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**EU-Beurteilungsbericht Pyridat
Rechtliche Regelungen der Europäischen Union
zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 15**

Review Report Pyridate
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 15

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Vorwort

Für neue Wirkstoffe werden die EU-Mitgliedstaaten in den Richtlinien zur Aufnahme der Wirkstoffe in Anhang I verpflichtet, den nach Abschluss aller Prüfungen erstellten Beurteilungsbericht (Review Report) mit allen Anlagen (mit Ausnahme von vertraulichen Informationen im Sinne von Artikel 14 der Richtlinie 91/414/EWG) allen Interessierten zur Verfügung zu stellen oder auf besonderen Antrag zugänglich zu machen. Für alte Wirkstoffe ergibt sich diese Verpflichtung für die Mitgliedstaaten bereits aus Artikel 7 Absatz 6 Unterabsatz 2 der Verordnung (EWG) Nr. 3600/92.

Die Mitgliedstaaten und die Europäische Kommission haben vereinbart, dass die Beurteilungsberichte, einschließlich der zum Teil sehr umfangreichen Hintergrunddokumente, vorzugsweise beim berichterstattenden Mitgliedstaat angefordert oder eingesehen werden sollen.

Die Biologische Bundesanstalt stellt die Beurteilungsberichte als Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft als Band D in der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" über den Saphir Verlag gegen Erstattung der Unkosten zur Verfügung. Das vorliegende 15. Heft dieser Reihe (Band D 15) enthält nicht die Hintergrunddokumente A, B und C des Beurteilungsberichtes. Diese können bei Bedarf bei der BBA eingesehen oder für die Wirkstoffe, für die Deutschland Berichtersteller ist, ebenfalls beim Saphir Verlag gegen Erstattung der Unkosten bezogen werden. Für Pyridat war Österreich Berichtersteller.

In der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" sind bisher erschienen:

Heft	Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen
35/97	Band A: Richtlinie 91/414/EWG und diesbezügliche Protokolle (3. Auflage, Stand: 01. November 1997)
68/2000	Band B: Verordnungen und Protokolle zur Wirkstoffprüfung (4. Auflage, Stand 01. Juli 2000)
	Band C: <i>Wird zur Zeit bearbeitet</i>

Preface

According to the Directives for the inclusion of active substances in Annex I with regard to new active substances, EU-Member States are obliged to keep available or make available on special request the review report which is prepared after completion of all evaluations including its appendices (excluding confidential information, in accordance with article 14 of Directive 91/414/EEC) to all interested parties. For existing active substance this obligation for Member States already arises from article 7 (6) subparagraph 2 of Regulation (EEC) No 3600/92.

Member States and the European Commission agreed that requests of review reports including their background documents which are partly very voluminous, shall preferably be addressed to the Rapporteur Member State.

The Federal Biological Research Centre makes available review reports as reports from the Federal Biological Research Centre for Agriculture and Forestry, Volume D of the series "Legal Regulations of the European Union for Plant Protection Products and their Active Substances" via Saphir Verlag against reimbursement of expenses. The present 15th report belonging to this series (Volume D 15) does not include background documents A, B and C of the review report. If the need arises, their inspection at the BBA is possible or they may be also obtained from Saphir Verlag against reimbursement of expenses, however, only for active substances with Germany as Rapporteur Member State. For pyridate Austria acted as Rapporteur Member State.

In the series Legal Regulations of the European Union for Plant Protection Products and their Active Substances the following Reports have been published:

Report	Legal Regulations of the European Union for Plant Protection Products and their Active Substances
35/97	Volume A: Directive 91/414/EEC and respective Protocols (3 rd Edition, date: 1 November 1997)
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4 th Edition, date: 1 July 2000)
	Volume C: <i>In Progress</i>

RICHTLINIE 2001/21/EG DER KOMMISSION

vom 5. März 2001

zur Änderung von Anhang I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufnahme der Wirkstoffe Amitrol, Diquat, Pyridat und Thiabendazol

DIE KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN —

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft,

gestützt auf die Richtlinie 91/414/EWG des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln⁽¹⁾, zuletzt geändert durch die Richtlinie 2000/80/EG der Kommission⁽²⁾, insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

- (1) Mit der Verordnung (EWG) Nr. 3600/92 der Kommission vom 11. Dezember 1992⁽³⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2266/2000⁽⁴⁾, wurden die Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln (im Folgenden „die Richtlinie“ genannt) erlassen. Gemäß vorgenannter Verordnung wurde mit der Verordnung (EG) Nr. 933/94 der Kommission vom 27. April 1994 über die Festsetzung der Wirkstoffe von Pflanzenschutzmitteln und die Bestimmung der berichterstattenden Mitgliedstaaten zur Durchführung der Verordnung (EWG) Nr. 3600/92⁽⁵⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2230/95⁽⁶⁾, die Liste der Wirkstoffe in Pflanzenschutzmitteln festgelegt, die im Hinblick auf ihre mögliche Aufnahme in Anhang I der Richtlinie zu bewerten sind.
- (2) Gemäß Artikel 5 Absatz 1 der Richtlinie ist ein Wirkstoff für einen Zeitraum von höchstens zehn Jahren in Anhang I aufzunehmen, wenn angenommen werden kann, dass weder die Anwendung von Pflanzenschutzmitteln, die diesen Wirkstoff enthalten, noch deren Rückstände schädliche Auswirkungen auf die Gesundheit von Mensch und Tier oder auf das Grundwasser bzw. unannehmbare Auswirkungen auf die Umwelt haben werden.
- (3) Die Auswirkungen von Amitrol, Diquat, Pyridat und Thiabendazol auf die menschliche Gesundheit und auf die Umwelt wurden gemäß den Bestimmungen der Verordnung (EWG) Nr. 3600/92 für eine Reihe von durch die Antragsteller vorgeschlagenen Anwendungen geprüft. Gemäß der Verordnung (EG) Nr. 933/94 wurde Frankreich zum berichterstattenden Mitgliedstaat für Amitrol, das Vereinigte Königreich zum berichterstattenden Mitgliedstaat für Diquat und Spanien zum berichterstattenden Mitgliedstaat für Thiabendazol benannt. Österreich wurde gemäß der Verordnung (EG) Nr. 491/95 der Kommission zur Änderung der Verordnung (EWG) Nr. 3600/92 und der Verordnung (EG) Nr. 933/94, insbesondere hinsichtlich der Berücksichtigung

der benannten Behörden und der Hersteller in Österreich, Finnland und Schweden bei der Durchführung der ersten Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie⁽⁷⁾ zum berichterstattenden Mitgliedstaat für Pyridat ernannt. Die berichterstattenden Mitgliedstaaten haben der Kommission ihre Bewertungsberichte und Empfehlungen am 30. April 1996 (Amitrol), am 2. April 1996 (Diquat), am 18. November 1996 (Pyridat) und am 30. April 1996 (Thiabendazol) gemäß Artikel 7 Absatz 1 Buchstabe c) der Verordnung (EWG) Nr. 3600/92 übermittelt.

