EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Glyphosate
6511/VI/99-final
21 January 2002

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

Review report for the active substance **glyphosate**

Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001
in view of the inclusion of glyphosate 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 glyphosate, 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. Glyphosate 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, Feinchemie Schwebda on 11 June 1993, Herbex Produtos Quimicos Ltd on 10 February 1993, Law Offices of Samuel Pisar on 25 June 1993, Stefes Agro GmbH on 20 July 1993, United Phosphorus Ltd on 26 July 1993, Alkaloida Europe on 23 July 1993, Phytorus SA on 26 July 1993, Marubeni UK plc (since November 1997 Sinon EU Coorperation) on 23 July 1993, Cequisa on 23 July 1993, Cheminova Agro A/S on 28 July 1993, Monsanto SA on 19 July 1993, I. Pi. Ci. Industrias Prodotti Chimici on 30 July 1993, Barclay Chemicals on 27 June 1993, Chimac-Agriphar SA on 27 July 1993, SANC on 23 July 1993, OXON Italia SpA on 20 July 1993, Makhteshim Agan on 20 July 1993, Hermoo Belgium NV on 30 July 1993, Industrial Kern Espag on 26 July 1993, Tessenderlo Chemie on 27 July 1993, Iberotam on 26 July 1993, Industrias Quimicas del Valles on 28 July

[1] OJ No L 366, 15.12.1992, p.10.

[2] OJ No L 244, 16.09.1999, p.41.

1993, Aragonesas Agro SA on 27 July 1993, Stefes Research GmbH on 9 July 1993, Pilar Iberica SL Juan Amich Gail on 23 July 1993, AgriChem on 15 July 1993, Elf Atochem on 26 July 1993, Portman Agrochemicals on 26 July 1993, Helm AG on 23 July 1993, Calliope on 21 July 1993, Industrias Afrasas on 27 July 1993, Grower on 29 July 1993, K.C.S. Products on 23 July 1993, B. V. Luxan on 21 July 1993 and Sanachem GmbH (subsequently Dow AgrowScience) on 25 April 1995 notified to the Commission of their wish to secure the inclusion of the active substance glyphosate (isopropylamin-, natrium-, ammonium-salts) in Annex I to the Directive.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Zeneca Agrochemicals (subsequently Syngenta) on 27 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance glyphosate (trimesium-salt) in Annex I to the Directive.

Three glyphosate task forces were formed. AgriChem on behalf of the tulip task force, comprising AgriChem, Aragonesas Agro SA, Industrias Afrasas, Calliope, Sundat and TKI Pinus Race submitted a dossier on 20 April 1995. Monsanto and Cheminova formed a task force and jointly submitted a dossier to the rapporteur Member State on 24 April 1995. Barclay Chemicals and Portman Agrochemicals formed a task force and jointly submitted a dossier to the rapporteur Member State on 25 April 1995. Further dossiers were submitted by Feinchemie Schwebda on 27 April 1995, Marubeni UK plc (Sinon EU Coorperation) on 28 April 1995, Herbex Produtos Quimicos Ltd on 28 April 1995, Luxan on 3 May 1995, I. Pi. Ci. Industrias Prodotti Chimici on 2 May 1995, Nufarm Limited on 17 May 1995, Alkaloida on 2 May 1995 and Sanachem (subsequently Dow AgroScience) on 9 April 1996, Zeneca Agrochemicals (Syngenta) on 19 December 1994. Nufarm and Alkaloida officially withdrew their notifications on 21 July 1999 and 14 February 2001, respectively.

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 Germany as rapporteur Member State to carry out the assessment of glyphosate 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 Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for glyphosate this deadline was 30 April 1995. For the dossier from Sanachem the deadline was extended to 31 October 1995.

The task force Monsanto/Cheminova as well as Feinchemie Schwebda were considered main data submitters (glyphosate), with a dossier which did not contain substantial data gaps, taking into account the supported uses. Sinon EU Corporation (Marubeni), Herbex Produtos Quimicos Ltd, AgriChem, Aragonesas Agro SA, Industrias Afrasas, Sundat, Calliope, TKI Pinus Race, B. V. Luxan, I. Pi. Ci. Industrias Prodotti Chimici, Nufarm, Barclay Chemicals, Portman Agrochemicals, Alkaloida Europe and Dow AgroScience (Sanachem) did not submit complete dossiers. With regard to glyphosate, additional information has been submitted by third parties including publications provided by the responsible authorities in other Member States (Denmark, Sweden) and data obtained from the German National Poisoning Information Centre.

Syngenta (Zeneca Agrochemicals) was main data submitter (glyphosate trimesium), with a dossier which did not contain substantial data gaps, taking into account the supported uses. With regard to glyphosate trimesium, some additional (published) information was submitted by the Finnish

[3] OJ No L 107, 28.04.1994, p.8.

[4] OJ No L 225, 22.09.1995, p.1.

authorities and data on poisoning incidents were provided by the German National Poisoning Information Centre.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Germany submitted on 1 February 1999 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 glyphosate 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 glyphosate from Feinchemie Schwebda and Monsanto/Cheminova and glyphosate trimesium from Syngenta (Zeneca Agrochemicals), on 2 March 1999.

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 Monsanto being the designated representative of the glyphosate task force and to Feinchemie Schwebda and Syngenta (Zeneca Agrochemicals) being main data submitters, on 11 January 1999.

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 Pesticide Safety Directorate (PSD) in York, United Kingdom, from March to October 1999.

The reports of the peer review (i.e. full report) were circulated, for further consultation, to Member States on 17 March 2000 (glyphosate) and on 24 March 2000 (glyphosate trimesium) and the main data submitters on 21 March 2000 (glyphosate) and on 24 March 2000 (glyphosate trimesium) for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossiers, the draft assessment report, the peer review reports (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 1999 to June 2001, and was finalised in the meeting of the Standing Committee on 29 June 2001.

The present review report contains the conclusions of this final examination; given the importance of the draft assessment report, the peer review reports (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. No specific questions were addressed to the Committee. Following an exchange of views the Committee noted that there

were no issues that it wished to raise regarding the active substances in the context of a possible inclusion in Annex I to the Directive[5]. The Committee reiterated its earlier statements that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of Commission Directive 2001/99/EC concerning the inclusion of glyphosate in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing glyphosate 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 glyphosate 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 glyphosate containing plant protection product for which Member States will grant or review the authorisation.

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

- herbicide against terrestrial annual weeds, perennial weeds and shrubs in fruit, vegetables, forestry, grassland, ornamentals and arable crops as well as non-crop uses[6].

[5] Minutes of the plenary of the Scientific Committee on Plants from March 7, 2001

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 15 % 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 glyphosate/glyphosate trimesium are given in Appendix I.

The active substance shall comply with the FAO specification and there seems not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitters Feinchemie Schwebda, Monsanto and Syngenta (Zeneca Agrochemicals), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern. Regarding glyphosate, the Syngenta product was evaluated by FAO and WHO and the decision on the proposal to the FAO Group on Specifications to accept the Syngenta product as equivalent will be taken at the meeting of the FAO Group end of June 2001.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Germany is also satisfied, on the basis of the information currently available, that the substance notified by the other data submitters Sinon EU Corporation, Herbex Produtos Quimicos Ltd, AgriChem, Aragonesas Agro SA, Industrias Afrasas, Sundat, TKI Pinus Race, B. V. Luxan, I. Pi. Ci. Industrias Prodotti Chimici, Barclay Chemicals, Portman Agrochemicals, Alkaloida Europe and Dow AgroScience 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 dossiers submitted by the main data submitters. Only the substances of Nufarm and Calliope deviated significantly from the impurity profiles of Monsanto/Cheminova.

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[6] The term non-crop uses is defined as proposed by the EPPO guideline for the efficacy evaluation of herbicides (PP 1/117(2): Weeds in Non-Agricultural Land)

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 glyphosate

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:

- Groundwater: Member States must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses.

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 glyphosate in Annex I under the current inclusion conditions. Some endpoints may still 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.

Extension of the use pattern beyond the uses described in Section 3 above may require the generation or submission of additional studies to the Member States. This will be the case in particular for uses of the substance related to the control of aquatic weeds.

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 have 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

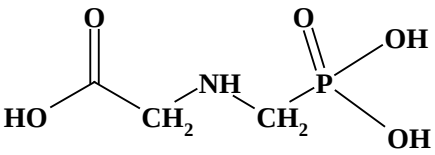
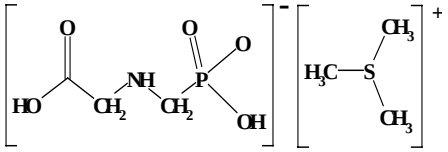
The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive

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 glyphosate in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

GLYPHOSATE / GLYPHOSATE TRIMESIUM

Common name (ISO)	**Glyphosate**	**Glyphosate trimesium**
Chemical name (IUPAC)	*N*-(phosphonomethyl)-glycin	*N*-(phosphonomethyl)-glycin trimesium salt
Chemical name (CA)	glycin, *N*-(phosphonomethyl)-	glycin, *N*-(phosphonomethyl)-trimethylsulfonium salt
CIPAC No	0284	0284.114
CAS No	1071-83-6	81591-81-3
EEC No	213-997-4	---
FAO SPECIFICATION	FAO 284 (2000)	FAO 284 (2000) (acid)
Minimum Purity	950 g/kg	950 g/kg (acid)
Molecular formula	$C_3H_8NO_5P$	$C_6H_{16}NO_5PS$
Molecular mass	169	245.2
Structural formula		
Melting point	189.5 °C (999 g/kg)	Decomposition.
Boiling point	Decomposition	Decomposition.
Appearance	colourless crystalls	White solid (pure as)
Relative density	1.705 (995 g/kg)	1.42 (pure as)
Vapour pressure	$1.31 \cdot 10^{-5}$ Pa (25 °C, acid)	$< 1 \cdot 10^{-11}$ Pa (20 °C)
Henry's law constant	$2.1 \cdot 10^{-7}$ Pa · m^3 ·mol^{-1}	$< 2 \cdot 10^{-9}$ Pa · m^3 ·mol^{-1}
Solubility in water	pH 2: 10.5 ± 0.2 g/l (20 °C, 995 g/kg)	pH 5- 9: 1050 g/l at 20°C

Solubility in organic solvents	acetone:	0.078 g/l	acetone:	<0.05 g/l (20°C)
	dichloro-methane:	0.233 g/l	xylene:	<0.05 g/l (20°C)
	ethyl acetate:	0.012 g/l	1,2-dichlorothene:	<0.05 g/l (20°C)
	hexane:	0.026 g/l	heptane:	<0.05 g/l (20°C)
	methanol:	0.231 g/l	methanol:	174 g/l (20°C)
	n-octanol:	0.020 g/l	n-octanol:	<0.05 g/l (20°C)
	propan-2-ol:	0.020 g/l	ethanol:	<0.05 g/l (20°C)
	toluene:	0.036 g/l	---	---

Partition co-efficient (log P_{ow})	pH 5 – 9: - 3.2 at 25 °C (999 g/kg)	- 2.9, pH and temperature not stated
Hydrolytic stability (DT_{50})	pH 5: stable (25 °C)	pH 5: stable; 25 and 40 °C (glyphosate and TMS)
	pH 7 : stable (25 °C)	pH 7: stable; 25 and 40 °C (glyphosate and TMS)
	pH 9: stable (25 °C)	pH 9: stable; 25 and 40 °C (glyphosate and TMS)
Dissociation constant	pKa: 2.34 (20 °C), 5.73 (20 °C), 10.2 (25 °C)	Glyphosate-trimesium is a salt which is fully dissociated in water. Glyphosate acid has 4 dissociation constants: < 2, 2.25, 5.5 and 10.34 (0.1 M at 20 °C).
Quantum yield of direct photo-transformation in water at ε >290 nm	Not determined.	Not determined.
Flammability	Not highly flammable.	Not flammable.
Explosive properties	Not explosive.	Not explosive.
UV/VIS absorption (max.)	ε: 0.086 (295 nm)	ε is less than 10 at wavelengths > 290 nm.
Photostability in water (DT_{50})	33 d (pH 5), 69 d (pH 7), 77 d (pH 9) (Xenon lamp).	DT_{50}: 81 d (pH 7) 37°N for glyphosate anion and stable for the cation.

