 2.12	Schneider, R.	1989 (b)	Flash point of technical Pyridate. Chemserv Industrie Service GmbH Report No.: - Non-GLP, unpublished	DE (05.1990)
IIA 2.13	Schneider, R.	1989 (c)	Explodability of technical Pyridate. Agrolinz Agrarchemikalien GmbH Report No.: - Non-GLP, unpublished	
IIA 2.13	Angly H.	1997	Test Report 97.4056.EXP, Explosive Properties Generated by: EZA Münchwilen Submitted by: Novartis Crop Protection AG. Company file No.: EZA Project No.: 56372, Desire No. SAN 319/58, 19-NOV-1997 GLP, not published	
IIA 2.15	Schneider, R.	1989 (d)	Oxidation and reduction potential of technical Pyridate. Agrolinz Agrarchemikalien GmbH Report No.: Non-GLP, unpublished	
IIA 4.1.2	Libert, H.	1990 (a)	See Annex C, 1.4.1 Agrolinz Report No.: 10907 Non-GLP, unpublished	DE (05.1990),

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 ² on previous use in granting national authorizations
IIA 4.1	R. Kettner	1999	Report on Validation of Linearity of Method 10865 Generated by: Novartis Crop Protection Mönchwil AG Submitted by: Novartis Crop Protection AG Company File No.: EZA study No. 70649, SAN 319/112, 28 January 1999 GLP, not published	
IIA 4.1.2	Libert, H.	1990 (b)	See Annex C, 1.4.1 Agrolinz Report No.: 10865 Non-GLP, unpublished	DE (05.1990)
IIA 4.1	R. Kettner	1999	Report on Validation of Linearity of Method 10907 Generated by: Novartis Crop Protection Mönchwil AG Submitted by: Novartis Crop Protection AG Company file No.: EZA study No. 70382, SAN 319/107, 28 January 1999 GLP, not published	
IIA 4.1.2	Libert, H.	1990 (c)	See Annex C, 1.4.1 Agrolinz Report No.: 10794 Non-GLP, unpublished	DE (05.1990)
IIA 4.1	R. Kettner	1999	Report on Validation of Linearity of Method 10794 Generated by: Novartis Crop Protection Mönchwil AG Submitted by: Novartis Crop Protection AG Company file No.: EZA study No. 71080, SAN 319/110, 28 January 1999 GLP, not published	
IIA 4.1.2	Libert, H.	1990 (d)	Content of impurities in Pyridate technical by method 10908. Agrolinz Report No.: 10908 Non-GLP, unpublished	DE (05.1990)

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 ² on previous use in granting national authorizations
IIA 4.1	R. Kettner	1999	Report on Validation of Linearity of Method 10908 Generated by: Novartis Crop Protection Munchwilen AG Submitted by: Novartis Crop Protection AG GLP, not published Company file No.: EZA study No. 70647, SAN 319/111, 28 January 1999 GLP, unpublished	
IIA 4.2.1	Mayr, H., Bayzer, H., Heegemann, W.	1983	Method of analysis for determination of residues of Pyridate and its main metabolites CL 9673 and conjugated CL 9673 in plant materials. Agrolinz Report No.: 758 a Non-GLP, unpublished	DE (05.1990)
IIA 4.2.1	Pfarl, C.	1989	Method of analysis for determination of residues of Pyridate and its main metabolites CL 9673 and hydrolysable CL 9673 conjugates in plant materials. Agrolinz Report No.: 758 d Non-GLP, unpublished	DE (05.1990) UK: 25/08/94
IIA 4.2.1	Pfarl, C.	1992	Method of analysis for determination of residues of Pyridate and its main metabolites CL 9673 and hydrolysable CL 9673 conjugates in plant materials. Agrolinz Report No.: 758 e Non-GLP, unpublished	
IIA 4.2.1	Pfarl, C.	1995 (a)	Method of analysis for determination of residues of Pyridate and its main metabolites CL 9673 and hydrolysable CL 9673 conjugates in plant materials. Agrolinz Report No.: 758 e, Addendum I Non-GLP, unpublished	
IIA 4.2.1	Pfarl, C.	1995 (b)	Validation of an analytical method for determination of residues of Pyridate and its main metabolite CL 9673 in foods of animal origin. Agrolinz Report No.: 1211 GLP, unpublished	DE (01.1995)