- (4) Diese Bewertungsberichte wurden von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfungen wurden am 12. Dezember 2000 in Form der jeweiligen Prüfungsberichte der Kommission für Amitrol, Diquat, Pyridat und Thiabendazol abgeschlossen. Sollten die Prüfungsberichte unter Berücksichtigung technischer und wissenschaftlicher Entwicklungen aktualisiert werden müssen, so sind auch die Bedingungen für die Aufnahme der betreffenden Wirkstoffe in Anhang I der Richtlinie gemäß der Richtlinie zu ändern.
- (5) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen zu Amitrol wurden auch dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Der Ausschuss hat in seiner Stellungnahme vom 6. Juni 2000⁽⁸⁾ die festgesetzte annehmbare Anwenderexposition (AOEL — acceptable Operator exposure level) bestätigt und Hinweise zur Interpretation von Langzeitstudien bei Nagern gegeben. Diesen Empfehlungen wurde bei der Erarbeitung dieser Richtlinie und des entsprechenden Prüfungsberichts Rechnung getragen.
- (6) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen zu Diquat wurden ebenfalls dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Der Ausschuss hat in seiner Stellungnahme vom 5. April 2000⁽⁹⁾ Hinweise zur Interpretation der vorliegenden Studien über die Reproduktion von Vögeln, über potentielle Langzeiteffekte von an Bodenpartikel gebundenen Rückständen, über die potentiellen Auswirkungen der Bekämpfung von Wasserunkräutern und über bestimmte Aspekte der Anwender- und Verbraucherexposition gegeben. In seiner Interpretation der verfügbaren Studien über die Reproduktion von Vögeln kam der Ausschuss zu dem Schluss, dass keine Anhaltspunkte dafür vorliegen, dass Rückstände im Boden unannehmbare Auswirkungen haben werden. Der Ausschuss stellte außerdem fest, dass Anwendungen von

⁽¹⁾ ABl. L 230 vom 19.8.1991, S. 1.⁽²⁾ ABl. L 309 vom 9.12.2000, S. 14.⁽³⁾ ABl. L 366 vom 15.12.1992, S. 10.⁽⁴⁾ ABl. L 259 vom 13.10.2000, S. 27.⁽⁵⁾ ABl. L 107 vom 28.4.1994, S. 8.⁽⁶⁾ ABl. L 225 vom 22.9.1995, S. 1.⁽⁷⁾ ABl. L 49 vom 4.3.1995, S. 50.⁽⁸⁾ Wissenschaftlicher Pflanzenausschuss SCP/AMITR/002-endg.⁽⁹⁾ Wissenschaftlicher Pflanzenausschuss SCP/DIQUAT/002-endg.

Diquat in der Bekämpfung von Wasserunkräutern möglicherweise mit einem hohen Risiko für nicht zu den Zielgruppen gehörende Wasserorganismen einhergehen können und unzureichende Daten über die wirksame Anwendung von Risikominimierungsmaßnahmen vorliegen. Was die Anwenderexposition betrifft, so empfahl der Ausschuss, Maßnahmen zur Begrenzung der Exposition von nichtprofessionellen Anwendern in Erwägung zu ziehen. Abschließend stellte der Ausschuss fest, dass nicht genügend Informationen vorliegen, um die Exposition von Verbrauchern durch die Aufnahme des Wirkstoffs mit der Nahrung bei Anwendungen als Sikkations-Mittel in feinkörnigen Getreidearten umfassend zu bewerten. Dieser Stellungnahme wurde bei der Erarbeitung dieser Richtlinie und des entsprechenden Prüfungsberichts Rechnung getragen.

- (7) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen zu Pyridat wurden ebenfalls dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Der Ausschuss hat in seiner Stellungnahme vom 6. Juni 2000 ⁽¹⁾ die Gültigkeit der vom Ständigen Ausschuss für Pflanzenschutz festgesetzten annehmbaren Anwenderexposition bestätigt.
- (8) Auch die Unterlagen und die aus der Prüfung hervorgegangenen Informationen zu Thiabendazol wurden dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Der Ausschuss hat in seiner Stellungnahme vom 22. September 2000 ⁽²⁾ bestätigt, dass die vorgesehenen Anwendungen von Thiabendazol bei Obst und Kartoffeln nach der Ernte kein unannehmbares Risiko für Wasserorganismen darstellen, vorausgesetzt, dass geeignete Risikominimierungsmaßnahmen getroffen werden. Dieser Empfehlung wurde bei der Erarbeitung dieser Richtlinie und des entsprechenden Prüfungsberichts Rechnung getragen.
- (9) Die Untersuchungen haben ergeben, dass davon ausgegangen werden kann, dass die betreffenden Wirkstoffe enthaltende Pflanzenschutzmittel, insbesondere hinsichtlich der geprüften und im Prüfungsbericht der Kommission behandelten Anwendungen, im Allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie erfüllen. Daher sollten die betreffenden Wirkstoffe in Anhang I aufgenommen werden, damit in allen Mitgliedstaaten die Zulassung von Pflanzenschutzmitteln, die diese Wirkstoffe enthalten, gemäß den Bestimmungen der genannten Richtlinie erfolgen kann.
- (10) Gemäß Artikel 5 Absatz 5 der Richtlinie kann die Aufnahme eines Wirkstoffes in Anhang I jederzeit überprüft werden, wenn es Anzeichen dafür gibt, dass die Kriterien für die Aufnahme nicht mehr erfüllt sind. Die Kommission wird daher die Aufnahme von Amitrol in Anhang I erneut prüfen, wenn die geforderten zusätzlichen Informationen gemäß Punkt 7 des Prüfungsberichts nicht vorgelegt werden.
- (11) Gemäß der Richtlinie stellen die Mitgliedstaaten nach Aufnahme eines Wirkstoffes in Anhang I sicher, dass die Zulassungen von Pflanzenschutzmitteln, die diesen Wirkstoff enthalten, innerhalb eines vorgeschriebenen Zeitraums erteilt, widerrufen bzw. geändert werden.

Pflanzenschutzmittel dürfen nur zugelassen werden, wenn die Bedingungen in Zusammenhang mit der Aufnahme des betreffenden Wirkstoffes in Anhang I sowie die einheitlichen Grundsätze gemäß der Richtlinie auf der Grundlage von Unterlagen, die den Datenanforderungen entsprechen, erfüllt sind.

- (12) Vor der Aufnahme eines Wirkstoffes in Anhang I ist eine angemessene Frist vorzusehen, um es den Mitgliedstaaten und Interessierten zu ermöglichen, sich auf die sich daraus ergebenden neuen Anforderungen vorzubereiten. Nach der Aufnahme ist den Mitgliedstaaten außerdem eine angemessene Frist einzuräumen, um die Bestimmungen der Richtlinie über Pflanzenschutzmittel, die Amitrol, Diquat, Pyridat oder Thiabendazol enthalten, umsetzen zu können. Die Mitgliedstaaten müssen innerhalb dieser Frist gemäß den Bestimmungen der Richtlinie insbesondere bestehende Zulassungen überprüfen und gegebenenfalls neue Zulassungen erteilen. Für die Einreichung und Bewertung der für jedes Pflanzenschutzmittel vollständigen Unterlagen gemäß den in der Richtlinie festgelegten einheitlichen Grundsätzen ist ein längerer Zeitraum vorzusehen. Pflanzenschutzmittel, die mehrere Wirkstoffe enthalten, können jedoch auf der Grundlage der einheitlichen Grundsätze erst vollständig bewertet werden, wenn alle enthaltenen Wirkstoffe in Anhang I der Richtlinie aufgenommen sind.
- (13) Es ist vorzuschreiben, dass die Mitgliedstaaten die endgültigen Prüfungsberichte (mit Ausnahme von vertraulichen Informationen) allen Interessierten zur Einsicht zur Verfügung stellen oder zugänglich machen.
- (14) Die Prüfungsberichte sind erforderlich für die ordnungsgemäße Umsetzung bestimmter Teile der in der Richtlinie festgelegten einheitlichen Grundsätze durch die Mitgliedstaaten, soweit sich diese Grundsätze auf die Bewertung der Angaben beziehen, die zwecks Aufnahme der Wirkstoffe in Anhang I der Richtlinie vorgelegt wurden.
- (15) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz vom 12. Dezember 2000 —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Anhang I der Richtlinie 91/414/EWG wird gemäß dem Anhang der vorliegenden Richtlinie geändert.