APPENDIX II

END POINTS AND RELATED INFORMATION

GLYPHOSATE/GLYPHOSATE TRIMESIUM

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

	Glyphosate	**Glyphosate Trimesium**
Rate and extent of absorption:	Rapidly but only to a limited extent (approx. 30%).	Rapidly; only moderate absorption of phosphonomethylglycine (i.e. glyphosate, PMG) anion (40 - 60 %); trimethylsulphonium (TMS) cation nearly completely absorbed (> 90%)
Distribution:	Generally low residues occurring in all tissues.	Generally low residues in all tissues.
Potential for accumulation:	No evidence of accumulation (< 1% after 7 days).	No evidence of accumulation (for PMG anion < 3% after 5 days, for TMS cation much less).
Rate and extent of excretion:	Rapid and nearly complete (approx. 30% via urine).	Rapid and nearly complete; PMG: 36 - 63% via urine and 35 - 58% via feaces, TMS: 91 - 99% via urine and 1 - 7% via faeces.
Toxicologically significant compounds:	Parent compound; main plant metabolite, aminomethyl-phosphonic acid(AMPA), also detected in rats (< 0.5%).	Parent compound; aminomethylphosphonic acid (AMPA, up to 8.5% in female rats receiving multiple doses), i.e. the main plant metabolite also occurring in water and soil.
Metabolism in animals:	Very limited (< 0.5%) if occurring at all.	Limited, confined to the PMG anion (<10%)

Acute toxicity

	Glyphosate	Glyphosate Trimesium
Rat LD_{50} oral:	> 2000 mg/kg bw	464 mg/kg bw (a.i.); R 22 748 mg/kg bw (technical)
Rat LD_{50} dermal:	> 2000 mg/kg bw	> 1240 mg/kg bw (a.i.; intact skin) > 2000 mg/kg bw (technical; intact skin)
Rat LC_{50} inhalation:	> 5 mg/l air (4-hour exposure)	> 5.1 mg/l air (a.i.; 4-hour exposure) > 9.0 mg/l air (technical; 4-hour exposure)
Skin irritation:	Not irritating	Not irritating.
Eye irritation:	Acid: moderately to severely irritating.	Not irritating.
	Salts: slightly or not irritating, no classification	
Skin sensitization (test method used and result):	Not sensitizing (M&K test, Buehler test).	Not sensitizing (Buehler as well as Magnusson & Kligman test).

Short term toxicity

	Glyphosate	Glyphosate Trimesium
Target / critical effect:	Liver, gastrointestinal mucosa, salivary glands	Clinical signs and mortality in dogs; body weight gain↓ in rats.
Lowest relevant oral NOAEL / NOEL:	90 days, rat: 2000 ppm (equal to 150 mg/kg bw/d)	90 days, dog: 25 mg/kg bw/d
Lowest relevant dermal NOAEL / NOEL:	21 days, rat: >1000 mg/kg bw/d	21 days, rabbit (systemic): 573 mg/kg bw/d (a.i.); 1000 mg/kg bw/d (technical)
Lowest relevant inhalation NOAEL / NOEL:	2 weeks, rat: >3.8 mg/l	Not required.

Genotoxicity

Glyphosate	Glyphosate Trimesium
Not genotoxic.	Not genotoxic.

Long term toxicity and carcinogenicity

	Glyphosate	**Glyphosate Trimesium**
Target / critical effect:	Liver (organ weight↑, clinicial chemistry, histology); salivary glands (organ weight↑, histology); stomach mucosa and bladder epithelium (histology); eye (cataracts)	Body weight (gain) and food consumption↓; chronic mucosal inflammation in nasopharynx and larynx in rats
Lowest relevant NOAEL:	2 years, rat: 31 mg/kg bw/d	2 years, rat: 500 ppm (about 21 mg/kg bw/d)
Carcinogenicity:	No evidence of carcinogenicity.	No evidence of carcinogenicity.

Reproductive toxicity

	Glyphosate	**Glyphosate Trimesium**
Target / critical effect - Reproduction:	Reduced pup weight at parentally toxic doses.	Litter size and pup body weight gain↓ at parentally toxic doses.
Lowest relevant reproductive NOAEL / NOEL:	10000 ppm (equal to 700 mg/kg bw/d)	150 ppm (approx. 7.5 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	Lower number of viable fetuses and reduced fetal weight; retarded ossification, higher incidence of skeletal and/or visceral anomalies; effects confined to maternally toxic doses.	Post-implantation losses↑, fetal weight↓, slightly higher incidence of rib variations; effects confined to maternally toxic doses
Lowest relevant developmental NOAEL / NOEL:	Rat: 300 mg/kg bw/d	Rabbit: 40 mg/kg bw/d

Delayed neurotoxicity

Glyphosate	**Glyphosate Trimesium**
No relevant effects.	No relevant effects.

Other toxicological studies

Glyphosate	Glyphosate Trimesium
Toxicological studies on AMPA revealing the metabolite to be less toxic than the parent compound, no evidence of mutagenicity and teratogenicity; toxicity studies in farm animals: no risk to be expected; mechanistic study on salivary gland findings	Studies on the metabolite AMPA: low acute oral toxicity in the rat (LD50>5000 mg/kg bw); Ames test: negative.

Medical data

Glyphosate	Glyphosate Trimesium
Comprehensive database, mainly related to accidental or intentional oral intake of glyphosate products.	No evidence of adverse health effects upon manufacturing; few reports of poisonings following oral ingestion confined to cases of clear misuse.

Summary of Toxicology

	Glyphosate			Glyphosate trimesium		
	Value	Study	Safety factor	Value	Study	Safety factor
ADI:	0.3 mg/kg bw	Long-term studies in rats	100	0.2 mg/kg bw	Long-term study in rats	100
AOEL systemic:	0.2 mg/kg bw/day (systemic)	Rabbit teratogeni-city study, NOEL for mater-nal toxicity (30% oral absorption)	100	0.1 mg/kg bw/d	90-day study in dogs (40% oral absorption)	100
ARfD (acute reference dose):	Not allocated (not necessary).			0.25 mg/kg bw	28-day and 90-day studies in dogs	100
Dermal absorption	Less than 3%			≤ 1 %		

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:	**Glyphosate**	**Glyphosate trimesium**
Mineralization after different periods of time (%):	3 soils, 3 different ^{14}C labels: 46.8 – 55.3 (28 d); 5.8 – 9.3 (112 d); 34.7 – 41.4 (84 d) 2 soils: 69.7 – 80.1 (150 d) 1 soil: 32.7 (112 d) 1 soil: 79.6 (100 d)	Glyphosate 2 soils: 37 (21 d), 75 (150 d) TMS: 2 soils: 46 (9 d), 74 (150 d)
Non-extractable residues after different periods of time (%):	3 soils, 3 different ^{14}C labels: 8.5 – 40.3 (28 d); 4.6 – 13.5 (112 d); 16.7 – 33.9 (84 d) 2 soils: 5.1 – 8.8 (150 d) 1 soil: 13.9 (112 d) 1 soil: 8.4 (100 d)	Glyphosate 2 soils: 32 (21 d), 20 (150 d) TMS: 2 soils: 26 (9 d), 10 (150 d)

Major metabolites above 10 % of applied, name and/or code, % of applied (range and maximum)	Aminomethylphosphonic acid (AMPA) 26-29% after 14 days	Aminomethylphosphonic acid (AMPA) 15.4% after 21 days (only in one study detected), no further degradation within 70 days.

Supplemental studies	**Glyphosate**	**Glyphosate trimesium**
Anaerobic degradation	Mineralization after different periods of time (%): 3 soils, 3 different ^{14}C labels: 33.5 – 51.4 (28 d); 1.4 – 5.0 (112 d); 24.2 – 38.6 (84 d) 1 soil, < 1 (120 d) Non-extractable residues after different periods of time (%): 3 soils, 3 different ^{14}C-labels: 12.8 – 29.7 (28d); 0.4 – 12.0 (112 d); 15.1 – 31.6 (84d) 1 soil, 20 (120 d)	Mineralization after different periods of time (%): Glyphosate: 43 (63 d) TMS: 57 (63d) Non-extractable residues after different periods of time (%): Glyphosate: 24 (63 d) TMS: 16 (63d)
Soil photolysis:	DT_{50}: 96 (90 d dark); 101 d (1236 d dark)	DT_{50} 200 hours (50 ° N) AMPA: max. 24 % DT_{50} 200 hours;No metabolites of TMS detected.

Remarks:	None.	None.

Rate of degradation

Laboratory studies	**Glyphosate**	**Glyphosate trimesium**
DT_{50}lab (20 °C, aerobic):	DT_{50lab} (20°C, aerobic): 4 – 180 d (20°C), mean 49 d, n=7 (first order kinetic)	Glyphosate: 3- 62 d , mean 29 d, n=8 (first order kinetic) TMS: 3-15 d, mean 7 d, n=8 (first order kinetic)
DT_{90}lab (20 °C, aerobic):	DT_{90lab} (20°C, aerobic): 40 – 280 d (20°C), mean 159 d,n=4 (first order kinetic)	Glyphosate: 81- 207 d n= 4(first or kinetic) TMS: 37-85 d (TMS anion), n= 4 (f order kinetic)
DT_{50}lab (10 °C, aerobic):	DT_{50lab} (10°C, aerobic): not submitted (see field studies)	Glyphosate:67d TMS: 70 d (8°C)
DT_{50}lab (20°C, anaerobic)	DT_{50lab} (20°C, anaerobic): comparable to aerobic (study one); (waterphase) 3 d, (system) 1699 d (study two)	No significant degradation.

Field studies (country or region)	**Glyphosate**	**Glyphosate trimesium**
DT_{50f} from soil dissipation studies:	DT_{50f} (best fit): Germany 5;12 d; Switzerland7; 21d; USA: 1 d (Texas), 7 d (Ohio), 9 d (Georgia), 12 d (California), 17 d (Arizona), 31 d (Minnesota), 106 d (New York), 130 d (Iowa); Canada: 11 d (Manitoba), 16 d (Ontario), 63 d (Alberta)	DT_{50f} (best fit): Germany: 9, 15, 17, 23, 34,34d; USA: 1.5, 1.8, 15 and 17 d
	AMPA DT_{50f} (best fit): Germany 218 d (Menslage); Switzerland 135; 139 d; USA: 76 d (Ohio), 93 d (Texas), 103 d (Arizona), 145 d (New York) 170 d (Georgia), 174 d (Minnesota) 240 d (California); Canada: 128 d (Manitoba), 185 d (Ontario)	**AMPA DT_{50f}** (first order kinetic) : Germany: 134, 242, 316, 362, 449, 875 d ; USA: 13, 23, 37,147d .

DT_{90f} from soil dissipation studies:	not calculated; see DT_{50f}	DT_{90f}: Germany: 76, 89, 113, 124, 166, 326 d; USA: 24, 48, 61, 68 d **AMPA DT_{90f}**: Germany: 445, 804, 1050, 1203, 1491, 2907 d; USA: 42, 77, 124, 489d
	Glyphosate	**Glyphosate trimesium**
Soil accumulation and plateau concentation	Plateau concentration for AMPA: 5.62 mg/kg (mean DT_{50f}: 697 d (first order kinetic))	Plateau concentration for AMPA: 0.91 mg/kg (mean DT_{50f} (Germany): 396 d (first order kinetic))
Remarks: e.g. effect of soil pH on degradation rate	None.	None.

