



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

S-Metolachlor

SANCO/1426/2001 - rev. 3

4 October 2004

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

Review report for the active substance **S-Metolachlor**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 8 October 2004 in view of the inclusion of S-Metolachlor 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 S-Metolachlor, 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, the Belgian authorities received on 01 August 1997 an application from Novartis N.V. (now Syngenta), hereafter referred to as the applicant, for the inclusion of the active substance S-Metolachlor in Annex I to the Directive. The Belgian authorities indicated to the Commission on 23 February 1998 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 S-Metolachlor was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 21 April 1998, 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 1998/512/EC<sup>1</sup> of 29 July 1998 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 Belgium, as rapporteur Member State and The Netherlands as co-rapporteur Member State, would carry out the detailed examination of the dossier and report the conclusions of the 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.

Belgium and The Netherlands submitted to the Commission on 03 May 1999 the report of their detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of S-Metolachlor in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Novartis N.V. (now Syngenta) being the sole applicant on 16 January 2001.

Further discussions between the Rapporteur Member State and the Co-rapporteur Member State were organised from April to October 2001, to review the draft assessment report and the comments received thereon 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 report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 14 October 2001.

The dossier, revised 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 the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final examination took place from December 2001 to October 2004, and was finalised in the meeting of the Standing Committee on 8 October 2004.

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

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<sup>1</sup> OJ No L 228, 15.08.1998, p.35

The review did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants or the Panel on Plant Health, Plant Protection Products and their Residues of the European Food Safety Authority.

## **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 2005/3/EC<sup>2</sup> concerning the inclusion of S-Metolachlor in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing S-Metolachlor 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.

## **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 S-Metolachlor 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 S-Metolachlor containing plant protection product for which Member States will grant or review the authorisation.

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

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<sup>2</sup> OJ No L 20, 22.01.2005, p. 19-23

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 S-Metolachlor 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 0.0458 % 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 Ecotoxicology**

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 S-Metolachlor are given in Appendix I.

The active substance shall have a minimum purity of 960 g/kg technical product.

The review has established that for the active substance notified by the applicant (Novartis N.V., 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 S-Metolachlor**

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:

In this overall assessment Member States

- should pay particular attention to the potential for groundwater contamination, particularly of the active substance and its metabolites CGA 51202 and CGA 354743, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- should pay particular attention to the protection of aquatic plants.

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 S-Metolachlor in Annex I.

Some endpoints however may require the generation or submission of additional studies to be submitted at Member State level in order to support national authorisations for the use under certain vulnerable conditions or to support extensions of the use pattern beyond the uses described under Point 3 above.

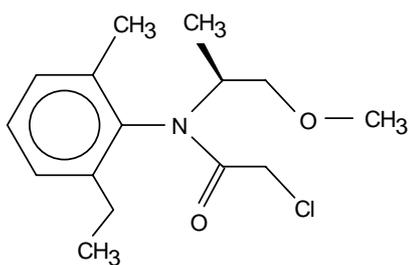
This may particular be the case for earthworm field studies and studies on the risk to terrestrial off-crop plants.

## **9. Updating of this review report**

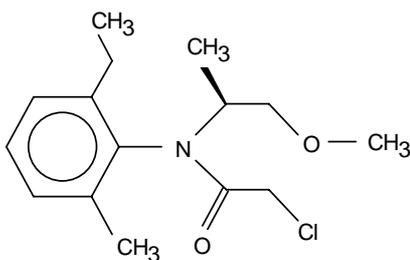
The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations 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 S-Metolachlor in Annex I of the Directive.

