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

Prosulfuron

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Review report for the active substance **prosulfuron**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 26 February 2002 in view of the inclusion of prosulfuron in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance prosulfuron, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, French authorities received on 14 May 1995 an application from Novartis Agro S.A. (now Syngenta), hereafter referred to as the applicant, for the inclusion of the active substance prosulfuron in Annex I to the Directive. French authorities indicated to the Commission on 30 May 1996 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on prosulfuron was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on Plant Health in the meeting of the working group ‘legislation’ thereof on 14 June 1996, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with

the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 97/137/EC[1] of 3 February 1997 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that France would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

France submitted to the Commission on 18 January 1999 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of prosulfuron in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States on 16 June 1999 as well as to Novartis Agro S.A. (now Syngenta) being the sole applicant on 22 June 1999.

The Commission organised further an intensive consultation of specialised scientific experts from a representative number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines :

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from November 1999 to July 2000.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States on 30 November 2000**.**

The dossier, draft assessment report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from December 2001 to February 2002, and was finalised in the meeting of the Standing Committee on the Food Chain and Animal Health on 26 February 2002.

The present review report contains the conclusions of this final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final

[1] OJ No L52, 22.02.1997, p.20.

examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The Committee was asked to comment on the acceptability of the risk of two breakdown products of the active substance to sediment dwelling organisms and on possible hormonal disruption effects observed in test animals. The report of this Committee was formally adopted on 21 June 2001 (SCP/PROSULF/002-Final[2]). Committee concluded that certain uterine and mammary changes, which were observed in rats after lifetime exposure are not considered relevant for human risk assessment of prosulfuron in the context of its intended uses. The Committee further commented that risks of the two breakdown products to sediment-dwelling species were not yet adequately assessed and noted that other persistent metabolites are formed in significant quantities in sediment-water tests, which also did not appear to have been assessed. The pending information and assessments were subsequently provided and the observations of the Scientific Committee were taken into consideration in formulating this Directive and the relevant review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2002/48/EC[3] concerning the inclusion of prosulfuron in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing prosulfuron they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the applicant.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated possession of regulatory access to the information on which this review report is based.

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[2] Opinion of the scientific Committee on Plants regarding the inclusion of prosulfuron (CGA 152005) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

[3] OJ L148, 06.06.2002, p.19

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 prosulfuron 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 prosulfuron containing plant protection product for which Member States will grant or review the authorisation.

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

- herbicide on maize, sorghum and sweet corn

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

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of prosulfuron in foodstuffs

The review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI) for a 60 kg adult is < 2 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require, however, confirmation for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

4.3 Environment

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 7 of this report.

5. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of prosulfuron are given in Appendix I.

The active substance shall have a minimum purity of 950 g/kg technical product.

The review has established that for the active substance notified by the applicant (Novartis Agro S.A., now Syngenta), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints as identified during the evaluation process are listed in Appendix II.

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

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Aquatic organisms: Member states must carefully consider the risk to aquatic plants if the active substance is applied adjacent to surface waters. The exposure input from drain flow with respect to local conditions should also be considered. Risk mitigation measures (e.g. buffer zones) should be applied where appropriate.

- Leaching to groundwater: Particular attention should be given to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.

8. List of studies to be generated

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of prosulfuron in Annex I. However, some endpoints may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may be the case, in particular, to demonstrate the safety of groundwater resources and aquatic ecosystems.

9. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the applicant has claimed data protection and which are not present in the original dossier neither mentioned in the draft assessment report. 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.

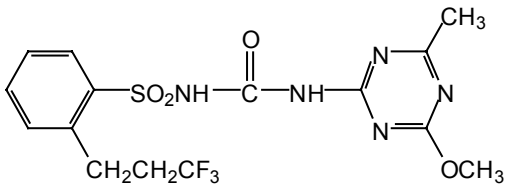
10. Updating of this review report

The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for prosulfuron in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

PROSULFURON

Common name (ISO)	Prosulfuron
Chemical name (IUPAC)	1-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea
Chemical name (CA)	N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-amino]-carbonyl]2-(3, 3,3-trifluoropropyl)-benzene-sulfonamide
CIPAC No	579
CAS No	94125-34-5
EEC No	Not available.
FAO SPECIFICATION	Not available.
Minimum purity	950 g/kg
Molecular formula	$C_{15}H_{16}F_3N_5O_4S$
Molecular mass	419.4
Structural formula	

Melting point	155°C
Boiling point	Not required.
Appearance	odourless white powder
Relative density	1.45 g/cm ^{3} at 22°C
Vapour pressure	< $3.5x10^{-6}$ Pa at 25°C
Henry's law constant	< $3x10^{-4}$ Pa m^3/mol
Solubility in water	pH4.5 : 29 mg/l at 25°C
	pH5 : 87 mg/l at 25°C
	pH 6.8 : 4000 mg/l at 25°C – pH 7.7 = 43000
	pH10 : instability of the solution
Solubility in organic solvents	In g/l at 20°C Acetone : 160 (purity : 95.1 %) Toluene : 6.1 Dichloromethane : 180 Ethyl acetate : 56 n-Hexane : 0.006 Ethanol : 8.4 n-octanol :1.4
Partition co-efficient (log P_{ow})	pH5 : 1.5 at 25°C
Hydrolytic stability (DT_{50})	pH5 : DT_{50}= 9.3 days at 25°C pH7 : DT_{50}= > 1 year pH9 : DT_{50}= > 1 year
Dissociation constant	pKa = 3.76
Quantum yield of direct photo-transformation in water at ε >290 nm	not investigated as ε <10 at λ>290 nm
Flammability	Not flammable. (not highly inflammable)
Explosive properties	Not explosive.
UV/VIS absorption (max.)	ε = 21645 lxmol^{-1}xcm^{-1} at λmax = 227.5 nm shoulder at 250 nm No absorption >290 nm
Photostability in water (DT_{50})	not investigated as ε <10 lxmol^{-1}xcm^{-1} at λ>290 nm

