

# ***Common Implementation Strategy for the Water Framework Directive***

**Environmental Quality Standards (EQS)**

**Substance Data Sheet**

**Priority Substance No. 1**

**Alachlor**

**CAS-No. 15972-60-8**

***Final version  
Brussels, 31 July 2005***

**Disclaimer**

*This data sheet provides background information on the setting of the Environmental Quality Standard in accordance with Article 16 of the Water Framework Directive (2000/60/EC). The information was compiled, evaluated and used as outlined in the Manual<sup>[4]</sup> and has been discussed in a consultative process with the Expert Advisory Forum on Priority Substances and the Expert Group on Quality Standards. Furthermore, it has been peer-reviewed by the SCTEE<sup>[1]</sup>. The substance data sheet may, however, not necessarily represent the views of the European Commission.*

*New upcoming information was considered and included up to the date of finalisation of this data sheet. Information becoming available after finalisation of this document will be evaluated in the review process of priority substances according to Art. 16(4) of the Water Framework Directive. If necessary, the Environmental Quality Standard substance data sheets will then be revised in the light of technical and scientific progress.*

## 1 Identity of substance

Priority Substance No: 1	Alachlor
CAS-Number:	15972-60-8
Classification WFD Priority List <sup>*</sup> :	PS

\* PS: priority substance; PHS: priority hazardous substance; PSR: priority substance under review according to Decision 2455/2001.

## 2 Proposed quality standards

### 2.1 Overall quality standards

Ecosystem	Quality Standard	Quality Standard "rounded values"	Comment
AA-QS all types of surface waters addressed by the WFD	0.25 µg/l	<b>0.3 µg/l</b>	See section 8.1
MAC-QS (ECO)	0.65 µg/l	<b>0.7 µg/l</b>	See section 8.1

### 2.2 Specific quality standards

Protection Objective <sup>#</sup>	Quality Standard	Comment
Pelagic community (freshwater, saltwater)	FHI: 0.25 µg/l	See section 8.1
Benthic community (freshwater & marine sediment)	Derivation not required	A new chironomus study confirms that QS for freshwater can be applied for benthic organisms.
Predators (secondary poisoning)	derivation of QS not required	trigger values for QS derivation not met, the BCF of alachlor is 50; see section 8.3
Food uptake by man	304 µg/kg seafood corresponding conc. in water 6.1 µg/l	based on ADI; see section 8.4
Abstraction of water intended for human consumption (AWIHC)	< 1 µg/l	A-1 value in CD 75/440/EEC for Σ pesticides is 1 µg/l; see 8.5
Water intended for human consumption (WIHC)	0.1 µg/l	Drinking water standard set in CD 98/83/EC

<sup>#</sup> If justified by substance properties or data available, QS for the different protection objectives are given independently for freshwater environments, transitional waters or coastal and territorial waters

### 3 Classification

R-Phrases and Labelling	Reference
Carc. Cat. 3; R40 - Xn; R22 - R43 - N; R50-53	[10]

### 4 Physical and chemical properties

Property	Value	Ref.
Vapour pressure	2.0 x 10 <sup>-3</sup> Pa at 25°C 1.32 x 10 <sup>-3</sup> Pa at 25°C 2.9 mPa at 25°C	[1]
Henry's law constant	3.2 x 10 <sup>-3</sup> Pa x m <sup>3</sup> x mol <sup>-1</sup> (at 20°C) 2.263 x 10 <sup>-3</sup> Pa/m <sup>3</sup> /mole	[1]
Solubility in water	0.13554 g/l at pH 7 & 5° C – 0.247 g/l at pH 6.6 & 25°C	[1]
Dissociation constant	material has no ionisable groups or dissociation constant	[1]

### 5 Environmental fate and partitioning

Property	Value	Ref.
Hydrolytic stability (DT <sub>50</sub> )	pH=5 DT50 >1y, 25 °C pH=7 DT50 >1y, 25 °C pH=9 DT50 >1y, 25 °C	[1]
Photostability (DT <sub>50</sub> ) (aqueous, sunlight, state pH)	ε <10 at λ = 290 nm.	[1]
Readily biodegradable (yes/no)	not ready biodegradable  Although a rapid degradation of alachlor under anaerobic laboratory conditions was reported, most data suggest that the rate of anaerobic degradation of alachlor would be very low.	[1]
Degradation in Water/sediment -DT <sub>50</sub> water - DT <sub>50</sub> whole system	23.7-22.24 d 21.1-41.7 d	[1]
Mineralization	very low mineralization level	[1]
Bound residue		[1]
Distribution in water / sediment systems (active substance)	1.08-3.75% (100 days)	[1]
Residues relevant to the aquatic environment	parent compound and metabolite M52 (for surface water and sediment)	[1]
Partition co-efficient (log P <sub>OW</sub> )	2.97	[1]
Koc	111.87 l/kg (average Koc in 8 soils) 103.9-192 (Koc range in 8 soils) log Koc 2.0-2.28 (100 – 190, published literature)	[1]
BCF (fish)	50	[1]

## 6 Effect data and effects assessment

### 6.1 Water

The Rapporteur (Spain) for the alachlor risk assessment in the context of Council Directive 91/414/EEC has conducted a new risk assessment of alachlor based on new information provided by the notifier. This information includes single species laboratory studies with 2 different alachlor formulations (lasso EC and MT) on different algae and aquatic plants as well as two microcosm studies and a mesocosm study.<sup>[9]</sup>

Alachlor is more toxic for algae and aquatic plants as was to be expected. The Rapporteur Member State considers the mesocosm study as most relevant for the assessment of the environmental risk of alachlor for aquatic organisms.<sup>[9]</sup>

Table 6.1: Relevant toxicity data for fish, aquatic invertebrates, algae and aquatic plants obtained in **single species laboratory tests** (data from alachlor monograph<sup>[6]</sup>, provided by Rapporteur)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Fish	Alachlor technical	Acute	96 h LC50	1.8
Fish	Alachlor formulation (Lasso M)	Acute	96 h LC50	1.5 (ai)
Fish	Alachlor technical	Chronic	96 d NOEC	0.19
Fish	Alachlor formulation (Sanachlor 480 EC)	Chronic	14 days NOEC	0.25
<i>Daphnia magna</i>	Alachlor technical	Acute	48 h LC50	10
<i>Daphnia magna</i>	Alachlor formulation (Alachlor 480 g/l EC)	Acute	48 h LC50	7.2 (ai)
<i>Daphnia magna</i>	Alachlor technical	Chronic	21 d NOEC	0.23
<i>Daphnia magna</i>	Alachlor formulation (Salachlor 480 EC)	Chronic	21 d NOEC	0.23
<i>Chironomus riparius</i>	Alachlor technical	Chronic	28d NOEC	0.75
Algae	Alachlor technical	Chronic	120 h NOEC	0.00035
Algae ( <i>Selenastrum capricornutum</i> )	Alachlor technical	Acute	96 h EC50	0.0029
Algae	Alachlor formulation (alachlor 480 g/l)	Chronic	72 h NOEC	0.0022 (0.001 ai)
Algae	Alachlor	Acute	EC50 72 h	0.0019