**APPENDIX I****Identity, physical and chemical properties****S-METOLACHLOR**

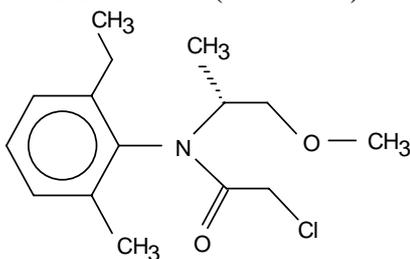
<b>Common name (ISO)</b>	S-Metolachlor
<b>Development Code (for new actives only)</b>	CGA 77102 (S-isomers) CGA 77101 (R-isomers)
<b>Chemical name (IUPAC)</b>	Mixture of : (aRS, 1 S)-2-chloro-N-(6-ethyl-o-tolyl)-N-(2-methoxy-1-methylethyl)acetamide (80-100%) and: (aRS, 1 R)-2-chloro-N-(6-ethyl-o-tolyl)-N-(2-methoxy-1-methylethyl)acetamide (20-0%)
<b>Chemical name (CA)</b>	Mixture of : 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(1 S)-2-methoxy-1-methylethyl]acetamide (80-100%) and: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(1 R)-2-methoxy-1-methylethyl]acetamide] (20-0%)
<b>CIPAC No</b>	607
<b>CAS No</b>	87392-12-9 (S-isomer) 178961-20-1 (R-isomer)
<b>EEC No</b>	Not available
<b>FAO SPECIFICATION</b>	Not available
<b>Minimum purity</b>	960 g/kg
<b>Molecular formula</b>	C <sub>15</sub> H <sub>22</sub> ClNO <sub>2</sub>
<b>Molecular mass</b>	283.8

**Structural formula**

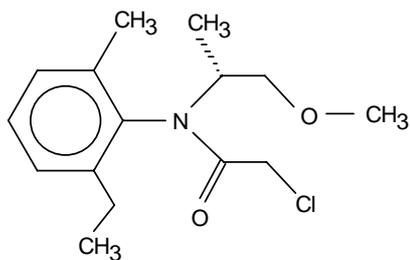
aS, 1S



aR, 1S

**CGA 77102 (S-isomers)**

aR, 1R



aS, 1R

**CGA 77101 (R-isomers)**

<b>Melting point</b>	freezing point = -61.1°C (99.8% (S+R), 88.4% (S))
<b>Boiling point</b>	Approx. 334°C (99.8% (S+R), 88.4% (S))
<b>Appearance</b>	Clear extremely pale-yellow liquid with a weak odour (99.8% (S+R), 88.4% (S))
<b>Relative density</b>	1117 kg/m <sup>3</sup> (99.8% (S+R), 88.4% (S))
<b>Vapour pressure</b>	3.7 10 <sup>-3</sup> Pa (25°C)
<b>Henry's law constant</b>	2.2 10 <sup>-3</sup> Pa .m <sup>3</sup> /mol (25°C)
<b>Solubility in water</b>	pH 7.3 , 25°C: 480 mg/l
<b>Solubility in organic solvents</b>	solubility at 25°C in : n-hexane : completely miscible toluene : completely miscible dichloromethane : completely miscible methanol : completely miscible n-octanol : completely miscible acetone : completely miscible ethyl acetate : completely miscible
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	pH 7, 25°C : log P <sub>ow</sub> = 3.05 ± 0.02
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	pH 5, 7 en 9, 25°C : hydrolytically stable
<b>Dissociation constant</b>	No dissociation constant (pKa) in an accessible pH-range
<b>Quantum yield of direct photo-transformation in water at λ &gt;290 nm</b>	No determination of quantum yield
<b>Flammability</b>	Not applicable (a.s. is a liquid with flash point >55°C)
<b>Explosive properties</b>	Not explosive
<b>UV/VIS absorption (max.)</b>	λ <sub>max</sub> 266 nm : ε = 534 L.mol <sup>-1</sup> .cm <sup>-1</sup> λ <sub>max</sub> 274 nm : ε = 443 L.mol <sup>-1</sup> .cm <sup>-1</sup> λ ≥ 290 nm : ε < 10 L.mol <sup>-1</sup> .cm <sup>-1</sup> (metolachlor, 99.7% pure)
<b>Photostability in water (DT<sub>50</sub>)</b>	pH 7, 25°C, Xenon lamp : DT <sub>50</sub> = 75 d