Adsorption/desorption

K_f / K_{oc}: K_d	**Glyphosate**				**Glyphosate trimesium**						
	soil type	1/n	K_{oc}	K_d	soil type	1/n	K_{oc}	K_d	1/n	K_{oc}	K_d
	silty clay loam	1.16	60000	900	silt loam	0.98	25100	427	0.89	1179	20
	silt loam	0.8	3800	34	loam	0.93	2860	66	0.89	530	12
	loamy sand	0.92	22300	245	sandy loam	0.88	7880	39	0.84	1758	9
	sand	*)	32830	263	clay	1.1	180000	2340	0.93	1659	22
	sand loam	*)	50660	810							
	sandy clay loam	*)	3598	50							
	loamy sand	*)	884	5.3							
	silt loam	*)	3404	47							
	loam (sediment)	*)	17819	510							
	*)The advanced adsorption isotherm test wasn't conducted because in the screening test equilibrium was not reached after 72 hours										

pH dependence:	No pH-dependence	No pH dependence.

K_f / K_{oc}: K_d	**AMPA**			
	soil type	1/n	K_{oc}	K_d
	clay loam	0.786	3640	76
	sand	0.904	8310	1554
	sand	0.752	1160	15
	clay loam	0.791	3330	30
	loamy sand	0.769	6920	111
	sand	0.788	24800	74

pH dependence:	No pH-dependence

Mobility

	Glyphosate	Glyphosate trimesium
Column leaching:	1. 0.12 – 1.45% as of applied in leachate (3 soils) 2. 0.03 – 6.56% as of applied in leachate (7 soils)	< 2 % as in leachate (BBA standard soils)
Aged residue leaching:	1.56, 0.22 and 0.02 % ^{14}C-activity in leachates 65.2, 59.0 and 2.1 % evolved as CO_2 30.3, 40.4 and 97.5 % ^{14}C in the upper 2 cm of columns	^{14}C distribution after 30 days: Glyphosate-^{14}C: 52 % extractable (AMPA 26 %), 12 % unextractable, 33 % CO_2; TMS-^{14}C: 10 % extractable, 21 % unextractable, 57 % CO_2 0.1 % Glyphosate and 0.5% TMS in leachate, total radioactivity in leachate not given.
Lysimeter/Field leaching studies:	Not submitted.	Not submitted.
Remarks:	None.	None.

2.2 Fate and behaviour in water

Abiotic degradation

	Glyphosate	Glyphosate trimesium
Hydrolytic degradation:	pH__5____: stable (25°C)	pH___5___: stable; 25 and 40 °C (glyphosate and TMS)
	pH__7____: stable (25°C)	pH___7___: stable; 25 and 40 °C (glyphosate and TMS)
	pH__8____: stable (25°C)	pH___9___: stable; 25 and 40 °C (glyphosate and TMS)
Photolytic degradation:	DT_{50}: 33 d (pH 5), 69 d (pH 7), 77 d (pH 9).	Glyphosate: DT_{50}: 81 d (pH 7) 37°N TMS: stable

Biological degradation

	Glyphosate	Glyphosate trimesium
Readily biodegradable:	No.	No.
Water/sediment study:		
DT_{50} water:	1 and 4 days (Möllerfeld and Römbke)	Glyphosate: 14 and 24 d; TMS: 4 and 3 d
DT_{90} water:	**not calculated**	Glyphosate: 46 and 80 d; TMS: 13 and11 d
DT_{50} whole system:	27 and 146 days (Möllerfeld and Römbke), 31 and 124 days (Muttzall)	Glyphosate: 21 and 202 (extrapol.) d; TMS: 5 and 7 d
DT_{90} whole system:	**2.1.4.1.1 not calculated**	Glyphosate: 69 d; TMS: 18 and 23 d
Mineralization	18 and 24 % after 100 days (Möllerfeld and Römbke), 6 and 26 % after 91 days (Muttzall)	Glyphosate: 48 and 6 % after 100 days; TMS: 67 and 68 % after 100 days
Non-extractable residues	14 and 22 % after 100 days (Möllerfeld and Römbke), 31 and 35 % after 91 days (Muttzall)	Glyphosate: 14 and 17 % after 100 days; TMS: 7 and 8 % after 100 days
Distribution in water /	after 1 day: 47-64% in water, 31-	Glyphosate water: 1 and 5 %;

	Glyphosate	**Glyphosate trimesium**
sediment systems (active substance)	44% in sediment; after 100 days 3% in water, 29-44% in sediment. In sediment: maximum 50-60% afte and 14 days, resp. and 30-50% after 100 days.	sediment: 4 and 58 % TMS water: < 1%; sediment: 2 and 5 %
Distribution in water / sediment systems (major metabolites)	AMPA: if found, only in the water phase: maximum 16% after 14 days and 0.5 % after 100 days. Water/sediment studies with ^{14}C-**AMPA** (Knoch and Spirlet): 1 st system: waterphase: 101% day 0; 4% day 100; sediment: max. 41% day 59; 20% day 100; 2 nd system waterphase: 100% day 0; 1% day 59; sediment: max. 46% day 14; 32% day 100	AMPA water: 4 and < 1 %: AMPA sediment: 18 and 3 %
Accumulation in water and/or sediment:	**No accumulation**	**No accumulation**

Degradation in the saturated zone

	Glyphosate	**Glyphosate trimesium**
	Not submitted.	Not submitted.

Remarks:	None.	None.

2.3 Fate and behaviour in air

Volatility

	Glyphosate	Glyphosate trimesium
Vapour pressure:	$1.31 \cdot 10^{-5}$ Pa (25 °C, acid)	$< 1 \cdot 10^{-11}$ Pa (20 °C)
Henry's law constant:	$2.1 \cdot 10^{-7}$ Pa m^3 mol^{-1}	$< 2 \cdot 10^{-9}$ Pa m^3 mol^{-1}

Photolytic degradation

	Glyphosate	Glyphosate trimesium
Direct photolysis in air:	No absorption for wavelengths > 290 nm. DT_{50} (water):33d (pH 5), 69 d (pH 7), 77 d (pH 9)	No absorption for wavelengths > 290 nm. DT_{50} (water): 81 d (pH 7) 37°N (stable for TMS)
	Glyphosate	**Glyphosate trimesium**
Photochemical oxidative degradation in air DT_{50}:	DT_{50}: 1.6 d (Atkinson estimation)	DT_{50}: about 1.4 hours
Volatilisation:	from plant surfaces: no significant volatilization from soil: no significant volatilization	from plant surfaces: negligible (glyphosate and TMS) from soil: negligible (glyphosate and TMS)

Remarks:	None.	None.

3 Ecotoxicology

Terrestrial Vertebrates

	Glyphosate	**Glyphosate-trimesium**
Acute toxicity to mammals:	2.1.6 LD_{50} > 2000 mg/kg bw	lowest LD_{50} 748 mg/kg bw
Acute toxicity to birds:	LD_{50} > 2000 mg/kg bw	lowest LD_{50} 950 mg/kg bw
Dietary toxicity to birds:	LC_{50} > 4640 ppm	LC_{50} > 5000 ppm
Reproductive toxicity to birds:	NOEC 200 ppm	NOEC 712 ppm
Short term oral toxicity to mammals:	NOAEL/NOEL 150 mg/kg bw/d (90 d, rat)	NOAEL/NOEL 25 mg/kg bw/d (90 d, rat)

Aquatic Organisms

	Glyphosate-IPA	**Glyphosate-trimesium**	**Glyphosate acid (1st metabolite)**
Acute toxicity fish: EC_{50}	>1000 mg /L	1800 mg/L	38 mg/L
Long term toxicity fish: NOEC	917 mg /L	50 mg/L	25 mg/L
Bioaccumulation fish:	Not relevant	Not relevant	Not relevant
Acute toxicity invertebrate: EC_{50}	930 mg /L	12 mg/L	40 mg/L
Chronic toxicity invertebrate: NOEC	455 mg /L	1.1 mg/L	30 mg/L
Chronic toxicity algae EC_{50}	72.9 mg/L	0.72 mg/L	0.64 mg/L (168 h)
Chronic toxicity sediment dwelling organism:	Not tested	Not tested	Not tested
Long-term toxicity aquatic plants: EC_{50}	53.6 mg/L	1.0 mg/L	12 mg/L

Honeybees

	Glyphosate	**Glyphosate-trimesium**
Acute oral toxicity:	LD50: 100 µg as/bee	LD50: > 400 µg as/bee
Acute contact toxicity:	LD50: > 100 µg as/bee	LD50: > 400 µg as/bee

Other arthropod species

Test species Test method	**Glyphosate** % Effect	**Glyphosate-trimesium** % Effect
Typhlodromus pyri Lab on inert substrate	Lifecycle: 100 % mortality (3.6 kg as/ha)	Lifecycle: 100 % mortality (5.760 kg as/ha) LR_{50}: 0.211 kg as/ha
Typhlodromus pyri Lab natural substrate on leaves	Lifecycle: 89 % mortality (7.720 kg as/ha)	LR_{50}: 5.089 kg as/ha
Typhlodromus pyri Lab natural substrate on plants	Lifecycle: 30 % mortality; 0 % effect on fertility (3.708 kg as/ha)	---
Aphidius rhopalosiphi Lab on inert substrate	Adult: 100 % mortality	Adults: 100 % mortality (5.76 kg as/ha) LR_{50}: 0.043 kg as/ha
Aphidius rhopalosiphi Lab natural substrate on plants	Adult: 25 % mortality; 6 % effect on fertility (3.720 kg as/ha)	---
Aphidius rhopalosiphi Lab natural substrate on leaves	---	LR_{50}:> 8.4 kg as/ha
Orius insidiosus Lab on inert substrate	---	Lifecycle: 95 % mortality (5.760 kg as/ha)
Chrysoperla carnea Lab on inert substrate	Larval stage: 53 % mortality (0.712 kg as/ha)	---
Chrysoperla carnea Lab on inert substrate	Larval stage: 59 % mortality; 20 % effect on fertility (3.708 kg as/ha)	---
Drino inconspicua Lab on inert substrate	---	Adults: 56 % mortality; 76 % effect on parasitization (2.4 kg as/ha)
Pterostichus melaniarius Lab on inert substrate	---	Adults: 26.7% mortality (3.6 kg as/ha) Adults: 10% mortality (7.2 kg as/ha)
Aleochara bilineata Lab on inert substrate	Lifecycle: 1% parasitation capacity (1.63 kg as/ha)	---
Bembidion lampros Semifield	Adult: 0% mortality (4,890 kg as/ha)	---
Poecilus cupreus Lab on inert substrate	Adult: 0% mortality; 31% effect on food uptake (3.6 kg as/ha)	---

Test species Test method	**Glyphosate** % Effect	**Glyphosate-trimesium** % Effect
Trechus quadristriatus Lab on inert substrate	Adult: 14% mortality (3.6 kg as/ha)	---
Pardosa spp. Lab on inert substrate	Adult: 56% mortality (3.7 kg as/ha)	Adults: 4 % mortality (3.6 kg as/ha) Adults: 0% mortality (7.2 kg as/ha)

Earthworms

	Glyphosate	**Glyphosate trimesium**
Acute toxicity:	LC_{50} > 480 mg as/kg	LC_{50} > 1000 mg as/kg
Reproductive toxicity:	NOEC 28.79 mg/kg (IPA-salt)	NOEC 28.79 mg/kg (IPA-salt)

Soil micro-organisms

	Glyphosate	**Glyphosate-trimesium**
Nitrogen mineralization:	No effects up to 18 kg as/ha	No effects up to 18 kg as/ha
Carbon mineralization:	No effects up to 18 kg as/ha	No effects up to 18 kg as/ha

APPENDIX III A

GLYPHOSATE

List of studies for which the main submitters have claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion[1].