APPENDIX II

END POINTS AND RELATED INFORMATION

PROSULFURON

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid and complete (> 90%) based on urinary excretion after oral and intravenous administration
Distribution:	Widely distributed
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	About 90% within 48 h, mainly via urine (69-83%)
Toxicologically significant compounds:	In rats : moderately to extensively metabolized, unchanged parent compound (up to 30% excreted as parent) Predominant metabolic reactions : hydroxylation at the side chains and the phenyl ring, O-demethylation of the triazine methoxy group, and generation of a double bond on the trifluoropropyl group
Metabolism in animals:	Parent compound and metabolites are qualitatively comparable in animals and plants. No evidence of toxicological relevance is supposed for animals, plants and environment

Acute toxicity

Rat LD_{50} oral:	986 mg/kg
Rat LD_{50} dermal:	> 2000 mg/kg
Rat LC_{50} inhalation:	> 5.4 mg/l, nose only
Skin irritation:	Non irritant
Eye irritation:	Non irritant
Skin sensitization (test method used and result):	Non sensitizing (1 Buehler test and 1 Magnusson & Kligman test)

Short term toxicity

Target / critical effect:	Liver (hepatocyte hypertrophy), heart (myocardial degeneration), hematopoietic system (red blood cells decreased)
Lowest relevant oral NOAEL / NOEL:	NOAEL = 6 mg/kg b.w./day (90-day, dog)

Lowest relevant dermal NOAEL / NOEL:	No valid study submitted, no further testing required
Lowest relevant inhalation NOAEL / NOEL:	No data required

Genotoxicity

No genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	Liver (hepatocellular hypertrophy in mice), indication of hormonal disruption (uterus and mammalian gland in rats) at high dose levels
Lowest relevant NOAEL:	NOAEL = 1,7 mg/kg bw/day (18-month, mouse)
Carcinogenicity:	No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:	Reduced pup weight at parental toxic doses
Lowest relevant reproductive NOAEL / NOEL:	NOAEL = 12 mg/kg bw/day (rat)
Target / critical effect - Developmental toxicity:	Skeletal variations (rat) and resorptions (rabbit) at maternal toxic doses
Lowest relevant developmental NOAEL / NOEL:	NOAEL = 10 mg/kg b.w./day (rabbit)

Delayed neurotoxicity

No specific neurotoxic effects in acute and 90-day rat studies

Other toxicological studies

No data, not required

Medical data

Limited, new compound

Summary

	Value	Study	Safety factor
ADI:	0.02 mg/kg/d	Dog, 1-year and mouse, 18-month	100
AOEL systemic:	0.06 mg/kg/d	Dog, 90-day	100
AOEL inhalation:	Not allocated		
AOEL dermal:	Not allocated		

ARfD (acute reference dose): (if ArfD is required, please provide also information on dietary intake for children, e.g. NESTI)	not allocated (not necessary taking into account toxicological profile of the active substance)

Dermal absorption

No data, 30% proposed for exposure estimation

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	< 5 % (phenyl and triazine label, degradation route) up to 19 % (phenyl) and 45 % (triazine) after 180 d at 20° C (leaching of aged residues)
Non-extractable residues after 100 days:	12-44 % from phenyl moiety (90 d) 10 % from triazine moiety (90 d)
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	CGA 159902 (phenyl sulfonamide) : max. 47 % (12 mo) CGA 150829 (triazine amine) : max. 31 % (12 mo) CGA 300406 (O-desmethyl) : max. 24 % (30 d) CGA 349707 (M4) : max. 22.6 % (12 mo) M5 : max. 16.4 % (87 d) CGA 325025 (amine) : max. 17.4 % (12 mo)

Supplemental studies

Anaerobic:	Similar degradation than under aerobic at least in poorly active soils
Soil photolysis:	Not significant (no difference between dark and light)
Remarks:	None

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):

DT_{50lab} (20°C, aerobic):

Soil type	OC	pH	Temp.	DT_{50} (d)
Sandy loam I	1.17	6.6	25°C	70/152*
Sandy loam II	1.49	6.1		112/138*
Sand	1.98	6.6	20°C	177
Sandy loam III	1.26	7.0		198
Loamy sand	1.9	7.2		138
Silt loam I	2.3	7.3		74
Silt loam II	2.7	7.0		25/77**

* 2 labels
** initial concentration 0.1/1 ppm

Metabolites : no data requested as no accumulation or no persistence was observed in the lysimeter studies.

DT_{90}lab (20 °C, aerobic):

DT_{90lab} (20°C, aerobic):
250 - 700 d (same soils)
107 d (silt loam II, 0.1 ppm)

DT_{50}lab (10 °C, aerobic):

104 d (silt loam II, 9°C)

DT_{50}lab (20 °C, anaerobic):

DT_{50lab} (20°C, anaerobic):
89 - 138 d (2 soils, 2 labels)

degradation in the saturated zone: no data.