## APPENDIX II

### END POINTS AND RELATED INFORMATION

#### S-METOLACHLOR

### 1 Toxicology and metabolism

#### Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	-oral: rapid (48h) and efficient (69.8-93.2%) -dermal: not determined
Distribution:	quite uniform, slight preference for well-perfused organs; at d7 in liver: 0.22% of dose
Potential for accumulation:	no evidence
Rate and extent of excretion:	rapid (most within 48h) elimination, faecal (53%) / urinary (42%) at high dose; important enterohepatic circulation
Toxicologically significant compounds:	S-Metolachlor, CGA46129 (propionic acid derivative), CGA 41638 (OH derivative), CGA 50026 and CGA 133275 (sulfonated derivatives)
Metabolism in animals:	Extensive metabolisation; *oxidative reactions (80%): (i) cleavage of the methyl ether, (ii) oxidation of the resultant alcohol to the corresponding acid, (iii) oxidation of the aryl methyl and/or ethyl groups, and (iv) substitution of the chlorine atom * glutathione conjugations (20%)

#### Acute toxicity

Rat LD <sub>50</sub> oral:	M :3267 mg/kg bw F :2577 mg/kg bw
Rat LD <sub>50</sub> dermal:	>2000 mg/kg bw
Rat LC <sub>50</sub> inhalation:	>2.91 mg/l air
Skin irritation:	not irritant
Eye irritation:	not irritant
Skin sensitization (test method used and result):	Guinea Pig Maximization Test, Bühler: sensitising

## Short term toxicity

Target / critical effect:	liver (rat, dog)
Lowest relevant oral NOAEL / NOEL:	9.7 mg/kg bw/d (1 yr dog: Alkaline Phosphatase) 15 mg/kg bw/d (90d dog: Liver weight change)
Lowest relevant dermal NOAEL / NOEL:	systemic NOAEL: 100 mg/kg bw/d (21 d rabbit: liver weight) local NOAEL: <10 mg/kg bw/d (21 d rabbit: erythema and hyperkeratosis)
Lowest relevant inhalation NOAEL / NOEL:	not determined

## Genotoxicity

not genotoxic (*in vitro*: Ames, HPRT, CA in CHO, UDS in fibroblasts and hepatocytes; *in vivo*: BM micronucleus in mouse, UDS in rat liver); transient increase of DNA-synthesis *in-vivo* (result of hepatotoxicity and possible stimulation of cell proliferation)

## Long term toxicity and carcinogenicity

Target / critical effect:	liver (rat)
Lowest relevant NOAEL:	14 mg/kg bw/d (2 yr rat: bw and liver focal changes)
Carcinogenicity:	none; emergence of eosinophilic foci and neoplastic nodules

## Reproductive toxicity

Target / critical effect - Reproduction:	2G: no reproductive effects
Lowest relevant reproductive NOAEL / NOEL:	NOAEL parental: 76 mg/kg bw/d (MTD) NOAEL foetal: 24 mg/kg bw/d Reproductive NOAEL > 76 mg/kg bw/d
Target / critical effect - Developmental toxicity:	rabbit (maternal): miosis, abortions, decreased bw gain rat (maternal): body weight / body weight gain
Lowest relevant developmental NOAEL / NOEL:	>360 mg/kg bw/d (rabbit)

## Delayed neurotoxicity

not conducted; not necessary in the absence of neurotoxic signs in standard repeated toxicity tests

## Other toxicological studies

- |       |   |
|-------|---|
| (i)   | Studies performed with the environmental metabolites CGA 51202 and CGA 354753 showed no relevant toxicity. CGA 51202 was irritant to eyes |
| (ii)  | increased DNA-synthesis in the liver <i>in-vivo</i> at 500 mg/kg bw (rat)   |
| (iii) | CYP2B induction in the liver <i>in-vivo</i> at 24.5 mg/kg bw (rat)  |

## Medical data

Not available

## Summary

	Value	Study	Safety factor
ADI:	0.1mg/kg bw/d	1 yr dog, oral	100
AOEL systemic:	0.15mg/kg bw/d	90 day dog, oral	100
AOEL inhalation:	Not required	-	-
AOEL dermal:	Not required	-	-
ARfD (acute reference dose):	Not required	-	-