Artikel 2

- (1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 1. Juli 2002 nachzukommen. Sie unterrichten die Kommission unverzüglich davon.

Gemäß der Richtlinie 91/414/EWG ändern oder widerrufen sie innerhalb dieses Zeitraums erforderlichenfalls insbesondere bestehende Zulassungen für Pflanzenschutzmittel, die Amitrol, Diquat, Pyridat oder Thiabendazol als Wirkstoff enthalten.

⁽¹⁾ Wissenschaftlicher Pflanzenausschuss SCP/PYRID/002-endg.

⁽²⁾ Wissenschaftlicher Pflanzenausschuss SCP/THIABEN/002-endg.

Bei Erlass dieser Vorschriften nehmen die Mitgliedstaaten in den Vorschriften selbst oder durch einen Hinweis bei der amtlichen Veröffentlichung auf diese Richtlinie Bezug. Die Mitgliedstaaten regeln die Einzelheiten der Bezugnahme.

(2) Hinsichtlich der Bewertung und der Entscheidungsfindung gemäß den einheitlichen Grundsätzen des Anhangs VI der Richtlinie 91/414/EWG auf der Grundlage von Unterlagen, die die Anforderungen des Anhangs III der genannten Richtlinie erfüllen, läuft die Frist für die Änderung oder den Widerruf von Zulassungen von Pflanzenschutzmitteln, die Amitrol, Diquat, Pyridat oder Thiabendazol als einzigen Wirkstoff enthalten, bis zum 1. Januar 2006.

(3) Bei Pflanzenschutzmitteln, die Amitrol, Diquat, Pyridat oder Thiabendazol zusammen mit einem anderen noch nicht in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, läuft die Frist für die Änderung oder den Widerruf von Zulassungen vier Jahre nach dem Inkrafttreten der Richtlinie zur Änderung des Anhangs I mit der Aufnahme des letzten dieser Wirkstoffe ab.

(4) Die Mitgliedstaaten stellen die Prüfungsberichte (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie 91/414/EWG) allen Interessierten zur

Einsicht zur Verfügung oder machen sie gegebenenfalls auf besonderen Antrag zugänglich.

(5) Die Mitgliedstaaten teilen der Kommission mit, falls die erforderlichen zusätzlichen Informationen gemäß Punkt 7 des Prüfungsberichts für Amitrol bis zum 1. Januar 2002 nicht übermittelt wurden. In diesem Fall wird die Kommission die Aufnahme von Amitrol in Anhang I der Richtlinie 91/414/EWG erneut überprüfen.

/Artikel 3

Diese Richtlinie tritt am 1. Januar 2002 in Kraft.

Artikel 4

Diese Richtlinie ist an die Mitgliedstaaten gerichtet.

Brüssel, den 5. März 2001

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

Die folgenden Einträge (Nummern 14 bis 17) werden an die Tabelle in Anhang I der Richtlinie 91/414/EWG angefügt:

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit (%)	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
„14	Amitrol CAS-Nr. 61-82-5 CIPAC-Nr. 90	H-[1,2,4]-Triazole-3-yl-amine	900 g/kg	1.1.2002	31.12.2011	Nur Anwendungen als Herbizid dürfen zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Amitrol und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — der Anwendersicherheit besondere Aufmerksamkeit widmen; — dem Grundwasserschutz in gefährdeten Gebieten, insbesondere im Hinblick auf Anwendungen in Nicht-Kulturland, besondere Aufmerksamkeit widmen; — dem Schutz von Nutzarthropoden besondere Aufmerksamkeit widmen; — dem Schutz von Vögeln und wildlebenden Säugetieren besondere Aufmerksamkeit widmen. Die Anwendung von Amitrol während der Brutzeit sollte nur zugelassen werden, wenn durch eine entsprechende Risikobewertung keine unannehmbaren Auswirkungen nachgewiesen wurden und wenn die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung umfassen.
15	Diquat CAS-Nr. 2764-72-9 (ion), 85-00-7 (Dibromid) CIPAC-Nr. 55	9,10-Dihydro-8a,10a-diazonia- phenanthren-ion (Dibromid)	950 g/kg	1.1.2002	31.12.2011	Auf der Grundlage der vorliegenden Informationen dürfen nur Anwendungen als Bodenherbizid und Sikkations-Mittel zugelassen werden. Anwendungen zur Bekämpfung von Wasserunkräutern dürfen nicht zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Diquat und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — besonders auf die potenziellen Auswirkungen auf Wasserorganismen achten und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikominderung umfassen; — der Anwendersicherheit bei nichtprofessioneller Anwendung besondere Aufmerksamkeit widmen und dafür Sorge tragen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung umfassen.
16	Pyridat CAS-Nr. 55512-33.9 CIPAC-Nr. 447	6-Chlor-3-phenylpyridazin-4-yl)-S- octyl-thiocarbonat	900 g/kg	1.1.2002	31.12.2011	Nur Anwendungen als Herbizid dürfen zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Pyridat und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — dem Grundwasserschutz besondere Aufmerksamkeit widmen; — besonders auf die potenziellen Auswirkungen auf Wasserorganismen achten und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikominderung umfassen.

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit (!)	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
17	Thiabendazol CAS-Nr. 148-79-8 CIPAC-Nr. 323	2-Thiazol-4-yl-1H-benzimidazol	985 g/kg	1.1.2002	31.12.2011	<p>Nur Anwendungen als Fungizid dürfen zugelassen werden. Blattspritzungen dürfen nicht zugelassen werden.</p> <p>Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Thiabendazol und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten:</p> <ul style="list-style-type: none"> — dem Schutz von Wasserorganismen und Sedimentlebewesen besondere Aufmerksamkeit widmen und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikominderung umfassen. <p>Es müssen geeignete Maßnahmen zur Risikobegrenzung (z. B. Klärung mit Kieselgur oder Aktivkohle) durchgeführt werden, um Oberflächengewässer vor übermäßiger Kontamination durch Abwasser zu schützen.</p>

(!) Nähere Angaben zur Identität und Spezifikation der Wirkstoffe sind in den betreffenden Prüfungsberichten enthalten."