Field studies (country or region)

DT_{50f} from soil dissipation studies:	DT_{50f}: Spring application (20 - 500 g as/ha) to maize. LOD 0.1 µg/kg. Austria < 30 d (1 site) Switzerland 4 - < 30 d (3 sites) France 4 - 14 d (2 sites) Italy 5 d (1 site) Germany 5 - 36 d (4 sites) No pH dependence (interval 5.8 - 7.9) USA : Georgia (sand pH 7.3), Iowa (sandy loam pH 5.4), 40 g as/ha, crop/bare soil, spring, LOD 0.5 µg/kg) prosulfuron 9 - 19 d CGA 300406 max. 1.1 µg/kg, not detected 45 d CGA 159902 max. 1.1 µg/kg, < 1 µg/kg 90 d CGA 150829 max. 1.8 µg/kg 90 d < 0.5-1.3 µg/kg 365 d <u>New studies</u> Germany : DT_{50f} 10 - 24 d (mean 14 d, 4 sites) Canada : DT_{50f} 13 - 31 d (3 sites), CGA 300406 > 10 %, CGA 150829 and CGA 159902 < 10 % USA : DT_{50f} 20 d (1 site), CGA 300406, CGA 159902 and CGA 150829 < 10 %
DT_{90f} from soil dissipation studies:	DT_{90f}: Same conditions Austria < 100 d (1 site) Switzerland 30 - < 150 d (3 sites) France 35 - 63 d (2 sites) Italy 54 d (1 site) Germany 60 - 222 d (4 sites) USA 29 - 64 d
Soil accumulation studies:	Residue studies, 2 swiss sites no phytotoxicity (Lepidium sativum, Beta vulgaris) 4 months after treatment at < 20 g as/ha, LOD 0.1 - 0.4 g as/ha Residue studies, 1 US site, 40 g as/ha Prosulfuron < 1 µg/kg 100 DAT CGA 159902 and 150829 : 7 - 9 µg/kg 100 DAT Accumulation studies, 1 french and 2 swiss sites, 3 x 40 g as/ha, LOD 0.1 µg/kg prosulfuron not detected one year after each

	treatment except for 1 swiss site 1.6 (year 1), 1.8 (year 2), 0.5 (year 3) µg/kg.
Soil residue studies:	see above
Remarks: e.g. effect of soil pH on degradation rate	None

Adsorption/desorption

K_f / K_{oc}:

K_d

pH dependence:

Prosulfuron

Soil type	OC	pH	Kf	Koc
Loamy sand	0.8	7.0	0.03	4
Sand	0.4	6.6	0.09	26
Silt loam	2.1	7.3	0.24	12
Silt loam	4.4	7.1	0.36	8
Humic soil	19.3	6.6	1.45	7
Loamy sand	0.4	7.7	0.07	18
Sandy loam	1.8	7.8	0.27	15
Silt loam	1.6	6.5	0.29	19
Silty clay loam	0.6	6.9	0.25	41

pH dependence not expected due to low pKa (3.76)

CGA 300406 (O-desmethyl)

Soil type	OC	pH	Kf	Koc
Loamy sand	0.4	6.5	0.53	126
Sandy loam	1.0	6.8	0.49	49
Loam	1.1	6.7	0.47	43
Silty clay loam	2.6	6.4	1.28	49

CGA 159902 (phenyl sulfonamide)

Soil type	OC	pH	Kf	Koc
Loamy sand	0.4	7.7	0.4	95
Sandy loam	1.8	7.8	1.24	69
Silt loam	1.6	6.5	0.77	48
Silty clay loam	0.6	6.9	0.59	96

CGA 325025 (amine)

Soil type	OC	pH	Kf	Koc
Sand	0.4	6.5	1.00	238
Sandy loam	1.0	6.8	1.02	102
Loam	1.1	6.7	1.02	92
Clay	1.7	6.8	1.01	60

New studies

CGA 349707 (M4) Koc 37 - 52 (mean 45), 3 soils (OC 2.0 - 4.7 %, pH 7.2 - 7.6)

CGA 150829 (triazine amine) Koc 55 - 281 (mean 144), 4 soils (OC 0.35 - 1.74 %, pH 6.5 - 7.9)

CGA 32508 Koc 11 - 31 (mean 20), 5 soils (OC 0.29-1.57%, pH 6.2-7.4)

CGA 325030 Koc 18 - 41 (mean 21), 4 soils (OC 0.29-1.57%,pH 6.2-6.8)

Mobility

Laboratory studies:

Column leaching:

4 soils (OC 0.4 - 2.6 %, pH 6.4 - 6.7), triazine label, 508 mm. RA in leachates : 54 - 95 % (prosulfuron)

4 soils (OC 0.4 - 4.4 %, pH 5.7 - 7.1), phenyl label, 200 mm. RA in leachates : 1 - 94 % depending on OC content (prosulfuron)

Aged residue leaching:

4 soils (OC 0.4 - 2.6 %, pH 6.4 - 7.0), 2 labels, 30 d incubation at 25°C, 508 mm
Residue prosulfuron 70 - 84 %
metabolites < 12 % (CGA 300406)
RA in leachates : 33 - 59 %
mainly prosulfuron, metabolites < 4 % each

2 soils (OC 1.7 - 2.1 %, pH 7.2 - 7.3), 2 labels, 180 d incubation at 20°C, 200 mm
Residue : prosulfuron 18 - 31 %, metabolites < 10 % each (CGA 159902, 150829, 300406, 349707, M5), CO_2 10 - 45 %
RA in leachates : 0.8 - 12 % of applied to columns (prosulfuron)

Field studies:

Lysimeter/Field leaching studies:

USA, undisturbed 20 cm diameter soil columns, silt loam (1.94 % OC, pH 5.6) in Kentucky and sand soil (0.3 % OC, pH 4.9) in North Carolina, 2 labels, 44 g as/ha. Overflow occurred in Kentucky.