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
	technical			
Algae	Alachlor formulation (alachlor 480 g/l)	Acute	EC50 72 h	0.0063 (0.003024 ai)
Algae	Alachlor formulation (alachlor 42.55%)	Acute	EC50 72 h	0.057
Algae ( <i>Selenastrum capricornutum</i> )	Alachlor formulation (Lasso EC)	Acute	EC50 72 h	0.0026 (ai)
Algae ( <i>Skeletonema costatum</i> )	Alachlor formulation (Lasso EC)	Acute	EC50 72 h	0.167 (ai)
Algae ( <i>Selenastrum capricornutum</i> )	Alachlor formulation (Lasso MT)	Acute	EC50 72h	0.0196( ai)
Algae ( <i>Skeletonema costatum</i> )	Alachlor formulation (Lasso MT)	Acute	EC50 72h	>0.226 (ai)
Aquatic plants ( <i>Lemna gibba</i> )	Alachlor formulation (Lasso EC)	Acute	EC 50 7 d	0.0068 (ai)
Aquatic plants ( <i>Lemna gibba</i> )	Alachlor formulation (Lasso MT)	Acute	EC 50 7 d	0.119 (ai)
Aquatic plants ( <i>Glyceria maxima</i> )	Alachlor formulation (Lasso MT)	Acute	EC 50 21 d NOEC 21d	>0.220 (ai) 0.220 (ai)
Aquatic plants ( <i>Lagarosiphon major</i> )	Alachlor formulation (Lasso MT)	Acute	EC 50 14 d NOEC 14 d	0.251 (ai) 0.0647 (ai)
Aquatic plant	Alachlor technical	Acute	14 d IC50	0.0023

### Mesocosm study<sup>[8]</sup>

(Description of the study and its results by Rapporteur)<sup>[9]</sup>

Guidelines: SETAC: Guidance Document on Higher tier Aquatic Risk Assessment for Pesticides (HARAP, 1999); SETAC/OECD: Guidance Document on Community Level Aquatic System Studies Interpretation Criteria (CLASSIC, 2000)

*Methodological deviations from the protocol: The alachlor formulation MON 39801 was used in the study instead of the newer alachlor emulsifiable concentrate formulation MON 39806. Since the difference between the two formulations is limited to only 1% by weight, this deviation is not considered to have affected the outcome of the study. At times some deviations were made from the time schedule proposed in the protocol. Since these deviations were never more than one day, they are not considered to have had an impact on the study results. During the 24-h dissolved oxygen monitoring, water temperature was measured as well. The values collected for water conductivity were not used in the discussion of the results because of calibration problems during*

the study. All these deviations are not considered to have affected the outcome or validity of the study.

The study was conducted under GLP.

Test conditions:

An outdoor mesocosm test was performed to investigate the fate and effect of a concentration series of MON 39801 (Lot A0G0705104, 44.3% w/w alachlor) on an aquatic ecosystem. The mesocosms consisted of circular glass-fibre tanks with a diameter of approximately 2 meters. The mesocosms were filled with a 15 cm thick layer of natural sediment, covered with an 85 cm deep column of natural surface water. Both water and sediment were taken from a relatively unpolluted lake in the Netherlands, the Markermeer. Phytoplankton, zooplankton and benthic organisms entered the systems with the natural water and sediment. Additional macrophyte and macrofauna species were also introduced into the mesocosms. Macrophytes included two submerged species (*Elodea Canadensis* and *Myriophyllum spicatum*), three emerging species (*Phragmites australis*, *Iris pseudacorus* and *Juncus effusus*) and one floating species (*Lemna gibba*). The macrofauna introduced into the mesocosms included bivalves (*Corbicula fluminae*), gastropods (*Bithynia tentaculata* and *Lymnaea stagnalis*), annelids (*Tubificidae*), crustaceans (*Asellus aquaticus* and *Gammarus sp.*). To determine effects at intermediate time points during the study, some macrofauna species, such as bivalves and crustaceans, were enclosed in cages. Finally, several flying insects naturally colonised the mesocosms. During the 29-day establishment phase, the water columns of all mesocosms were connected by means of a recirculation system to ensure similar development in all systems.

At the start of the exposure phase the mesocosms were disconnected from each other. For each mesocosm, required amounts of MON 39801 were diluted in 5 L of demineralised water and the solution was sprayed on the water surfaces of the mesocosms at nominal concentrations of 0.1, 0.4, 1.8, 7.4 and 31.1 µg a.i./L, along with a control. There were two replicates for each of the MON 39801 treatment levels and three replicates for the control level. The exposure phase started on the 4<sup>th</sup> June 2002 and lasted for 56 days.

Biological observations on all the components of the mesocosms were made at regular intervals during the exposure phase. Phytoplankton and zooplankton density and species composition were determined on Days -1, 3 and 6 and afterwards at weekly intervals. For submerged and floating macrophytes, effects of both a chronic (during the whole exposure period) and a short-term (in 14-day assays) exposure were assessed. The 14-day assays were performed by determining the variation in biomass of plants introduced in small pots (submerged species) or in floating baskets (floating species). New plants were added to the mesocosms after such assessments. The assessments started on Day -1 and were conducted every 14 days. Emerging macrophytes were introduced in small pots and their stems cut at a height of 2.5 cm during the establishment phase. Height development, number of stems emerging from the water surface, flower and seed production were monitored on Day -1 and afterwards at 14-day intervals. The development of periphyton in the mesocosms was followed during the course of the study by determination of the biomass (as chlorophyll a) on glass microscope slides. Two sets of slides were introduced in the tanks, which were sampled alternately every 14 days and replaced by new slides. The exposure period for each set of slides was therefore 28 days. The assessments of periphyton biomass were conducted on Day -1 and at 14-day interval afterwards. Finally assessments were made on the macrofauna species. The number of emerging insects and of snail egg packages on substrate were determined on Days -1 and 6 and afterwards at weekly intervals. The survival of enclosed species was assessed every 14 days during the exposure phase. The number of animals trapped in litter traps were determined on Day -1 and afterwards at biweekly intervals. At the end of the

exposure phase, besides the assessments described above, the biomass of the chronically exposed macrophytes and of the annelids were determined.

Water and sediment samples were collected on Days 0, 1, 3, 7, 13, 27 and 55 for determination of alachlor concentrations by GC-MS.

At the end of the mesocosm study, a 17-day post mesocosm assay was performed for *Elodea canadensis* and for *Iris pseudacorus*. One tank (height 80 cm and diameter 40 cm) for each of the mesocosms was filled with water from the corresponding mesocosm water and was then supplemented with nutrients to mitigate their limitation. Rooted *E. canadensis* plants from the mesocosms were introduced in a basket (diameter of approximately 30 cm) containing approximately 20 cm of the corresponding mesocosm sediment. Baskets were placed on the bottom of the tanks. Additionally, two small pots filled with mesocosm sediment and containing groups of 4 stems of *E. canadensis* were introduced into the tanks following the procedure for the macrophyte bioassay used during the exposure phase. This procedure was also followed for newly acquired plants of *Iris pseudacorus*. The test containers were aerated gently to mix the water column and to stimulate gas exchange. At the end of the post mesocosm assay the biomass of *E. canadensis* and the number of leaves, the height and the biomass above the sediment of *I. pseudacorus* were determined.

Univariate (Dunnnett's multiple comparison test) and multivariate (redundancy analysis (RDA) and principal response curve analysis (PRC)) statistical analyses were conducted. Differences in any of the measured parameters were considered significant if  $p < 0.05$ .

#### Findings:

A summary of the significant effects observed in the mesocosms is given in Table 6.2. The majority of the species were not affected by exposure to MON 39801, indicating that the NOEC for these taxa is the highest concentration tested (i.e. 31.1 µg a.i./L). A list of these species is provided in Table 6.3.