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labeling, 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; IIA-2.11; IIA-2.13; IIA-2.14; IIA-2.2; IIA-2.4; IIA-2.5; IIA-2.6; IIA-2.8	Cowlyn, T.C.	1993	Glyphosate, ammonium salt: Determination of physico-chemical properties. Source: Monsanto Report no. 93/MON032/0343	Germany 1995
II A-2.1	Dommrose, A.M.	1989	Determination of the melting point of the test sample Glyphosate acid 99.9% pure acc. to OECD Guideline 102. Source: Monsanto Report no. NA 89 9641/I	Germany 1995
IIA-2.1	Krips, H.J.	1995	Determination of the melting temperature of MON 77209 Pure. Source: Monsanto Report no. 134145	Germany 1995
IIA-2.2	Bates, M.L.	1992	Glyphosate ipa salt: determination of relative density. Source: Monsanto Report no. 7067-676/7-1	Germany 1995
IIA-2.4	Roels, M.	1999	Odour of glyphosate isopropylamine salt Source: Monsanto/Cheminova Report no. 205-15750/2	Germany 1999
IIA-2.4	Dieudonne, M.	1999	Appearance of an active ingredient: a sodium salt of glyphosate. Source: Monsanto/Cheminova Report no. F-99-Na_gly-01	Germany 1999

[1] List based on an analysis from Germany (background document C).

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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-2.4	Dieudonne, M.	1999	Appearance of an active ingredient: an ammonium salt of glyphosate. Source: Monsanto/Cheminova Report no. F-99-NH_4-gly-01	Germany 1999
IIA-2.4	Krips, H.J.	1995	Determination of appearance of MON 77209 (tech) and Pure. Source: Monsanto Report no. 134145	Germany 1995
IIA-2.5	Krips, H.J.	1995	Determination of the H-NMR Spectrum of MON 77209 Pure (IPA salt). Source: Monsanto Report no. 134167	Germany 1995
IIA-2.5	Snoddy, C.B.; La Monica, R.	1992	Analytical standard data package for N-nitroso, N-(phosphonomethyl) glycine. Source: Cheminova Report no.Lot no. NPD-9205-4204-A	Germany 1995
IIA-2.5	Søensen, E.V.; Bjorholm, T.	1992	Characterisation of glycine, N-nitroso-(phosphonomethyl)mono sodium salt Report No: REF 026-01	Germany 1995
IIA-2.5	Verhoeven, S.G.L.	1995	Determination of the IR-Spectrum of MON 77209 Pure (IPA salt) Source: Monsanto Report no. 134156	Germany 1995
IIA-2.6	Vogel, W.	1990	Solubility determination of glyphosate (pmg) in water at different pH values Source: Cheminova Report no. 240963	Germany 1995
IIA-2.6	Vogels, M.P.W.	1995	Determination of the water solubility of MON 77209 (Pure) Source: Monsanto Report no. 134191	Germany 1995
IIA-2.6	Verbist, F.	1999	Preparation of sodium glyphosate and elemental analysis Source: Monsanto Report no. none	Germany 1999
IIA-2.7	Bates, C.	1999	The solubility of sodium and ammonium glyphosate salts in organic solvents. Source: Monsanto/Cheminova Report no. MLL31266	Germany 1999
IIA-2.9	Cowlyn, T.C.	1993	Glyphosate, ammonium salt: Determination of hydrolysis as a function of pH Source: Monsanto Report no. 93/MON033/0344	Germany 1995
IIA-2.9; IIA-7.2.1	Schneider, E.	1993	Glyphosate isopropylamine salt, Hydrolysis in water at 3 different pH-Values Source: Feinchemie Report no. PR93/009 (Proj./lab-no) ! B/7-28	Germany 1995

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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-2.10	Anonym	1995	Estimation of the photochemical-oxidative degradation of Glyphosate in the atmosphere Source: Agrichem Report no. 136384	Germany 1995
IIA-2.11; IIA-2.13	Gibson, A., Jackson, W.	1993	Glyphosate, sodium salt (MON 8722): Determination of physico-chemical properties. Addendum to final report. Source: Monsanto Report no. 93/MON023/0146	Germany 1995
IIA-2.11	Krips, H.J.	1995	Determination of the flammability of MON 77209 (technical) (IPA salt). Source: Monsanto Report no. 134235	Germany 1995
IIA-2.11	Krips, H.J.	1995	Determination of the relative self-ignition temp-erature of MON 77209 (technical) (IPA salt). Source: Monsanto Report no. 134257	Germany 1995
IIA-2.13	Garnett, R.P.	1999	Thermal stability of glyphosate and its salts: review of differential thermal analysis, accelerated rate calorimetry and differential scanning calorimetry Source: Monsanto/Cheminova Report no. 12/21/99	Germany 1999
IIA-2.13	Krips, H.J.	1995	Determination of explosive properties of MON 77209 technical (IPA salt). Source: Monsanto Report no. 134246	Germany 1995
IIA-2.14	Krips, H.J.	1995	Determination of the surface tension of an aqueous solution of MON 77209 technical (IPA salt). Source: Monsanto Report no. 134268	Germany 1995
IIA-2.15	Krips, H.J.	1995	Determination of the oxidising properties of MON 77209 technical (IPA salt). Source: Monsanto Report no. 134279	Germany 1995
IIIA-2.8.4	Toussaint, M.	1995	Dilution stability of MON 52276, a water soluble concentrate (SL) formulation of glyphosate. Source: Monsanto Report no. F-95-52276-01	
IIIA-2.7	Campbell, C.N., Calierno, A.	1997	MON 44068: long term storage stability of MON 44068 (metallised sachet) Source: Monsanto Report no. 10499	

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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
IIIA-2.7	Campbell, C.N., Calierno, A.	1997	MON 44068: long term storage stability of MON 44068 (cardboard box and polyester/SiO_2/PE foil liner) Source: Monsanto Report no. 10498	
IIA-4.2.1	Schneider, E.	1992	Analyseverfahren auf behandelte Pflanzen, pflanzliche Erzeugnisse, Nahrungsmittel, Futtermittel Source: Feinchemie Report no.	Germany 1995
IIA-4.2.3	Egloff, K.	1996	Bestimmung der Konzentration an Glyphosat und AMPA in Trink- wasserproben Source: Feinchemie Report no. IF-95/26884-00	Germany 1996
IIA-4.2.3	Jonas, W.	1996	Analytische Konzentrationsbestimmungen; NATEC Institut Source: Feinchemie Report no. NA 96 9402	Germany 1996
IIA-4.2.3	Klumpp, M.	1996	Residue analysis of glyphosate and aminomethylphosphonic Acid in water; Arbeitsgemeinschaft GAB & IFU; Source: Feinchemie Report no. 95208/01-RW	Germany 1996
IIA-4.2.3	Schneider, E.	1996	Determination of glyphosate residues and AMPA residues in drinking water; Source: Feinchemie Report no. 95/014	Germany 1996
IIA-4.2.3	Schulz, M., Ullrich-Mitzel, A.	1996	Determination of the residues of glyphosate and its metabolite AMPA in drinking water; Source: Feinchemie Report no. RCC 615071	Germany 1996

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[2] on previous use in granting national authorizations
IIA-5.2.1	Dreher, D.M.	1994	Glyphosate premix: Acute oral toxicity (limit test) in the rat. Source: Cheminova Project no. 545/37	Germany 1995
IIA-5.2.1	Reagan, E.L.	1987	Acute oral toxicity study of MON 8750 in Sprague-Dawley rats Source: Monsanto FDRL study no. 9308A	Germany 1995
IIA-5.2.3	Blagden, S.M.	1994	Glyphosate premix: Acute inhalation toxicity study four-hour exposure (nose only) in the rat. Source: Cheminova Project no.. 545/39	Germany 1995
IIA-5.2.4	Dreher, D.M.	1994	Glyphosate premix: Acute dermal irritation test in the rabbit. Source: Cheminova Project no. 545/40	Germany 1995
AIIA-5.2.3	Bechtel, C.L.	1988	Acute inhalation study of MON 8750 technical Source: Monsanto PROJ. No. EHL 87147	Germany 1995
AIIA-5.2.4	Busch, B.	1987	Primary dermal irritation study of MON 8750 in New Zealand white rabbits Source: Monsanto FDRL study no. 9308A	Germany 1995
IIA-5.2.5	Dreher, D.M.	1994	Glyphosate premix: Acute eye irritation test in the rabbit. Source: Cheminova Project no. 545/41	Germany 1995
AIIA-5.2.5	Busch, B.	1987	Primary eye irritation study of MON 8750 in New Zealand white rabbits Source: Monsanto FDRL study no. 9307A	Germany 1995
IIA-5.2.5	Kuhn, J.O.	1996	Primary eye irritation study in rabbits. Source: Cheminova Report no. 2981-96	Germany 1999
IIA-5.2.6	Dreher, D.M.	1994	Glyphosate premix: Magnusson & Kligman maximisation study in the guinea pig. Source: Cheminova Project no. 545/42	Germany 1995
IIA-5.4.1	Kier, L.D., Stegeman, S.D., Costello, J.G., Schermes, S.	1992	Ames/S*almonella* mutagenicity assay of MON 2139 (Roundup herbicide formulation). Source: Monsanto Project no. EHL 91183 ! MSL-11729	Germany 1998
IIA-5.4.1	Stegeman, S.D., Li, A.P.	1990	Ames/*Salmonella* mutagenicity assay of MON 0818. Source: Monsanto Project no. EHL 89178 ! MSL-10625	Germany 1998

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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-5.4.1	Vargas, A.A.T.	1996	The *Salmonella typhimurium* reverse mutation by Glifos. Source: Cheminova Report no. G.1.1 - 050 / 96	Germany 1999
IIA-5.4.2	Kier, L.D.	1992	Mouse micro-nucleus study of Rodeo herbicide formulation Source: Monsanto Report no. MLL-91-438	Germany 1995
IIA-5.4.2	Zaccaria, C.B.	1996	A micro-nucleus study in mice for the product Glifos. Source: Cheminova Report no. G.1.2 - 60 / 96	Germany 1999
IIA-5.8.1	Bakke, J.P.	1991	Evaluation of the potential of AMPA to induce unscheduled DNA synthesis in the in vitro hepatocyte DNA repair assay using the male F-344 rat. Source: Monsanto Study no. 2495-V01-91	Germany 1995
IIA-5.8.1	Estes, F.L., Jefferson, N.D., Blair, M., Goldenthal, E.I.	1979	90 day sub-acute rat toxicity study. Source: Monsanto Report no. 401-050 ! IRD-78-174	Germany 1995
IIA-5.8.1	Cuthbert, J.A. and Jackson, D.	1992	AMPA: Magnusson-Kligman maximisation test in guinea pigs. Source: Cheminova Project no. 552409	Germany 1995
IIA-5.8.1	Cuthbert, J.A. and Jackson, D.	1992	AMPA: Acute dermal toxicity (limit) test in rats. Source: Cheminova Project no. 552409	Germany 1995
IIA-5.8.1	Holson, J.F.	1991	A developmental toxicity study of AMPA in rats. Source: Monsanto Project no. WIL-50159	Germany 1995
IIA-5.8.1	Lauer, R., Blount, L.M., Kramer, R.M.	1979	Analysis of animal feed diets in the aminomethylphosphonic acid (AMPA) 90-day sub-acute rat toxicity study. Source: Monsanto Report no. MSL-0682	Germany 1995
IIA-5.8.1	Stout, L.D.	1991	One month study of AMPA administered by capsule to beagle dogs. Source: Monsanto Report no. ML-90-186/EHL 90074	Germany 1995
IIA-5.8.1	Tompkins, E.C.	1991	90-day oral (capsule) toxicity study in dogs with AMPA. Source: Monsanto. Project no. WIL-50173	Germany 1995