Total residues in drainage water (LOD 0.4 µg/l)
soil depth 0.90 m
silt loam < 0.4 %, mean conc. 0.13 µg/l (phenyl)
< 0.1 % (triazine)
sand mean 0.98 µg/l max. 3 µg/l (phenyl)
mean 0.08 µg/l max. 1 µg/l (triazine)

Compounds in drainage water from sand soil, NC
prosulfuron traces in initial preferential flow
soil depth 0.90 m
CGA 159902 max. 2.4 µg/l
M5 max. 1 µg/l
CGA 325028 max. 0.74 µg/l

CGA 300406 max. 0.08 µg/l

No realistic mean concentrations can be calculated for individual compounds. Triazine moiety less mobile than phenyl moiety. No CGA 150829 in soil after 1 year.

Swiss lysimeter, sandy soil (1.05 % OC, pH 6.1), phenyl label, 28 or 2 x 28 g as/ha (Spring)

Total residues (LOD 0.05 µg/l)
mean concentrations, soil depth 1.2 m
1 appl. 0.23 / 0.12 / 0.07 µg/l (year 1 / 2 / 3)
2 appl. 0.24 / 0.31 / 0.22 µg/l (year 1 / 2 / 3)
max. concentrations 0.46 / 0.42 µg/l (1 / 2 appl.)

Prosulfuron, CGA 159902, CGA 300406, CGA 349707, M5, CGA 325025 and unknowns < 0.1 µg/l each. Total extractable RA in soil < 2.5 µg/kg after 3 years.

Remarks:

No accumulation of the soil metabolites in the Swiss lysimeter study

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 5 (25°C) DT_{50} 5 - 12 d CGA 159902 (phenyl sulfonamide) 58 % CGA 150829 (triazine amine) 43 % CGA 325030 (polyimide) 22-31 % G28533 16 %
	pH 7 (25°C) DT_{50} 424 - 651 d
	pH 9 (25°C) DT_{50} 682 - 1690 d
Major metabolites:	see above (no major metabolite at pH 7 and 9)
Photolytic degradation:	Not significant. DT_{50} 178 - 337 d (darkness, pH 9, 25°C) DT_{50} 257 - 198 d (sunlight)
Major metabolites:	None

Biological degradation

Readily biodegradable:	Not readily biodegradable
Water/sediment study:	
DT_{50} water:	45 - 55 d 33 - 35 d (triazine)
DT_{90} water:	not calculated 627 - 721 d (triazine)
DT_{50} whole system:	120 - 140 d 174 - 191 d (triazine)
DT_{90} whole system:	not calculated 904 - > 1000 (triazine)
	DT_{50} (aerobic, 9° C) : 85 d (water), 430 d (total) DT_{50} (anaerobic, 25° C) : 16 d (water and total) DT_{50} (anaerobic, 20° C) : 50 d (water), 105 d (total) DT_{50} (anaerobic, 9° C) : 195 d (water), 390 d (total)
Mineralization:	0.9 - 1.4 % (phenyl), 0 - 1.1 % (triazine) after 90 d
Non-extractable residues:	4.0 - 8.7 % (phenyl), 5.5 - 38.0 % (triazine) after 90 d
Distribution in water / sediment systems (active substance)	Phenyl: not reported Triazine 25.1 % prosulfuron in sediment after 90d

	anaerobic, 25ºC < 10 % in sediment anaerobic, 20ºC not reported
Distribution in water / sediment systems (metabolites)	phenyl : not reported; metabolites in whole systems CGA 159902 max. 21.6 % (365 d) CGA 300406 max. 34.3 % (181 d) CGA 349707 + M5 max. 43.5 % (365 d) 9° C : same metabolites, lower amounts triazine : CGA 300406 max. 17.7 % in water and 12.7 % in sediment after 365 d, M5 max. 9.3% in water (362d) anaerobic, 25° C, 2 labels CGA 159902 max. 55 % water, < 7 % sediment CGA 150829 max. 36 % water (4 mo), < 10 % sediment CGA 300406 max. 13 % water (14 d), < 2 % sediment CGA 325028 max. 22 % water, < 5 % sediment CGA 325030 max. 12 % water (1 mo), < 2 % sediment G 28533 max. 22 % water, < 3 % sediment anaerobic, 20° C, phenyl label CGA 159902 max. 34 % (total) CGA 300406 max. 34.4 % (total, 120d)
Accumulation in water and/or sediment:	Not expected (one application per year at low rate)
Degradation in the saturated zone	no data, not required
Remarks:	None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	< 3.5 x 10^{-6} Pa at 25° C
Henry's law constant:	< 3 x 10^{-4} Pa m^3 mol^{-1}

Photolytic degradation

Direct photolysis in air:	No data, not required
Photochemical oxidative degradation in air DT_{50}:	DT_{50} .4.7 - 46 hours (Atkinson)
Volatilisation:	from plant surfaces: negligible (measured)
	from soil: negligible (measured)
Remarks:	None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 = 986 mg as/kg bw (rat)
Acute toxicity to birds:	LD50 = *ca.* 1000 mg as/kg bw (duck) LD50 = 625 mg PEAK® [1]/kg bw (duck)
Dietary toxicity to birds:	LC50 > 5000 ppm (quail and duck)
Reproductive toxicity to birds:	NOEC = 28 ppm (duck)
Short term oral toxicity to mammals:	NOAEL = 3 mg/kg bw/d (90-d, rat)

