EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Paraquat

SANCO/10382/2002 -final

3 October 2003

Review report for the active substance **paraquat**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 October 2003 in view of the inclusion of paraquat 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 paraquat, 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. Paraquat is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, United Phosphorus Ltd on 26 July 1993, Zeneca Agrochemicals (now Syngenta) on 27 July 1993, Barclay Chemicals Ltd on 27 July 1997, Aporta SA on 19 July 1993, Pilar Ibérica SL on 23 July 1993, Marubeni UK plc on 23 July 1993, Helm AG on 23 July 1993, Calliope SA on 21 July 1993, Industrias Afrasa on 27 July 1993, Grower on 29 July 1993, Agrolac SA on 26 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance paraquat 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 the United Kingdom as rapporteur Member State to carry out the assessment of paraquat on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of

[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.

Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for paraquat this deadline was 31 October 1995.

Zeneca Agrochemicals (now Syngenta), United Phosphorus Ltd, Barclay Chemicals Ltd and Marubeni UK plc submitted each a dossier to the rapporteur Member State. No dossiers were submitted by the other notifiers. Zeneca Agrochemicals (now Syngenta) was the main data submitter, with a dossier which did not contain substantial data gaps, taking into account the supported uses. United Phosphorus Ltd, Barclay Chemicals Ltd and Marubeni UK plc did not submit complete dossiers. Information has furthermore been submitted by third parties, European Federation of Agricultural Workers and the European Chemical Bureau.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, the United Kingdom submitted on 31 October 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 paraquat 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 paraquat from Zeneca Agrochemicals (now Syngenta), on 26 February 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 Zeneca Agrochemicals (now Syngenta) being the main data submitter, on 11 February 1996.

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 the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from June 2000 to July 2003, and was finalised in the meeting of the Standing Committee on 3 October 2003.

The documents and information were also submitted to the Scientific Committee for Plants for a separate independent consultation. The Committee was asked to comment on the relevance for consumers and operators of the ocular and pulmonary changes, which were observed in the long-term rat study; on the risk for operators, taking into particular account potential inhalatory and dermal exposure; on potential long-term effects to soil dwelling organisms; and on the risks the intended uses might pose to reproducing birds and hares.

In its opinion[5], the Scientific Committee concluded that the systemic effects on the eye, observed in rats and not in other species, are not relevant to the risk assessment for operators and consumers. Furthermore the Scientific Committee expressed the opinion that pulmoray lesions are not expected to occur under the exposure conditions that can take place in occupational settings or for consumers, when paraquat is used as a plant protection product as recommended. Based on the field exposure studies, corroborated by information on health surveys on operators, the SCP voiced the opinion that when paraquat is used as a plant protection product as recommended under prescribed good working practices, its use does not pose any significant health risk for the operators.

The Committee also noted that uses at recommended field rates are unlikely to pose a significant risk to soil-dwelling organisms. However, a more detailed appraisal of the likely effects of paraquat on the rate of degradation of organic material in soil was requested in view of remaining uncertainty. This information was subsequently delivered and evaluated by the Rapporteur Member State.

Furthermore, the Scientific Committee concluded that available studies indicate a hazard to ground breeding birds but further information on realistic exposures is needed for a definitive assessment of the risk. This information was subsequently provided and the evaluation within the Standing Committee on the Food Chain and Animal Health concluded that there are several situations where exposure to ground nesting birds is negligible. However, there are also scenarios where exposure may occur. The evaluation within the Standing Committee on the Food Chain and Animal Health concluded that the risk would be acceptable, provided appropriate risk mitigation measures are applied. Finally, the Scientific Committee concluded that paraquat may be expected to cause lethal and sublethal effects for hares, but the available data are inadequate to estimate the proportion of hares affected. The views of the Scientific Committee were taken into consideration when drafting this Directive and the Review Report. The evaluation within the Standing Committee on the Food Chain and Animal Health concluded that the risk would be acceptable if appropriate risk mitigation measures are applied.

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.

[5] Opinion of the Scientific Committee on Plants on specific questions from the Commission regarding the evaluation of paraquat in the context of Council Directive 91/414/EEC; SCP/PARAQ/002 adopted on 20 December 2001.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2003/112/EC[6] concerning the inclusion of paraquat in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing paraquat 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 paraquat 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 paraquat containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

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[6] OJ L 321, 6.12.2003, p. 32.

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 17 % 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 results of acute dietary risk assessment show that acceptable uses can be demonstrated.

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 paraquat are given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report. Technical concentrates shall comply with the FAO specification and, in particular, shall contain an effective emetic. Liquid formulations shall contain an effective emetic, blue/green colourants and stenching or other olfactory alerting agent or agents. Other safeners, such as thickeners, may also be included.

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.
In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, the United Kingdom is unable to determine, on the basis of the information currently available, that the substances notified by the other data submitters (United Phosphorus Ltd, Barclay Chemicals Ltd, Aporta SA, Pilar Ibérica SL, Marubeni UK plc, Helm AG, Calliope SA, Industrias Afrasa, Grower, Agrolac SA, and B.V. Luxan) do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter.

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 set out under point 1 above. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing paraquat

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:

- Member States must pay particular attention to the protection of operators, in particular for knapsack and handheld applications. Use restrictions and risk mitigation measures should be used where appropriate. The following specific measures should be implemented
  - the availability of the product should be limited to *bona fide* agriculturists, horticulturalists and professional users;
  - the maximum spray concentration must not exceed 2 g bipyridyl/litre for knapsack and hand held applications.

- For use scenarios where potential for exposure of eggs of ground nesting birds exists - use of paraquat 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.

- For use scenarios where potential for exposure of hares exists - use of paraquat 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. Risk mitigation measures may include:
  - no aerial spraying (to avoid over spraying);
  - to provide that a repellent, which it is effective against hares e.g. ammonium sulphate, is added to the plant protection product or the tank mix;
  - avoid spray patterns which would trap hares within the spray area e.g. spray from the centre of the field outwards;
  - avoid spraying the whole field with paraquat on the same day if there is no alternative forage adjacent to the sprayed field.

- Member States must pay particular attention to the protection of aquatic organisms. Conditions of authorization should include risk mitigation measures, where appropriate.

In addition to the above particular issues, Member States should also consider to limit knapsack and handheld use to trained/certified personnel where appropriate training and certification schemes are in operation at Member State level.

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 paraquat in Annex I under the current inclusion conditions.

However the authorization holders of plant protection products containing paraquat should undertake to monitor and to report at the latest by 31 March each year until 2008 on incidences of operator health problems and impact on hares in one or more representative areas of use, which should be supplemented by sales data and a survey of use patterns, so that a realistic picture of the toxicological and ecological impact of paraquat can be obtained. This will allow a further evaluation, without delay and in line with scientific progress, of the properties and potentially related risks to humans and the environment.

Some uses however may require the generation or submission of additional studies or assessments to be submitted to the Member States to support 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.