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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-5.8.2	Rowe, L.D., Lovering, S.L., Martin, B.W., Harvey, R.B., Peterson, H.D., Farr, F.M. Moore, E.G.	1987	The sub-acute toxicity of the isopropylamine salt of glyphosate (Mon-0139) in female cattle. Source: Monsanto Report no. VT-80-451	Germany 1995

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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[2] on previous use in granting national authorizations
IIA-6.1/6.9	McMullen, P.C., Honneger, J.L., Logusch, E.W.	1990	Confined rotational crops study of glyphosate: part II: quantitation, characterization and identification of glyphosate and its metabolites in rotational crops. Source: Monsanto Report no. MSL-9811	Germany 1999
IIA-6.1	Hattermann, D.R.	1998	(Glyphosate technical) Confined rotational crop study on lettuce, radish, and wheat in California. Source: Cheminova Report no. 91233/9028	
IIA-6.1	Mehrsheikh, A.	2000	Metabolism of glyphosate in Roundup Ready sugar beet. Source: Monsanto/Cheminova Report no. MSL-16247	Germany 2000
IIA-6.3	Balasubramanian M.	1999	Studies on the residues of glyphosate (Roundup CT – 41%SL) in processed tea, decoction and soil (three seasons, Assam) Source: Monsanto/Cheminova Report no. 6482	
IIA-6.3	Bleeke, M.S.	1997	Nature of Glyphosate residues in cotton plants tolerant to Roundup® herbicide. Source: Monsanto Report No. MSL-14113	Germany 1999
IIA-6.3	George, C.	1995	Nature of Glyphosate residues in corn plants which are tolerant to Roundup® herbicide. Source: Monsanto Report No. MSL-14018	Germany 1999
IIA-6.3	Hontis, A.M.	1992	Residues of glyphosate/AMPA in olives and olive oil following use of Sting SE – Spanish field trials Source: Monsanto Report no. MLL 30.297	Germany 1999
IA-6.3	Hontis, A.M.	1993	Residues of glyphosate/AMPA in olives and olive oil following soil treatment with MON 65040 herbicide. Field trials in Italy Source: Monsanto Report no. MLL 30.319	Germany 1999
IIA-6.3	Hontis, A.M.	1996	Residues of glyphosate and AMPA in field beans (Vicia faba) treated preharvest with MON 52276 herbicide. UK and Belgian field trials, 1995. Source: Monsanto Report No. MLL 30463	Germany 1999

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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-6.3	Hontis, A.M.	1996	Residues of glyphosate and AMPA in peas treated preharvest with MON 52276 herbicide. UK and Belgian field trials, 1995. Source: Monsanto Report No. MLL 30464	Germany 1999
IIA-6.3	Hontis, A.M.	1996	Residues of glyphosate and AMPA in olives and olive oil, following a soil treatment with Roundup® heribicide. Spanish field trials, 1995. Source: Monsanto Report No. MLL 30469	Germany 1999
IIA-6.3	Hontis, M.A.	1997	Residues of Glyphosate and AMPA in cotton treated preharvest with Roundup® (MON 2139), Roundup® Plus (MON 60612) and MON 52276 herbicide. Spanish field trials, 1996. Source: Monsanto Report no. MLL 30611	
AII-6.3	Hontis, M.A.	1998	Residues of Glyphosate and AMPA in cotton treated preharvest with Roundup® (MON 2139), Roundup® Plus (MON 60612) and MON 52276 herbicide. Spanish field trials, 1997. Source: Monsanto Report no. MLL 30763	
AII-6.3	Hontis, M.A.	1998	Residues of Glyphosate and AMPA in cotton containing Roundup Ready® genes, after multiple treatment with MON 52276 herbicide. Spanish field trials, 1997. Source: Monsanto Report no. MLL 30762	Germany 1999
AII-6.3	Hontis, M.A.	1999	Residues of Glyphosate and AMPA in sugar beet, B*eta vulgaris spp*., containing Roundup Ready® genes, after multiple treatment with MON 52276 herbicide. Belgian field trial, 1998. Source: Monsanto Report no. MLL 30919	Germany 1999
AII-6.3	Hontis, M.A.	1999	Residues of Glyphosate and AMPA in sugar beet, B*eta vulgaris spp*., containing Roundup Ready® genes, after multiple treatment with MON 52276 herbicide. UK and French field trial, 1998. Source: Monsanto Report no. MLL 30918	Germany 1999

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
AII_6.3	Hubbard, N.S.	1993	Determination of Glyphosate in soybean raw agricultural commodities (RAC), stability report: analytical phase final report. Source; Cheminova Report no. 91210	
AII-6.3	Hubbard, NS.	1993	Determination of glyphosate in pasture grasses, stability report: analytical phase final report. Source: Cheminova Report no. 91212	
AII-6.3	Morgenroth, U.	1995	Storage stability of Glyphosate and AMPA in wheat grain and straw and in rye grain and straw. Source: Cheminova Report no. 303614	
IIA-6.3	Mueth, M.G.	1991	Storage stability of glyphosate residues in crop commodities Source: Monsanto Report no. MSL-10843	Germany 1999
IIA-6.3	Oppenhuizen, M.E.	1994	Magnitude of glyphosate residues in milo processed commodities following preharvest use of Roundup® herbicide. Source: Monsanto Report No. MSL-13038	
IIA-6.3	Oppenhuizen, M.E.	1995	Magnitude of glyphosate residues in glyphosate tolerant cotton raw agricultural and processed commodities. Source: Monsanto Report No. MSL-13884	Germany 1999
IIA-6.3	Oppenhuizen, M.E.	1995	Magnitude of glyphosate residues in corn raw agricultural commodities following pre-harvest application of Roundup® herbicide. Source: Monsanto Report No. MSL-13654	Germany 1999
IIA-6.3	Oppenhuizen, M.E.	1995	Magnitude of glyphosate residues in corn processed commodities following pre-harvest application of Roundup® herbicide. Source: Monsanto Report No. MSL-13655	Germany 1999
IIA-6.3	Oppenhuizen, M.E.	1995	Magnitude of glyphosate residues in glyphosate tolerant corn raw agricultural commodities. Source: Monsanto Report No. MSL-13882	Germany 1999

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-6.3	Schulz, H.	1995	Determination of residues of glyphosate in winter oats (grain and straw). Treatment with either CHE 3607 or CHE 3607/Frigate - UK, season 1993. Source: Cheminova Report no. IF-94/01227-01	
IIA-6.3	Schulz, H.	1995	Determination of residues of glyphosate in grass (grass and silage). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01236-01	
IIA-6.3	Schulz, H.	1995	Determination of residues of glyphosate in winter field beans (seed and haulm). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. :IF-94/01230-01	
IIA-6.3	Schulz, H.	1995	Determination of residues of glyphosate in linseed. Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01233-01	
AII-6.3	Schulz, H.	1995	Determination of residues of glyphosate in winter sown oilseed rape. Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01229-01	
AII-6.3	Schulz, H.	1995	Determination of residues of glyphosate in grass (grass and hay). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01235-01	
AII-6.3	Schulz, H.	1995	Determination of residues of glyphosate in peas (peas and haulm). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01231-01	
AII-6.3	Schulz, H.	1995	Determination of residues of glyphosate in winter sown oilseed rape (seed and pods). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01240-01	
AII-6.3	Schulz, H.	1995	Determination of residues of glyphosate in winter field beans (seed and haulm). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01242-01	

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
AII-6.3	Schulz, H.	1995	Determination of residues of glyphosate in peas (peas and haulm). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01241-01	
AII-6.3	Schulz, H.	1995	Determination of residues of glyphosate in grass (grass and silage). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01244-01	
AII-6.3	Schulz, H.	1995	Determination of residues of glyphosate in grass (grass and hay). Treatment with CHE 3607 - UK, season 1993. Source: Cheminova Report no. IF-94/01243-01	
AII-6.3	Schulz, H.	1994	Determination of residues of glyphosate in winter oats (grain, straw and whole plant). Treatment with either CHE 3607 or CHE 3607/Frigate - UK, season 1993. Source: Cheminova Report no. IF-94/01239-01	
AII-6.3	Schulz, H.	1995	Determination of the dissipation of glyphosate in oranges following treatment with Glifos under field conditions in Portugal, 1994 Source: Monsanto/Cheminova Report no. IF-94/10285-00	
AII-6.3	Schulz, H.	1995	Determination of the dissipation of glyphosate in oranges following treatment with Glifos under field conditions in Portugal 1994. Source: Monsanto/Cheminova Report no. IF-94/10285-00	
AII-6.3	Schultz, H.	1997	Determination of the storage stability of Glyphosate in beans, oilseed rape and linseed. Source: Cheminova Report no. IF-94/13882-00	
AII-6.5	Zietz, E.	1995	Determination of residues of Glyphosate in products of the processing of barley to beer and whisky following treatment with Glyfos - England, season 1993. Source: Cheminova Report no. IF-94/00451-01	
AII-6.5	Zietz, E.	1995	Determination of residues of Glyphosate in products of the processing of oats to rolled oats following treatment with Glyfos - England, season 1993. Source: Cheminova Report no. IF-94/00453-01	

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4 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[2] on previous use in granting national authorizations
IIA-7.1.1	Matla, YA. Vonk, JW.	1993	Rate of degradation and metabolism of [14C]-Glyphosate in soil under aerobic conditions Source: Luxan, Agrichem Report no. IMW-R 93/047 ! IMW-92-0022-01	Germany 1995
IIA-7.1.1	Schneider, E.	1991	Behaviour of Glyphosate in water and soil, Part 5 Degradation in soil Source: Feinchemie Report no. PR90/002	Germany 1995
IIA-7.1.1.2.1	Keirs, D.C., Mackie, J.A.	2000	The degradation of [^{14}C]- glyphosate in soil under anaerobic conditions. Source: Monsanto/Cheminova Report no. MSL-16796	Germany 2000
IIA-7.1.1.2.2	Harnish, W.N.	1998	Terrestrial field dissipation of glyphosate and its metabolite, AMPA, in soil. Source: Cheminova Report no. 91205	Germany 1999
IIA-7.1.1.2.2	Oppenhuizen, ME.	1993	The terrestrial field dissipation of Glyphosate: Final Report Source: Monsanto Report no. MSL-12651	Germany 1995
IIA-7.1.1.2.2	Oppenhuizen, ME.	1993	The terrestrial field dissipation of Glyphosate in Canadian soil Source: Monsanto Report no. MSL-12605	Germany 1995
IIA-7.1.2	Weeden, DM.	1993	Aminomethylphosphonic acid – Determination of the sorption and desorption properties. Source: Monsanto Report no. MSL-12703	Germany 1995
IIA-7.2.1.3.2	Morgenroth, U.	1995	Storage stability of glyphosate and AMPA in soil. Source: Cheminova Report no. 303625	Germany 1995
IIA-7.2.1.3.2	Oppenhuizen, ME.	1993	Storage stability of Glyphosate and AMPA in soil and stream sediment Source: Monsanto Report no. MSL-12682	Germany 1995
IIA-7.2.1	Heintze, A.	1996	Degradation and Metabolism of glyphosate in two Water/Sediment Systems under Aerobic Conditions - Laboratory Test Source: Monsanto/Cheminova Study no. 96138/01-CUWS	Germany 1997
IIA-7.2.1	Knoch, E., Spirlet, M.	1999	Aminomethylphosphonic acid: water/ sediment metabolism Source: Monsanto/Cheminova Lab project no. IF-98/14727-00	Germany 1999