[1] 75 WG preparation (75% prosulfuron)

Aquatic Organisms

Acute toxicity fish: *(Onchorhynchus mykiss)*	LC50 > 160 mg/l (96 h) LC50 = 63 mg CGA 159902 /l (96 h) LC50 > 100 mg CGA 300406 /l (96 h) LC50 > 200 mg CGA 150829 /l (96 h) LC50 > 42 mg CGA 349707 /l (96 h) LC50 > 100 mg PEAK® /l (96 h)
Long term toxicity fish: *(Onchorhynchus mykiss)*	NOEC = 5.8 mg/l (21 d)
Bioaccumulation fish:	Not relevant (log P_{ow} = - 0.21)
Acute toxicity invertebrate: *(Daphnia magna)*	EC50 > 120 mg/l (48 h) EC50 = 74 mg CGA 159902 /l (48 h) EC50 > 100 mg CGA 300406 /l (48 h) EC50 = 16 mg CGA 150829 /l (48 h) EC50 > 100 mg CGA 349707 /l (48 h) EC50 > 100 mg PEAK® /l (48 h)
Chronic toxicity invertebrate: *(Daphnia magna)*	NOEC = 148 mg/l (21 d)
Acute toxicity algae:	EbC50 = 0.0089 mg/l (72 h - *S. capricornutum*) EC50 = 86 mg CGA 159902 /l (72 h – *Sc. subspicatus*) EC50 > 100 mg CGA 300406 /l (72 h – *Ps. subcapitata*) EC50 > 90 mg CGA 150829 /l (72 h – *Sc. subspicatus*) EC50 > 64.3 mg CGA 349707 /l (72 h – *S. capricornutum*) EC50 = 3.2 mg PEAK® /l (72 h– *Sc.*

	subspicatus)
Chronic toxicity sediment dwelling organism:	Not required
Acute toxicity aquatic plants:	EC50 = 0.00126 mg/l (14 d – *L. gibba*)

Honeybees

Acute oral toxicity:	> 100 µg as/bee 62 µg ECLAT®/bee [1]
Acute contact toxicity:	> 100 µg as/bee > 105 µg ECLAT®/bee

[1] 63 WG preparation (3% prosulfuron and 60% bromoxynil)

Other arthropod species

	% Effect
A. rhopalosiphi	mortality : 0 % fecundity : 99 % [1] (adults; PEAK®, 0.04 kg as/ha)
T. pyri	mortality : 20 % fecundity : 120 % [1] (protonymphs; PEAK®, 0.015 kg as/ha)
P. cupreus	mortality : 0 % predation : 97 % [1] (adults; PEAK®, 0.015 kg as/ha)
A. bilineata	parasitism (emergence of offspring) : 102 % [1] (adults; PEAK®, 0.015 kg as/ha)

[1] (control : 100 %)

Earthworms

Acute toxicity: *(Eisenia foetida)*	LC50 (14 d): > 1 000 mg prosulfuron /kg soil > 1 000 mg PEAK® /kg soil > 1 000 mg CGA 150829 /kg soil > 1 000 mg CGA 349707 /kg soil = 420 mg CGA 159902 /kg soil > 1 000 mg CGA 300406 /kg soil
Reproductive toxicity:	Not required

Soil micro-organisms

Nitrogen mineralisation:	< 25 % effect on nitrogen mineralisation by d 28
Carbon mineralisation:	< 25% effect on short-term respiration by d 28

APPENDIX III

PROSULFURON

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

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

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Owner** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
IIA 4.1/07	Burkhard, N.	2000	Prosulfuron: Statement on non-formation of nitrosamines NCP Novartis Crop Protection AG, Basle 07.02.2000 non GLP, not published Novartis File N.: 152005/----
IIA 4.1/08	Naegele, M.	2000	Nitrosamines in CGA 152005, Validation of the Analytical Method NCP Novartis Crop Protection AG, Basle 26.02.2000 non GLP, not published Novartis File N.: 152005/----
IIA 4.2.1/03	Hofherr, W.	1995	Prosulfuron (CGA 152005), Residue Method Validated, Determination of Parent Compound by High Performance Liquid Chromatography (HPLC), NCP Novartis Crop Protection AG, Basle REM 156.05, 07.12.1995 GLP, not published Novartis File N.: 152005/0576
IIA 4.2.3	Kissling, M.	2000	Validation on Method AG 583, Novartis Crop Protection AG, Residue Analysis, NCP Report N.: 309/00, 22.05.2000, GLP, unpublished, Novartis File N.: 152005/0699
IIIA 2.7 /04	Hofmann, E.	1995	Report on product stability (2 years, 20°C) Ciba-Geigy Muenchwilen AG, Crop NCP Protection, Muenchwilen, Rep. No. 11204, 04.07.1995 GLP, unpublished, Novartis File N.: 152005/0232

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Owner** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
IIIA 2.8.6.3	Gerhardt, P.	1997	Report on Physical-Chemical Properties: Attrition Resistance (CIPAC MT 178), NCP Novartis Crop Protection Münchwilen AG, Münchwilen, Project N.: 52828, GLP, unpublished, Novartis File N.: 152005/0641
IIIA 4.	Burkhard, N.	2000	PEAK 75 WG: Procedures for Destruction of the Plant Protection Product and its Packaging, NCP Novartis Crop Protection AG, Basle, Non-GLP, unpublished, Novartis File N.: 152005/----