Exposure of the freshwater community to MON 39801 resulted in various effects ranging from a slight stimulation of specific phytoplankton species at the lower test concentrations to a significant reduction in the development of some macrophyte species in the mesocosms at the highest test concentration. The majority of the observed effects were rather subtle. No species were eliminated by the treatment and recovery was seen in most of the cases. Although the highest test concentrations reduced macrophyte production, the affected macrophytes were not killed and during the study oxygen concentrations were never lower than 8 mg/L (i.e. 85% of air saturation at the water temperature observed on that occasion). Also, the zooplankton community was not directly affected by MON 39801 nor was it indirectly impacted by MON 39801 by effects to their main food source, the phytoplankton. Overall, application of MON 39801 did not result in a substantial change to either ecosystem structure or function.

Recovery of ecosystem structure and function within the exposure period was observed in all mesocosms with exception of the 31.1 µg a.i./L treatment. Observed effects to macrophytes in the 31.1 µg a.i./L treatment were reversed in the post mesocosm assay.

During the exposure period, air temperature ranged from 13.3 to 26.6°C and the rainfall was equivalent to 148.8 mm. The average water temperature during the exposure phase was 18.9°C, generally ranging between 15 and 20°C. The highest recorded water temperature was 24.6°C.

Initial measured alachlor concentrations in the water column ranged between 60 and 100% of the nominal concentrations. Initial mean measured concentrations were 0.07, 0.30, 1.30, 5.65 and 30.5 µg a.i./L for the 0.1, 0.4, 1.8, 7.4 and 31.1 µg a.i./L treatments, respectively. The half-life of



alachlor in the water column ranged between 10.2 and 20.2 days, with an average of 15.5 days. Alachlor concentrations were below the detection limit of 0.01 mg/kg in all sediment samples.

Conclusion:

The rapporteur is the opinion that a NOEC<sub>mesocosm</sub> of 7.4 µg a.i./L as proposed by the notifier cannot be considered valid due to the nature and duration of effects observed at this concentration (i.e., decreased biomass of *Elodea canadensis* still at day 56 post treatment, recovery only observed in the post-test period from day 56 to 73, see table 6.2). In the opinion of the rapporteur, 0.4 µg a.i. /L could be considered as valid NOEC of the system. At this concentration, no significant effects were observed for any taxonomic group (the effects observed at 0.1µg a.i./L were not treatment related). The rapporteur considers 1.3 µg a.i./L (analysed concentration, nominal 1.8µg/l) as Environmentally Acceptable Concentration (EAC) of this study due to the low ecological relevance of the effects observed at this concentration and complete recovery at the end of the study at day 56.

In line with the opinion of the MS-Rapporteur, the consultant FHI considers the transient decrease of the total number of trapped chironomid larvae at the 1.3 µg/l exposure levels (table 6.2) as not relevant for the assessment of alachlor because the reduction in chironomid numbers was not concentration dependent (i.e. no dose-response relationship observed). Further, this effect occurred only in one trapping interval (days 13-27, counting of trapped larve at the end of the 14 day exposure interval) whereas in three other observation intervals (days 0-13, 27-41, 41-55) no reduction of trapped chironomidae in relation to the controls were observed (see figure 1). Because of a lacking concentration-effect relationship, this transient decrease in chironomid larvae abundance cannot be attributed as effect caused by the test substance alachlor. This is as well true for the second effect seen at the 1.3 µg/l exposure level, the increase in density of flagellates >10 µm (see table 6.2).

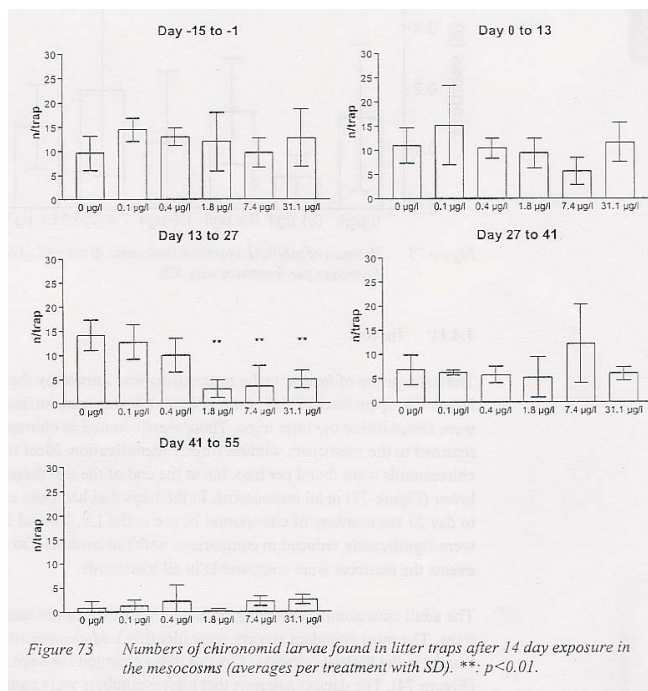


Figure 1: Numbers of chironomid larvae in relation to treatment levels [8]

Table 6.2: Effects observed on the freshwater community at the MON 39801 treatments tested in the study. The affected taxa/endpoints, the effect type, the first day the effect was observed and the last day the effect was observed (recovered) are listed.

Initial concentration (4h post treatment) / Taxa/Endpoints	Effect	Day	Recovered
<b>0.065 µg a.i./L (analysed)</b> 0.1 µg a.i./L (nominal)			
Flagellates 3-10 µm	Increased density	20	Day 27
Flagellates >10 µm	Increased density	20	Day 27
<i>Ankyra ancora</i>	Increased density	20	Day 48
<b>0.30 µg a.i./L (analysed)</b> 0.4 µg a.i./L (nominal)	No significant effects were observed		
<b>1.3 µg a.i./L (analysed)</b> 1.8 µg a.i./L (nominal)			
Chironomid larvae	Reduced numbers trapped	13-27	Day 27-41
Flagellates >10 µm	Increased density	55	-
<b>5.65 µg a.i./L (analysed)</b> 7.4 µg a.i./L (nominal)			
PH	Decrease	20	Day 30
Flagellates <3 µm	Increased density	27	Day 34
Chironomid larvae	Reduced numbers trapped	13-27	Day 27-41
<i>Elodea canadensis</i>	Decreased biomass	56	Day 56-73, in post test
Dissolved oxygen	Decreased concentration	55	-
<b>30.5 µg a.i./L (analysed)</b> 31.1 µg/l µg a.i./L (nominal)			
<i>Asellus aquaticus</i>	Reduced survival	0-13	Day 13-27
Chironomid larvae	Reduced numbers trapped	13-27	Day 27-41
<i>Ankyra ancora</i>	Decreased density	48	Day 55
<i>Amphora veneta</i>	Decreased density	27-55	-
PH	Decrease	6	No
Dissolved oxygen	Decreased concentration	13	No
Flagellates >10 µm	Density increase	48	No
<i>Lemna gibba</i> (chronic)	Accelerated senescence	55	No
<i>Iris pseudacorus</i>	Reduced growth	27	Day 56-73, new plants in post test
<i>Elodea canadensis</i>	Decreased biomass	56	Day 56-73, in post test
<i>canadensis</i>	Reduced growth rate	13	Day 27-41
<i>Myriophyllum spicatum</i>	Increased biomass	56	-

Table 6.3: List of taxa/endpoints not affected by the MON 39801 treatment.