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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-7.2.1	Muttzall, PI.	1993	Water/sediment biodegradation of [14C]-glyphosate Source: Feinchemie, Agrichem, Luxan Report no. IMW-92-0022-	Germany 1995
IIA-7.2.1	Schneider, E.	1993	Glyphosate isopropylamine salt, hydrolysis in water at 3 different pH values. Source: Feinchemie Report no. PR93/009	Germany 1995
IIA-7.2.1.3.2	Steginsky, CA. Powell, JM.	1995	Determination of the degradability and persistence of 14C-Glyphosate in the water/sediment-system (Amendment) Source: Cheminova Report no. ET01SE01	FIN: 1.3.1995 Germany 1998
IIA-7.2.2	Schulz, J.	1995	Final report – About testing the volatilization behaviour of TAIFUN forte in bush beans under field conditions Source: Feinchemie Report no. AGR/RV-95/FSG	Germany 1996

B.9 Ecotoxicology

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-8.1.1	Campbell, S.M., Grimes, J., Lynn, St.P., Smith, G.J.	1991	AMPA: An acute oral toxicity study with the northern bobwhite. Source: Monsanto Report no. 139-277 ! WL 90-397	
IIA-8.1.2	Long, R.D., Beavers, J.B., Smith, G.J., Lynn, S.P.	1991	AMPA: A dietary LC50 study with the mallard. Source: Monsanto Report no. 139-276	
IIA-8.1.2	Long, R.D., Beavers, J.B., Smith, G.J., Lynn, S.P.	1991	AMPA: A dietary LC50 study with the northern bobwhite. Source: Monsanto Report no. 139-275 ! WL-90-398	
IIA-8.2.6	Thun, S.	1993	Algae growth inhibition test.Test article: "Glyphosate isopropylamine salt". Source: Feinchemie Report no. 80-91-2328-01-93	Germany 1993
IIA-8.3.1	Kock	1991	Testing on bee toxicity for the registration procedure, laboratory test: test substance: Taifun 360. Source: Feinchemie Report no.	Germany 1995
IIA-8.3.1	Schulz	1991	Testing on bee toxicity for the registration procedure, laboratory test, test substance: Taifun 360. Source: Feinchemie Report no.	UK: Submitted to PSD 14 May 1993 and recorded as having being used as part of a regulatory decision for a product approval dated 25 April 1995. Germany 1995
IIA-8.3.1	Warnke U.	1991	Testing on bee toxicity for the registration procedure, laboratory test: test substance: Taifun 360. Source: Feinchemie Report no.	UK: Submitted to PSD 14 May 1993 and recorded as having being used as part of a regulatory decision for a product approval dated 25 April 1995. Germany 1995

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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-8.4.1	Klenner, Bathelt, A.	1995	Acute toxicity of glyphosate to Eisenia fetida – laboratory test Source: Feinchemie Report no. RL502	Germany 1995
IIIA-10.6.1.1	Hänisch, D.	1991	Auswirkungen von FSG 03090 H (Taifun 360) auf Regenwürmer im Labor Source: Feinchemie Report no. WL 102	Germany 1991
IIA-8.6	Bohn, J.A.	1987	An evaluation of the pre-emergence herbicidal activity of CP 70139 (glyphosate) Source: Monsanto Report no. MSL-6574	Germany 1995
IIA-8.6	Chetram, R.S. Lucash, K.J..	1994	Tier2 Vegetative Vigor non-target phytotoxicity study using Glyphosate Source: Monsanto Report no. MSL-13320	Germany 1995
IIA-8.4.2	Hayward, J.C., Mallett, M.J.,	2000	A laboratory investigation of the effects of glyphosate and its breakdown product AMPA on reproduction in the earthworm, *Eisenia fetida.* Source: Monsanto/Cheminova Report no. CEMR-1173	Germany 2000
IIA-8.3.2 IIIA-10.5.1	Barton, R.	1999	A laboratory evaluation of the effects of MON 52276 on the green lacewing *Chrysoperla carnea.* Source: Monsanto Report no. MON-99-3	Germany 1999
IIA-8.3.2 IIIA-10.5.1	Kleiner, R.	1995	Roundup Ultra: testing toxicity to beneficial arthropods. Carabid beetles – *Poecilius cupreus*. Source: Monsanto Report no. 95 10 48 055	Germany ???
IIA-8.3.2 IIIA-10.5.1	Kleiner, R.	1995	Testing toxicity to beneficial arthropods Spider - *Pardosa* spp. Source Monsanto Report no. 95 10 48 053	Germany ???
IIA-8.3.2 IIIA-10.5.1	Kleiner, R.	1995	Testing toxicity to beneficial arthropods Cereal aphid parasitoid - *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) Imagines. Source: Monsanto Report no. 95 10 48 054	Germany ???
IIA-8.3.2 IIIA-10.5.1	Kleiner, R.	1995	Roundup Ultra: Testing toxicity to beneficial arthropods Predacious mite - *Typhlodromus pyr*i (SCHEUTEN). Source: Monsanto Report no. 95 10 48 056	Germany ???

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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-8.3.2 IIIA-10.5.1	Kleiner, R.	1998	MON 52276: Testing toxicity to beneficial arthropods Cereal aphid parasitoid - *Aphidius rhopalosiphi* (Destefani-Perez) (extended laboratory test Source: Monsanto Report no. XX-98-196 / 98 10 48 066	Germany 1999
IIA-8.3.2 IIIA-10.5.1	Kleiner, R.	1998	MON 52276: Testing toxicity to beneficial arthropods Predatory mite - *Typhlodromus pyri* (Scheuten) (extended laboratory test Source: Monsanto Report no. XX-98-195 / 98 10 48 065	Germany 1999
IIA-8.3.2 IIIA-10.5.1	Vinall, S.	1999	An extended laboratory test to determine the effects of MON 52276 on the predatory mite, *Typhlodromus pyri* (Phytoseiidae). Source: Monsanto Report no. MON-99-092	Germany 1999
AIIA-8.5 AIIIA-10.7.1	Andre, W.	1991	Auswirkung auf die Aktivität der Bodenmikroflora nach Richtlinie Teil VI 1-1 Report no: BMF9500060 not GLP unpublished	Germany 1991

APPENDIX III B

GLYPHOSATE TRIMESIUM

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[1].

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-2.3	Wollerton, C. and Husband, R.	1995	Glyphosate-trimesium: physico-chemical study on pure active ingredient. RJ1724B GLP or GEP : yes Unpublished	Austria 1998 Netherlands 1998 Germany 1994
IIA-2.9	Ericson, L.J.	1992	Glyphosate-Trimesium - Aqueous Photolysis RR 91-065B GLP or GEP : no Unpublished	Germany 1994
IIA-2.10	Hayes, S.E.	1995	Glyphosate-Trimesium - Calculation Of Half-Life By Reaction With Atmosheric Hydroxyl Radicals GLP or GEP : no Unpublished	Germany 1995 Austria 2000 Netherlands 1998
IIA-1.10; IIA-4.1	Farina, L.S.	1990	Analysis And Certification Of Product Ingredients In Icia0224, Non-Selective Herbicide (Wrc-90-410). GLP or GEP : no Unpublished	Netherlands 1998 Germany 1994
IIA-4.2.1	Alferness, P. L.	1993	Touchdown: Determination Of Glyphosate And Aminomethylphosphonic Acid In Corn Grain, Corn Forage, And Corn Fodder By Gas Chromatography And Mass-Selective Detection (Wrc-92-061) RR 92-042B GLP or GEP : yes Unpublished	Germany 1994
IIA-4.2.1	Alferness, P.L.	1996	Touchdown: Determination Of Glyphosate [N-(Phosphonomethyl)Gly- Cine] In Crops By Gas Chromatography And Mass-Selective Detection; Report No. RR 92-042B RES2 GLP or GEP : no Unpublished	Austria 1998 Netherlands 1998 Germany 1997
IIA-4.2.1	Hill, S. and Veal, P.	1996	Residues Analytical Method For The Analysis Of N-(Phosphonomethyl)Glycine (Pmg) In Crops; RAM 245/03 GLP or GEP : no Unpublished	Austria 1998 Netherlands 1998 Germany 1997

[1] List based on a detailed analysis from the rapporteur Member State.

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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-4.2.1	Iwata, Y.	1993	Touchdown: Determination Of Residue Of The Trimethylsulfonium Cation In Agricultural Crops By Gas Chromatography (Wrc-93-199) (WINO 12690) RR 93-105B GLP or GEP : yes Unpublished	Netherlands 1998 Germany 1994
IIA-4.2.1	Iwata, Y.	1996	Touchdown: Determination Of Residues Of The Trimethylsulfonium Cation In Agricultural Crops By Gas Chromatography; Report No. RR 93-105B RES2 GLP or GEP : no Unpublished	Austria 1998 Netherlands 1998 Germany 1997
IIA-4.2.1	McGinley, A.	1994	N-(Phosphonomethyl)Glycine (Pmg): Validation Of The Residue Analytical Method In Crops RJ 1599B GLP or GEP : yes Unpublished	Germany 1994
IIA-4.2.1	Tummon, O. J.	1994	Validation Of A Residue Analytical Method For The Determination Ofthe Trimethylsulphonium Cation (Tms+) Of Glyphosate-Trimesium In Crops Report RJ1601B GLP or GEP : yes Unpublished	Germany 1994
IIA-4.2.1; IIA-4.2.2	Veal, P.; Robinson, N.J. and Hargreaves, S.L.	1997	Glyphosate-trimesium: validation of an analytical method for the determination of the trimethylsulphonium cation (tms+) in apples, grapes, mushrooms, pea seed, soil and wheat grain using ion chromatography with mass spectrometry in the selected reaction monitoring mode RJ2236B GLP or GEP : no Unpublished	Austria 1998 Germany 1997
IIA-4.2.2	Alferness, P L.	1994	Touchdown: Determination Of Glyphosate And Aminomethylphosphonic Acid In Soil By Gas Chromatography And Mass-Selective Detection RR 92-010b GLP or GEP : yes Unpublished	Germany 1994
IIA-4.2.2; IIA-4.2.3	Iwata, Y.	1994	Touchdown: Determination of residues of the trimethylsulfonium cation in soil and water by gas chromatography (WRC-94-015) (WINO 10517) RR 94-010B GLP or GEP : yes Unpublished	Germany 1994
AIIA-4.2.2	Wood, B.	1998	ILV Determination of PMG and AMPA in soil by GC-MS RR 98-042B, GLP, unpublished	France 2000 Germany 1999
AIIA-4.2.2	James, J.W. Ervin, R.L.	1998	ILV Determination of TMS in soil and water by GC RR 98-043B, GLP, unpublished	Germany 1999 Germany 1999

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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-4.2.3	Davy, G. S.	1993	Glyphosate Trimesium: Development and validation of a method for the determination of N-phosphonomethyl glycine in water RJ1372B GLP or GEP : yes Unpublished	Germany 1994
IIA-4.2.3	Klumpp, M.	1995	Residue analysis of N-phosphonomethylglycine and aminomethylphos- phonic acid in water; Report no. 95059/95060/01-RW GLP or GEP : no Unpublished	Austria 1998 Netherlands 1998 Germany 1996
IIA-4.2.3	Klumpp, M.	1995	Residue analysis of trimethylsulfonium ion in water; Report no. 95061/01-RW GLP or GEP : no Unpublished	Austria 1998 Netherlands 1998 Germany 1996
IIA-4.2.3	Mich, G. and Seiler, H.	1995	Quantitative determination of trimethylsulfonium cation in water; Project no. EF 95-59-02 GLP or GEP : no Unpublished	Austria 1998 Germany 1996
IIA-4.2.3	Pelz, S.	1995	Determination of residues of trimethylsulfonium cation (TMS+) in tap water; Report no. ZEN-9506, AZ. 36535/95 GLP or GEP : no Unpublished	Netherlands 1998 Germany 1996
IIA-4.2.3	Roth, A.	1995	Quantitative determination of glyphosate and AMPA in water; EF 95-59-01 GLP or GEP : no Unpublished	Austria 1998 Germany 1996
IIA-4.2.3	Schulz, H.	1995	Determination of N-(phosphonomethyl)glycine (PMG) and aminomethyl-phosphonic acid (AMPA) in water - Validation of the DFG method - - Determination of PMG and AMPA in fortified water samples -; Study no. 95 JH 007 GLP or GEP : no Unpublished	Austria 1998 Germany 1996
IIA-4.2.3	Schulz, H.	1995	Determination of trimethylsulfonium cation (TMS+) in water - Validation of the method SOP RAM/229/02 by Zeneca Agrochemicals - Determination of trimethylsulfonium cation (TMS+) in fortified water samples -; Study no. 95 JH 007 GLP or GEP : no Unpublished	Austria 1998 Germany 1996
IIA-4.2.3	Tummon, O.J.	1993	Validation of an analytical residue method for the trimethylsulphonium cation (TMS+) in water RJ 1393B GLP or GEP : yes Unpublished	Germany 1993
AIIA-4.2.3	Crook, S.J.	1999	Analytical method for the determination of residues of PMG and AMPA in water TL 49290/01, not GLP, unpublished	France 2000 Germany 1999
AIIA-4.2.3	Bolygo, E.	1999	Analytical method for the determination of TMS in water TL 49291/01, not GLP, unpublished	Germany 1999