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 5.8.1.1/01	Hartmann, H.R.	1993	CA 1118 A = CGA 159902 (Intermediate of CGA 152005) – Acute oral toxicity in the rat (Limit test) Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 931092, 07.09.1993 GLP, not published Novartis File No. 159902/0004
IIA 5.8.1.1/02	Hartmann, H.R.	1991b	CGA 150829 tech. – Acute oral toxicity in the rat Owner: NCP Ciba-Geigy Ltd., Experimental Toxicology, 4332 Stein, Switzerland Study Report No. 901504, 24.05.1991, GLP, not published Novartis File No. 150829//0018
IIA 5.8.1.2/01	Hartmann, H.R.	1993a	CA 1118 A = CGA 159902 (Intermediate of CGA 152005) – Acute dermal toxicity in the rat (Limit test) Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 931093,18.08.1993 GLP, not published Novartis File No. 159902/0005
IIA 5.8.1.2/02	Hartmann, H.R.	1991b	CGA 150829 tech. - Acute dermal toxicity in the rat (Limit test) Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 901507, 08.04.1991 GLP, not published Novartis File No. 150829/0017

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
B.5.8.1.3/01	Hartmann, H.R.	1991a	CGA 150829 tech. - Acute inhalation toxicity in the rat (Limit test) Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 901509, 22.04.1991 GLP, not published Novartis File No. 150829/0016
IIA 5.8.1.3/01	Hartmann, H.R.	1991a	CGA 150829 tech. - Acute inhalation toxicity in the rat (Limit test) Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 901509, 22.04.1991 GLP, not published Novartis File No. 150829/0016
IIA 5.8.1.4/01	Hagemann, Ch	1993a	CA 1118 A = CGA 159902 (Intermediate of CGA 152005) – Acute dermal irritation/corrosion study in the rabbit Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 931094, 19.07.1993 GLP, not published Novartis File No. 159902/0006
IIA 5.8.1.4/02	Hagemann, Ch.	1991b	CGA 150829 tech. - Acute dermal irritation/corrosion study in the rabbit Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 901506, 18.03.1991 GLP, not published Novartis File No. 150829/0019
IIA 5.8.1.5/01	Hagemann, Ch.	1993	CA 1118 A = CGA 159902 (Intermediate of CGA 152005) – Acute eye irritation/corrosion study in the rabbit Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 931095, 10.08.1993 GLP, not published Novartis File No. 159902/0007
IIA 5.8.1.5/02	Hagemann, Ch.	1991b	CGA 150829 tech. – Acute eye irritation/corrosion study in the rabbit Ciba-Geigy Ltd., Experimental Toxicology, 4332 Stein, Switzerland Study Report No. 901505, 18.03.1991, GLP, not published Novartis File No. 150829//0015
IIA 5.8.1.6/01	Hagemann, Ch.	1993a	CA 1118 A = CGA 159902 (Intermediate of CGA 152005) – Skin sensitisation test in the Guinea pig (maximisation test). Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 931096, 27.10.1993 GLP, not published Novartis File No. 159902/0008

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 5.8.1.6/02	Hagemann, Ch.	1991b	CGA 150829 tech. – Skin sensitisation test in the Guinea pig (maximisation test). Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 901508, 12.07..1991 GLP, not published Novartis File No. 150829/0014
IIA 5.8.1.7/01	Hertner, Th.	1993a	CA 1118 A = CGA 159902 (Intermediate of CGA 152005) – Salmonella and Escherichia/Liver microsome test, Genetic Toxicology Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 931097, 23.08.1993 GLP, not published Novartis File No. 159902/0009
IIA 5.8.1.7/02	Geleick, D.	1991b	CGA 150829 – Salmonella and Escherichia/Liver microsome test, Genetic Toxicology Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 901510, 17.04.1993 GLP, not published Novartis File No. 159902/0002
IIA 5.8.1.7/03	Dollenmeier, P.	1987c	CGA 150829 tech. – Chromosome studies on human lyphocytes in vitro. Experimental Pathology Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 680159, 12.03.1987 GLP, not published Novartis File No. 150829/0012
IIA 5.8.1.7/04	Meyer, A.	1991d	CGA 150829 tech. – Cytogenetic test on Chinese hamster cells in vitro (EU conform), Genetic Toxicology Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 901511, 03.07.1991 GLP, not published Novartis File No. 150829/0009
IIA 5.8.1.7/05	Meyer, A.	1988e	CGA 150829 tech. – Autoradiographic DNA repair test on human fibroblasts, Genetic Toxicology Owner: NCP Ciba-Geigy Ltd., Experimental Toxicology, 4332 Stein, Switzerland Study Report No. 871188, 11.03.1988, GLP, not published Novartis File No. 150829//0010
IIA 5.8.1.7/06	Hertner, Th.,	1988f	CGA 150829 tech. – Autoradiographic DNA repair test on rat hepatocytes, Genetic Toxicology Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 871186, 22.01.1988 GLP, not published Novartis File No. 159902/0011

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 5.8.1.7/07	Strasser, F.	1988g	CGA 150829 tech. – Chromosome studies on somatic cell of Chinese hamster (OECD –conform), Genetic Toxicology Owner: NCP Ciba-Geigy Ltd., Toxicology, 4332 Stein, Switzerland Study Report No. 871187, 14.09.1988 GLP, not published Novartis File No. 150829/0013