<b>Phytoplankton</b>	<b>Macrophytes</b>	<b>Zooplankton</b>	<b>Amphipods</b>
Algal biomass	<i>Juncus effusus</i>	<i>Daphnia longispina</i>	<i>Gammarus</i> sp.
Flagellates 3-10 µm	<i>Phragmites australis</i>	<i>Bosmina</i> sp.	
<i>Crucigenia</i> sp.		<i>Ceriodaphnia</i> sp.	
Periphyton biomass		<i>Chydorids</i>	
		<i>Cyclopoid copepods</i>	
		<i>Calanoid copepods</i>	
		<i>Polyarthra</i> sp.	
		<i>Keratella</i> sp.	
		<i>Filinia</i> sp.	
<b>Molluscs</b>	<b>Annelids</b>	<b>Insects</b>	
<i>Corbicula fluminae</i>	Tubificid worms	<i>Micropsectra tenellula</i>	
<i>Bithynia tentaculata</i>		<i>Corynoneura carriana</i>	
		<i>Procladius choreus</i>	
		<i>Tanytarsus gregarius</i>	

## 6.2 Sediment

The effects of alachlor (lot no. GLP-9905-9564-T, purity 94.3%) on the life cycle of the midge (*Chironomus riparius*) were determined in a 28-day study under static conditions with aeration. The study was conducted under GLP with some exceptions, and followed the draft OECD guidelines (guideline 219).

Description of test conditions, findings and conclusions by the rapporteur<sup>[11]</sup>:

### Test conditions:

Groups of twenty midge larvae (2 days old) were exposed in a water:sediment system composed of well water (300 mL per group) and natural sediment (75 mL per group) for 28 days to nominal concentrations of <sup>14</sup>C-alachlor at 0.75, 1.5, 3.0, 6.0, and 12 mg/L. A solvent (acetone) control at the highest solvent concentration (0.10 mL/L) and a dilution water control were included in addition to the test concentrations. There were eight replicates for each test concentration: four replicates for the monitoring of biological results, and four replicates for determining exposure concentrations of alachlor in the overlying water, pore water, and sediment. Well water and field-collected sediment from a freshwater site were used in the test; calcium carbonate (1.0 g/kg) was added to buffer the sediment. The water : sediment volume ratio was 4:1, and the sediment depth was 1.5 cm. The test vessels were kept in a water bath at a target temperature of 20 ± 2 °C under fluorescent lighting with a 16:8 hour light:dark regimen. Test vessels were gently aerated (1 to 3 bubbles/second) beginning 4 days prior to addition of test organisms and throughout the duration of the exposure period, except for 24 hours immediately after addition of the larvae to the test vessels.

Water and sediment were placed in the test vessels 7 days before test initiation; midge larvae were added to the test vessels 1 day before test initiation. Aeration was suspended from just before larvae addition to 24 hours after larvae addition. Midge larvae were fed flaked fish food (5 mg) daily beginning before addition of the larvae to the test vessels and throughout the exposure period. The amount of food was doubled from test day 11 onwards. All vessels were observed for midge emergence and abnormal behaviour at test initiation and daily during the 28-day exposure period. The sex and number of adult midge that emerged daily were recorded. Adult midge were then removed from the vessels to avoid the introduction of egg ropes into the test vessel. The

development rate of male, female, and male and female midge combined was determined for each exposure vessel.

Dissolved oxygen, and temperature of each replicate were measured on day -1, day 0, and daily through the exposure period. On day -1, day 0 and day 28, pH was also measured in each test vessel. Temperature was also measured continuously in one replicate throughout the exposure period. Water quality parameters (total hardness, total alkalinity, specific conductivity, and ammonia) were measured on Days 0 and 28 in overlying water of a composite sample from the solvent control and the 12 mg/L test concentration. Conditions of the test solutions were observed at the beginning and the end of the exposure. Samples were removed for alachlor concentration measurements in the overlying water, pore water, and sediment on Day 0, 7, and 28. Alachlor and selected degradates were quantified in water and sediment of the lowest, middle and highest test concentrations (0.75, 3.0, and 12 mg/L) by HPLC with radiochemical detection. Flow-through radioactivity detection was used to characterize the nature of the radioactivity in the day 7 sediment and water samples and the day 28 sediment samples from the 3.0 and 12 mg/L test concentrations. Fraction collection (LCS) was utilized for day 7 and day 28 water and sediment samples from the 0.75 mg/L concentration and the day 28 water samples from the 3.0 and 12 mg/L concentrations. Pore water samples were analyzed directly by liquid scintillation counting.

#### Findings:

Effects of alachlor on midge emergence and development rate are reported in Table 6.4. Effects were analysed using the mean replicate organism response in each treatment group. Based on the analysis of stock solutions and stock solution volumes added, the Day 0 concentrations in overlying water were 89 to 103% of nominal values. Since a natural sediment was used, degradation of alachlor occurred during the exposure period, and degradation products were formed. On Day 28, for the 0.75, 3.0, and 12 mg/L concentrations, the total amount of alachlor present in both the sediment and water was found to represent 18, 24, and 38% of the applied radioactivity, respectively. For the 0.75 mg/L test concentration, on day 28, 28% of total radioactivity was found in the water column, 22% could be extracted from the sediment, and the remaining radioactivity could not be extracted from the sediment. The majority of the radioactivity extracted from the sediment on day 28 had the retention time of alachlor (59 %) while only 19% of the radioactivity in the water phase was alachlor. For the two higher test concentrations, a larger percentage of applied radioactivity was present in the system as alachlor. In the 0.75 mg/L test concentration where more sensitive analysis was available as a result of fraction collection, at least 14 other peaks were observed in the water or sediment extracts on day 28 with the largest peak (possibly *t*-oxanilic acid) comprising 8.4% and 1.8% of the applied radioactivity found in the water and sediment extracts, respectively.

The temperature measured during the test for the continuously monitored replicate and the daily manual temperature measurements ranged from 19 to 23 °C. pH values ranged from 7.8 to 8.1 and dissolved oxygen values ranged from 7.0 to 9.4 mg/L. Light intensity (measured after termination of the test) ranged from 970 to 1300 lux.

Results were expressed based on the nominal concentrations.

Table 6.4: Effects of alachlor to the midge (*Chironomus riparius*) under static conditions

Alachlor concentration (mg/L) <sup>1</sup>	Mean Percent Emerged	Mean Development Rate (day <sup>-1</sup> )		
		Male	Female	Combined Male/Female
Control	93	0.0663	0.0577	0.0620
Solvent control	94	0.0646	0.0592	0.0623
Pooled control	93	0.0654	0.0585	0.0621
0.75	90	0.0651	0.0564	0.0611
1.5	80	0.0635	0.0562	0.0587 *
3.0	69 *	0.0602 *	0.0506 *	0.0543 *
6.0	80	0.0593 *	0.0505 *	0.0549 *
12	65 *	0.0556 *	0.0470 *	0.0515 *

<sup>1</sup> Nominal values.

\* Statistically different compared to pooled control data ( $p < 0.05$ ).

### Conclusions:

Minimum standard criteria from the OECD 219 draft guideline were met (=70% emergence, development rate =0.0444 and =0.0870, and mean emergence between day 12 and 23 in the controls). Based on nominal concentrations applied and the male/female midge development rate, the 28-day no-observed-effect-concentration (**NOEC**) of alachlor was determined to be **0.75 mg a.i./L** based on a 5.5% reduction in male/female development rate. The NOEC for only male or only female development rate is 1.5 mg/L. The 28-day EC<sub>50</sub>, based on midge emergence, was estimated to be > 12 mg a.i./L.