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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-4.2.3	Weber, H.	1995	Determination of residues of glyphosate (PMG) and AMPA in tap water; Study no. 95JH007 GLP or GEP : no Unpublished	Austria 1998 Netherlands 1998 Germany 1996
IIA-4.2.4	Tummon, O. J.; Freeman, B. L.	1994	Glyphosate Trimesium: Validation of a model to determine residues in air RJ 1665B GLP or GEP : yes Unpublished	Germany 1994
IIA-4.2.5	Iwata, Y.	1993	Touchdown: Determination of residues of the trimethylsulphonium cation in milk, eggs, and animal tissues by gas chromatography (WRC-93-184) (WINO 12732) RR 93-100B GLP or GEP : yes Unpublished	Germany 1994

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

B.6 Toxicology and metabolism

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
AIIA-5.2.2	Johnson, I.R.	2000	Glyphosate-trimesium: Acute dermal toxicity in rats CTL/CR3536 GLP, unpublished	Germany 2000
AIIA-5.2.6	Lees, D. and Leah, A.M.	1995	Glyphosate trimesium: Skin sensitisation to the guinea pig. REPORT NO.: CTL/P/4723 GLP, unpublished	Netherlands 1998 Germany 1998
AIIA-5.2.6	Robinson, P.	1994	Glyphosate trimesium: Skin sensitisation to the guinea pig. REPORT NO.: CTL/P/4339 GLP, unpublished	Germany 1998 FI: 21.12.1999
AIIA-5.3.2	Pinto, P.J.	1993	Glyphosate trimesium: 90 day oral toxicity study in dogs. REPORT NO.: CTL/P/3962 GLP, unpublished	
AIIA-5.4.1	Callander, R.D.	1990	ICIA0224 - An evaluation of mutagenic potential using S. typhimurium and E. coli. REPORT NO.: CTL/P/3129 GLP, unpublished	FI: 01.12.1993
AIIA-5.4.2	Kennelly, J.C.	1990	ICIA0224: Assessment for the induction of unscheduled DNA synthesis in rat hepatocytes in vivo. REPORT NO.: CTL/P/2789 GLP, unpublished	BE: 19.11.1991 FI: 02.12.1993
AIIA-5.7	Horner, S.A.	1993	Glyphosate trimesium: Acute neurotoxicity study in rats. CTL/P/3813 GLP, unpublished	Germany 1999
AIIIA-7.2	Anonym	1999	Operator exposure assessment according to german and UK POEM models. not GLP, unpublished	Germany 1999
AIIIA-7.2	Ward, R.J. and Scott, R.C.	1991	Fluazifop-p-butyl: In vitro absorption from a 125g/l EC formulation trough human epidermis. REPORT NO.: CTL/P/3494 GLP, unpublished	
AIIIA-7.3	Somers, K.A. and Speirs, G.C.	1995	The dermal absorption of [14C]-anion glyphosate trimesium in rats. CTL/C/2992 GLP, unpublished	Netherlands 1998

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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
AIIIA-7.3	Ward, R.J. and Thornton, H.Y.	1995	Glyphosate-trimesium: In vitro absorption from a 480 g/l SL formulation through rat skin. CTL/P/4574 GLP, unpublished	Germany 1995
AIIIA-7.3	Ward, R.	1994	ICIA0224: In vitro absorption from a 480g/l SL formulation through human epidermis. REPORT NO.: CTL/P/4345 GLP, unpublished	Netherlands 1998

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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[2] on previous use in granting national authorizations
IIA-6.1	Parker, S. and Harris, M.	1991	Glyphosate-trimesium: Uptake and metabolism in USA grape vines. RJ 1002B GLP, UNPUBLISHED	Germany 2000
IIA-6.1	Spillner, C.J.	1993	[^{14}C -Anion] Glyphosate-Trimesium: Confined Accumulation Studies On Rotational Crops. RR92-096B. GLP, UNPUBLISHED	Germany 2000
IIA-6.1	Subba-Rao, R.V. and Tamichi, E.H.	1994	[^{14}C-TMS] Glyphosate-Trimesium: Confined Accumulation Studies On Rotational Crops. RR93-045B GLP, UNPUBLISHED	
IIA-6.1	Tambling, D.R.	1992	[^{14}C -ANION] ICIA0224: NATURE OF THE RESIDUE: SOYBEANS. RR91-092B GLP, unpublished	Germany 2000
IIA-6.1	Wilkinson, M.J. and Joseph, R.S.I.	1990	Icia0224: uptake and metabolism in grape vines. RJ 0815B GLP, UNPUBLISHED	BE: 19.11.1991 Germany 2000
IIA-6.1	Tambling, D.R. Burnett, T.J.	1989	Metabolism of 14C anion ICIA0224 in corn and supplement RR 89-010B, GLP, unpublished	
IIA-6.1	Tambling, D.R. Burnett, T.J.	1989	Metabolism of 14C cation ICIA0224 in corn and supplement RR 89-011B, GLP, unpublished	
IIA-6.2; IIA-6.4	Bowler, D.T.	1994	[14c-Pmg] Glyphosate-Trimesium: Nature Of The Residue In Tissues And Eggs Of Laying Hens. RR93-064B GLP, UNPUBLISHED	Germany 2000
IIA-6.2; IIA-6.4	Corden, M.T. and Skidmore, M.W.	1994	Glyphosate-trimesium: metabolism in hens following dosing at 20 mg/kg in the diet. Rj 1606b GLP, UNPUBLISHED	
IIA-6.2; IIA-6.4	Ericson, J.L.	1994	The nature of residues of orally administered [phosphonomethylene-14c] glyphosate-trimesium in goat tissues and milk. RR93-062B GLP, UNPUBLISHED	Germany 2000
IIA-6.2; IIA-6.4	Hand, L.H. and Skidmore, M.W.	1994	Glyphosate-trimesium: metabolism in lactating goats following dosing at 25 mg/kg in the diet. RJ 1608B GLP, UNPUBLISHED	

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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-6.3	Anderson, L.	1996	Glyphosate-trimesium: residue levels in oil seed rape from a trial carried out in Denmark during 1995. RJ 2148B GLP, UNPUBLISHED	
IIA-6.3	Anderson, L., Ely, S.V., Alevra, E.	1997	Glyphosate-trimesium: residue levels in olives and processed fractions from trials carried out in Greece during 1996. RJ2397B GLP, UNPUBLISHED	Germany 2000
IIA-6.3	Anderson, L., Ely, S.V., Volpi, E.	1997	Glyphosate-trimesium: residue levels in olives and processed fractions from trials carried out in Italy during 1996. RJ2383B GLP, UNPUBLISHED	Germany 2000
IIA-6.3	Anderson, L., Leek, S.	1997	Glyphosate-trimesium: residue levels in spring oil seed rape from trials carried out in the united kingdom during 1996. RJ2316B GLP, UNPUBLISHED	
IIA-6.3	Anderson, L., Sanderson, D.J.	1997	Residue Levels in Woodland Mushrooms from Trials carried out in Germany during 1996. RJ 2347B GLP, unpublished	Germany 1997
IIA-6.3	Jones, R.N.	1996	Residue Levels in Field Peas from Trials carried out in Germany during 1995. RJ2207B GLP, unpublished	
IIA-6.3	Jones, R.N., Alevra, E.	1996	Glyphosate-trimesium: Residue Levels in Olives from Trials carried out in Greece during 1995. RJ2217B GLP, unpublished	
IIA-6.3	Jones, R.N., Ely, V., Sanderson, D.	1995	Residue Levels in Field Peas from Trials carried out in Denmark during 1994. RJ1968B GLP, unpublished	
IIA-6.3	Jones, R.N., Hall, G.	1997	Glyphosate-trimesium: Residue Levels in Winter Oilseed Rape from Trials carried out in the United Kingdom during 1995. RJ2171B GLP, unpublished	
IIA-6.3	Jones, R.N., Sanderson, D.	1995	Residue Levels in Field Peas from Trials carried out in Germany during 1994. RJ1969B GLP, unpublished	

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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-6.3	Jones, R.N., Volpi, E.	1996	Glyphosate-trimesium: Residue Levels in Olives from Trials carried out in Italy during 1995. RJ2218B GLP, unpublished	
IIIA-8.2	Ely, S.V. and Runnalls, J.K.	1993	Glyphosate-trimesium: Residue levels in oranges from a field trial carried out in Greece during 1991. RJ 1376B GLP, unpublished	
IIIA-8.2	Hill, S.E.	1993	Glyphosate-trimesium: Residue levels in cereals (barley, wheat, rye and oats) from a field study carried out in Germany during 1991. RJ 1396B GLP, unpublished	Germany 1993
IIIA-8.2	Hill, S.E. and Runnalls, J.K.	1992	Glyphosate-trimesium: Residue levels in winter wheat from a trial carried out in Denmark during 1989. RJ 1180B GLP, unpublished	Germany 1992
IIIA-8.2	Hill, S.E. and Runnalls, J.K.	1992	Glyphosate-trimesium: Residue levels in spring barley from trials carried out in Denmark during 1989. RJ 1181B GLP, unpublished	Germany 1992
IIIA-8.2	Hill, S.E. and Runnalls, J.K.	1993	Glyphosate-trimesium: Residue levels in winter wheat from trials carried out in France during 1991. RJ 1463B GLP, unpublished	
IIIA-8.2	Iwata, Y.	1992	Touchdown: Magnitude-of-the-residue study on grapes. RR 92-015B GLP, unpublished	
IIIA-8.2	Jones, R.N. and Freeman, B.L.	1995	GLYPHOSATE-TRIMESIUM: Residue levels in pome fruit from trials carried out in Germany during 1994. RJ 1831B GLP, unpublished	Netherlands 1998 Germany 1995
IIIA-8.2	Jones, R.N., Cross, R.C. and Sanderson, D.J.	1994	Glyphosate-trimesium: Residue levels in winter wheat straw from trials carried out in France during 1992. RJ 1622B GLP, unpublished	