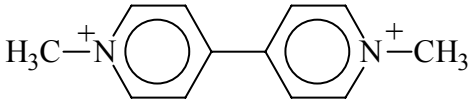
9. Updating of this review report

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 the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for paraquat in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

PARAQUAT

Common name (ISO)	Paraquat
Chemical name (IUPAC)	1,1'-dimethyl-4,4'-bipyridinium
Chemical name (CA)	1,1'-dimethyl-4,4'-bipyridinium
CIPAC No	56 (paraquat)
CAS No	4685-14-7 (paraquat ion)
EEC No	225-141-7 (paraquat ion) 217-615-7 (paraquat dichloride)
FAO SPECIFICATION	The technical concentrate shall consist essentially of an aqueous solution of paraquat dichloride, together with related manufacturing impurities containing not more than a trace of suspended matter, immiscible solvents or sediment, and containing an effective emetic. Aqueous solutions of technical paraquat dichloride, should include wetting and safening agents which will include an effective emetic and blue/green colourants, and may include other safeners including stenching agents and thickeners. It shall contain not more than a trace of suspended matter, immiscible solvents and sediment. Technical concentrates may also include colourants. The paraquat dichloride content (Note 1) shall be declared (not less than 500 g/l at 20°C, Note 2) and, when determined, the content obtained shall not differ from that declared by more than ± 25g/kg. An effective emetic must be included at a specified level. The content shall be declared and, when determined, shall not differ from that declared by more than ± 15% (Note 3). Impurity: free 4,4¢-bipyridyl Maximum: 0.2% by weight of the paraquat dichloride content AGP: CP/344 Rome 1996 (56/SL/S/F & 56/TK/S/F)
Molecular formula	$C_{12}H_{14}N_2$
Molecular mass	186.3
Structural formula	
Melting point	Paraquat dichloride decomposes at approximately 340 °C.
Boiling point	Paraquat dichloride decomposes at approximately 340 °C.

Appearance	Hygroscopic solid Liquid (technical)
Relative density	1.5 g/cm^3 at 25 °C (purity 99.5 % w/w) 1.13 g/cm^3 at 25 °C (technical)
Vapour pressure	< 10^{-8} kPa at 25 °C (purity 99.5 % w/w) [Vapour pressure too low to be measured, therefore the value was estimated]
Henry's law constant	$4 \cdot 10^{-12}$ Pa·m^3·mol^{-1} (purity 99.5 % w/w)
Solubility in water	At 20 °C: pH 5.2: 618 g/l (purity 99.5 % w/w) pH 7.2: 620 g/l (purity 99.5 % w/w) pH 9.2: 620 g/l (purity 99.5 % w/w)
Solubility in organic solvents	At 20 °C: Methanol: 143 g/l (purity 99.5 % w/w) Acetone: <0.1 g/l (purity 99.5 % w/w) Dichloromethane: <0.1 g/l (purity 99.5 % w/w) Toluene: <0.1 g/l (purity 99.5 % w/w) Ethyl acetate: <0.1 g/l (purity 99.5 % w/w) Hexane: <0.1 g/l (purity 99.5 % w/w)
Partition co-efficient (log P_{OW})	-4.5 at 20 °C (purity 99.5 % w/w)
Hydrolytic stability (DT_{50})	Hydrolytically stable at pH 5, 7 and 9 after 30 days at 25 and 40°C
Dissociation constant	Paraquat ion does not dissociate.
Quantum yield of direct photo-transformation in water at ε >290 nm	6 hours
Flammability	Paraquat dichloride technical is an aqueous solution it does not evolve highly flammable gases and the determination of the flammability of paraquat dichloride as manufactured is therefore inappropriate.
Explosive properties	The chemical structure of paraquat does not include bond groupings which confer explosive properties
UV/VIS absorption (max.)	290 nm e M^{-1} cm^{-1}
Photostability in water (DT_{50})	Photolytically stable at pH 7 with no significant decrease in concentration having been recorded after the equivalent of 37 days of summer sunlight in Florida.

APPENDIX II

END POINTS AND RELATED INFORMATION

PARAQUAT

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid. Approximately 10 % absorption.
Distribution:	Extensive
Potential for accumulation:	Some potential in lungs
Rate and extent of excretion:	> 90 % in 72 h
Toxicologically significant compounds:	Parent compound
Metabolism in animals:	Minimal metabolism, representing < 1 % of recovery

Acute toxicity[7]

Rat LD_{50} oral:	93.4 - 113.5 mg/kg/bw paraquat ion
Rat LD_{50} dermal:	(in rabbit) > 660 mg/kg bw (paraquat ion) Other studies about 200 mg/kg bw (paraquat ion)
Rat LC_{50} inhalation:	0.6 - 1.4 mg/m^3
Skin irritation:	Slight but not classifiable in animal studies.
Eye irritation:	Irritant
Sensitization (test method used and result):	Negative in Magnusson & Kligman protocol

Short term toxicity

Target / critical effect:	Lungs - alveolar damage by oral route. Upper respiratory tract damage by inhalation.
Lowest relevant oral NOAEL / NOEL:	0.45 mg/kg bw/d, 1 year dog study
Lowest relevant dermal NOAEL / NOEL:	No studies available
Lowest relevant inhalation NOAEL / NOEL:	10µg/m^3, 3 week (15 exposure) rat study

Genotoxicity

Negative *in vivo.* Some *in vitro* positives.

[7] Expressed as paraquat ion.

Long term toxicity and carcinogenicity

Target / critical effect:	Eyes (cataract), kidney (tubule degeneration), lung and testes.
Lowest relevant NOAEL:	1.2 mg/kg bw/d (25 ppm) in chronic rat study
Carcinogenicity:	Not carcinogenic

Reproductive toxicity

Target / critical effect - Reproduction:	Lung lesions in parental animals. No specific effects on reproduction.
Lowest relevant reproductive NOAEL / NOEL:	2.5 mg/kg bw/d based on lung lesions in parents
Target / critical effect - Developmental toxicity:	Target / critical effect: Embryotoxic at maternally toxic doses.
Lowest relevant developmental NOAEL / NOEL:	3 mg/kg bw/d

Delayed neurotoxicity

No indication of neurotoxicity.

Other toxicological studies

None submitted.

Medical data

Published literature and company records report fatalities in cases of oral ingestion of concentrate i.e. not as a consequence of occupational exposure. Cases of skin irritation, nail discolouration and nosebleeds in manufacture and occupational use have been reported, related to inadequate working practices and poor hygiene.

Summary

	Value	Study	Safety factor
ADI:	0.004 mg/kg bw based on NOAEL	1 year dog study	100 fold factor
AOEL systemic (long term)	0.0004 mg/kg bw/d	on 1 y dog study corrected for 10 % oral absorption	100 factor
AOEL systemic (short term)	0.0005 mg/kg bw/d	on 90 day dog study corrected for 10 % oral absorption	100 factor
AOEL inhalation:	N/A, use systemic value	-	-
AOEL dermal:	N/A, use systemic value	-	-
ARfD (acute reference dose):	0.005 mg/kg bw/d	90 day dog study	100 factor

Dermal absorption

0.5 % based on overall weight of evidence.

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	Due to strong adsorption to soil, the route of microbial degradation has only been demonstrated in pure cultures.
Non-extractable residues after 100 days:	Not relevant. See comment above
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	Not relevant. See comment above

Supplemental studies

Anaerobic:	Relatively stable, withstands degradation.
Soil photolysis:	No significant degradation.
Remarks:	Standard requirements are not applicable due to strong adsorption to soil.

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	Not relevant. See comment above.
DT_{90}lab (20 °C, aerobic):	Not relevant. See comment above.
DT_{50}lab (10 °C, aerobic):	Not relevant. See comment above.
DT_{50}lab (20 °C, anaerobic):	Not relevant. See comment above.

Field studies

(country or region)

DT_{50f} from soil dissipation studies:	7 - 8 y (UK) and 10 - 20 y (USA)
DT_{90f} from soil dissipation studies:	DT_{90} values were never reached
Soil accumulation studies:	UK study with annual application, soil residues were 17 % of theoretical maximum after 20 y (3.5 times initial concentration). US study, 26 % of theoretical maximum after 20 y.