### 6.3 Effects relevant for the food chain (secondary poisoning)

Table 6.5: Mammal and bird oral toxicity data relevant for the assessment of non compartment specific effects relevant for the food chain (secondary poisoning)

Type of study	Species, test result	Ref.
Long-term toxicity to mammals	Rat developmental NOAEL = 150 mg/kg bw/day	[1]
Acute oral toxicity to birds	Chicken, LD50 916 mg/kg bw	[1]
Short term dietary toxicity to birds	The toxicity of the active substance to all tested species is very low, with all LC <sub>50</sub> values greater than 5620 ppm. This figure is used for the estimations	[1]
Long-term toxicity to birds	No information on the chronic toxicity of alachlor technical on birds has been presented	[1]
Reproductive toxicity to birds	Mallard duck NOEC = 50 ppm ai.	[1]

## 6.4 Summary on endocrine disrupting potential

Comment	Reference
Alachlor is a substance with evidence of ED or evidence of potential ED.	[2]
The new addendum to the monograph includes studies to assess the endocrine disruption of alachlor. The conclusion is that alachlor capacity to disrupt endocrine systems appears to be low. However, since it has been reported that alachlor is able to interact with estrogen receptor in some species/systems, it could be matter of concern in these particular cases.	Rapporteur-MS (Spain) [9]

## 7 Effect data (human health)

Table 7.1: Acceptable daily intake as derived in the risk assessment monograph<sup>[1]</sup>

	Value	Study	Safety factor
ADI	0.005 mg/kg/day	The ADI is calculated on the basis of chronic feeding studies in the dog, rat, mouse, and reproductive toxicity in rat and rabbit. It is also assumed that nasal tumours in rats are not formed via a genotoxic mechanism for which exists a threshold, and that these tumours are not relevant to humans. With all these premises, an acceptable daily intake (ADI) should be based on the lowest No Observed Effect Level in rodents which is 0.5 mg/kg/day for rat.	100

## 8 Calculation of quality standards

### 8.1 Quality standards for water

#### *Freshwater*

Long-term single species test validated in the context of the risk assessment under Council Directive 91/414/EEC are available for fish, aquatic invertebrates (crustacean and insect species), algae and higher plants. Higher plants and in particular algae are the by far most sensitive organisms. For algae and higher plants, NOECs obtained in single species tests range from 0.35 – 220 µg/l (table 6.1). With the conventional assessment factor approach (equivalent to the long-term toxicity exposure ratio trigger (TER) of the plant protection product risk assessment), the quality standard for the protection of the freshwater pelagic community would be derived on the basis of the lowest NOEC available (0.35 µg/l) divided by an assessment factor of 10. This approach would hence result in a  $QS_{\text{freshwater}}$  of 0.035 µg/l.

However, there is a mesocosm study available in that the substance was tested under more environmentally realistic and relevant conditions as in the single species tests. The larger degree of realism is the reason why mesocosm studies are used to refine the effects assessment. Very often it can be shown that the occurrence of low effect concentrations seen in single species test is not realistic under environmentally more relevant conditions. In such cases, the results of the more complex and environmentally realistic test systems are normally used to override the single species test results.

For this reason, is suggested by the Rapporteur Member State to use the available Higher-Tier mesocosm study<sup>[8]</sup> as basis for the derivation of a water quality standard referring to the protection of the pelagic community.

However, the initially measured concentration of 1.3 µg a.i./l suggested by the rapporteur (section 6.1, Conclusion)<sup>[9]</sup>, cannot be considered as “ecologically acceptable concentration” (EAC) for the purpose of quality standard setting<sup>1</sup>.

In contrast to the exposure situation at the edge of a field (occasional exposure, time for recovery between exposure events) the exposure situation in a draining river is different and might best be characterized as prolonged exposure over the entire period in that an active substance is used, however at levels normally lower than the PEC estimates for a “edge of the field scenario”. Because the exposure pattern to be considered for a quality standard is different, absence of the occurrence of effects upon exposure rather than the potential to recover to the *status quo ante* within some weeks upon exposure to a single peak is the decisive criterion. The long-term quality standard in the context of the Water Framework Directive refers by definition to an average concentration over a prolonged time interval. Hence, **not the potential to recover after transient exposure but long-term undisturbed function and lack of impact on community structure of aquatic ecosystems at a prevailing average concentration level set by the QS is the protection objective under the WFD.**

Therefore, the time weighted average concentration ( $C_{TWA}$ ) from the start of the exposure until complete recovery of observed transient effects is the decisive parameter for the QS derivation. Based on the data shown in Figure A2.1 (Annex 2), this  $C_{TWA}$  can be estimated as being 0.75 µg a.i./l<sup>2</sup>.

As a further factor to be considered in the derivation of the quality standard, the representativeness of the microcosm/mesocosm test system(s) for the water bodies to be covered by the quality standard needs to be taken into account. The QS must be protective for all types of surface waters and communities that are addressed by the standard. There is however only one mesocosm study available and this study is, as usual in the context of the plant protection product risk assessment, focused to water body types occurring in the immediate vicinity of agriculturally used areas. A QS under the WFD, however, must assure protection also for water bodies that significantly differ from this paradigm<sup>[7]</sup>.

Taking the above considerations into account, an additional assessment factor of 3 on the  $C_{TWA}$  of 0.75 µg/l seems appropriate to derive the required annual average quality standard for the protection of the pelagic community. The resulting quality standard covers the lowest NOEC of 0.35 µg/l obtained in single species tests but is approximately 7-fold higher than the QS derived with this single species NOEC by the conventional assessment factor method.

$$QS_{\text{freshwater}} = C_{TWA} (0.75 \mu\text{g/l}) / AF (3) = 0.25 \mu\text{g alachlor / l}$$

### **Transitional, coastal and territorial waters**

The mode of action of alachlor appears to be inhibition of protein synthesis in susceptible plants<sup>[1]</sup> Algae and higher plants appear to be the by far most sensitive organisms (see table 6.1). Effects data on a marine alga species (*Skeletonema costatum*) have been included in the monograph. The results showed that the lowest acute value corresponds to freshwater algae and no specific

<sup>1</sup> Differences in the objectives of the risk assessment for plant protection products and environmental quality standard setting are set out in section 4.3.5 of the Manual<sup>[4]</sup>.

<sup>2</sup> Figures of water concentrations analysed during the study were not available from the mesocosm-report<sup>[8]</sup>. Therefore, the  $C_{TWA}$  was estimated from the data shown in figure A2.1. The measured initial concentration for the (nominal) 1.8 µg/l exposure level was 1.3 µg/l at day 0 and dropped nearly linearly to approx. 0.2 µg/l.  $C_{TWA}$  was estimated as follows:  $((1.3 \mu\text{g/l} - 0.2 \mu\text{g/l}) * 0.5) + 0.2 \mu\text{g/l} = 0.75 \mu\text{g/l}$ .

differences for marine organisms are detected<sup>3</sup>. Thus, the rapporteur proposes<sup>[9]</sup> to set the same QS for transitional, coastal and territorial waters than for freshwater.

$$QS_{\text{saltwater}} = QS_{\text{freshwater}} = 0.25 \mu\text{g alachlor / l}$$

### **Quality standard accounting for transient concentration peaks (MAC-QS)**

Acute single species toxicity tests for fish, crustaceans, algae and higher plants were validated in the context of the risk assessment under Council Directive 91/414/EEC. Algae are the most sensitive species and the lowest EC50 in the data set is 1.9 µg/l. As algae are clearly the most sensitive species (the mode of action of alachlor appears to be inhibition of protein synthesis in susceptible plants<sup>[1]</sup>), an assessment factor ( $\approx$  short-term toxicity exposure ratio (TER) trigger) of 10 would be appropriate to derive the MAC-QS by the conventional assessment factor method. The resulting MAC-QS would be 0.19 µg/l.