COMMISSION DIRECTIVE 2001/21/EC
of 5 March 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include amitrole, diquat, pyridate and thibendazole as active substances

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, as last amended by Commission Directive 2000/80/EC ⁽²⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽³⁾, as last amended by Regulation (EC) No 2266/2000 ⁽⁴⁾, laid down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive'). Pursuant to that Regulation, Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Regulation (EEC) No 3600/92 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, laid down the list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to the Directive.
- (2) In accordance with Article 5(1) of the Directive, an active substance should be included in Annex I for a period not exceeding 10 years if it may be expected that neither the use of, nor residues from, plant protection products containing the active substance will have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.
- (3) For amitrole, diquat, pyridate and thibendazole the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the respective notifiers. Under Regulation (EC) No 933/94, France was designated as rapporteur Member State for amitrole, the United Kingdom for diquat, and Spain for thibendazole. Austria was designated as rapporteur Member State for pyridate under Regulation (EC) No 491/95 ⁽⁷⁾ amending Regulation

(EEC) No 3600/92 and Regulation (EC) No 933/94, in particular with regard to the integration of the designated public authorities and the producers in Austria, Finland and Sweden in the implementation of the first stage of the programme of work referred to in Article 8(2) of the Directive. The rapporteur Member States submitted the relevant assessment report and recommendation to the Commission on 30 April 1996 (amitrole), on 2 April 1996 (diquat), on 18 November 1996 (pyridate) and 30 April 1996 (thibendazole) in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

- (4) These assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The reviews were finalised on 12 December 2000 in the format of the respective Commission review reports for amitrole, diquat, pyridate and thibendazole. If the review reports have to be updated to take account of technical and scientific developments, the conditions for the inclusion of the substances concerned in Annex I to the Directive will also need to be amended in accordance with the Directive.
- (5) The dossier and the information from the review of amitrole were submitted to the Scientific Committee for Plants for consultation. In its opinion of 6 June 2000 ⁽⁸⁾, the Committee confirmed the acceptable operator exposure level selected and offered advice on the interpretation of the long-term studies in rodents. The recommendations were taken into consideration in this Directive and in the relevant review report.
- (6) The dossier and the information from the review of diquat were also submitted to the Scientific Committee for Plants for consultation. In its opinion of 5 April 2000 ⁽⁹⁾, the Committee offered advice on the interpretation of the available studies on bird reproduction, on potential long-term effects of residues bound to soil particles, on the potential environmental impact of aquatic weed control, and on certain aspects of operator and consumer exposure. The Committee offered its interpretation of the bird reproduction studies available. It concluded that there are no indications that residues in soil will have unacceptable effects. Further, the Committee noted that aquatic weed control uses of diquat may pose a high risk to non-target aquatic organisms and insufficient data is available to demonstrate that efficient risk mitigation measures can be applied.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 309, 9.12.2000, p. 14.

⁽³⁾ OJ L 366, 15.12.1992, p. 10.

⁽⁴⁾ OJ L 259, 13.10.2000, p. 27.

⁽⁵⁾ OJ L 107, 28.4.1994, p. 8.

⁽⁶⁾ OJ L 225, 22.9.1995, p. 1.

⁽⁷⁾ OJ L 49, 4.3.1995, p. 50.

⁽⁸⁾ Scientific Committee on Plants SCP/AMITR/002 final.

⁽⁹⁾ Scientific Committee on Plants SCP/DIQUAT/002 final.

With regard to operator exposure, the Committee advised that measures should be considered to limit exposure of non-professional users. Finally, the Committee noted that insufficient information is available to fully assess the dietary exposure of consumers related to uses as desiccant in small grain cereals. Those opinions were taken into consideration in this Directive and in the relevant review report.

- (7) For pyridate also, the dossier and the information from the review were submitted to the Scientific Committee for Plants for consultation. In its opinion of 6 June 2000 ⁽¹⁾, the Committee confirmed the validity of the acceptable operator exposure level selected within the Standing Committee on Plant Health.
- (8) For thiabendazole as well, the dossier and the information from the review were submitted to the Scientific Committee for Plants for consultation. In its opinion of 22 September 2000 ⁽²⁾, the Committee confirmed that the intended post-harvest uses of thiabendazole for fruit and potatoes will not pose an unacceptable risk to aquatic organisms, provided that adequate risk mitigation measures are applied. This recommendation was taken into consideration in this Directive and in the relevant review report.
- (9) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of the Directive, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include the active substances concerned in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing the active substances concerned can be granted in accordance with the provisions of the said Directive.
- (10) Article 5(5) of the Directive provides that the inclusion of an active substance in Annex I can be reviewed at any time if there are indications that the criteria for inclusion are no longer satisfied. Therefore, the Commission will reconsider the inclusion in Annex I of amitrole if the requested additional information as outlined in point 7 of the review report were not submitted.
- (11) The Directive provides that after inclusion of an active substance in Annex I, Member States must, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, plant protection products should not be authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in the Directive on the

basis of a dossier satisfying the prescribed data requirements.

- (12) A reasonable period must be provided for before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion. Moreover, after inclusion, a reasonable period is necessary to permit Member States to implement the provisions of the Directive on plant protection products containing amitrole, diquat, pyridate or thiabendazole. In particular, Member States must, within that period, review existing authorisations and, where appropriate, grant new authorisations in accordance with the provisions of the Directive. A longer period should be provided for the submission and assessment of the complete dossier of each plant protection product in accordance with the uniform principles laid down in the Directive. For plant protection products containing several active substances, the complete evaluation on the basis of the uniform principles can only be carried out when all the active substances concerned have been included in Annex I to the Directive.
- (13) It is appropriate to provide that the finalised review reports (except for confidential information) are kept available or made available by the Member States for consultation by any interested parties.
- (14) The review reports are required for the proper implementation by the Member States, of several sections of the uniform principles laid down in the Directive, where those principles refer to the evaluation of the data which were submitted for the purpose of the inclusion of the active substances in Annex I to the Directive.
- (15) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 12 December 2000,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, by 1 July 2002 at the latest. They shall forthwith inform the Commission thereof.

In particular they shall, in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing amitrole, diquat, pyridate or thiabendazole as active substances by that date.

⁽¹⁾ Scientific Committee on Plants SCP/PYRID/002 final.

⁽²⁾ Scientific Committee on Plants SCP/THIABEN/002-final.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. With regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the deadline for amending or withdrawing authorisations for plant protection products containing amitrole, diquat, pyridate or thiabendazole as the only active substance shall be 1 January 2006.

3. For plant protection products containing amitrole, diquat, pyridate or thiabendazole together with another active substance which is in Annex I to Directive 91/414/EEC, the period for amending or withdrawing authorisations shall expire four years after the entry into force of the Directive which amended Annex I so as to add the last of those substances to it.

4. Member States shall keep available the review reports for amitrole, diquat, pyridate and thiabendazole (except for confidential information within the meaning of Article 14 of

Directive 91/414/EEC) for consultation by any interested parties or shall make it available to them on specific request.

5. Member States shall inform the Commission if the requested additional information outlined in point 7 of the Review Report for amitrole is not submitted by 1 January 2002. In such case the Commission will reconsider the inclusion of amitrole in Annex I to Directive 91/414/EEC.

Article 3

This Directive shall enter into force on 1 January, 2002.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 5 March 2001.