Soil residue studies:	Monitoring (220 sites) following extensive commercial use in northern and southern Europe gave residues between <0.2 and 15 mg/kg

Remarks

e.g. effect of soil pH on degradation rate	The strong adsorption of paraquat to soil precludes paraquat degradation in soil being studied effectively by standard guideline methods. The strong adsorption also greatly reduces the rate of formation of degradation products to amounts that would not be detectable using standard methods. Soil microbial studies fulfil the scientific intent of demonstrating the intrinsic degradability of paraquat.

Adsorption/desorption

K_f / K_{oc}:	K_{oc} values (220 soils in study) ranged from 8400 to 40 000 000 (very strong adsorption in all the soils tested).
K_d:	K_d values (224 soils in study) ranged from 480 to 400,000. Adsorption increased with clay content. No measurable correlation with % OC**.**
pH dependence:	Not relevant

Mobility

Laboratory studies:

Column leaching:	Not relevant as all studies indicate that paraquat is immobile.
Aged residue leaching:	Not relevant as all studies indicate that paraquat is immobile.

Field studies:

Lysimeter/Field leaching studies:	Not relevant as all studies indicate that paraquat is immobile.

Remarks:	Adsorption is correlated to clay content. The amount of paraquat deactivated by adsorption is determined by a wheat bioassay (SAC-WB). Most soils have a large excess of adsorption capacity relative to use rate. Exceeding SAC-WB values may be possible only in soils with very low SAC-WB values following repeated application at high rates.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	Hydrolytically stable at pH 5, 7 and 9 after 30 d at 25 and 40 °C.
Major metabolites:	None
Photolytic degradation:	Photolytically stable at environmentally relevant wavelengths.
Major metabolites:	None

Biological degradation

Ready biological degradability:	Not studied since not relevant. Paraquat will not be used under conditions where sewage water or sludge contamination occurs.
Water/sediment study: DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system: Distribution in water / sediment systems (active substance) Distribution in water / sediment systems (metabolites)	Not studied since not relevant. In the unlikely event of paraquat entering an aquatic body at biologically significant concentrations, it will dissipate initially in a similar way to in soil, i.e. mainly by adsorption onto sediment, with an expected DT50 in the region of <24 h.
Accumulation in water and/or sediment:	Significant residues found in plant material and sediment, after complete dissipation from water. Not relevant for water, since any residues will rapidly dissipate to sediment. From soil studies, there is no evidence of desorption of paraquat back into the water phase.

Degradation in the saturated zone

	Not studied since not relevant. Paraquat will Not be used under conditions where contamination of the saturated zone occurs.

Remarks:	None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	$< 10^{-8}$ kPa at 25 °C
Henry's law constant:	$< 4 \cdot 10^{-12}$ Pa·m^3·mol^{-1}

Photolytic degradation

Direct photolysis in air:	Not relevant, due to low vapour pressure.
Photochemical oxidative degradation in air DT_{50}:	Not relevant, due to low vapour pressure.
Volatilisation:	Not relevant, due to low vapour pressure.

Remarks:	None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD_{50} = 93.4 mg as/kg bw
Acute toxicity to birds:	LD_{50} = 35 mg as/kg bw
Dietary toxicity to birds:	LC_{50} = 698 ppm
Reproductive toxicity to birds:	NOEC 30 mg/kg diet
Short term oral toxicity to mammals:	NOEC of 100 ppm from 13 week rat study

Aquatic Organisms

Acute toxicity fish:	LC_{50} = 19 mg as/l (Rainbow trout, 96 h study)
Long term toxicity fish:	Continuous or repeated exposure not anticipated therefore study not submitted.
Bioaccumulation fish:	Log P_{ow} is -4.5 therefore no bioconcentration study submitted.
Acute toxicity invertebrate:	EC_{50} = 4.4 mg as/l (*Daphnia magna* - 48 h study)
Chronic toxicity invertebrate:	14 – 21 day NOEC = 0.12 mg as/l
Acute toxicity algae:	EC_{50} = 0.00023 mg as/l (*Navicula pelliculosa* 96h study)
Chronic toxicity sediment dwelling organism:	*Chironomus riparius*: 21 day NOEC in sediment = 100 mg as/kg;, 21 day water phase only NOEC = 0.367 mg as/l.
Acute toxicity aquatic plants: (for herbicides only)	EC_{50} = 0.037 mg as/l for *Lemna gibba* (14 day semi-static study)

Honeybees

Acute oral toxicity:	LD_{50} = 9.06 µg as/bee - 120 h study
Acute contact toxicity:	LD_{50} = 9.26 µg as/bee - 120 h study

Other arthropod species

Test species	% Effect
Pardosa sp.	Mortality: No effect on adults (1.0 g as/ha, SL formulation)
Aleochara bilineata	Mortality: No effect on adults (1.0 g as/ha, SL formulation)
Pterostichus melanarius	Mortality: No effect on adults (1.0 g as/ha, SL formulation)

Earthworms

Acute toxicity:	LC_{50} >1000 mg as/kg soil - 14 d study
Reproductive toxicity:	No adverse effects were observed on earthworm populations in a field study following an application of up to 720 kg as/ha in one year.

Soil micro-organisms

Nitrogen mineralization:	No adverse effects were observed after application up to 720 kg as/ha in one year.
Carbon mineralization:	No adverse effects were observed after application up to 720 kg as/ha in one year.

APPENDIX IIIA

PARAQUAT

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

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

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[8] on previous use in granting national authorizations
IIA 4.1	Baker H A J Duffin M R	1995	The determination of volatile (solvent type) impurities in technical material by capillary gas chromatography. Report No.: PAM 595/1 GLP status: Not applicable Unpublished.	
IIA 4.1	Duffin M R	1996	The determination of volatile paraquat associated impurities in technical material concentrate by capillary gas chromatography. Report No.: AMP10042-01B GLP status: Not applicable Unpublished.	
IIA 4.1	Navarro P C	1999	The determination of paraquat cation and associated impurities in technical material concentrate by capillary electrophoresis. Report No.: AMP10076-01B GLP status: Not applicable Unpublished.	
IIA 4.1	Navarro P C and Duffin M R	1999	Method validation: AMP10076-01B/VAL-01 The determination of paraquat cation and associated impurities in technical material concentrate by capillary electrophoresis. Report No.: AMP10076-01B/VAL-01 Not GLP Unpublished.	

[8] Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

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[8] on previous use in granting national authorizations
IIA 4.1	Thorndycraft MD	1994	The determination of paraquat in aqueous concentrates and formulated materials by spectrophotometry. PAM 179/2 GLP status: Not applicable Unpublished	
IIA 4.2.1	Anderson, L and Boseley, A D	1997	The determination of residues of paraquat and diquat in crops and soil - a High Performance Liquid Chromatographic Method. SOP RAM 272/02 GLP status: Not applicable Unpublished.	
IIA 4.2.1	Anderson L	1994a	The determination of residues of paraquat and diquat in crops: a second derivative spectrophotometric method. RAM 252/01 GLP status: Not applicable Unpublished	
IIA 4.2.1 4.2.2 4.2.3	Coombe N	1994a	Validation of Zeneca Agrochemicals standard operating procedures for the analysis of diquat and paraquat residues in crops, soil and water containing both compounds. CEM-322 GLP Unpublished	
IIA 4.2.1	Greenstreet C A	1997	Paraquat and diquat: Validation of Zeneca Agrochemicals SOP RAM 272/02 for Hops. Report No.: CEMR-730 GLP Unpublished.	
IIA 4.2.2	Anderson L	1994b	The determination of residues of paraquat and diquat in soils: a second derivative spectrophotometric method. RAM 253/01 GLP status: Not applicable Unpublished	
IIA 4.2.3 4.2.5.1	Anderson L	1994c	The determination of residues of paraquat and diquat in water, milk, oils and other liquids: a second derivative spectrophotometric method with confirmatory method for water residues by high performance liquid chromatography. RAM 254/01 GLP status: Not applicable 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[8] on previous use in granting national authorizations
IIA 4.2.4	Anderson L	1994b	Paraquat and diquat: validation of model to determine residues in air. RJ1659B GLP Unpublished	
IIA 4.2.5.1	Anderson L	1994d	The determination of paraquat in animal products a high performance liquid chromatographic method. RAM 004/05 GLP Unpublished	
IIA 4.2.5.1	Coombe N	1994b	Paraquat : Animal tissue method validation - Zeneca Agrochemicals standard operating procedure. CEM-299 GLP Unpublished	
IIA 4.2.5.1	Green M	1994	Paraquat analysis in tissue extracts using the Enviroguard paraquat plate kit. WIU/009 Not GLP Unpublished	
IIA 4.2.5.1	Jones A	1994	Clean up and detection method for paraquat (HPLC) R009/94 Not GLP Unpublished	
IIA 4.2.5.2	Thomas D	1994a	The determination of paraquat in plasma, tissues and urine by radioimmunoassay. CT05-085 GLP Unpublished	
IIA 4.5.2.2	Thomas D Woollen BH	1994b	Rapid methods for the semi-quantitative determination of paraquat and diquat in urine. CTL/R/1191 GLP Unpublished	