It is, however, again suggested to derive the MAC-QS on the basis of the available Higher-Tier mesocosm study, as best use should be made of data obtained with test systems that are closer to reality than single species tests. At an initial concentration (i.e. a single transient concentration peak, exactly the exposure pattern to be covered by the MAC-QS) of 1.3 µg a.i./L, denominated as the "Ecologically Acceptable Concentration" (EAC) by the Rapporteur, no treatment related effects could be observed. The next higher concentration of initially 5.65 µg/l (measured) caused already severe long lasting effects on the growth of the macrophyte *Elodea canadensis*. (approximately 25-30% reduction in biomass at the end of the testing period at day 56 (see Figure A2.2 in Annex 2), recovery of *Elodea* did only occur in the post testing period, starting 56 days after the initial exposure event<sup>[8]</sup>).

For the derivation of the MAC-QS the highest initial concentrations in Higher-Tier studies that caused no ecologically relevant effects should ideally be used as starting point<sup>[7]</sup>. However, a thorough evaluation of the study results and the expected exposure pattern of the active substance in draining water bodies of a catchment area is required. Time needed to recover from impacts (if any) versus the probability that concentrations that caused the observed effects will recur is the decisive criterion. A further criterion to be considered is the representativeness of the microcosm/mesocosm test system(s) for the water bodies to be covered by the quality standard. The MAC-QS must be protective for all types of inland and transitional surface waters that are addressed by the standard.

Based on these considerations an assessment factor of 2 applied on the lowest concentration that caused no treatment related effects in the mesocosm study (1.3 µg/l, analysed concentration) seems appropriate. The resulting MAC-QS is 3 times lower than the lowest EC50 seen in single species tests with algae and 3.5 times higher than the MAC-QS if it were derived with the assessment factor method and the lowest single species test.

$$\text{MAC-QS} = 1.3 \mu\text{g a.i. / l} / \text{AF (2)} = 0.65 \mu\text{g alachlor / l}$$

<sup>3</sup> Recently, The Netherlands provided newly generated data on a test of alachlor with a further marine alga species (*Phaeodactylum tricornutum*). 96 h NOEC, EC10 and EC50 values were  $\geq 0.005$  mg/L (the highest concentration tested)<sup>[7]</sup>. This test result corroborates the conclusion that marine algae are not more sensitive to alachlor than freshwater species.



## 8.2 Quality standard for sediment

The log  $K_{p_{susp}}$  of alachlor is 1.52 and therefore the trigger criterion to calculate a sediment quality standard is not met.

An ecotoxicological study conducted with chironomids and recently submitted confirms that the  $QS_{water}$  established to protect the pelagic community from waterborne exposure also protects the sediments (see section 6.2).

## 8.3 Secondary poisoning of top predators

A BCF-value of 50 is estimated for alachlor<sup>[1]</sup>. Hence, the trigger criterion for the derivation of a quality standard referring to the protection of top predators from secondary poisoning is not met ( $BCF \geq 100$ , see table 1a of the Manual<sup>[4]</sup>).

## 8.4 Quality Standards referring to food uptake by humans

Alachlor is classified as carcinogen of category 3. According to the monograph<sup>[1]</sup> the acceptable daily intake (ADI) of alachlor is 0.005 mg/kg bw/day.

In the Manual<sup>[4]</sup> it is suggested that the ADI may not be exhausted for more than 10% by consumption of food originating from aquatic sources. For a person weighing 70 kg this results in an acceptable daily intake of 35 µg alachlor per day.

The average fish consumption of an EU citizen is 115 g d<sup>-1</sup> (TGD<sup>[3]</sup>). Thus, 115 g edible fish tissue (or fishery products) must not contain more than 35 µg alachlor.

$$QS_{hh.food} = \frac{35 \mu\text{g Alachlor}}{115\text{g fishery products}} * 1000 \text{ g} = \mathbf{304 \mu\text{g Alachlor / kg fishery products}}$$

In the TGD approach for the assessment of secondary poisoning (see sections 4.3.2.5 and 4.3.2.6 of the Manual<sup>[4]</sup>) it is foreseen to consider bioconcentration and biomagnification as relevant factors affecting body burdens and the PEC, respectively. If no information on BMF values is available, it is proposed in the TGD to use default BMFs for substances with a  $BCF_{fish} > 2000$ .

As the  $BCF_{fish}$  of Alachlor is 50<sup>[5]</sup>, biomagnification is not considered for the calculation of the concentration in water corresponding to the  $QS_{hh.food}$ , which is calculated as follows:

$$QS_{hh.food.water} = \frac{QS_{hh.food} (304 [\mu\text{g/kg}])}{BCF (50 [\text{kg/l}])} = \mathbf{6.08 \mu\text{g Alachlor / l}}$$

## 8.5 Quality Standards for drinking water abstraction

The imperative A1 value referring to drinking water abstraction by simple treatment is 1 µg/l for the total amount of pesticides (Council Directive 75/440/EEC). The drinking water standard (DWS) set in CD 98/83/EC is 0.1 µg/l for individual pesticides.

The DWS is a limit value never to be exceeded at the tap. The MAC-QS (ECO) derived for the protection of the freshwater community may therefore not suffice to allow for compliance with the

DWS if only simple purification techniques (category A1 of CD 75/440/EEC, i.e. filtration and disinfection) are used for the abstraction of drinking water from surface water bodies according to Art. 7 of the WFD.

An assessment by experts in drinking water technology with regard to the question which fraction of alachlor present in raw water can be removed by usual simple treatment procedures might be helpful. If the respective fraction were known, this figure could be used together with the drinking water standard to set the maximum acceptable concentration in surface water bodies designated for the abstraction of water intended for human consumption (AWIHC).

**MAC-QS (AWIHC) = DWS (0.1 µg/l) / fraction not removable by simple treatment**

## 8.6 Overall quality standard

The  $QS_{\text{water}}$  referring to the protection of pelagic communities may be considered as overall annual average quality standard (AA-QS) for inland waters as well as transitional, coastal and territorial waters. If the drinking water standard is exceeded in areas designated for the abstraction of water intended for human consumption in accordance with Art. 7 of the WFD, specific measures need to be taken in order to guarantee compliance with the drinking water standard at the tap.