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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
IIIA-8.2	Jones, R.N., Ely, V.	1996	GLYPHOSATE-TRIMESIUM: Residue Levels in Woodland Mushrooms from trials carried out in Germany during 1995. RJ 2157B GLP, unpublished	Germany 1996
IIIA-8.2	Jones, R.N., Ely, V. and Sanderson, D.	1994	Glyphosate-trimesium: Residue levels in grapes from trials carried out in Germany during 1993. RJ 1707B GLP, unpublished	Germany 1994
IIIA-8.2	Jones, R.N., Ely, V., Sanderson, D, and Hill, S.	1995	GLYPHOSATE-TRIMESIUM: Residue levels in grapes from trials carried out in Germany during 1994. RJ 1853B GLP, unpublished	Germany 1995
IIIA-8.2	Lant, M.S. and McGinley, A.	1994	Glyphosate-trimesium: Residue levels in pome fruit from trials carried out in Germany during 1993. RJ 1712B GLP, unpublished	Germany 1994
IIIA-8.2	Lant, M.S. and Tummon, O.J.	1993	Glyphosate-trimesium: Residue levels in winter barley from a field trial carried out in the UK during 1990. RJ 1437B GLP, unpublished	
IIIA-8.2	Lant, M.S. and Tummon, O.J.	1993	Glyphosate-trimesium: Residue levels in following crops from a field study carried out in Germany during 1991/2. RJ 1450B GLP, unpublished	Germany 1993
IIIA-8.2	Lant, M.S. and Tummon, O.J.	1993	Glyphosate-trimesium: Residue levels in winter wheat from trials carried out in the UK during 1990. RJ 1438B GLP, unpublished	
IIIA-8.2	McGinley, A. and Runnalls, J.K.	1992	Glyphosate-trimesium: Residue levels in winter cereals (wheat and barley) from trials carried out in Germany during 1990. RJ 1287B GLP, unpublished	Germany 1993
IIIA-8.2	McKay, J.C.	1990	ICIA-0224: Magnitude-of-the-residue study on grapes. RR 90-411B GLP, unpublished	

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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
IIIA-8.2	Runnalls, J.K.	1993	Glyphosate-trimesium: Residue levels in grapes from a field trial carried out in Greece during 1991. RJ 1375B GLP, unpublished	
IIIA-8.2	Runnalls, J.K. and Hill, S.E.	1993	Glyphosate-trimesium: Residue levels in spring crops (maize, peas, sugarbeet and sunflowers) from trials carried out in Germany during 1990. RJ 1369B GLP, unpublished	Germany 1993
IIIA-8.2	Runnalls, J.K. and McGinley, A.	1993	Glyphosate-trimesium: Residue levels in spring barley from a field study carried out in Sweden during 1991. RJ 1314B GLP, unpublished	Germany 1993
IIIA-8.2	Sadler, J.K.	1991	Glyphosate-trimesium: Residue levels in spring barley from field trials carried out in Denmark during 1988. RJ 1013B GLP, unpublished	Germany 1992
IIIA-8.2	Sadler, J.K.	1991	Glyphosate-trimesium: Residue levels in winter wheat from trials carried out in Denmark during 1988. RJ 1012B GLP, unpublished	BE: 21.09.1992 Germany 1992
IIIA-8.2	Sadler, J.K.	1991	Glyphosate-trimesium: Residue levels in spring barley from trials carried out in Sweden during 1988. RJ 1001B GLP, unpublished	Germany 1992
IIIA-8.2	Sadler, J.K.	1991	Glyphosate-trimesium: Residue levels in peas from trials carried out in Denmark during 1988. RJ 1007B GLP, unpublished	
IIIA-8.2	Sanderson, D.J. and Austin, D.J.	1991	Phosphonomethylglycine: Residues in olive from ICIA0224 trials carried out in Italy during 1988. M 5354B GLP, unpublished	
IIIA-8.2	Sanderson, D.J. and Austin, D.J.	1991	Trimethylsulphonium Cation: Residues in olive from ICIA0224 trials carried out in Italy during 1989. M 5120B GLP, unpublished	

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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
IIIA-8.2	Tummon, O.J. and Lant, M.S.	1993	Glyphosate-trimesium: Residue levels in olive from a field trial carried out in Greece during 1991. RJ 1414B GLP, unpublished	
IIIA-8.2	Wiebe, L.A.	1993	Touchdown: Magnitude-of-the-residue study for residues of glyphosate-trimesium on almonds, pecans and walnuts from trials conducted in the USA during 1990. RR 93-058B GLP, unpublished	
IIIA-8.4	Hill, S.E. and Lant, M.S.	1994	Glyphosate-trimesium: Residue levels in winter wheat processed fractions from a trials carried out in France during 1991. RJ 1572B GLP, unpublished	Germany 2000
IIIA-8.4	Hill, S.E. and Lant, M.S.	1993	Glyphosate-trimesium: Residue levels in winter wheat and common oat processed fractions from trials carried out in Germany during 1992. RJ 1492B GLP, unpublished	Germany 1993
IIIA-8.4	Lant, M.S. and Hill, S.E.	1995	Glyphosate-Trimesium: Storage Stability of Residue of N-(phosphonomethyl)glycine (PMG) and Trimethylsulphonium Cation (TMS) (both derived from Glyphosate-trimesium) in Processed Fractions of Winter Wheat and Common Oats. RJ2030B GLP, unpublished	

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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[2] on previous use in granting national authorizations
IIA-7.1.1.2.1	Runnalls, J.K.,	1991	Glyphosate-Trimesium: Laboratory degradation in four soils. RJ1064B GLP, Unpublished	Germany 1994
IIA-7.1.1.2.2	Hill, S.E.	1992	Glyphosate-Trimesium: Soil dissipation study (Germany 1990-1992). RJ1294B GLP, Unpublished	Netherlands 1998 Germany 1994
IIA-7.1.2	Subba-Rao, R.V.	1992	[14C-TMS] Glyphosate-Trimesium: Adsorption/desorption in four soils. RR92-017B Not GLP, Unpublished	Germany 1994
IIA-7.1.2	Subba-Rao, R.V. and McGowan, N.G.	1992	[14C-PMG] Glyphosate-Trimesium: Adsorption/desorption in four soils. RR 92-016B Not GLP, Unpublished	Germany 1994
IIA-7.1.3.1	McGinley, A.M.	1992	Glyphosate-Trimesium: Leaching of material in soil columns. RJ1247B GLP, Unpublished	Germany 1994
AIIA-7.2.1.3.2	Bowler, D.T. Johnson, J.A.	1999	Glyphosate-trimesium: Degradation of 14C PMG labelled compound in natural water sediment systems under laboratory conditions. RR 99-039B, GLP, Unpublished	Germany 1999 France 2000
AIIA-7.2.1.3.2	Shi, C-T. Ericson, J.L.	1999	Glyphosate-trimesium: Degradation of 14C TMS labelled compound in natural water sediment systems under laboratory conditions. RR 99-040B, GLP, Unpublished	Germany 1999
IIA-7.2.2	Hand, L.H.	1992	Glyphosate-trimesium: Volatilization from soil and leaf surfaces. RJ 1237B GLP, Unpublished	Germany 1998 Netherlands 1998

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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[2] on previous use in granting national authorizations
IIA-8.1.3	Marselas, G., Beavers, J.B. and Jaber, M.J.	1990	ICIA0224: A one-generation reproduction study with the mallard (Anas platyrhynchos). 123-151 GLP, unpublished	Germany 1992
IIA-8.1.3	Marselas, G., Beavers, J.B. and Jaber, M.J.	1990	ICIA0224: A one-generation reproduction study with the bobwhite quail (Colinus virginianus). 123-150 GLP, unpublished	Germany 1992
IIA-8.2.2	Tapp, J.F., Sankey, S.A., Caunter, J.E., Grinell, A.J. and Adams, D.S.	1991	GLYPHOSATE TRIMESIUM: The 21 day LC50 to rainbow trout (Oncorhynchus mykiss). BL4178/B GLP, unpublished	Germany 1992
IIA-8.2.4	Anonym	1993	AMPA: Acute toxicity to Daphnia magna. BL5061/B GLP, unpublished	Germany 1993
AIIA-8.2.6	Smyth, D.V., Kent, S.J. and Shillabeer, N.	1997	Glyphosate-Trimesium: Toxicity to blue-green alga Anabaena flos-aquae . BL5962/B GLP, unpublished	Germany 1998 Austria 1998 Netherlands 1998
IIA-8.2.8	Smyth, D.V., Kent, S.J. and Shillabeer, N.	1997	Glyphosate-Trimesium: Toxicity to duckweed (Lemna gibba). BL5965/B not GLP, unpublished	Germany 1998 Austria 1998 Netherlands 1998
IIA-8.3.2 IIIA-10.5	Canning, L., Lloyd, E.J. and Lewis, G.B.	1992	GLYPHOSAT-TRIMESIUM - Investigation of the Toxicity of a 400 g/l SL Formulation to the Carabid Beetle Pterostichus melanarius and a Lycosid Spider. RJ 1066B GLP, unpublished	Netherlands 1998 Germany 1994
IIA-8.3.2	Turner, C. R.	1995	The effects of Glyphosat-Trimesium on the predatory mite Typhlodromus pyri. REPORT NO: 95.02 GLP, unpublished	Austria 1998 Netherlands 1998 Germany 1995
IIA-8.3.2 IIIA-10.5.1	Austin, H.M.	1995	The effect of glyphosate-trimesium on the heteropteran bug Orius laevigatus ER 95-13 GLP, unpublished	Austria 1998 Netherlands 1998 Germany ???
IIA-8.3.2 IIIA-10.5.1	Kleiner, R.	1995	Testing toxicity to beneficial arthropods Tachid - Drino inconspicua 95-10-48-001, GLP, unpublished.	Austria 1998 Netherlands 1998 Germany 1996

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.

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-8.3.2 IIIA-10.5.1	Coulson, M.J. Fleming, T.M. Yearsdon, H.A. Farrelly, L.C.	1995	Glyphosate-trimesium: Investigation into the toxicity of a 480 g/l soluble concentrate formulation on the cereal aphid parasitoid Aphidius rhopalosiphi RJ1962B, GLP, unpublished.	Austria 1998 Netherlands 1998 Germany ???
IIA-8.3.2 IIIA-10.5.1	Mead-Briggs, M.	1999	A laboratory test to determine the effects of glyphosate-trimesium 480 g/l SL on the parasitoid Aphidius rhopalosiphi, ZEN-98-2, GLP, unpublished	Netherlands 1998 Germany 1999 France 2000
IIA-8.3.2 IIIA-10.5.1	Gough, H.J. Hargreave, N.J. Travis, A. Yearsdon, H.M.	1999	Glyphosate-trimesium: An extended laboratory study to determine the ffects of an SL formulation of the cereal aphid parasitoid Aphidius rhopalosiphi RJ2852B, GLP, unpublished	Netherlands 1999 Germany 1999 France 2000 Austria 2000
IIA-8.3.2 IIIA-10.5.1	Bakker, F.M.	1999	A laboratory dose response study to evaluate the effects of glyphosate-trimesium on the predaceous mite Typhlodromus pyri. Z003TPL-CV, GLP, unpublished	Netherlands 1999 Germany 199 France 2000
IIA-8.3.2 IIIA-10.5.1	Aldershof, S.A.	1999	An extended laboratory dose response study to evaluate the effects of glyphosate-trimesium on the predaceous mite Typhlodromus pyri Z006TPE-CV, GLP, unpublished	Netherlands 1999 Germany 1999 France 2000 Austria 2000
AIIA-8.4.2	Hayward, J.C. Mallett, M.J.	2000	A laboratory investigation of the effects of glyphosate and its breakdown product AMPA on reproduction in the earthworm, Eisenia fetida CEMR-1173, GLP, unpublished	Germany 2000 Austria 2000
IIIA-10.2.1	Smyth, D.V. Tapp, J.F. Sankey, S. Grinnell,A.J.	1991	Glyphhosate-trimesium: Toxicity to the green alga Selenastrum capricornutum of a 480 g/l SL formulation FT38/91, GLP, unpublished	Germany 1994
IIIA-10.6.1	Yearsdon, H. Smith, D.L. Jackson, D. Wilson, A. Coulson,M.J.	1991	Glyphosate-trimesium: Toxicity to the earthworm Eisenia fetida of a 480 g/l SL formulation RJ1061B GLP, unpublished	Germany 1992

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive); Dates referring to Germany indicate the submission for the national authorization.