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 5.1	Lythgoe RE	1995a	Paraquat: excretion and tissue retention of a single oral dose (1 mg/kg) in the rat. CTL/P/4683 GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.1	Lythgoe RE	1995b	Paraquat: excretion and tissue retention of a single oral dose (50 mg/kg) in the rat. CTL/P/4684 GLP Unpublished	
IIA 5.1	Lythgoe RE	1995c	Paraquat: excretion and tissue retention of a single oral dose (1 mg/kg) in the rat following repeat dosing. CTL/P/4685 GLP Unpublished	
IIA 5.1.2	Macpherson D	1995	Paraquat: biotransformation in the rat CTL/P/4806 GLP Unpublished	
IIA 5.2.1	Duerden L	1994c	Paraquat dichloride technical concentrate: acute oral toxicity to the rat. CTL/P/4424 3B.1/40 GLP Unpublished	
IIA 5.2.1 III A 10.3	Farnworth M., Foster J and Lock E	1993	The toxicity of paraquat to rabbits following oral administration. Report no CTL/R/1164 Not GLP Unpublished	
IIA 5.2.2	Duerden L	1994b	Paraquat dichloride technical concentrate: acute dermal toxicity to the rat. CTL/P/4412 3B.1/39 GLP Unpublished	
IIA 5.2.4	Duerden L	1994a	Paraquat dichloride technical concentrate: irritation to the rabbit. CTL/P/4411 GLP Unpublished	
IIA 5.2.5	Bugg L Duerden L	1994	Paraquat dichloride technical concentrate: eye irritation to the rabbit. CTL/P/4566 3B.1/42 GLP Unpublished	
IIA 5.2.6	Duerden L	1994d	Paraquat dichloride technical concentrate: sensitisation to the guinea pig. CTL/P/4460 GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.5	Busey W M	1986	An independent pathology review of the lung slides from a rat chronic toxicity/carcinogenicity study with paraquat. Experimental Pathology Laboratories Inc C2.4/03 Not GLP Unpublished.	
IIA 5.5	Ishmael, J and Godley, M J	1983	Paraquat : lifetime feeding study in rats histopathological examination of the lungs. ICI Central Toxicology Laboratory Report No. CTL/P/738 Not GLP Unpublished.	
IIA 5.6.2	Hodge MCE	1992	Paraquat: developmental toxicity study in the rat. CTL/P/3864 4B.4/12 GLP Unpublished	
IIA 5.6.2	Palmer K	1992	Paraquat (technical): oral (gavage) mouse developmental toxicity study. ICL/19/92 CTL/C/2830 4B.4/11 GLP Unpublished	
IIA 5.9.6	Calderbank A	1992	Paraquat mortality statistics in UK for the period 1980 - 1991 ODM52 AC/RB GLP Unpublished	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.1.1	Grout SJ	1994b	Paraquat: Quantification and characterisation of radioactive residues in root and oilseed crop after dessicant treatment of foliage. RJ1683B GLP Unpublished	
IIA 6.1.1 6.1.2	Grout SJ	1994a	Paraquat: quantification and characterisation of radioactive residues in root and leafy crop after preplant soil treatment. RJ1595B GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.1.2	Vickers JA Hurt AD Bewick DW	1990	Paraquat: Rotational crop study RJ0867B GLP Unpublished	
IIA 6.3.1	Anderson L Earl M	1993	Paraquat: Residues in olives from trials carried out in Spain during 1991/1992. RJ1292B GLP Unpublished	
IIA 6.3.1	Dick JP Taylor PS Bonfanti F	1995a	Paraquat: Residue levels in oranges from trials carried out in Italy during 1993. RJ1808B GLP Unpublished	
IIA 6.3.1	Dick JP Taylor PS Bonfanti F	1995b	Paraquat: Residue levels in olive fruit and oil from trials carried out in Italy during 1993. RJ1810B GLP Unpublished	
IIA 6.3.1	Earl M Anderson L	1992a	Paraquat: Residues in grapes from trials carried out in Germany during 1990. RJ1051B GLP Unpublished	
IIA 6.3.1	Earl M Anderson L	1992b	Paraquat: Residues in pome and stone fruits from trials carried out in Germany during 1990. RJ1053B GLP Unpublished	
IIA 6.3.1	Roper EM	1989a	Gramoxone Super: Residues of paraquat in fresh market and dried prunes. TMU3657B GLP Unpublished	
IIA 6.3.1	Roper EM	1989b	Paraquat: Magnitude of residues in fresh and dried figs. TMR0015B GLP Unpublished	
IIA 6.3.1	Roper EM	1989k	Paraquat: Magnitude of residues in olives and processing fractions. TMR0039B GLP Unpublished	
IIA 6.3.2	Roper EM	1989e	Paraquat: Magnitude of residues in whole tomatoes and processing fractions. TMR0024B GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.3.2	Roper EM	1989i	Paraquat: Magnitude of residues in sugar beet processing fractions. TMR0036B GLP Unpublished	
IIA 6.3.2	Roper EM	1989c	Paraquat: Magnitude of residues in cucumbers, melons and summer squash. TMR0017B GLP Unpublished	
IIA 6.3.2	Roper EM	1989e	Paraquat: Magnitude of residues in whole tomatoes and processing fractions. TMR0024B GLP Unpublished	
IIA 6.3.2	Roper EM	1989h	Paraquat: Magnitude of residues in sugar beet tops and roots. TMR0031B GLP Unpublished	
IIA 6.3.5	Earl M Anderson L	1991	Paraquat: Residues in potatoes from trials carried out in Germany during 1990. RJ1040B GLP Unpublished	
IIA 6.3.6	Roper EM	1989j	Paraquat: Magnitude of residues in hops and processing fractions. TMR0038B GLP Unpublished	
IIA 6.3.7	Anderson L Lant M	1994	Paraquat and diquat: Residue levels in maize from trials carried out in Italy during 1993. RJ1731B GLP Unpublished	
IIA 6.3.7	Anderson L Lant MS Bonfanti F	1995	Paraquat and diquat: Residue levels in rice, grain and straw from trials carried out in Italy during 1993. RJ1728B GLP Unpublished	