## Dermal absorption

determined on EC formulation: 3% for the concentrate, and 10% for the field dilution
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## 2 Fate and behaviour in the environment

### 2.1 Fate and behaviour in soil

#### Route of degradation

##### Aerobic:

Mineralization after 100 days:

15.3% after 3 months

Non-extractable residues after 100 days:

4.6 % after 3 months

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

CGA 51202/CGA351916 : max 10.9%

CGA 354743/CGA380168 : max 12.4%

#### Supplemental studies

##### Anaerobic:

No mineralization,  
Non-extractable : 33.7% after 90 d  
CGA 41507 : 44.2%

##### Soil photolysis:

No photolysis observed

##### Remarks:

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#### Rate of degradation

##### Laboratory studies

DT<sub>50lab</sub> (20 °C, aerobic):

DT<sub>50lab</sub> (20°C, aerobic): 7.6-37.6 d, median : 14.5 d, 6 soils (6 figures)

DT<sub>50lab</sub> (CGA354743, 20°C, aerobic): 94-169 d, median : 131 days, 2 soils

DT<sub>50lab</sub> (CGA351916, 20°C, aerobic): 19.8-165 d, median : 46 days, 6 soils

DT<sub>50lab</sub> (CGA357704, 20°C, aerobic): 59-109 (or not defined) days, median 109 d, 5 soils

DT<sub>50lab</sub> (CGA41507, 20°C, aerobic): 52 d, 1 soil

DT<sub>50lab</sub> (CGA376944, 20°C, aerobic): 68 d, 1 soil

DT<sub>50lab</sub> (CGA50720, 20°C, aerobic): 37.5 d, 1 soil (recalculated)

DT<sub>90lab</sub> (20 °C, aerobic):

DT<sub>90lab</sub> (20°C, aerobic): 25.1-125 d, median : 50.1 d, 6 soils (6 figures)

DT<sub>50lab</sub> (10 °C, aerobic):

DT<sub>50lab</sub> (10°C, aerobic): 41.3 d, 1 soil

DT<sub>50lab</sub> (20 °C, anaerobic):

DT<sub>50lab</sub> (20°C, anaerobic): 48.3 d, 1 soil

##### Field studies (country or region)

DT<sub>50f</sub> from soil dissipation studies:

DT<sub>50f</sub>: 11-31 d, 6 soils in Switzerland and France

DT<sub>90f</sub> from soil dissipation studies:

DT<sub>90f</sub>: 36-148 d, 6 soils in Switzerland and France

Soil accumulation studies:

Not required
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Soil residue studies:

Not required
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**Remarks:**

e.g. effect of soil pH on degradation rate

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## Adsorption/desorption

$K_f / K_{oc}$ :

$K_{oc}$  (S-metolachlor) : 110-369, median : 226 l/kg, 9 soils  
 $K_{oc}$  (CGA354743) : 3-22, median : 9 l/kg, 7 soils  
 $K_{oc}$  (CGA51202) : 2.82-62, median : 12.2 l/kg, 7 soils  
 $K_{oc}$  (CGA40172) : 143-204, median : 182 l/kg, 3 soils  
 $K_{oc}$  (CGA376944) : 8-12, median : 10 l/kg, 3 soils  
 $K_{oc}$  (CGA41507) : 81.3-93.8, median : 84.9 l/kg, 3 soils  
 $K_{oc}$  (CGA357704) : no adsorption, 3 soils

$K_d$ :

$K_d$  (S-metolachlor) : 1.3-55.8, 9 soils  
 $K_d$  (CGA354743) : 0.27 – 0.54, 3 soils  
 $K_d$  (CGA51202) : 0.13-9.99, 7 soils  
 $K_d$  (CGA40172) : 2.21-6.98, 3 soils  
 $K_d$  (CGA376944) : 0.24-0.55, 3 soils  
 $K_d$  (CGA41507) : 2.88-5.56, 3 soils  
 $K_d$  (CGA357704) : no adsorption, 3 soils

no

pH dependence:

## Mobility

### Laboratory studies:

Column leaching:

Aged residue leaching:

Not required
508 mm rainfall, 2 d, 4 soils, RR in the leachate : a.s. : 0.2-36.3% CGA51202 : 5.5-11.0% CGA46129 : 0.4-1.5% CGA 50720 : 1.1-6.9% CGA 40919,40172, 41638 : 0.7-3.2% CGA 354743 : 3.3-4.1% CGA 322966 : 0-2.0%
200 mm rainfall, 2 d, 2 soils, RR in the leachate : a.s. : < 0.01% CGA51202 : 8.29-11.27% CGA 50720 : 3.77-5.88% CGA46129 : 0-0.4% CGA 37735, 48081 : < 0.1%
200 mm rainfall, 2 d, 1 soil, RR in the leachate : a.s. : < 0.01% CGA 40172 : 0-0.38% CGA 40919 : 0-1.63% CGA 354743 : 12.11-12.57% CGA51202 : 6.28-6.93% CGA382594 : 1.10-1.92% CGA46129 : 0.46-1.87% CGA 50720 : 3.49-1.79% CGA 357704 : 2.32-2.86%

### Field studies:

Lysimeter/Field leaching studies:

2 loamy sand lysimeters, 3 year experiment, 1250 g a.s./ha, 1 appl/year, mean annual concentration a.s. : <0.01-0.08 µg/l CGA 354743 : 1.08-27.96µg/l CGA 368208 : 0.05-7.82 µg/l CGA 51202 : 0.25-16.29 µg/l CGA 50720 : 0.03-4.71 µg/l CGA 357704 : 0.07-5.11 µg/l CGA 37735 0.16-0.98 µg/l CGA 50267 : 0.25-1.03 µg/l Not identified : 5.14-47.19 µg/l
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### Remarks:

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## 2.2 Fate and behaviour in water

### Abiotic degradation

Hydrolytic degradation:

pH 5, 7, 9 at 25°C : no degradation within 30 d

Major metabolites:

none

Photolytic degradation:

No photolysis

Major metabolites:

none

### Biological degradation

Readily biodegradable:

No

Water/sediment study:

DT<sub>50</sub> water:

6-12 d

DT<sub>90</sub> water:

60-99 d

DT<sub>50</sub> whole system:

42-53 d

DT<sub>90</sub> whole system:

138-176 d

Distribution in water / sediment systems  
(active substance)

Equal distribution in sediment and water phases

Distribution in water / sediment systems  
(metabolites)CGA 41507 (14.3-17.8%) , CGA 51202 (12.3-21.2%) in  
water and sediment phases

Accumulation in water and/or sediment:

No accumulation

### Degradation in the saturated zone

Not required

Remarks:

-

## 2.3 Fate and behaviour in air

### Volatility

Vapour pressure:

3.7 10<sup>-3</sup> Pa (25°C)

Henry's law constant:

2.2 10<sup>-3</sup> Pa .m<sup>3</sup>/mol (25°C)

### Photolytic degradation

Direct photolysis in air:

Not available

Photochemical oxidative degradation in air

DT<sub>50</sub> 2-5 hDT<sub>50</sub>:

Volatilisation:

from plant + soil surfaces: 10% in 24 h

from soil: 2.7-5.3% in 24 h

Remarks:

-

### 3 Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals:

LD<sub>50</sub> > 2000 mg a.s./kg bw

Acute toxicity to birds:

LD<sub>50</sub> > 2510 mg a.s./kg bw

Dietary toxicity to birds:

LC<sub>50</sub> > 5620 mg a.s./kg food

Reproductive toxicity to birds:

NOEC &gt; 800 mg a.s./kg food

~~Short term oral~~ reproductive toxicity to mammals:

NOEC = 300 mg a.s./kg food

#### Aquatic Organisms

Acute toxicity fish:

LC<sub>50</sub> (S-metolachlor, 96 h, *Oncorhynchus mykiss*) : 1.23 mg/L

Long term toxicity fish:

NOEC (metolachlor, 35 d, *Pimephales promelas*) : 0.78 mg/L

Bioaccumulation fish:

BCF (metolachlor, 28 d, *Lepomis macrochirus*, 28 d, whole fish) : 68.79  
Depuration t<sub>1/2</sub> : 1-2 d

Acute toxicity invertebrate:

LC<sub>50</sub> (S-metolachlor, 96 h, *Mysidopsis bahia*) : 1.40 mg/L

Chronic toxicity invertebrate:

NOEC (metolachlor, 21 d, *Daphnia magna*) : 5.9 mg/L

Acute toxicity algae:

EbC<sub>50</sub> (S-metolachlor, 120 h, *Selenastrum capricornutum*) : 0.008 mg/L

Chronic toxicity sediment dwelling organism:

NOEC (metolachlor, 62 d, benthic estuarine community containing 26 species of annelids, arthropods and molluscs) : 0.54 mg/L

Acute toxicity aquatic plants:

EdC<sub>50</sub> (S-metolachlor, 14 d, *Lemna gibba*) : 0.023 mg/L

Mesocosm

NOEC (Dual , EC containing 960 g/L metolachlor, 167 d, mesocosm) : 0.02 mg/L

#### Honeybees

Acute oral toxicity:

LD<sub>50</sub> > 85 µg a.s./bee

Acute contact toxicity:

LD<sub>50</sub> > 200 µg a.s./bee

#### Other arthropod species

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
<i>Poecilus cupreus</i>	Adults	A 9396 B EC containing 960 g a.s./L	2.12	Mortality	0%	30%
<i>Aphidius colemani</i>	Adults	A 9396 B	2.12	Mortality	100%	30%
<i>Orius laevigatus</i>	II-instar nymphs	A 9396 B	2.12	Beneficial capacity	68.9%	30%
<i>Aleochara bilineata</i>	Adults	A 9396 B	2.12	Beneficial capacity	20.1%	30%
<i>Typhlodromus pyri</i>	Protonymphs	A 9396 B	2.12	Beneficial capacity	96%	30%
Extended laboratory tests						
<i>Aphidius rhopalosiphi</i>	Adults	A 9396 B	1.54	Beneficial capacity	25.39%	30%
<i>Typhlodromus pyri</i>	Protonymphs	A 9396 B	1.54	Beneficial capacity	30.12%	30%
<i>Orius laevigatus</i>	II-instar nymphs	A 9396 B	1.54	Beneficial capacity	-9.63%	30%

## Earthworms

Acute toxicity:

LC50 = 570 mg a.s./kg substrate
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Reproductive toxicity:

NOEC < 2.54 kg a.s./ha (lowest concentration tested)
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## Soil micro-organisms

Nitrogen mineralization:

Negligible effects at application rate equivalent to 3.8, 4.37, 9.5 and 10.9 kg a.s./ha
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Carbon mineralization:

Negligible effects at application rate equivalent to 3.8, 4.37, 9.5 and 10.9 kg a.s./ha
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**APPENDIX III****S-METOLACHLOR**

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**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 1.11	Naegele, M.	2001	Chemical composition of CGA 77102 tech.: Analysis of 5 representative pilot batches for content of CGA 77102 and impurities Study number: 107839 Syngenta Crop Protection AG, Basel GLP, not published

**B.6 Toxicology and metabolism**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 5.8.1, IIIA 9.2.1	B. Lang / L. Meyer	Sept 2002	STATEMENT: Toxicological Relevance of Non-Identified Residues (NIR) in Lysimeter Leachates. Syngenta Crop Protection AG, Basel; not GLP, not published

**B.7 Residue data**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
none	-	-	-

**B.8 Environmental fate and behaviour**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
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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
IIA 7.1.1.2.1	Nicollier, G	2003	Rate of Degradation of [Phenyl-U- <sup>14</sup> C]-labelled CGA 51202 in Various Soils under Aerobic Laboratory Conditions at 20 °C; Report Nr. 02TB05, Syngenta Crop Protection AG, Basel GLP, not published
IIIA 9.2.1	Huber, A	2002	Leaching Behaviour of S-Metolachlor and its Metabolites CGA345743 and CGA51202 in Europe. Modelling study conducted with FOCUS PELMO 3.3.2, Syngenta Crop Protection AG, Basel, Switzerland, Final Report No. Mod02AH20 (CGA77102/0623). Not GLP, not published
IIA 7.1.1.2.1	Nicollier, G., and A. Glaenzel	2003	Rate of Degradation of [Phenyl-U- <sup>14</sup> C] Labelled CGA 354743 in Various Soils under Aerobic Laboratory Conditions at 20°C; Report Nr. 02GN08, Syngenta Crop Protection AG, Basel GLP, not published
IIA 7.1.2	Nicollier, G	2003	Time Dependent Sorption of [Phenyl-U- <sup>14</sup> C]-labelled CGA 51202 in Various Soils; Report Nr. 02TB06, Syngenta Crop Protection AG, Basel GLP, not published
IIA 7.1.2	Nicollier, G., and A. Glaenzel	2003	Time Dependent Sorption of [Phenyl-U- <sup>14</sup> C] Labelled CGA 354743 in Various Soils; Report Nr. 02GN09, Syngenta Crop Protection AG, Basel GLP, not published
IIA 7.4	Duefer, B., and Kuechler, T.,	2003	Generation of field monitoring data in Germany to prove the product-fitness on registration hurdles (0.1 µg/l parent + 10 µg/l metabolite), Substances: Metolachlor (S-Metolachlor) and Metabolites. Interim summary no GLP, not published
IIIA 9.2.1	French, D., Lang, B., Pluecken, U., Harms, C.T., Huber, A	2003	Statement: Relevance of Environmental Metabolites in Groundwater; Syngenta Crop Protection AG, Basel (CGA77102/0661) Not GLP, not published
IIIA 9.2.1	French, D., Lang, B., Pluecken, U., Harms, C.T., Huber, A	2003	Statement: S-Metolachlor: Relevance of Environmental Metabolites in Groundwater – revised August 2003; Syngenta Crop Protection AG, Basel Not GLP, not published

**B.9 Ecotoxicology**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIIA 10.6.1.3	Papaja, S.	2002	The effects of A-9476 B (Gardoprim Plus Gold <sup>®</sup> , 312.5 g/L S-metolachlor + 187.5 g/L terbuthylazine) on earthworms under field conditions, BioChem agrar GmbH; report No. 001035605, 12.11.2002 GLP, not published
IIIA 10.6.1.3	Goerge, G.	2002	Assessment: A9476B S-Metolachlor/Terbuthylazine 500SC Effects on Earthworms in the Field, Syngenta Crop Protection AG, Basel Not GLP, not published

## APPENDIX IV

## List of uses supported by available data

## S-Metolachlor

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Maize	N/S	DUAL GOLD 960 EC	F	Annual weeds	EC	960 g/l	spray	BBCH 00-12 of the weeds, spring	1	-	0.200-0.600	300	0.58-1.54	NA	
Sweet corn	N/S	DUAL GOLD 960 EC	F	Annual weeds	EC	960 g/l	spray		1	-	0.200-0.600	300	0.58-1.54	NA	
Sorghum	S	DUAL GOLD 960 EC	F	Annual weeds	EC	960 g/l	spray		1	-	0.200-0.600	300	0.58-1.54	NA	
Sugar beets/ beets	N/S	DUAL GOLD 960 EC	F	Annual weeds	EC	960 g/l	spray		1	-	0.200-0.600	300	0.58-1.21.5	NA	
Soybean	S	DUAL GOLD 960 EC	F	Annual weeds	EC	960 g/l	spray		1	-	0.200-0.600	300	0.58-1.54	NA	
Sunflower	S	DUAL GOLD 960 EC	F	Annual weeds	EC	960 g/l	spray		1	-	0.200-0.600	300	0.58-1.54	NA	
Potato	S	DUAL GOLD 960 EC	F	Annual weeds	EC	960 g/l	spray		1	-	0.200-0.600	300	0.58-1.54	NA	

**Remarks:**

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

S-Metolachlor

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APPENDIX IV  
List of uses supported by available data  
30 August 2004

the plants - type of equipment used must be indicated