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

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 7.1.2	Perdue, D.	1995	"Soil adsorption/desorption of Phenyl [14C]CGA 325030 by the batch equilibrium method" Owner: NCP PTRL East, Inc., Richmond, United States Study Report No. 862, 27.05.1995 GLP, not published Novartis File N° CGA325030/0001
IIA 7.1.3.3	Burgener, A.	1996	Mobility and degradation in soil in oudoor lysimeters Owner: NCP RCC AG, Itingen, Switzerland Study Report No. RCC 321570, 24.01.1996 GLP, not published Novartis File N° CGA152005/0152
IIA 7.2.1	Purdy, J.	1995	"Soil adsorption/desorption of Phenyl [14C]CGA 325030 by the batch equilibrium method" Owner: NCP PTRL East, Inc., Richmond, United States Study Report No. 862, 27.05.1995 GLP, not published Novartis File N° CGA325030/0001

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 7.1.3.3	Burgener, A.	1996	Mobility and degradation in soil in oudoor lysimeters Owner: NCP RCC AG, Itingen, Switzerland Study Report No. RCC 321570, 24.01.1996 GLP, not published Novartis File N° CGA152005/0152
IIA 7.2.1	Purdy, J.	1995	Aquatic dissipation study with CGA 152005 75 WG No Organization, -, Switzerland Owner: NCP Study Report No. CER 01002/94, 03.11.1995 GLP, not published Novartis File N° CGA152005/0573
IIA 7.2.1	Schulze-Aurich, J.	1996	Metabolism of [4-14C] Triazine-Ring labelled CGA 152005 under aerobic and anaerobic conditions in aquatic systems Owner: NCP Ciba-Geigy Ltd., Basel, Switzerland Study Report No. 94SA05, 28.11.1996 GLP, not published Novartis File N° CGA152005/0626
IIA 7.2.1.3.1	Grade, R.	1995	Report on the test for ready biodegradability of CGA 152005 in the carbondioxide evolution test Owner: NCP Ciba-Geigy Ltd., Basel, Switzerland Study Report No. 951528, 21.09.1995 GLP, not published Novartis File N° CGA152005/0569
IIA 7.2	Reischmann, F.J.	1995	Volatilization of CGA 152005 from water (calculation) Owner: NCP Ciba-Geigy Ltd., Basel, Switzerland Study Report No. 95RF06, 20.03.1995 GLP, not published Novartis File N° CGA152005/0535
IIA 7.2	Sandmeier, P.	1995	Volatilization of CGA 152005 from Plant and Soil after Postemergent Spray Application of 14C-labelled Material on Maize under Indoor Conditions Owner: NCP Ciba-Geigy Ltd., Basel, Switzerland Study Report No. 95PSA38, 19.06.1995 GLP, not published Novartis File N° CGA152005/0548
IIA 7.1.3	Resseler, H.	1995	Evaluation of the leaching and degradation behaviour of prosulfuron (CGA 152005) with simulation Model Pelmo 2.01 Owner: NCP Ciba-Geigy GmbH, Frankfurt a.Main, Germany Study Report No. SM 0395, 15.09.1995 GLP, not published Novartis File N° CGA152005/0607

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA 9.1.1.2	Purdy, J.	1995	Soil dissipation study at three trial sites with CGA 152005 75 WG Owner: NCP Envirotest Labs, Edmonton, Alberta, Canada, Novartis Crop Protection, Inc., Mississauga, Ontario, Canada Study Report No. 644-97, 08.06.1995 GLP, not published Novartis File N° CGA152005/0608
IIIA 9.1.1.2	Wiepke, Th. et, al.	1997	Final report: Dissipation of Peak(TM) (Prosulfuron) in soil under field conditions with and without winter wheat in Kansas Owner: NCP ABC Analytical Bio-Chemistry Lab. Inc., Columbia, United States Study Report No. 43065, 12.12.1997 GLP, not published Novartis File N° CGA152005/0649
IIIA 10.2.2	Purdy, J.	1995	Aquatic Dissipation Study with CGA 152005 75 WG, Envirotest Labs, Edmonton, Alberta, Canada, Owner: NCP Study Report No. CER 01002/94, 03.11.1995, GLP, unpublished, Novartis File N.: 152005/0573

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.2.1	Gries, Th.	1999a	CGA 159902 (Metabolite of CGA 152005) Static acute toxicity test with Rainbow trout (Oncorhynchus mykiss) Owner: NCP Springborn Lab., Horn, Switzerland Study Report No. 1047.058.103, 17.08.1999 GLP, not published Novartis File N° CGA159902/0013
IIA 8.2.1	Gries, Th.	1999b	Acute toxicity test of CGA 300406 (Metabolite of CGA 152005) to Rainbow trout (Oncorhynchus mykiss) under static conditions Owner: NCP Springborn Lab., Horn, Switzerland Study Report No. 1047.059.103, 29.10.1999 GLP, not published Novartis File N° CGA300406/0004