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 7.1.1.1.1 7.1.1.2.1	Vickers JA Hurt AD Bewick DW	1989a	Paraquat: Degradation in Aerobic soil. RJ0788B 5B.1/62 GLP Unpublished	
IIA 7.1.1.1.2 7.1.1.1.1 7.1.1.2.1	Vickers JA Hurt AD Bewick DW	1989b	Paraquat: Degradation in Anaerobic soil. RJ0810B 5B.1/60 GLP Unpublished	
IIA 7.1.1.2.2	Dyson J S Chapman P	1995	Paraquat: Long-term, High-rate trial, Frensham, Fate of Soil Residues. RJ3430B Not GLP Unpublished	
IIA 7.1.1.2.2	Dyson JS Kirsch O Stevens JEB	1995a	Paraquat: Long-term soil trial at Goldsboro, USA, 1979-1991. 1. Trial description and crop measurements. TMJ3328B Not GLP Unpublished	
IIA 7.1.1.2.2	Dyson JS Chapman P Farmer K	1995b	Paraquat: Long-term soil trial at Goldsboro, USA, 1979-1991. 2. Fate of soil residues. TMJ3329B Not GLP Unpublished	
IIA 7.1.1.2.2	Dyson JS Chapman P	1995c	Paraquat: Long-term, High-rate trial, Frensham, UK, 1971-1991. Fate of soil residues. TMJ3430B Not GLP Unpublished	
IIA 7.1.1.2.2	Stevens JEB Bewick DW	1991	Paraquat: A survey of residues and deactivation capacities of soils in the United Kingdom. RJ0594B 5B.2/41 GLP Unpublished	
IIA 7.1.2	Dyson JS Ferguson RE Lane MCG	1994	Paraquat: Adsorption and desorption properties in temperate soils. TMJ3225B 5B.1/77 Not GLP Unpublished	
IIA 7.1.2	Lane MCG Bouwman JJ Bewick DW	1992	Paraquat: Long-term, High-rate trials in the Netherlands (1986-1991). Final report. RJ1186B 5B.2/46 GLP Unpublished	

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	Tapp JF Sankey SA Caunter JE Stanley RD Adams DS	1990a	Paraquat: determination of acute toxicity to Rainbow trout (*Salmo gairdneri*). BL3801/B 5C.4/21 GLP Unpublished	
IIA 8.2.1	Tapp JF Sankey SA Caunter JE Stanley RD Penwell AJ	1990b	Paraquat: Determination of acute toxicity to Mirror carp (*Cyprinus carpio)* BL3800/B 5C.4/20 GLP Unpublished	
IIA 8.2.2.2	Tapp JF Sankey SA Caunter JE Stanley RD Penwell AJ	1990c	Paraquat: determination of the 21 day LC50 to Rainbow trout (*Salmo gairdneri).* BL3860/B 5C.4/22 GLP Unpublished	
IIA 8.2.4	Allison N Hamer MJ	1990	Paraquat: acute toxicity to first instar *Daphnia magna* of technical concentrate YF6219. RJ0851B 5C.6/6 GLP Unpublished	
IIA 8.2.5	Stewart KM Tapp JF Sankey SA Stanley RD	1991	Paraquat dichloride: chronic toxicity to *Daphnia magna.* BL4151/B 5C.6/9 GLP Unpublished	
IIA 8.2.6	Smyth DV Tapp JF Sankey SA Stanley RD	1990	Paraquat: determination of toxicity to the green alga *Selenastrum capricornutum.* BL3748/B GLP Unpublished	
IIA 8.2.6	Smyth D V, Sankey, S A and Cornish S K	1992	Paraquat dichloride: toxicity to the blue green alga *Anabaena flos-aquae.* Report No.: BL4579/B GLP Unpublished	
IIA 8.2.6	Smyth D V, Sankey, S A and Cornish S K	1992	Paraquat dichloride: toxicity to the fresh water diatom *Navicula pelliculosa.* Report No.: BL4464/B GLP Unpublished	
IIA 8.2.7	Hamer M J	1998	Paraquat: Sediment toxicity test with *Chironomus riparius* Report No.: RJ2649B GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.2.7	Hamer M J and Ashwell J A	1997	Paraquat: BBA sediment toxicity test with sediment dwelling *Chironomus riparius.* Report No.: RJ2392B GLP Unpublished.	
IIA 8.2.8	Hamer M J	2000	Paraquat: Risk to aquatic plants following use in the EU. Report No.: RAJ0034B Not GLP Unpublished.	
IIA 8.2.8	Smyth D V, Sankey, S A Cornish S K Penwell A J	1992	Paraquat dichloride: toxicity to the duckweed *Lemna gibba.* Report No.: BL4493/B GLP Unpublished.	
IIA 8.3	Grant R	2000	Non target arthropod risk assessment for Europe. Not GLP Report No.: RAJ0025B Unpublished.	
IIA 8.3.2 / IIIA 10.5.1	Austin H M	1999	Paraquat: A Tier I Laboratory Study to determine the LC_{50} of a 100g l^{-1} SL formulation to the parasitic wasp *Aphidius rhopalosiphi*. Ecotox Ltd Report No. ER-99-14 GLP Unpublished.	
IIA 8.3.2 / IIIA 10.5.1	Austin H M	1999	Paraquat: A Tier 2 Laboratory Study to determine the LC_{50} of a 100g l^{-1} SL formulation to the predatory mite *Typhlodromus pyri*. Ecotox Ltd Report No. ER-99-25. GLP Unpublished	
IIA 8.3.2 / IIIA 10.5.1	Austin H M and Elcock V L	1999	Paraquat: A Tier I Laboratory Study to determine the LC_{50} of a 100g l^{-1} SL formulation tot he predatory mite *Typhlodromus pyri*. Ecotox Ltd Report No. ER-99-12 GLP Unpublished.	
IIA 8.3.2	Gill, A and Austin, H M	1996	The effects of paraquat on the predatory mite *Typhlodromus pyri.* Ecotox Limited Report No. ER-96-06 GLP Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.3.2.1 10.3.2.1	Jackson D McMullin LC Canning L White JS	1991	Gramoxone 100: Investigation of the toxicity of the formulation (containing paraquat dichloride) to the Carabid beetle *P.melanariusl* and a Lycosid spider. RJ0928B GLP Unpublished	
IIA 8.3.2.1	Petto R	1993	Effects of Gramoxone 100 on *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) in the laboratory. RCC 405000 5E.3(a)/2 GLP Unpublished	
IIA 8.3.2.2	Kendall DA Smith BD Chinn NE	1989	A field study of the effects of paraquat and glyphosate herbicides on the invertebrate fauna of arable farmland in SW England. RIC 1821 5E.3(b)/1 Not GLP Unpublished	
IIA 8.3.3.1	Edwards P J Coulson J M	1993	Paraquat: toxicity to the earthworm Eisenia foetida of a 200g litre^{-1} SL formulation . TMJ3067B Not GLP Unpublished	
IIA 8.3.5	Canning L White JS	1992a	Paraquat: a glasshouse study to evaluate the effects on vegetative vigour of a 300 g ai litre (2.5 lb ai US gal $^{-1}$) soluble concentrate formulation on terrestrial non-target plants. RJ1279B 6E./1 GLP Unpublished	
IIA 8.3.5	Canning L White JS	1992b	Paraquat: a glasshouse study to evaluate the effects on seedling emergence of a 300 g ai litre^{-1} (2.5 lb ai US gal $^{-1}$) formulation on terrestrial non-target plants. RJ1280B 6E./2 GLP Unpublished	