For the Commission

David BYRNE

Member of the Commission

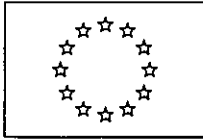
ANNEX

The following entries (numbered 14 to 17) shall be added at the end of the table in Annex I to Directive 91/414/EC:

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
14	Amitrole CAS No 61-82-5 CIPAC No 90	H-[1,2,4]-triazole-3-ylamine	900 g/kg	1.1.2002	31.12.2011	<p>Only uses as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on amitrole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of operators — must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses — must pay particular attention to the protection of beneficial arthropods — must pay particular attention to the protection of birds and wild mammals. Use of amitrole during the breeding season may only be authorised when an appropriate risk assessment has demonstrated that there is no unacceptable impact and when the conditions of authorisation include, where appropriate, risk mitigation measures
15	Diquat CAS No 2764-72-9 (ion), 85-00-7 (dibromide) CIPAC No 55	9,10-Dihydro-8a,10a-diazonia-phenanthrene ion (dibromide)	950 g/kg	1.1.2002	31.12.2011	<p>On the basis of currently available information, only uses as terrestrial herbicide and desiccant may be authorised. Uses in aquatic weed control shall not be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on diquat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures — must pay particular attention to operator safety as related to non-professional use and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures
16	Pyridate CAS No 55512-33,9 CIPAC No 447	6-Chloro-3-phenylpyridazin-4-yl S-octyl thiocarbonate	900 g/kg	1.1.2002	31.12.2011	<p>Only uses as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pyridate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of groundwater — must pay particular attention to the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
17	Thiabendazole CAS No 148-79-8 CIPAC No 323	2-Thiazol-4-yl-1H-benzimidazole	985 g/kg	1.1.2002	31.12.2011	<p>Only uses as fungicide may be authorised. Foliar spray applications shall not be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on thiabendazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of aquatic and sediment-dwelling organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures <p>Suitable risk mitigation measures (e.g. depuration with diatom earth or activated carbon) have to be implemented to protect surface waters from unacceptable levels of contamination via wastewater</p>

(1) Further details on identity and specification of active substance are provided in the review report.



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, Aventis (former 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. AgriChem and Aventis (former Stefes Agro GmbH) have withdrawn their notification on 27 September 1994 and 19 January 1995 respectively. Information has furthermore been submitted by the Austrian Umweltbundesamt .

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 12 December 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.

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

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

- 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.

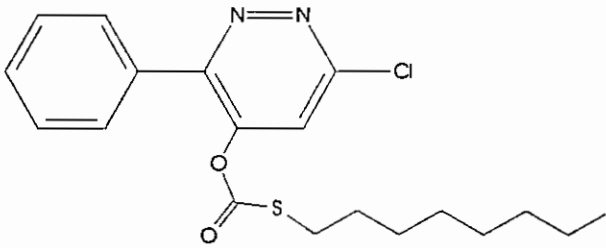
9. Updating of this review report

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	 <chem>CCCCCCCCSC(=O)Oc1cc(Cl)nc2ccccc12</chem>

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, minimal 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 F₁ and F₂).
Decreased thyroid weight (parental males (F₂).
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 studiesMetabolite CL9673: acute oral LD₅₀ 1420 mg/kg bw; not sensitizing; no point mutations.**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: (Hydroly.)	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.	
< 0.4 d	
not relevant	
<1 d	
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*Poecilus cupreus*

0 – 3 % (adults, mortality, 1.37 kg a.s./ha, lab test with Lentagran 45 WP)

0 % (adults, mortality, 0.9 kg a.s./ha, lab test with Lentagran 45 EC)

Aleochara bilineata

5.5 – 35 % (adult, mortality and reproduction, 1.37 kg a.s./ha, lab test with Lentagran 45 WP)

10 % (adults, reduction of parasitism, 1.37 kg a.s./ha, semi-field test with Lentagran 45 WP)

0-70 % (adults, mortality and reproduction, 0.91 kg a.s./ha, lab test with Lentagran 45 EC)

2.4 % (adults, reduction of parasitism, 0.91 kg a.s./ha, semi-field test with Lentagran 45 EC)

Typhlodromus pyri

4.2 % (protonymphs, mortality, 0.91 kg a.s./ha, ext. Lab test with Lentagran 45 WP)

-21.6 % (protonymphs, reduction in reproduction, 0.91 kg a.s./ha, ext. Lab test with Lentagran 45 WP)

-8 % (protonymphs, mortality, 0.91 kg a.s./ha, ext. Lab test with Lentagran 45 EC)

-63 % (protonymphs, reduction in reproduction, 0.91 kg a.s./ha, ext. Lab test with Lentagran 45 EC)

Aphidius rhopalosiphi

6.9 % (adults, mortality, 0.90 kg a.s./ha, ext. Lab test with Lentagran 45 WP)

11 % (adults, reduction in reproduction, 0.90 kg a.s./ha, ext. Lab test with Lentagran 45 WP)

10 % (adults, mortality, 0.90 kg a.s./ha, ext. Lab test with Lentagran 600 EC)

15 % (adults, reduction in reproduction, 0.90 kg a.s./ha, ext. Lab test with Lentagran 600 EC)

Episyrphus balteatus

4 % (larvae, mortality and fecundity, 1.36 kg a.s./ha, lab test with Lentagran 45 WP)

0 % (larvae, mortality, 1.31 kg a.s./ha, lab test with Lentagran 45 EC)

Earthworms

Pyridate techn.

Acute toxicity:

LC50: 799 mg/kg (*Eisenia foetida*)

Reproductive toxicity:

Not required.

Metabolit CL 9673 techn.

Acute toxicity:

LC50: 348 mg/kg (*Eisenia foetida*)

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)

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)

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	Reports ² 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	Reports ² on previous use in granting national authorizations
IIA 2.2	Földner, 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	

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 2.9.3	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)
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	

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 2.15	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),
IIA 4.1	R. Kettner	1999	Report on Validation of Linearity of Method 10865 Generated by: Novartis Crop Protection Mönchwilten 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 Mönchwilten 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)

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 10794 Generated by: Novartis Crop Protection Mönchwilten 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)
IIA 4.1	R. Kettner	1999	Report on Validation of Linearity of Method 10908 Generated by: Novartis Crop Protection Mönchwilten 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	

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 ² on previous use in granting national authorizations
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)
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	
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), 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)

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
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)

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	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 (Addendum: 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
IIA 7.1.2, IIA 7.1.3, IIIA, IIIA 9.1.2	Krüger, B.	1992	¹⁴ C-CL9673: Adsorption / Desorption of Four American Soils. Agrolinz Agrarchemikalien Report No.: 1126 GLP, unpublished	
IIA 7.1.2, IIA 7.1.3, IIIA, IIIA 9.1.2	Mittelstaedt, W., Führ, F.	1991	Field Lysimeter Studies with ¹⁴ C- Pyridate. Institut für Radioagronomie Report No.: AL 2/89 Non-GLP, unpublished	DE (09.1991) UK 25/08/94