## 9 References

- [1] Monograph prepared in the context of the inclusion of the following active substance in Annex I of the Council Directive 91/414/EEC: Alachlor, Volume 1 –Report and Proposed Decision, Levels 1-4, Annexes A & B1-B9; Instituto Nacional de Inveestigació y Tecnología Agraria y Alimentaria (I.N.I.A.), April 1999
- [2] COM(2001)262 final: Communication from the Commission to the Council and the European Parliament on the implementation of the Community Strategy for Endocrine Disrupters – a range of substances suspected of interfering with the hormone system of humans and wildlife.
- [3] Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and the Council Concerning the placing of biocidal products on the market. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, © European Communities 2003. Available at the internet-site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-chemicals/>
- [4] Manual of the Methodological Framework Used to Derive Environmental Quality Standards for Priority Substances of the Water Framework Directive. Peter Lepper, Fraunhofer-Institute Molecular Biology and Applied Ecology, 15 November 2004. Available at the internet-site of the European Commission: [http://europa.eu.int/comm/environment/water/water-dangersub/pri\\_substances.htm](http://europa.eu.int/comm/environment/water/water-dangersub/pri_substances.htm)
- [5] MONSANTO Europe S.A.: Submission of data and a proposal for an environmental quality standard for Alachlor. Dossier dated 29 June 2001.
- [6] Tarazona JV, Pablos MV and Navas JM. 2003. Addendum B8- Ecotoxicology. Addendum to the Monograph prepared in the context of the inclusion of the following active substance in Annex I of the Council Directive 91/414/EEC: Alachlor, June 2003.
- [7] AquaSense (2005). Toxicity tests with priority substances in the Water Framework Directive. Sponsor: Institute for Inland Water Management and Waste Water Treatment (RIZA). Report number: 2034
- [8] Determination of the biological effect and fate of MON 39801 (43% w/w Alachlor) in outdoor ponds according to HARAP (1999) and CLASSIC (2000) guidance documents. TNO-report R2002/280, Intended for Monsanto Europe S.A. Unpublished.
- [9] Data sheet and quality standard proposal for alachlor. Personal communication (e-mail by Victoria Pablos, Instituto Nacional De Investigación Y Tecnología Agraria Y Alimentaria (I.N.I.A.), Madrid, 18.06.2003)
- [10] ESIS: European Chemicals Bureau – ESIS (European Substances Information System), July 2005. <http://ecb.jrc.it/existing-chemicals/> ⇒ tick ESIS button, then enter CAS or EINECS number of substance.
- [11] Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) on “The Setting of Environmental Quality Standards for the Priority Substances included in Annex X of Directive 2000/60/EC in Accordance with Article 16 thereof”, adopted by the CSTEE during the 43<sup>rd</sup> plenary meeting of 28 May 2004, European Commission Health & Consumer Protection Directorate General, Brussels. [http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out230\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out230_en.pdf)

## Annex 1: Aquatic toxicity data of alachlor (from Annex B.8 of [1])

The validated data are included in the following tables.

**Table 2.9.2-1: Summary of acute toxicity data on fish.**

Chemical	Test organisms	Test conditions	Toxicity endpoint	Result (mg a.i./l)
Technical alachlor	Bluegill sunfish	static/nominal	96 hours LC <sub>50</sub>	2.8
Technical alachlor	Rainbow trout	static/nominal	96 hours LC <sub>50</sub>	1.8
Technical alachlor	Channel catfish	static/nominal	96 hours LC <sub>50</sub>	2.1
Technical alachlor	Bluegill sunfish	flow-through/measured	96 hours LC <sub>50</sub>	5.5
Technical alachlor	Rainbow trout	flow-through/measured	96 hours LC <sub>50</sub>	5.3
Technical alachlor	Fathead minnow	flow-through/measured	96 hours LC <sub>50</sub>	5.0
Technical alachlor	Singui	static/nominal	96 hours LC <sub>50</sub>	3.7
Lasso M	Rainbow trout	static/nominal	96 hours LC <sub>50</sub>	1.5
Lasso M	Bluegill sunfish	static/nominal	96 hours LC <sub>50</sub>	3.2
Lasso EC	Rainbow trout	static/nominal	96 hours LC <sub>50</sub>	1.8
Lasso EC	Bluegill sunfish	static/nominal	96 hours LC <sub>50</sub>	2.8
Sanachlor 480 EC	Zebra fish	static/measured	96 hours LC <sub>50</sub>	1.8
Sanachlor 480 EC	Rainbow trout	static/measured	96 hours LC <sub>50</sub>	>2
Metabolite 65	Rainbow trout	static/measured	96 hours LC <sub>50</sub>	>104 mg/l
Metabolite 70	Rainbow trout	static/measured	96 hours LC <sub>50</sub>	>100 mg/l

**Table 2.9.2-2: Summary of acute toxicity data on aquatic invertebrates.**

Chemical	Test organisms	Test conditions	Toxicity endpoint	Result (mg a.i./l)
Technical alachlor	Daphnia magna	flow-through/measured	48 hours EC <sub>50</sub>	13
Technical alachlor	Daphnia magna	static/nominal	48 hours EC <sub>50</sub>	10
Technical alachlor	Daphnia magna	static/nominal	48 hours EC <sub>50</sub>	26
Technical alachlor	Crayfish	static/nominal	96 hours LC <sub>50</sub>	>320
Lasso EC	Daphnia magna	static/nominal	48 hours EC <sub>50</sub>	15.1
Lasso	Daphnia pulex	static/nominal	48 hours EC <sub>50</sub>	9.0
Sanachlor 480 EC	Daphnia magna	static/measured	48 hours EC <sub>50</sub>	10.8
Metabolite 65	Daphnia magna	static/measured	48 hours EC <sub>50</sub>	>104 mg/l
Metabolite 70	Daphnia magna	static/measured	48 hours EC <sub>50</sub>	>95 mg/l

Data added by the Rapporteur in autumn 2003

<i>Chironomus riparius</i>	Alachlor technical	Chronic	28d NOEC	0.75
----------------------------	--------------------	---------	----------	------

**Table 2.9.2-3:** Summary of chronic toxicity data on fish and aquatic invertebrates.

Chemical	Test organisms	Test conditions	Toxicity endpoint	Result (mg a.i./l)
Technical alachlor	Rainbow trout	flow-through/measured	96 days NOEC	0.19
Technical alachlor	Fathead minnow	flow-through/measured	60 days NOEC	0.52
Technical alachlor	Daphnia magna	flow-through/measured	21 days NOEC	0.23
Technical alachlor	Mud crab	static/nominal	NOEC developm.	14
Lasso	Mud crab	static/nominal	NOEC developm	10
Sanachlor 480 EC	Rainbow trout	flow-through/measured	14 days NOEC	0.25
Sanachlor 480 EC	Daphnia magna	flow-through /measured	21 days NOEC	0.23

**Table 2.9.2-4:** Summary of toxicity data on algae and aquatic plants.

Chemical	Test organisms	Toxicity endpoint	Result (mg a.i./l)
Technical alachlor	<i>Selenastrum capricornutum</i>	72 hours EC <sub>50</sub>	0.0012
Technical alachlor	<i>Selenastrum capricornutum</i>	120 hours NOEC	0.00035
Technical alachlor	<i>Selenastrum capricornutum</i>	72 hours EC <sub>50</sub>	0.00115
Technical alachlor	<i>Selenastrum capricornutum</i>	72 hours NOEC	0.006
Technical alachlor	<i>Selenastrum capricornutum</i>	96 hours EC <sub>50</sub>	0.062
Technical alachlor	<i>Selenastrum capricornutum</i>	96 hours NOEC	0.0056
Lasso EC	<i>Selenastrum capricornutum</i>	72 hours EC <sub>50</sub>	0.0082
Lasso EC	<i>Selenastrum capricornutum</i>	72 hours NOEC	0.0043
Sanachlor 480 EC	<i>Selenastrum capricornutum</i>	72 hours EC <sub>50</sub>	<0.005
Lasso	<i>Lemna minor</i>	48 hours EC <sub>50</sub>	0.01
Alachlor 48 %	<i>Chlorella pyrenoidosa</i>	96 hours EC <sub>50</sub>	0.096
Alachlor 48 %	<i>Chlorella pyrenoidosa</i>	96 hours NOEC	0.02
Alachlor 63.3 %	<i>Chlorella pyrenoidosa</i>	96 hours EC <sub>50</sub>	0.126
Alachlor 63.3 %	<i>Chlorella pyrenoidosa</i>	96 hours NOEC	0.05