APPENDIX IIIB

PARAQUAT

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA 2.7.3	Shaunak , R	1996	Paraquat: Determination of the long-term storage stability and physico-chemical characteristics of a 200 g/l SL formulation. Report No. RY0102B GLP Unpublished.
IIA 4.1	Navarro P C	1999	The determination of paraquat cation and associated impurities in technical material concentrate by capillary electrophoresis. Report No.: AMP10076-01B GLP status: Not applicable Unpublished.
IIA 4.1	Baker H A J and Duffin M R	1995	The determination of volatile (solvent type) impurities in technical material by capillary gas chromatography. Report No.: PAM 595/1 GLP status: Not applicable Unpublished.
IIA 4.1	Duffin M R	1996	The determination of volatile paraquat associated impurities in technical material concentrate by capillary gas chromatography. Report No.: AMP10042-01B GLP status: Not applicable Unpublished.
IIA 4.1	Navarro P C and Duffin M R	1999	Method validation: AMP10076-01B/VAL-01 The determination of paraquat cation and associated impurities in technical material concentrate by capillary electrophoresis. Report No.: AMP10076-01B/VAL-01 GLP status: Not applicable 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
IIA 4.2.1	Anderson, L and Boseley, A D	1997	The determination of residues of paraquat and diquat in crops and soil - a High Performance Liquid Chromatographic Method. SOP RAM 272/02 GLP status: Not applicable Unpublished.
IIA 4.2.1	Anderson, L	1996	The determination of paraquat in animal products - a High Performance Liquid Chromatographic Method. Report No.: SOP RAM 004/06 GLP status: Not applicable Unpublished.
IIA 4.2.1	Greenstreet C A	1997	Paraquat and diquat: Validation of Zeneca Agrochemicals SOP RAM 272/02 for Hops. Report No.: CEMR-730 GLP Unpublished.

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
IIA 5.3.3	Grimshaw, P *et al*	1979	Three week inhalation study in rats exposed to an aerosol of paraquat (Repeat Study). Huntingdon Research Centre Report No. ICI 279/79476 (CTL/C/810) Not GLP Unpublished.
IIA 5.3.3	Hardy, C J and Clark, G C	1980	Assessment of accumulation of paraquat in the lungs - 3 week inhalation study in rats (15 Exposures). Huntingdon Research Centre Report No. ICI 301/8037 (CTL/C/965) Not GLP Unpublished.
IIA 5.3.3	Hardy, C J *et al*	1979	Three week inhalation study in rats exposed to an aerosol of paraquat. Huntingdon Research Centre Report No. ICI 254/7949 (CTL/C/729) Not 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
IIA 5.3.3	Laird, W J D *et al*	1979	Paraquat concentrations in rat lungs following exposure to paraquat aerosols (Study No. ICI 254/7949). ICI Central Toxicology Laboratory Report No. CTL/P/460 Not GLP Unpublished.
IIA 5.5	Busey W M	1986	An independent pathology review of the lung slides from a rat chronic toxicity/carcinogenicty study with paraquat. Experimental Pathology Laboratories Inc C2.4/03 Not GLP Unpublished.
IIA 5.5	Ishmael, J and Godley, M J	1983	Paraquat : lifetime feeding study in rats histopathological examination of the lungs. ICI Central Toxicology Laboratory Report No. CTL/P/738 Not GLP Unpublished.
IIA 5.8.2	Smith, P and Heath, D	1974	The ultrastructure and time sequence of the early stages of paraquat lung in rats. Journal of Pathology, Volume 114, pp 117 – 184 Not GLP Published.
IIA 5.8.2	Rose, M S; Lock, E A; Smith, L L and Wyatt, I	1976	Paraquat accumulation. Tissue and species specificity. Biochemical Pharmacology, Volume 25, pp 419 – 423 Not GLP Published.
IIA 5.9	Clark, D.G., McElligot, T.F and Hurst, E.W	1966	The toxicity of paraquat. Brit .J.Indust.Med 23, 126-132. Not GLP Published.
IIA 5.9	Davies, D S; Hawksworth, G M and Bennett, P N	1977	Paraquat poisoning. Proceedings of the European Society of Toxicologists, Volume 18, pp 21 – 26 Not GLP Published.
IIIA 7.2.1.2	Findlay, M L, Chester G and Wiseman J M	1998	Worker exposure during mixing, loading and application of Gramoxone with knapsack sprayers. Report No.: WER004 GLP (part) Unpublished.
IIIA 7.2.1.2	Findlay M L and Hall M	1997	Diquat: worker exposure during mixing, loading and application of 'Reglone' with knapsack sprayers Report No. CTL/P/5379 GLP (part) 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
IIIA 7.2.3.2	Iwata, T and Findlay, M L	1995	Worker exposure during re-entry into paraquat-treated cotton fields: biological monitoring in Georgia in 1994 (WRC-95-019) (WINO 18630). Zeneca Ag Products Western Research Center Report No. RR 95-010B GLP Unpublished.
IIIA 7.3	Feldman, K J and Maibach, H I	1974	Percutaneous penetration of some pesticides and herbicides in man. Toxicology and Applied Pharmacology, Volume 28, pp 126 – 132 Published.

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not

No new information

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
IIA 7.1.1.1	Ricketts D. C	1999	The microbial biodegradation of paraquat in soil. Pesticides Science 55: 566-614. Not GLP Published

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
IIA 8.1	Blank	1968/ 69	The effect of Gramoxone on the hatchability of pheasant eggs. The Game Conservancy Annual Review pp 82-83. Not GLP Published
IIA 8.1	Edwards P J	1979	Status of common bird populations on an intensively managed farm where paraquat has been used extensively. ICI Plant Protection Division Report No:RJ0037B. Not GLP Unpublished.
IIA 8.1	Edwards, P.J., Newman, J.F., and Ward, R.J	1979	Paraquat: Effects of spraying eggs on hatchability and reproductive organs of Japanese Quail, *Coturnix coturnix japonica*. ICI Plant Protection Division Report No:RJ0044B. Not GLP Unpublished.
IIA 8.1	Hakin, B., and Chanter, D.O	1988	The measurement of residues of paraquat penetrating the egg shells of fertile mallard duck eggs. Huntingdon Research Centre Ltd Report No: ISN172/88. GLP Unpublished
IIA 8.1	Hakin, B., and Chanter, D.O	1989	The effect of paraquat on the hatchability of fertile mallard duck eggs. Huntingdon Research Centre Ltd Report No: ISN170/881711. GLP Unpublished
IIA 8.1	Newman JF and Edwards PJ	1980	Effect of spraying eggs on hatchibility and on the reproductive organs of the chicks of pheasant, *Phasianus colchicus* Not GLP Unpublished
IIA 8.1	Roberts, N.L., Hakin, B., and Chanter, D.O	1989	The effect of paraquat on the hatchability of fertile pheasant eggs. Huntingdon Research Centre Ltd Report No: ISN171/881712. GLP Unpublished
IIA 8.1.1	Johnson A J	1998	Acute oral LD50 to the mallard duck. Huntingdon Life Sciences Report number ISN 399/96360 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**
IIA 8.2.8 / IIIA 10.2	Hamer M J	2000	Paraquat: Risk to aquatic plants following use in the EU. Report No.: RAJ0034B Not GLP Unpublished.
IIA 8.2.6	Smyth D V, Sankey, S A and Cornish S K	1992	Paraquat dichloride: toxicity to the blue green alga *Anabaena flos-aquae.* Report No.: BL4579/B GLP Unpublished.
IIA 8.2.6	Smyth D V, Sankey, S A and Cornish S K	1992	Paraquat dichloride: toxicity to the fresh water diatom *Navicula pelliculosa.* Report No.: BL4464/B GLP Unpublished.
IIA 8.2.6	Smyth D V, Tapp J F, Sankey, S A and Stanley R D	1990	Paraquat dichloride: determination of toxicity to the green alga (*Selenastrum capricornutum*). BL3748/B GLP Unpublished.
IIA 8.2.7	Hamer M J	1998	Paraquat: sediment toxicity test with *Chironomus riparius* RJ2649B GLP Unpublished
IIA 8.2.7	Hamer M J Ashwell J A	1997	Paraquat: BBA toxicity test with sediment-dwelling Chironomus riparius. RJ2392B GLP Unpublished
IIA 8.2.8	Smyth D V, Sankey, S A Cornish S K Penwell A J	1992	Paraquat dichloride: toxicity to the duckweed *Lemna gibba.* Report No.: BL4493/B GLP Unpublished.
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IIA 8.3 / IIIA 10.4/5	Grant R	2000	Non target arthropod risk assessment for Europe. Not GLP Report No.: RAJ0025B Unpublished.