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.2.1	Rufli, H.	1988	Report on the test for acute toxicity CGA 150829 (Metabolite of CGA 152005) to rainbow trout (Oncorhynchus mykiss) Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 871326, 01.03.1988 GLP, not published Novartis File N° CGA150829/0004
IIA 8.2.1	Rufli, H.	1995	Acute toxicity test of CGA 349707 (Metabolite of CGA 152005) to rainbow trout (Oncorhynchus mykiss) in the dynamic system Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 95R018, 19.09.1995 GLP, not published Novartis File N° CGA349707/0003
IIA 8.2.4	Gries, Th.	1999c	CGA 159902 (Metabolite of CGA 152005) static acute toxicity test with daphnids (Daphnia magna) Owner:NCP Springborn Lab., Horn, Switzerland Study Report No. 1047.058.110, 09.07.1999 GLP, not published Novartis File N° CGA159902/0012
IIA 8.2.4	Gries, Th.	1999d	CGA 300406 (Metabolite of CGA 152005) Static acute toxicity test with daphnids (Daphnia magna) Owner: NCP Springborn Lab., Horn, Switzerland Study Report No. 1047.059.110, 17.08.1999 GLP, not published Novartis File N° CGA300406/0003
IIA 8.2.4	Neumann, Ch.	1996	Acute toxicity test of CGA 349707 (Metabolite of CGA 152005) to the cladoceran daphnia magna straus under static conditions Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 95N007, 15.03.1996 GLP, not published Novartis File N° CGA349707/0007
IIA 8.2.4	Rufli, H.	1987a	Report on the test for acute toxicity CGA 150829 (Metabolite of CGA 152005) to Daphnia magna Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 871324, 07.12.1987 GLP, not published Novartis File N° CGA150829/0003
IIA 8.2.4	Vial, A	1991	Report on the test for acute toxicity CGA 150829 (Metabolite of CGA 152005) to Daphnia magna Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 901539, 02.01.1991 GLP, not published Novartis File N° CGA150829/0020

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.2.6	Grade, R.	1995	Growth inhibition test of CGA 349707 (Metabolite of CGA 152005) to green algae (Selenastrum capricornutum) in a static system Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 95G023, 06.11.1995 GLP, not published Novartis File N° CGA349707/0006
IIA 8.2.6	Gries, Th.	1999e	CGA 300406 (Metabolite of CGA 152005): Alga, growth inhibition test with the freshwater Alga Pseudokirchneriella subcapitata Owner: NCP Springborn Lab., Horn, Switzerland Study Report No. 1047.059.430, 20.12.1999 GLP, not publishedY Novartis File N° CGA300406/0005
IIA 8.2.6	Hertl, J.	1997	Toxicity of CGA 159902 (Metabolite of CGA 152005) to Scenedesmus subspicatus in a 72 hour algal growth inhibition test Owner: NCP RCC AG, Itingen, Switzerland Study Report No. 667855, 25.09.1997 GLP, not published Novartis File N° CGA159902/0003
IIA 8.2.6	Rufli, H.	1987b	Report on the algal growth inhibition test with CGA 150829 (Metabolite of CGA 152005) Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 871325, 22.12.1987 GLP, not published Novartis File N° CGA150829/0007
IIA 8.2.8	Purdy, J.	1995	Aquatic dissipation study with CGA 152005 75 WG No Organization, -, Switzerland Owner: NCP Study Report No. CER 01002/94, 03.11.1995 GLP, not published Novartis File N° CGA152005/0573
IIA 8.6	Candolfi, M. Grimm, C.	1998b	Acute Toxicity Test of CGA 150829 to the Earthworm (Eisenia fetida) Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 981743, 12.10.1998 GLP, not published Novartis File N° CGA150829/0021
IIA 8.6	Noack, U.	1995	Acute effects on Earthworm Eisenia fetida (Savigny) of CGA 349707 (Metabolite of CGA 152005) Owner: NCP No Organization, -, Switzerland Study Report No. RRA47511, 02.10.1995 GLP, not published Novartis File N° CGA349707/0005

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.6	Rufli, H.	1997a	Acute toxicity test of CGA-159902 (Metabolite of CGA 152005) to the earthworm (Eisenia foetida) Owner: NCP Novartis Crop Protection AG, Stein, Switzerland Study Report No. 961754, 14.03.1997 GLP, not published Novartis File N° CGA159902/0002
IIA 8.6	Rufli, H.	1997b	Acute toxicity test of CGA-300406 (Metabolite of CGA 152005) to the earthworm (Eisenia foetida) Owner: NCP Novartis Crop Protection AG, Stein, Switzerland Study Report No. 961755, 14.07.1997 GLP, not published Novartis File N° CGA300406/0002
IIA 8.9	Kerber, E.	1994	Herbicidal activity of 6 metabolites of CGA 152005 Ciba-Geigy Ltd., Basel, Switzerland Owner: NCP Study Report No. , 04.10.1994 GLP, not published Novartis File N° CGA152005/0691
IIA 8.9	Kerber, E.	1995	Herbicidal activity of CGA 349`707, a metabolite of CGA 152`005 Owner: NCP Ciba-Geigy Ltd., Basel, Switzerland Study Report No. , 20.06.1995 GLP, not published Novartis File N° CGA349707/0001
IIA 8.10	Bader, H.	1991	Report on the test for inhibitory concentration on aerobic bacteria of CGA 150829 (Metabolite of CGA 152005) Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 918003, 11.03.1991 GLP, not published Novartis File N° CGA150829/0006
IIA 8.10	Baumann, W.	1993	Report on the test for inhibitory concentration on aerobic bacteria of CA 741 A (Intermediate of CGA 152005) Owner: NCP Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland Study Report No. 938236, 27.08.1993 GLP, not published Novartis File N° CGA150829/0005
IIIA 10.3.3.1/6	Candolfi, M.P.	1997a	CGA 152005, WG 75 (A-8714 C): Laboratory acute contact toxicity test with the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera: braconidae) Owner: NCP Springborn Lab., Horn, Switzerland Study Report No. 961688, 09.01.1997 GLP, not published Novartis File N° CGA152005/0627

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA 10.3.3.1/7	Kleiner, R.	1997a	Testing toxicity to beneficial arthropods Predatory mite - Typhlodromus pyri (Scheuten) / laboratory Owner: NCP BioChem GmbH, Cunnersdorf, Germany Study Report No. 941048058, 30.10.1997 GLP, not published Novartis File N° CGA152005/0642
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