Data added by the Rapporteur in autumn 2003

Chemical	Test organisms	Toxicity endpoint	Result (mg a.i./l)	
Alachlor technical	Algae	120 h NOEC	0.00035	Chronic
Alachlor technical	Algae ( <i>Selenastrum capricornutum</i> )	96 h EC50	0.0029	Acute
Alachlor formulation (alachlor 480 g/l)	Algae	72 h NOEC	0.0022 (0.001 ai)	Chronic
Alachlor technical	Algae	EC50 72 h	0.0019	Acute
Alachlor formulation (alachlor 480 g/l)	Algae	EC50 72 h	0.0063 (0.003024 ai)	Acute
Alachlor formulation (alachlor 42.55%)	Algae	EC50 72 h	0.057	Acute
Alachlor formulation (Lasso EC)	Algae ( <i>Selenastrum capricornutum</i> )	EC50 72 h	0.0026 (ai)	Acute
Alachlor formulation (Lasso EC)	Algae ( <i>Skeletonema costatum</i> )	EC50 72 h	0.167 (ai)	Acute
Alachlor formulation (Lasso MT)	Algae ( <i>Selenastrum capricornutum</i> )	EC50 72h	0.0196( ai)	Acute
Alachlor formulation (Lasso MT)	Algae ( <i>Skeletonema costatum</i> )	EC50 72h	>0.226 (ai)	Acute
Alachlor formulation (Lasso EC)	Aquatic plants ( <i>Lemna gibba</i> )	EC 50 7 d	0.0068 (ai)	Acute
Alachlor formulation (Lasso MT)	Aquatic plants ( <i>Lemna gibba</i> )	EC 50 7 d	0.119 (ai)	Acute
Alachlor formulation (Lasso MT)	Aquatic plants ( <i>Glyceria maxima</i> )	EC 50 21 d NOEC 21d	>0.220 (ai) 0.220 (ai)	Acute
Alachlor formulation (Lasso MT)	Aquatic plants ( <i>Lagarosiphon major</i> )	EC 50 14 d NOEC 14 d	0.251 (ai) 0.0647 (ai)	Acute
Metabolite 65	Algae	72 h EC50	3.5	Acute
Metabolite 70	Algae ( <i>Navicula pelliculosa</i> )	96 h EC50	>132	Acute
Metabolite 70	Algae ( <i>Selenastrum capricornutum</i> )	72 h EC50	>123	Acute
Metabolite 54	Algae ( <i>Navicula pelliculosa</i> )	72 h EC50	46	Acute
Metabolite 54	Algae ( <i>Selenastrum capricornutum</i> )	72 and 96h EC50	>127	Acute
Metabolite 78	Algae ( <i>Navicula pelliculosa</i> )	96 h EC50	>116	Acute
Metabolite 78	Algae ( <i>Selenastrum capricornutum</i> )	96 h EC50	>116	Acute
Metabolite 39	Algae ( <i>Selenastrum capricornutum</i> )	96 h EC50	55	Acute
Alachlor technical	Aquatic plant	14 d IC50	0.0023	Acute
Metabolite 65	Aquatic plant	14 d IC50	> 120	Acute
Metabolite 70	Aquatic plant ( <i>Lemna gibba</i> )	7 d IC50	> 203	Acute
Metabolite 54	Aquatic plant ( <i>Lemna gibba</i> )	7 d IC50	> 209	Acute
Metabolite 78	Aquatic plant ( <i>Lemna gibba</i> )	7 d IC50	>204	Acute
Metabolite 39	Aquatic plant ( <i>Lemna gibba</i> )	7 d IC50	68	Acute

[1]: The toxicity of the technical product and the different formulations falls within the same range, thus the lowest data for technical alachlor will be used in the assessment.

**Annex 2: Selected data of the mesocosm study<sup>[8]</sup>**

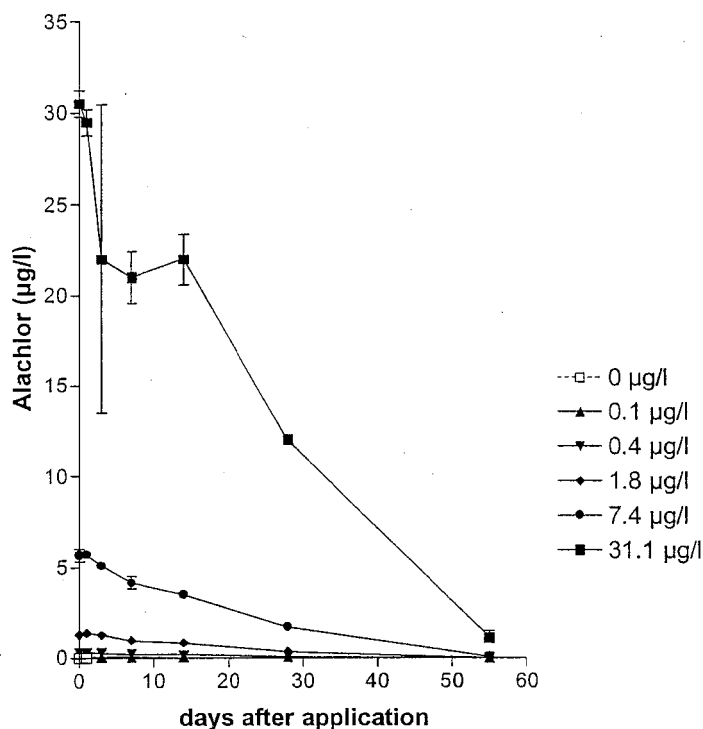


Figure 5: Measured alachlor concentrations in mesocosm water (average with SD).

Figure A2.1: Measured alachlor concentrations in mesocosm water<sup>[8]</sup>

Figures of water concentrations analysed during the study were not available from the mesocosm-report. Therefore, the  $C_{TWA}$  was estimated from the data shown in the figure. The measured initial concentration for the (nominal) 1.8 µg/l exposure level was 1.3 µg/l at day 0 and dropped nearly linearly to approx. 0.2 µg/l.

$C_{TWA}$  was estimated as follows:  $((1.3 \mu\text{g/l} - 0.2 \mu\text{g/l}) * 0.5) + 0.2 \mu\text{g/l} = 0.75 \mu\text{g/l}$ .

***Elodea canadensis***

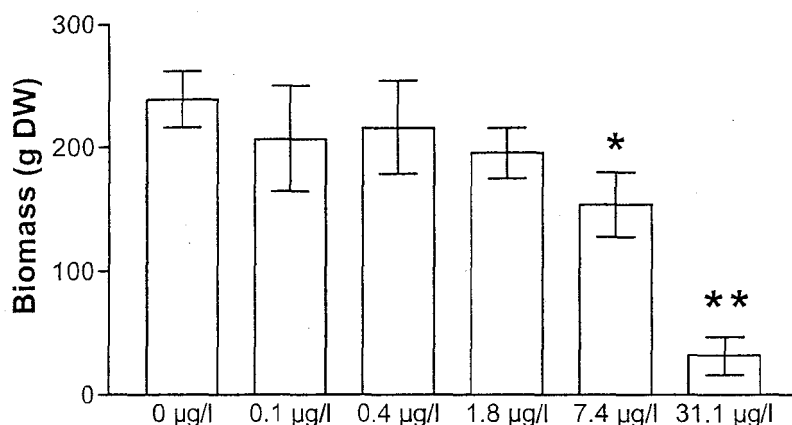


Figure 34 Total biomass of *Elodea canadensis* at the end of the study (day 56) (averages per treatment with SD). \*:  $p < 0.05$ , \*\*:  $p < 0.01$ .

Figure A2.2: *Elodea canadensis* biomass at the end of the mesocosm study<sup>[8]</sup>