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IIA 8.3.2 / IIIA 10.5.1	Austin H M	1999	Paraquat: A Tier I Laboratory Study to determine the LC_{50} of a 100g l^{-1} SL formulation to the parasitic wasp *Aphidius rhopalosiphi*. Ecotox Ltd Report No. ER-99-14 GLP Unpublished.
IIA 8.3.2 / IIIA 10.5.1	Austin H M	1999	Paraquat: A Tier 2 Laboratory Study to determine the LC_{50} of a 100g l^{-1} SL formulation to the predatory mite *Typhlodromus pyri*. Ecotox Ltd Report No. ER-99-25. GLP Unpublished.
IIA 8.3.2 / IIIA 10.5.1	Austin H M and Elcock V L	1999	Paraquat: A Tier 2 Laboratory Study to determine the LC_{50} of a 100g l^{-1} SL formulation to the parasitic wasp *Aphidius rhopalosiphi*. Ecotox Ltd Report No. ER-99-HMA 310 GLP Unpublished.
IIA 8.3.2 / IIIA 10.5.1	Austin H M and Elcock V L	1999	Paraquat: A Tier I Laboratory Study to determine the LC_{50} of a 100g l^{-1} SL formulation tot he predatory mite *Typhlodromus pyri*. Ecotox Ltd Report No. ER-99-12 GLP Unpublished.
IIA 8.3.2	Gill, A and Austin, H M	1996	The effects of paraquat on the predatory mite *Typhlodromus pyri.* Ecotox Limited Report No. ER-96-06 GLP Unpublished.
IIIA 10.1	Carter N, Muirhead L, and Greenwood C	1998	The use of minor crops by birds in the breeding season as measured by the Common Birds Census. British Trust for Ornithology Services Ltd Report. Not GLP Unpublished.
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IIIA 10.1	Edwards P J	1999	Risk assessment for the effect of long term exposure of birds to paraquat residues in their diet. Not GLP Unpublished.

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IIIA 10.1	Fletcher M R and Greig-Smith P W	1998	The use of direct observations in assessing pesticide hazard to birds. In BCPC Monograph No.40. Field Methods for the study of environmental effects of pesticides. Eds Greaves M P, Smith B D and Greig-Smith P W. Not GLP Published.
IIIA 10.1	Green R	1978	Factors affecting the diet of farmland skylarks, *Alauda arvensis.* Journal of Animal Ecology, 47, 9 13-928. Not GLP Published.
IIIA 10.1.2	Edwards, P J	1979	Status of common bird populations on an intensively managed farm where paraquat has been used extensively. ICI Plant Protection Division Report No. RJ0037B Not GLP Unpublished..
IIIA 10.2.1	Ibrahim E A	1990	The influence of the herbicide paraquat 'Gramoxone' on growth and metabolic activity of three chlorophytes. Water, Air and Soil Pollution 51 pp89-93 Not GLP Published.
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IIIA 10.3	Barnes, R.F.W., Tapper, S.C and Williams, J	1983	Use of pastures by brown hares. Journal of Applied Biology 20, 179-185. Not GLP Published.
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IIIA 10.3	Broekuizen, S and Maaskamp,F	1982	Movement, home range, and clustering in the European hare (*Lepus europaeus* Pallas) in The Netherlands. Z. Saugetierkunde 47, 22-32. Not GLP Published.
IIIA 10.3	Chapuis, J.L.	1990	Comparison of the diets of two sympatric lagomorphs, *Lepus europeus* (Pallas) and Oryctolagus cuniculus (L) in an agroecosystem of the Ile-de-France. Z.Saugetierkunde *55, 176-185.* Not GLP Published.
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IIIA 10.3	De Lavaur, E., Grolleau, G and Siou, G	1973	Intoxication experimentale de lievres par de la luzerne traitee au paraquat. Ann. Zool - Ecol. Anim. 5 (4) 609-622 Not GLP Published.
IIIA 10.3	Duff, J.P., D Chasey, D., Munro, R and Wooldndge, M	1994	European brown hare syndrome in England. The Veterinary Record, June *25,* 669-673. Not GLP Published.
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IIIA 10.3	Edwards P J, Fletcher M R and Berny P	2000	Review of the factors affecting the decline of the European brown hare, *Lepus europeus* (Pallas, 1778) and the use of wildlife incident data to evaluate the significance of paraquat. Agriculture Ecosystems and Environment 79 pp95-103 Not GLP Published.
IIIA 10.3	Edwards, P J	1985	Investigation into the possible involvement of paraquat in hare deaths in the UK during Autumn 1984. ICI Plant Protection Division Report No. M4028A Not GLP Unpublished.

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IIIA 10.3/ IIA 5.2.1	Farnworth M., Foster J and Lock E	1993	The toxicity of paraquat to rabbits following oral administration. Report no CTL/R/1164 Not GLP Unpublished
IIIA 10.3	Fletcher, M.R and Grave, R.C., 1992	1992	Post-registration surveillance to detect wildlife problems arising from approved pesticides. Proceedings British Crop Protection Council: Pests and Diseases (2) 793-798. Not GLP Published.
IIIA 10.3	Fletcher, M.R., Hunter, K., Barnett, E.A. and Sharp E.A.	1997	Pesticide Poisoning of animals 1996: Investigations of suspected incidents in the United Kingdom. Report of the Environmental Panel of the Advisory Committee on Pesticides, MAFF, London. Not GLP Published.
IIIA 10.3	Flux, J.E.C	1997	Status of rabbits (*Oryctolagus cuniculus*) and hares (*Lepus europeus*) in New Zealand. Gibier Faune Sauvage, Game Wildl. 14 (3) 267-280. Not GLP Published.
IIIA 10.3	Frolich, K., Meyer, H.H.D.Pielowski, Z., Ronsholt, L., Seck-Lanzendorf, S.V and Stolte, M	1996	European brown hare syndrome in free-ranging hares in Poland. Journal of Wildlife Diseases, 32 (2) 280-285. Not GLP Published.
IIIA 10.3	Frylestam, B	1976	Effects of cattle - grazing and harvesting hay on density and distribution of an European hare population. Proceedings of a Symposium on Ecology and management of European hare populations, Warszawa. Not GLP Published.
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IIIA 10.3	Goszczynski, J and Wasilewski, M	1992	Predation of foxes on a hare population in central Poland. Acta Theriologica 37 (4), 329-33 8. Not GLP Published
IIIA 10.3	Grolleau, G	1981	Les repuls, moyen pour eviter les intoxications chez les animaux-gigier et la faune vertebree en general. Phytiatrie-Phytopharmacie. 30 97-113. Not GLP Published.
IIIA 10.3	Hansen, K	1992	Reproduction in European hare in a Danish farmland. Acta Theriologica 37, (1-2) 27-40. Not GLP Published.
IIIA 10.3	Kaluzinski, J and Pielowski, Z	1976	The effect of technical operations on the hare population. Procedings of a Symposium on Ecology and management of European hare populations, Warszawa. Not GLP Published.
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IIIA 10.3	Marboutin, E and Peroux, R	1996	Trends and fluctuations in European hare hunting bags: The limits of multiple regression analysis. In: Botev, N., (Ed) Proceedings of the International Union of Game Biologists; XXII Congress, Bulgaria. 115-122. Not GLP Published.
IIIA 10.3	Marcato, P.S., Benazzi, C., Vecchi, G., Galeotti, M., Della Salda, L., Sarli, G and Lucidi, P	1991	Clinical and pathological features of viral haemorrhagic disease in rabbits and European brown hare syndrome. Rev. Sci. tech. Off . Epiz. 10 (2) 37 1-392. Not GLP Published