Annex point/ reference number	Author(s)	Year	Title Source (where different from company), Report No. GLP or GEP status (where relevant) Published or not	Reports² on previous use in granting national authorizations
IIA 4.2.1	Pfarl, C.	1990	Method of analysis for determination of Pyridate and its main metabolites CL 9673 and CL 9673-O-methyl in soil. Agrolinz Report No.: 1064 GLP, unpublished	DE (05.1990)
IIA 4.2.3	Heegemann, W.	1987	Method of Analysis for Determination of Traces of 6-chloro-3-phenylpyridazine-4-ol (CL 9673) in groundwater and drinking water. Agrolinz Report No.: 887 Non-GLP, unpublished	DE (05.1990) UK: 25/08/94
IIA 4.2.3	Pfarl, C.	1995 (c)	Method of Analysis for Determination of Traces of 6-chloro-3-phenylpyridazine-4-ol (CL 9673) in groundwater and drinking water. Agrolinz Report No.: 887, Addendum I Non-GLP, unpublished	
IIA 4.2.4	Pfarl, C.	1995 (d)	Validation of an analytical method for determination of Pyridate in air. Agrolinz Report No.: 1224 GLP, unpublished	DE (03.1995)

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.2.1	W. R. Pels Rijcken	1996	Pyridate TC (in 1% CMC): Assessment of acute oral toxicity in the rat Generated by: NOTOX B. V. Submitted by: Sandoz Agro Ltd. Company file No.: 175084, BS 9583 Date: September 1996 GLP, unpublished	
IIA 5.2.1	W. R. Pels Rijcken	1996	Pyridate TC (in corn oil): Assessment of acute oral toxicity in the rat Generated by: NOTOX B. V. Submitted by: Sandoz Agro Ltd. Company file No.: 175095, BS 9584 Date: September 1996 GLP, unpublished	
IIA 5.2.1	W. R. Pels Rijcken	1996	Pyridate TC (in PEG 200): Assessment of acute oral toxicity in the rat Generated by: NOTOX B. V. Submitted by: Sandoz Agro Ltd. Company file No.: 175106, BS 9585 Date: September 1996 GLP, unpublished	

² ~~Reports received from Member States at the date of finalisation of the present review report (not exhaustive).~~

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 5.8.1	L. Ullmann P. Althaus T. Janiak O. Vogel	1990	Acute oral toxicity study with CL 9673-N-Glucosid in rats Generated by: Research&Consulting Company Company file No.: 263171, BS 5450 Date: May 7, 1990 GLP, unpublished	
IIA 5.8.1	A. Van Dijk	1992	CL 9673-N-Glucoside: Absorption, Distribution, Metabolism and Excretion after single oral administration to rats Generated by: RCC Umweltchemie Company file No.: 254621, BS 5451 Date: August 3, 1992 GLP, unpublished	

B.7 Residue data

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 6.3	Ch. Pfarl	1994	Residues of Pyridate and its main metabolites free CL 9673 and hydrolysable CL-9673 conjugates in rape treated with 2.0 kg Lentagran WP/ha; Generated by: Agrolinz Agrarchemikalien GmbH Submitted by: Sandoz Agro Ltd. Company file No.: 1167, BS 6054 Date: February 1994 GLP, unpublished	DE (07.1994)
IIA 6.3	Ch. Pfarl	1994	Residues of Pyridate and its main metabolites free CL 9673 and hydrolysable CL-9673 conjugates in rape treated with 2.0 kg Lentagran WP/ha; Generated by: Agrolinz Agrarchemikalien GmbH Submitted by: Sandoz Agro Ltd. Company file No.: 1208, BS 6044 Date: August 1994 GLP, unpublished	
IIA 6	M. Kaethner Ch. Pfarl	1997	Determination of Pyridate Residues in Brussels Sprouts after application of Lentagran WP Under Field Conditions in Great Britain, 1995 (Decline Curve, Residue at Harvest) Generated by: Novartis Agro Europe Submitted by: Novartis Crop Protection AG Company file No.: R 95-38, SAN 319/03, 15.04.97 GLP, not published	UK (16/07/98)

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive).

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 6	Ch. Pfarl	1997	Determination of Pyridate Residues in Leek Following Treatment with Lentagran WP Under Field Conditions in France, 1996 Generated by: Agrolinz Melamin GmbH Submitted by: Novartis Crop Protection AG Company file No.: R 96-031, SAN 319/56, 01.10.97 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Kale, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3083/98, 04.02.1999 Novartis File N° SAN319/0115 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Kale, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3084/98, 04.02.1999 Novartis File N° SAN319/0116 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Kale, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3085/98, 04.02.1999 Novartis File N° SAN319/0117 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Kale, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3086/98, 04.02.1999 Novartis File N° SAN319/0118 GLP, not published	DE (04.2000)

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 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Kale, Switzerland Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3043/98, 02.02.1999 Novartis File N° SAN319/0113 GLP, not published	DE (04.2000)
IIA 6	Gasser, A	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Kale, Switzerland Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3044/98, 02.02.1999 Novartis File N° SAN319/0114 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Kale, United Kingdom Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3005/98, 26.02.1999 Novartis File N° SAN319/0119 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Kale, United Kingdom Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3006/98, 26.02.1999 Novartis File N° SAN319/0120 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Red clover, France (North) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3112/97, 26.02.1999 Novartis File N° SAN319/0123 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Red clover, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3113/97, 26.02.1999 Novartis File N° SAN319/0124 GLP, not published	DE (04.2000)

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 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Red clover, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3114/97, 26.02.1999 Novartis File N° SAN319/0125 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Red clover, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3118/97, 26.02.1999 Novartis File N° SAN319/0126 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Red clover, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3119/97, 26.02.1999 Novartis File N° SAN 319/0127 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Red clover, United Kingdom Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3007/98, 26.02.1999 Novartis File N° SAN319/0121 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Alfalfa, France (North) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3062/98, 08.04.1999 Novartis File N° SAN319/0139 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Alfalfa, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3063/98, 08.04.1999 Novartis File N° SAN319/0140 GLP, not published	DE (04.2000)

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 6	Gasser, A.	1999	SAN 319, SAN 319 H 45 WP, A-8985 A, Alfalfa, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3064/98, 08.04.1999 Novartis File N° SAN319/0141 GLP, not published	DE (04.2000)
IIA 6	Gasser, A.	1999	SAN 319, EC 600, A-9921 A (SAN 319 H 600 EC 418 LZ), Red Clover (forage), France (North) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3115/97, 06.04.1999 Novartis File N° SAN319/0130 GLP, not published	
IIA 6	Gasser, A.	1999	SAN 319, EC 600, A-9921 A (SAN 319 H 600 EC 418 LZ), Red Clover (forage), France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3116/97, 06.04.1999 GLP, not published Novartis File N° SAN319/0131 GLP, not published	
IIA 6	Gasser, A.	1999	SAN 319, EC 600, A-9921 A (SAN 319 H 600 EC 418 LZ), Red Clover (forage), France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3117/97, 06.04.1999 Novartis File N° SAN319/0132 GLP, not published	
IIA 6	Gasser, A.	1999	Residue Study with Pyridate (SAN 319) in or on Red Clover in France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3120/97, 19.04.1999 Novartis File N° SAN319/6024 GLP, not published	

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 6	Gasser, A.	1999	SAN 319, EC 600, A-9921 A (SAN 319 H 600 EC 418 LZ), Red Clover (forage), France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3121/97, 07.04.1999 Novartis File N° SAN319/0133 GLP, not published	
IIA 6	Gasser, A.	1999	S AN 319, SAN 319 H 600 EC 418 LZ, A-9921 A, Alfalfa, France (North) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3087/98, 08.04.1999 Novartis File N° SAN319/0142 GLP, not published	
IIA 6	Gasser, A.	1999	SAN 319, SAN 319 H 600 EC 418 LZ, A-9921 A, Alfalfa, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3088/98, 08.04.1999 Novartis File N° SAN319/0143 GLP, not published	
IIA 6	Gasser, A	1999	SAN 319, SAN 319 H 600 EC 418 LZ, A-9921 A, Alfalfa, France (South) Novartis Crop Protection AG, Basel, Switzerland Study Report No. 3089/98, 08.04.1999 Novartis File N° SAN319/0144 GLP, not published	

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	Reports on previous use in granting national authorizations
IIA 7.1.1, IIA 7.1.2, IIA 7.1.3, IIIA 9.1.1, IIIA 9.1.2	Dykeman, R.G.,	1992 (a)	Dissipation of Pyridate residues from an Iowa loam and an Illinois sandy clay loam corn field treated with Tough 3.75 EC Herbicide EN-CAS (resp. ACRES) Report No.: AGRO-9003 GLP, unpublished	
IIA 7.1.1, IIA 7.1.2, IIA 7.1.3, IIIA 9.1.1, IIIA 9.1.2	Dykeman, R.G.	1992 (b)	Dissipation of Pyridate residues from a Wisconsin silt loam cabbage field treated with Tough 3.75 EC Herbicide. EN-CAS (resp. GLARS) Report No.: AGRO-9005 GLP, unpublished	
IIA 7.1.1, IIA 7.1.2, IIA 7.1.3, IIIA 9.1.1, IIIA 9.1.2	Dykeman, R.G.	1992 (c)	Dissipation of Pyridate residues from a California sandy loam cabbage field treated with Tough 3.75 EC Herbicide. EN-CAS (resp. Hulst Research) Report No.: AGRO-9006 GLP, unpublished	UK: 25/08/94
IIA 7.1.1, IIA 7.1.2, IIA 7.1.3, IIIA 9.1.1, IIIA 9.1.2	Ellgehausen, H.	1985	¹⁴ C-Pyridate: Soil Metabolism in a Model Study under Outdoor Conditions. RCC Umweltchemie AG Report No.: 049511 GLP, unpublished	DE (05.1990) UK: 25/08/94
IIA 7.1.1, IIA 7.1.2, IIA 7.1.3, IIIA 9.1.1, IIIA 9.1.2	Heegemann, W., Bayzer, H., Mayr, H.	1983	Examination of degradation of Pyridate and CL 9673 in soil, site Biolabor Haag, 1983 - Part of a long term test of LENTAGRAN WP in maize. Chemie Linz AG Report No.: 766 Non-GLP, unpublished	DE (05.1990)
IIA 7.1.1, IIIA 9.1.1	Morgenroth	1995	Metabolism and Degradation of ¹⁴ C-labelled Pyridate in four Soils. RCC Umweltchemie Report No.: 286694 GLP, unpublished	UK: 25/08/94

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive).

Annex point/ reference number	Author(s)	Year	Title Source (where different from company), Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIIA 9.1.2 IIA 7.1.3	Krüger, B.	1996	Computer simulation with PELMO for PEC calculation in ground water Project No. M96-13 SAN 1367/5004 Non-GLP, unpublished	DE (08.1997)
IIA 7.1.1	Van Dijk, A., Baranowski, D.	1992	Photodegradation Study of ¹⁴ C-Pyridate on Soil. RCC Umweltchemie AG Report No.:287550 GLP, unpublished	UK: 25/08/94
IIA 7.1.1 IIA 9.1.1	Zohner, A	1988	Aerobic soil metabolism study ¹⁴ C- Pyridate at two specified temperatures (26°C and 7°C) in a laboratory test Agrolinz Agrarchemikalien File No.: 930, SAN 319/5098 Non GLP, unpublished	DE (04.2000)
IIA 7.1.1, IIIA 9.1.1	Zohner, A.	1985 (Adde ndum: 1989)	Aerobic soil metabolism study of ¹⁴ C-CL 9673, the main metabolite of ¹⁴ C- Pyridate in soil. Chemie Linz AG Report No.: 832 Non-GLP, unpublished	DE (04.2000)
IIA 7.1.1, IIIA 9.1.1	Zohner, A.	1992	¹⁴ C-Pyridate: Degradation and Metabolism in One Soil Incubated under Anaerobic Conditions. Agrolinz Agrarchemikalien Report No.: 1116 GLP, unpublished	
IIA 7.1.1	Zohner, A.	1990	Photodegradation Study of ¹⁴ C-Pyridate on a silty loam Soi. Agrolinz Agrarchemikalien Report No.: 942-1 Non-GLP, unpublished	DE (02.1991) UK 16/07/98
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B.9 Ecotoxicology

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IIA 8.2.8	Grade, R.	1998	Acute toxicity of Pyridate (techn.) on duckweed <i>Lemna gibba</i> G3 under static conditions Project No. 971651 GLP-compliance Not published	DE (09.1998)
IIA 8.3.2 IIIA 10.5	Adelberger	2000	Toxicity to the Predatory mite, <i>Typhlodromus pyri</i> under extended laboratory conditions Project No. 991610 GLP-compliance Not published	
IIA 8.3.2 IIIA 10.5	Großmann, A; Lührs, U	1998	Effects of Lentagran 45 WP (A-8985 A) on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) Extended laboratory study Project No.: 3871062 Generated by: IBACON GmbH GLP-compliance Not published	

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 8.3.2 IIIA 10.5	Großmann, A; Lührs, U	1998	Effects of Lentagran 450 ECP (A-6710 A) on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) Extended laboratory study Project No.: 3860062 Generated by: IBACON GmbH GLP-compliance Not published	
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IIA 8.3.2 IIIA 10.5	Moll, M	1999	Effects of Lentagran 45 WP (A-8985A) on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, Aphidiidae)- Extended laboratory study Generated by: IBACON GmbH Report No. 4980002 GLP-compliance Not published	
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IIA 8.3.2 IIIA 10.5	Thompson, B	1998	A laboratory study to evaluate the side effects of the herbicide Lentagran WP (SAN 145000 H 450 WP) on the hoverfly <i>Episyrphus balteatus</i> Generated by: Agrochemical evaluation unit, school of biological sciences, University Southampton, UK AEU Report N0. SAN-97-12 GLP-compliance Not published	
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