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 7.1.2, IIA 7.1.3, III A, III A 9.1.2	Pfarl, Ch.	1989 (1990)	Ergebnisse der CL 9673 Spurenanalysen (Hauptmetabolit von Pyridate) in Rohwasser (Grundwasser). Agrolinz Agrarchemikalien Report No.: 1000 a + 1000 b Non-GLP, unpublished	DE (09.1991)
IIA 7.1.2, IIA 7.1.3, III A, III A 9.1.2	Pfarl, Ch.	1991	Ergebnisse der CL 9673 Spurenanalysen (Hauptmetabolit von Pyridate) in Rohwasser (Grundwasser). Agrolinz Agrarchemikalien Report No.: 1086 Non-GLP, unpublished	DE (09.1991)
IIA 7.1.2, IIA 7.1.3, III A, III A 9.1.2	Zohner, A.	1987	Determination of mobility of soil-aged ¹⁴ C-Pyridate residues on four soils by soil column leaching test. Agrolinz Agrarchemikalien Report No.: 877-1 Non-GLP, unpublished	DE (05.1990)
IIA 7.2.1.2	Van Dijk, A, Betschart, B.	1992	Photodegradation Study of ¹⁴ C-Pyridate in water at pH 5, 7 and 9. RCC Umweltchemie Report Nr.: 287548 GLP, unpublished	UK 25/08/94
IIA 7.2.1.2	Werle, H.	1993	Direct Phototransformation Study CL 9673 -Determination of Quantum Yield in water at pH 7. BioChem Report No.: 92 50 40 035 B Non-GLP, unpublished	DE (01.1994)
IIA 7.2.1.2	Zohner, A.	1988 (a)	Aqueous photolysis study on ¹⁴ C-CL 9673, the hydrolysis product of ¹⁴ C-Pyridate. Agrolinz Agrarchemikalien Report No.: 941 (VI/38) Non-GLP, unpublished	DE (05.1990) UK 25/08/94
IIA 7.2.3	Ewald, G	1993	Photochemical-oxidative degradation of Pyridate, Theoretical calculation according to Atkinson ECON Report No.: Non-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	Reports on previous use in granting national authorizations
IIA 7.1.2	Zohner, A.	1985	Aerobic metabolism study of ¹⁴ C-Pyridate in water/sediment. Chemie Linz AG Report No.: 840 Non-GLP, unpublished	DE (05.1990)
IIA 7.1.2	Zohner, A.	1988	Partition of ¹⁴ C-Pyridate in water sediment. Agrolinz Agrarchemikalien Report No.: 925 Non-GLP, unpublished	DE (05.1990)
IIA 7.1.3.3	Burgener, A.	1996	¹⁴ C-Pyridate (as WP Formulation): Mobility and degradation in soil in outdoor lysimeters RCC Project 274206 SAN 319/5108 GLP-compliance GLP, unpublished	DE (08.1997)
IIA 7.2.1.1	Lutringer, C.	1997	Pyridate: Hydrolysis as a Function of pH Report No. TDS BS 12456 Study No. E96-23 GLP-compliance GLP, unpublished	DE (04.2000)
IIA 7.2.3	Knoch, E., Knoell, E.	1991	Determination of the evaporation of LENTAGRAN WP from surfaces. RCC Umweltchemie AG Report No.:228317 GLP, unpublished	DE (09.1991) UK 25/08/94

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	Reports on previous use in granting national authorizations
IIA 8.2.1	Wüthrich, V.	1993	CL 9673 technical: 96-Hour acute toxicity study (LC ₅₀) in the rainbow trout under flow through conditions. RCC Umweltchemie AG Report No.: 345328	
IIA 8.2.6	Grade, R.	1998	Growth inhibition test of Pyridate (techn.) on Blue Algae <i>Anabaena flos-aquae</i> under static conditions Project No. 971650 GLP-compliance Not published	DE (09.1998)
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; Lühns, 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	
IIA 8.3.2 IIIA 10.5	Großmann, A; Lühns, 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	

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	Kühner, C	1997	Lentagran 600 EC (A-9921 A): Determination of Side-effects on the Aphid Parasitoid, <i>Aphidius</i> spp. (Hymenoptera, Aphidiidae) using an extended laboratory test Generated by: GAB Biotechnology GmbH. Rep. No.: 97190/01-NEAp GLP-compliance Not published	
IIA 8.3.2 IIIA 10.5	Longley, M	1997	A laboratory study to evaluate the side effects of the herbicide Lentagran WP (SAN 145000 H 450 WP) on the parasitic wasp <i>Aphidius rhopalosiphi</i> Generated by: Agrochemical evaluation unit, school of biological sciences, University Southampton, UK Report No. SAN-97-11 GLP-compliance Not published	
IIA 8.3.2 IIIA 10.5	Longley, M	1997	A laboratory study to evaluate the side effects of the herbicide Lentagran EC (SAN 90001 H 450 EC) on the parasitic wasp <i>Aphidius rhopalosiphi</i> Generated by: Agrochemical evaluation unit, school of biological sciences, University Southampton, UK Report No. SAN-97-9 GLP-compliance Not published	
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	

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	Schmitzer, S	1997	Effects of Lentagran 45 WP on Predatory mites <i>Typhlodromus pyri</i> in the laboratory Generated by: IBACON GmbH Rep.No.: 2180063 GLP-compliance Not published	
IIA 8.3.2 IIIA 10.5	Schmitzer, S	1997	Effects of Lentagran 450 EC on Predatory mites <i>Typhlodromus pyri</i> in the laboratory Generated by: IBACON GmbH Rep.No.: 2170063 GLP-compliance Not published	
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 NO. SAN-97-12 GLP-compliance Not published	
IIA 8.3.2 IIIA 10.5	Thompson, B	1998	A laboratory study to evaluate the side effects of the herbicide Lentagran EC (SAN 90001 H 450 EC) on the hoverfly <i>Episyrphus balteatus</i> Generated by: Agrochemical evaluation unit, school of biological sciences, University Southampton, UK AEU Report NO. SAN-97-10 GLP-compliance Not published	

**SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 12 DECEMBER 2000 IN BRUSSELS**

President : G. Del Bino

All Member States were present.

- 1 Examination and possible vote on a Draft Commission Decision making it possible for Member States to extend provisional authorisations granted for the new active substances IKI 11454, TO 1145 (fosthiazate), CGA 329351 (metalaxyl-m), MON 37500 (sulfosulfuron) and Spodoptera nuclear polyhedrosis virus (Sanco/4000/2000 rev. 3).**

Vote : favourable opinion by qualified majority (84 in favour, 4 against).

The decision will allow Member States to extend provisional authorisations of products containing these substances until a final decision on Annex I inclusion can be made.

- 2 Examination and possible vote on a Draft Commission Directive concerning the inclusion of pyridate in Annex I to Council Directive 91/414/EEC (Directive Sanco/4043/2000 rev 3 (Pyridate) Review Report 7576/VI/97-rev. 5).**

The Commission presented the Review Report. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: “The Dutch delegation is of the opinion that for national authorisations of pyridate it might be appropriate to use, under national use conditions, a different dermal absorption figure than that indicated in the endpoint lists of the Review Reports. The Dutch delegation is further of the opinion that for national authorisations of pyridate it might be appropriate to use a long-term AOEL instead of the present short-term AOEL in the endpoint list of the review reports.”

Commission: At the adoption of the Uniform Principles by Council in 1997, the Council and Commission agreed to the following declaration:

“The Council and the Commission note that application of this Directive is without prejudice to the legislation in force concerning the protection of workers. The Council and the Commission state that this principle will be unequivocally clarified in Directive 91/414/EEC on the occasion of the first amendment of that Directive. The Commission intends to submit a proposal for such amendment within one year from the date of notification of this Directive.”

The Commission can for its part confirm its agreement with this declaration (subject to adequate adaptation of the deadline in the declaration).

Vote : unanimous favourable opinion.

3 Examination and possible vote on a Draft Commission Directive concerning the inclusion of amitrole in Annex I to Council Directive 91/414/EEC (Directive Sanco/4043/2000 rev 3 (Amitrole); Review Report 6839/VI/97-rev. 4).

The Commission presented the Review Report. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

Sweden: In our view it is not possible to include amitrole in Annex I to Directive 91/414/EEC, since it cannot be expected that products containing this substance will fulfil the conditions stated in Article 5 of the Directive, particularly with regard to the protection of operators and environment.

One of our concerns is that amitrole could be regarded as an endocrine disruptor and is listed in group I in the Commission draft document “Establishment of a priority list of substances for further evaluation of their role on endocrine disruption” COM (1999)706. This mechanism may imply that not all relevant endpoints are being covered by the standard toxicity tests. Thus, there is a larger uncertainty for these kinds of substances, which has not been taken into adequate consideration in the present risk assessment.

Commission: Same declaration as for pyridate.

The Commission further declares that Article 5 (5) of Directive 91/414/EEC provides that the inclusion of an active substance in Annex I can be reviewed at any time if there are indications that the criteria for inclusion are no longer satisfied. Therefore, the Commission will reconsider the inclusion of amitrole in Annex I if the additional information as outlined in point 7 of the Review Report would not be submitted within the timelines provided.

Vote : favourable opinion with qualified majority (67 votes in favour, 20 against).

4 Examination and possible vote on a Draft Commission Directive concerning the inclusion of diquat in Annex I to Council Directive 91/414/EEC (Directive Sanco/4043/2000 rev 3 (Diquat); Review Report 1688/VI/97-rev.8).

The Commission presented the Review Reports on the four substances. The Committee took note of the Review Reports.

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

Portugal: The portugese delegation considers that the phrase “uses in aquatic weed control shall not be authorised” included in the specific provisions of Annex I of the Directive, is

not clear. Our favourable vote is based on the understanding that this phrase refers to the direct application of the herbicide into the water against aquatic weeds.

This declaration is supported by Spain and Greece.

Ireland: The terms of the proposed inclusion of diquat in Annex I of Directive 91/414/EEC contravenes the provisions of Art. 4 of that Directive to the extent that it pre-empts decisions to be made by Member States in granting authorisations following application of the Uniform Principles (Annex VI) in relation to plant protection products containing diquat.

Germany: Germany votes against the proposed Directive concerning diquat for the sole reason that it contains specific provisions concerning the authorisation and restriction of certain uses, which should be subject to national regulatory decisions. Germany would welcome if this principal question would be clarified soon within the Commission, in view of future decisions and with the aim to speed up decision making.

United Kingdom: The United Kingdom believes that the use of diquat as an aquatic herbicide under carefully controlled conditions is acceptable and should not be restricted in the Annex I decision. It believes that this use should be permitted and regulated by Member States in accordance with the Uniform Principles.

However, the United Kingdom is prepared to support the Commission's proposal in the interest of making progress with the review. This support is on the understanding that the issue of aquatic use will be re-considered before the Directive comes into force. The United Kingdom will prepare a revised risk assessment for consideration by the Scientific Committee on Plants to facilitate this process.

This declaration is supported by Ireland and Greece.

France: France has decided to vote in favour of the inclusion of diquat in Annex I of Council Directive 91/414/EEC. It would like to associate the following declaration to this vote: France considers the restriction introduced into the specific provisions of the Annex as inadequate. The evaluation of non-representative uses and/or uses specific to local conditions must be conducted by the Member States. Further, the phrasing concerning the specific conditions of use is not sufficiently clear. France therefore hopes that the present Directive will be revised, if the acceptability of aquatic uses can be demonstrated.

Commission: Same declaration as for pyridate.

In response to the declarations made by the United Kingdom and France the Commission declares that it will do its part to ensure that further information concerning aquatic weed control with diquat will be evaluated without delay in the working groups of the Standing Committee for Plant Health and the Scientific Committee on Plants.

Vote: favourable opinion with qualified majority (71 votes in favour, 16 against).

5 Examination and possible vote on a Draft Commission Directive concerning the inclusion of thiabendazole in Annex I to Council Directive 91/414/EEC (Directive Sanco/4043/2000 rev 3 (Thiabendazole) Review Report 7603/VI/97-rev. 3).

The Commission presented the Review Report. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

Sweden: Sweden declares that post harvest disease control on fruit and ware potatoes is not and has never been approved in Sweden. These uses have been considered not to be in line with the national risk reduction policy on pesticides, with regard to consumer safety, and on the principles of integrated pest management. Control of storage diseases has sufficiently been achieved by other means, such as climatic control in warehouses. Our opinion is that even if the MRL's are not exceeded, a national approval for post harvest use will lead to increased dietary exposure for consumers and thereby counteract the national risk reduction policy on pesticides. Sweden intends to continue its line of action to prevent the use of pesticides on edible plant products.

Germany: Germany votes in favour, but confirms that the declaration given on diquat also applies to the specific provisions given for thiabendazole.

Commission: Same declaration as for pyridate.

Vote : favourable opinion with qualified majority (80 votes in favour, 7 against).

6 Examination of a Commission project concerning the non-inclusion of parathion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.

A text for a draft proposal was not tabled. With the exception of Germany, which had not yet defined its position, all delegations expressed their support in principle for the non-inclusion of parathion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations.

7 Examination and possible vote on a Draft Commission Decision concerning the possible inclusion of certain active substances into Annex I to Directive 91/414/EEC (Sanco/4090/2000 rev.2; report from the Working Group Legislation).

In relation to giving its opinion on the Draft Commission Decision concerning the possible inclusion of certain active substances into Annex I to Directive 91/414/EEC, the Standing Committee on Plant Health took note of the following data requirements, established by the Commission, having consulted the Committee, for the active substances listed in its Annex.

	Data requirements contained in document :
2,4-DB	Doc. 7602/VI/97 rev. 15 of 15/11/00
Acephate	Doc. SANCO/3056/99 rev. 0-2 of 07/07/00
Amitraz	Doc. 6493/VI/99 rev. 5 of 05/10/00
Chlorpropham	Doc. SANCO/3040/99 rev. 0-3 of 06/09/00
Chlorpyrifos	Doc. SANCO/3058/99 rev. 0-3 of 08/09/00
Chlorpyrifos-methyl	Doc. SANCO/3060/99 rev. 0-3 of 08/09/00
Daminozide	Doc. SANCO/3042/99 rev. 1 of 15/11/00
Deltamethrin	Doc. 6488/VI/99 rev. 3 of 21/12/99
Linuron	Doc. 7596/VI/97 rev. 9 of 20/03/00
Mecoprop	Doc. SANCO/3062/99 rev. 0-2 of 07/07/00
Mecoprop-P	Doc. SANCO/3064/99 rev. 0-2 of 07/07/00
Molinate	Doc. SANCO/3046/99 rev. 0-3 of 06/07/00
Pendimethalin	Doc. 7476/VI/98 rev. 7 of 22/08/00
Propiconazole	Doc. 3048/SANCO/99 rev. 0-3 of 07/07/00
Propyzamide	Doc. 6486/VI/99 rev. 3 of 27/12/99
Thiram	Doc. 6491/VI/99 rev. 6 of 15/11/00
Ziram	Doc. 6492/VI/99 rev. 5 of 15/11/00

The following long term studies have been identified as necessary :

Linuron : Earthworm reproduction study (Annex II, point 8.4.2)

Molinate : Avian reproduction study (Annex II, point 8.1.3)

Vote : unanimous favourable opinion.

The Decision sets timelines for the submission of additional or outstanding information on 17 substances being evaluated under the first review program.

8 Any other business.

8.1: Final report of the FOCUS workgroup for groundwater scenarios (SANCO/321/2000 rev. 2).

The Committee took note of the report. It is agreed that questions concerning the interpretation and decision making related to the groundwater scenarios will be further discussed in the Working Group "Plant Protection Products - Evaluation " in the context of the review of individual substances.

8.2: Proposal for a symposium concerning the consequences of the review program under Council Directive 91/414/EEC for European agriculture (Point raised by Germany).

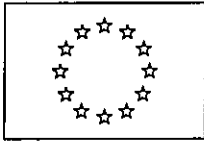
The Commission at this stage sees no priority to hold such a symposium. As agreed in the Working Group "Plant Protection Products - Legislation" Member States are asked to report on the expected consequences of Regulation (EC) N° 451/2000 by May 2001 and further steps will be decided thereafter.

8.3: Participation of accession countries in the peer review and the working groups of the Standing Committee for Plant Health (Point raised by Greece).

The Commission notes that accession countries can not, at this stage, participate in the Standing Committee for Plant Health and its working groups. The Commission will consider options of their participation in the peer review meetings.

The measures on which the Committee has given its opinion are subject to the appropriate procedures for formal adoption by the Commission.

A CHECCHI LANG
Director



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate B – Scientific Health Opinions
Unit B2 – Management of scientific committees I

SCIENTIFIC COMMITTEE ON PLANTS

**SCP/PYRID/002-Final
13 July 2000**

**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**

(Opinion expressed by the Scientific Committee on Plants on 6 June 2000)

1. TITLE

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

2. TERMS OF REFERENCE

In the context of the Commission's work on the implementation of Directive 91/414/EEC¹ concerning the placing of plant protection products on the market the Scientific Committee on Plants is requested to comment on the suitability of the three-generation study in rats for the estimation of the AOEL² for pyridate.

3. BACKGROUND

The opinion is based on the documentation generated in the context of possible inclusion of pyridate in Annex I to Directive 91/414/EEC³, and on the evaluation of four original studies (1,2,3,4), relevant to the Terms of Reference.

In order to prepare its opinion, the Scientific Committee on Plants had access to documentation comprising a monograph prepared by Austria as Rapporteur Member State (RMS) and the recommendations of the ECCO⁴ Peer Review Programme.

Pyridate is a pyridazine derivative, used as post-emergence contact herbicide in agriculture and horticulture. The evaluation of the toxicological dossier indicates that pyridate is of low toxicity to rats (oral LD₅₀⁵ >2000 mg/kg bw), skin irritant and skin sensitizer. There is no experimental evidence of teratogenicity, mutagenicity or carcinogenicity. A neurotoxic potential of pyridate is quite consistently observed in short-term studies performed in several species (rat and dog, even if at different dose levels), with dose-dependent clinical symptoms and signs (hypoactivity, salivation, emesis, ataxia, etc.).

In the context of the ECCO⁶ Peer Review Programme, the originally established AOEL of 1.2 mg/kg bw, based on clinical neurotoxic signs in the 1-year study in dog (NOAEL=30 mg/kg bw, SF⁷ = 25), was revised to a new systemic AOEL of 0.036

¹ OJ L 230, 19. 08. 1991, p.1.

² Acceptable Operator Exposure Level

³ OJ 230, 19.08.1991, p.1

⁴ European Community Co-ordination

⁵ Lethal Dose 50%

⁶ European Community Coordination

⁷ Safety Factor

mg/kg bw/day. The new AOEL was established by applying a SF of 100 to the NOAEL of 3.6 mg/kg bw/day in the 3-generation study in rat, based on increased relative kidney weights in the F₂ and F₃ generations and decreased relative thyroid weights in males of the F₂ generation at 400 ppm (18.8 mg/kg bw/day).

4. OPINION OF THE COMMITTEE

4.1 Question

“Is the three generation study in rats suitable for the estimation of the AOEL for pyridate? If not, would the ninety-day study provide a more adequate basis?”

Opinion

The three generation study in rats is suitable for the estimation of the AOEL for pyridate. In the absence of a mechanistic explanation of the observed effects on organ weights, and in the absence of data to predict the relevance of similar effects to humans, it is justified to use the NOAEL of 3.6 mg/kg bw/day, based on decreased thyroid weight and increased kidney weight for AOEL setting.

4.1.1 Scientific background on which the opinion is based

The reproductive study indicates that pyridate induces dose-dependent effects in the weights of thyroid and kidney. A slight increase in kidney weights was observed in the top-dose group of both sexes in the F₁ and F₂ generation, in females of the mid-dose group of the F₂ generation, and in both sexes of the mid-dose group of the F₃ generation. A dose-dependent decrease of the thyroid weights was observed in males of the mid- and top-dose groups of the F₂ generation. Liver weight was increased only in F₂ females of the top-dose group.

Effects on organ weights similar to those reported in the multigeneration study were observed also in short-term and long-term studies in rat (not in dog), even if not consistently and at higher doses.

Increased kidney weights were reported in two 90-day studies in rat: at 398 mg/kg bw (3) and at 177 mg/kg bw (2). Increased liver weights were noted in the latter study in both sexes at 177 mg/kg bw, and decreased thyroid weights were recorded in females at all dose levels (63.5, 177, and 500/600 mg/kg bw) and in males at the top dose of 500 mg/kg bw.

An increase of kidney weights in males at the top dose of 115 mg/kg bw, and a dose-dependent decrease of thyroid weights in males at all doses (lowest dose=18 mg/kg bw) were seen in the long-term study in rat, at the interim kill after one year. These effects were only transient and reverted to control values at the end of the study.

The notifier argued that, since the kidney effect observed in the reproductive study is not associated with deviations in clinical chemistry data or histopathological findings, they should not be considered as adverse but more as “adaptive” effects, “due to an overload of the organism as the result of a higher feed intake, especially in young animals”. The notifier considered also that the findings on thyroid were not related to the treatment. It is opinion of the SCP, however, that the observation of similar results in the short-term study, and in the long-term study after one year may rather indicate a higher sensitivity of younger and middle age animals.

The AOEL should be based on the NOAEL in the most sensitive relevant species. In the case of pyridate, effects seen in the reproduction study represent the most sensitive end-points. The mechanism of action responsible for the observed effects is not clear from the overall body of data. The weight of evidence for the observed effects is supported by similar results observed in other studies of different design. It is important to remark that, in the absence of data to disregard the relevance of similar effects to humans, any effect in reproduction studies should be considered to be of particular biological importance.

In conclusion, the NOAEL of 3.6 mg/kg bw from the reproductive study should be regarded as relevant for AOEL setting.

5. REFERENCES

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- (2) HENCK, 1987, 90-day rat oral subchronic toxicity study with a 28-day recovery period of Pyridate technical Toxicity Research Lab. Report N° 043-005 Annex IIA, 5.3.2
- (3) DANKS, 1991, Pyridate technical: Toxicity study by dietary administration to CD rats for 13 weeks, Life Sci. Res. Report N° 90/AGL002/0614, Annex IIA, 5.3.2
- (4) TIL, 1990, Lifespan oral carcinogenicity study of Pyridate in rats (Revised Final Rep.), TNO-CIVO Institutes TNO Report V89.237, Annex IIA, 5.5

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- (2) Pyridate: Report from Rapporteur Member State (Austria) on the dossier.
- (3) Pyridate: Evaluation table – doc 7756/VI/97-Rev.4 (SCP/PYR/3).

7. ACKNOWLEDGEMENTS

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Toxicology: Professor M. Maroni (Chairman), and Committee Members
Dr. M.-P. Delcour-Firquet, Dr. O. Meyer, Dr A. Moretto, Prof. K. Savolainen, Prof. A. Silva Fernandes, Dr. G. Speijers and invited expert A Fait.

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