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IIIA 10.3	Mary, C and Trouvilliez, J	1995	(Eds). Special lievre d'Europe. Bulletin Mensuel, De L'Office National de la Chasse. No 204. Not GLP Published.
IIIA 10.3	McLaren, G.W., Hutchins, M.R and Hams, S	1997	Why are brown hares (*Lepus europeus*) rare in pastoral landscapes in Great Britain. Gibier Fauna Sauvage, Game Wildlife 14:3, 335-348. Not GLP Published.
IIIA 10.3	Milanov, Z.B	1996	Effect of mowing fodder plants on small game populations in central Bulgaria. Proceedings of the International Union of Game Biologists; XXII Congress: The Game and the Man, Sofia, Bulgaria, September 4-8. 1995. Pp 394-397. PENSOFT Publishers: Sofia, Bulgaria. ISBN *954-642-013-1* Not GLP Published.
IIIA 10.3	Pepin, D	1989	Variation in survival of brown hare (*Lepus europeus*) leverets from different farmland areas in Paris basin. J.Appl. Ecol 26:13-23. Not GLP Published.
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IIIA 10.3	Reynolds, J.C and Tapper, S.C	1995	Predation by foxes *Vulpes vulpes* on brown hares *Lepus europeus* in central southern England, and its potential impact on annual population growth. Wildlife Biology 1 (3) 145-157. Not GLP Published.
IIIA 10.3	Sostaric, B., Lipej, Z., Fuchs, R and Paukovic, C	1991	Disappearance of free living hares in Croatia: European Brown Hare Syndrome. Veterinarski Ashiv 61, 133-150. Not GLP Published.

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IIIA 10.3	Strandgaard, H and Asferg, T	1980	The Danish Bag Record II. Fluctuations and trends in the Game bag record in the years 1941-1976 and the geographical distribution of the bag in 1976. Danish Review of Game Biology *11(5)* 32-33. Tapper, 5., 1987. The brown hare. Published by Shire Natural History. IBSN 0 85263 881 7. Not GLP Published.
IIIA 10.3	Tapper, S.C and Barnes, R.F.W	1986	Influence of farming practice on the ecology of the brown hare (*Lepus europeus*). Journal of Applied Ecology, 23, *39-52.* GLP Published.
IA 10.3	Tapper, S.C. and Parsons, N	1984	The changing status of the brown hare (*Lepus capensis*) in Britain. Mammal rev. 14:2, 57-70. Not GLP Published.
IIIA 10.4	Anon	1987-1989	Risk to honey bees: Results of nine semi-field tent studies conducted in Germany to assess the risk of paraquat to honeybees. Not GLP Submitted as Annex in Notifier's response to ECCO Full Report on paraquat. Unpublished.

APPENDIX IV

List of uses supported by available data

PARAQUAT

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Citrus	Southern Europe		F	Non-selective weed control	SL	120-200	Between the plants		1-2			250-1500	0.264 1.100	NR	Total not to exceed 1.1 kg/ha
Tree nuts -Hazelnut	Southern Europe		F	Non-selective weed control	SL	132-200	Between the plants		1-2			1000-1500	0.528 1.000	NR	Total not to exceed 1.1 kg/ha
Pome fruit - Apple	Southern Europe			Non-selective weed control	SL	100-200	Between the plants		1-2			250-1500	0.300 1.100	NR	Total not to exceed 1.1 kg/ha
	Northern Europe		F	Non-selective weed control	SL	120-200	Between the plants		1			100-600	0.360 1.100	NR	
Grape	Southern Europe		F	Non-selective weed control	SL	120-200	Between the plants		1-2			250-1500	0.300 1.100	NR	Total not to exceed 1.1 kg/ha
			F	Sucker Control	SL	100	Plant bases	In Spring	1-2		0.100 0.140	200-400		NR	
	Northern Europe		F	Non-selective weed control	SL	100	Between the plants		1			250-1000	0.300 0.630	NR	
Strawberry	Northern Europe		F	Non-selective weed control	SL	120-200	Between the plants/runner control		1-2			100-1000	0.240 1.100	NR	Total not to exceed 1.1 kg/ha

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Olives	Southern Europe		F	Non-selective weed control	SL	120-200	Between the plants		1-2			250-1500	0.198 1.100	3	Total not to exceed 1.1 kg/ha
Fruiting vegetables Tomatoes/ Cucumbers	Southern Europe		F, G	Non-selective weed control	SL	120-200	Between the plants		1			300-1000	0.360 0.600	7	
Vegetable crops - Beans	Southern Europe		F	Non-selective weed control	SL	120-200	Between the plants		1-2			250-1000	0.180 1.100	7	Total not to exceed 1.1 kg/ha
	Northern Europe			Non-selective weed control	SL	100-200	Between the plants		1			100-1000	0.360 1.100	7	
Potato	Southern Europe		F	Non-selective weed control	SL	120-200		Before or at emergence	1			250-1000	0.180 1.100	NR	
	Northern Europe		F	Non-selective weed control	SL	100-200		Before or at emergence	1			100-1000	0.240 1.100	NR	
Lucerne	Southern Europe		F	Non-selective weed control	SL	120-200		When crop dormant in winter, or immediately after cutting	1			200-1000	0.180 1.00	*	Only one application of 1.0 kg/ha Lucerne has a unique use pattern. Trials are ongoing to define the PHI.
	Northern Europe		F	Non-selective weed control	SL	100-200		When crop dormant in winter, or immediately after cutting	1			200-1000	0.180 0.600	*	Lucerne has a unique use pattern. Trials are ongoing to define the PHI.

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Autumn stubbles	Northern Europe		F	Non-selective weed control	SL	100-200		Before cultivation sowing or pre-emergence including minimum tillage	1-2			100-1000	0.084 1.000	NR	
	Southern Europe		F	Non-selective weed control	SL	100-200		Before cultivation sowing or pre-emergence including minimum tillage	1			200-1500	0.300 1.000	NR	
Spring land preparation	Northern Europe		F	Non-selective weed control	SL	100-200		Before cultivation sowing or pre-emergence including minimum tillage	1			100-1000	0.240 1.100	NR	
	Southern Europe		F	Non-selective weed control	SL	100-200		Before cultivation sowing or pre-emergence including minimum tillage	1			300-1500	0.180 1.000	NR	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Forestry, Ornamentals	Northern Europe		F	Non-selective weed control	SL	120-200	Between the plants	Before or after emergence	1			100-1000	0.360 1.100	NR	
	Southern Europe		F	Non-selective weed control	SL	100		Before cultivation sowing or pre-emergence including minimum tillage	1			150-600	0.400 0.600	NR	
Non-crop land –	Northern Europe		F	Non-selective weed control	SL	100-200			1			100-500	0.360 1.100	NR	
	Southern Europe		F	Non-selective weed control	SL	100-200			1			300-1500	0.360 1.000	NR	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions