Conclusion regarding the peer review of the pesticide risk assessment of the active substance

metazachlor

Finalised: 14 April 2008

SUMMARY

Metazachlor is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

The United Kingdom being the designated rapporteur Member State submitted the DAR on metazachlor in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 30 September 2005. The peer review was initiated on 6 October 2006 by dispatching the DAR for consultation of the Member States and the two applicants BASF and Makhteshim Agan. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and remaining issues were agreed on during a written procedure in July – August 2007. The identified issues as well as further data made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in November – December 2007.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in March 2008 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide on winter and spring oilseed rape and ornamentals for the control of annual grasses and broad-leaved weeds as proposed by the notifiers. Full details of the GAP can be found in the attached end points.

The representative formulated products for the evaluation were “Butisan S” (BASF) and “Fuego” (MAK), both suspension concentrates (SC) containing 500 g/l metazachlor.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products

[1] OJ No L 224, 21.08.2002, p. 25, as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

are possible. Adequate methods are available to monitor all compounds given in the respective residue definitions for monitoring for food/feed of plant and animal origin and for environmental matrices, however subject to the final agreement on the hazard classification of metazachlor, additional analytical methods for groundwater monitoring would be required.

As for mammalian toxicology, metazachlor acute toxicity is low via oral, dermal and inhalation routes (LD50>2000 mg/kg and LC50>34.5 mg/l). Metazachlor is neither a skin nor an eye irritant. Metazachlor was proposed to be classified as skin sensitiser R43 “May cause sensitisation by skin contact”. The relevant NOAELs for subacute and subchronic exposure in rats are 110 mg/kg bw/day and 21 mg/kg bw/day (BASF and FSG, LOAELs 330 and 137 mg/kg bw/day, respectively). Metazachlor did not show any genotoxic potential.

Liver adenomas and thyroid tumours occurred in the rat, while the mouse showed slight increases in bladder transitional cell tumours at high dose levels. Since there was no genotoxicity and clear no-effect levels for tumour development were seen in all tests, it was apparent that tumour development could be considered to involve a threshold mechanism. A classification as Carc. Cat. 3 R40 (“Limited evidence of a carcinogenic effect”) was proposed. The parental NOAEL for the BASF study (limited validity) is 1000 ppm as well as the reproductive and the offspring NOAELs. The parental and the reproductive NOAELs of the FSG study are 151 and 192 mg/kg bw/day (2000 ppm), respectively. For the offspring the NOAEL is 20 mg/kg bw/day (200 ppm) based on reduced pup weight and survival in the F3 generation. No evidence of teratogenicity was seen in developmental toxicity studies in the rat and rabbit. The relevant maternal NOAELs are 50 mg/kg bw/day in rat and rabbit (BASF) and 30 and 250 mg/kg bw/day in rabbit and rat, respectively (FSG); the relevant developmental NOAELs are 250 and 450 mg/kg bw/day in rabbit and rat, respectively (BASF) and 120 and 250 mg/kg bw/day in rabbit and rat, respectively (FSG).

Metazachlor did not show any potential for acute, repeated dose or delayed neurotoxicity.

An ADI of 0.08 mg/kg bw/day was derived for metazachlor, based on the NOAEL of 8.5 mg/kg bw/day; an ARfD of 0.5 mg/kg bw was derived, based on the NOAEL of 50 mg/kg bw/day from the developmental study in rats, and the AOEL was set at 0.2 mg/kg bw/day, based on the relevant short term toxicity NOAEL 21 mg/kg bw/day in rat. The safety factor applied is 100.

The operator exposure is below the AOEL for Butisan only with the use of gloves when handling the concentrate, coveralls and gloves during application (German model); for Fuego the exposure is below the AOEL even without PPE for field application estimated with the German model, with use of gloves during mixing/loading (tractor application, UK POEM) and with the use of gloves when handling the concentrate, coveralls and gloves during application (knapsack spraying, UK POEM).

The re-entry exposure is estimated to be above the AOEL for both Butisan and below the AOEL for Fuego. Bystander exposure is below the AOEL for both plant protection products.

The metabolism of metazachlor in plant and livestock is extensive and the parent compound does not participate to the toxicological burden the consumer is exposed to. The residue definition for monitoring is proposed to include all residual compounds containing the 2,6-dimethylaniline moiety.

For monitoring of plant products, 3 metabolites have been identified as valid indicator compounds: metabolites 479M04, 479M08 and 479M16.

A possible transfer of soil residues to rotational crops has been identified, but under usual rotation practices with rape seed no measurable residue level above the analytical limit of quantification is expected in food commodities from rotational crops.

There is a low exposure of livestock to residues present in feeding stuff but their transfer to edible animal commodities is not expected to reach analytically measurable levels.

No risk for the consumer has been identified resulting from short or long term dietary exposure to residues in food commodities and to metabolites contaminating groundwater resulting from the representative use of metazachlor in rape seed.

The available data on the aerobic degradation in soil indicated that the metabolic pathway of metazachlor under aerobic conditions is complex. Two metabolites were found in soil at concentrations of greater than 10% applied radioactivity (AR), these were the metazachlor acid 479M04 (max. 16.2% AR at 91d) and the sulfonic acid derivative 479M08 (max. 21.6 at 181d). Two further metabolites, 479M09 and 479M11 were detected in smaller amounts, with 479M11 measured at levels > 5% AR on 3 consecutive time points. All metabolites identified contained both ring systems, (both the phenyl and the pyrazol rings). Cleavage of either of the ring systems is not a significant route of breakdown.

Under anaerobic conditions, also 479M06 occurred in amounts greater than 10% AR. But it appeared in higher amounts only after longer incubation times under anaerobic conditions and therefore not considered to be of environmental relevance.

Metazachlor degraded in soil under laboratory conditions fast with a mean first order DT_{50} value of 10.8 days (at 20ºC and pF2) and under field conditions even faster, with a geometric mean value of 6.8 days (normalised to 20ºC). The degradation rates (first order $DT_{50\ 20ºC,\ pF2}$) of the major soil metabolites 479M04 and 479M08 in soil under laboratory conditions were 89.9 days and 123.2 day, respectively. Under field conditions the geometric mean value of the $DT_{50\ 20ºC}$ was 56.4 days for 479M04 and 71.1 days for 479M08.

Metazachlor is adsorbing moderately to soil with Kf_{oc} values between 53.8 and 220 mL/g. The adsorption of the metabolites 479M04, 479M06 and 479M08 is even weaker (K_{foc} 1-94 mL/g, 44-62 mL/g and 4-78.5 mL/g, respectively). Therefore, lysimeter studies with metazachlor were performed on oilseed rape. There was no substantial leaching of metazachlor to groundwater. However, some metabolites were found in the lysimeter leachates, the most important were 479M04 (max annual average concentrations 6.33-21.39 µg/L) and 479M08 (max concentrations in 2 leachate samples: 5.8-12 µg/L). These results were confirmed by the results of FOCUS groundwater modelling. The potential for groundwater exposure from the applied for intended uses above the parametric drinking water limit of 0.1 µg/L by parent metazachlor is concluded to be low. As for 479M04 and 479M08, FOCUS modelling results indicated that these metabolites are expected to exceed 0.75 µg/L in all the FOCUS groundwater scenarios where it is defined that oilseed rape is grown. For soil metabolites 479M09, 479M11 and 479M12 the PECgw values could not be calculated using the FOCUS groundwater models. The PEC_{gw} values were instead estimated for these metabolites on the basis of transfer factors derived from the comparison of simulated and measured concentrations of the metabolites BH479-4 and BH479-8, for which lysimeter and modelling results are available. Estimated PECgw values for FOCUS scenarios were in the range 0.31-1.72 µg/L, 0.24-1.30 µg/L and 0.34-1.88 µg/L for BH479-9, BH479-11 and BH479-12 respectively. The classification as Carc. Cat. 3 R40 ("Limited evidence of a carcinogenic effect") proposed by the expert meeting on mammalian toxicology has implications for the relevance of the metabolites with the potential to contaminate groundwater. Should the proposed classification of the parent, Carc. Cat.3 R40 be confirmed in the context of the European Chemicals Agency (ECHA) programme for classification and labelling under Directive 67/548/EEC this would, in line, with the guidance document on groundwater metabolites, require that, for those metabolites with the potential to contaminate groundwater, convincing evidence must be provided that the metabolites will not lead to the risk of carcinogenicity.

Metazachlor is hydrolytically stable at pH 5, pH 7 and pH 9. It is also photolytically stable under the influence of light and it is not readily biodegradable.

In water/sediment studies metazachlor disappeared from the water phase relatively rapidly and reached moderate (10.9-19.8% AR after 3-15 days) amounts in the sediment. The most significant metabolites identified were 479M04 (7.33-8.41% AR in water and 1.6-2.8% AR in sediment at 99 days) and 479M06 (ca. 8% AR in water and 5.1-8.0% AR in sediment extracts at 99d). The mineralisation rate was very low and the amount of bound residues high with values up to 67% AR at the end of the study (day 99). Metazachlor decreased in aerobic water sediment systems with first order $DissT_{50}$ values from 13.4 to 27.8 days for the whole system. DT_{50} for the water phase was in the range 48.8-384 days, and DT_{50} for the sediment dissipation 3.0-6.8 days.

The aquatic exposure assessments available are sufficient to complete the necessary EU level estimated of Predicted Environmental Concentrations (PEC) in surface water bodies for the representative uses applied for, for annex I listing.

The volatility of metazachlor from aqueous system/soil water is likely to be low. Losses from plant surfaces are also low. The small proportion lost to the upper atmosphere is expected to degrade relatively rapidly (DT_{50}air = 6.5 hours derived by the Atkinson method of calculation assuming a hydroxyl radical concentrations of $5x10^5$ radicals/cm^3). Metazachlor is therefore unlikely to be subject to long range transport.

The acute and long-term TERs were above the Annex VI trigger for the acute and short-term risk to birds for all standard scenarios. However the long-term TERs were below the trigger. The suggested refinements were accepted by the experts for the uses of Butisan in oilseed rape. A data gap for further refinement of the risk to insectivorous birds was identified for the use of Fuego in ornamental trees and shrubs. The risk to mammals was assessed as low for the use of Butisan. The long-term TER for herbivorous mammals was below the trigger of 5 for the use of Fuego in ornamentals and a data requirement to refine the risk to herbivorous mammals was identified by the RMS and confirmed by the experts. Algae and higher aquatic plants were the most sensitive groups of organisms tested and a potential high risk to primary producers was indicated in the lower tier risk assessment. Refined risk assessments based on species sensitivity distribution (SSD) and mesocosm endpoints were presented by the applicants. A new risk assessment based on the geometric mean (113.6 µg a.s./L) was submitted by BASF. It was noted in the expert meeting that the tested emergent plants were less sensitive than the submerged plants and hence should not be combined in the SSD or geomean calculation. Based on the endpoints of the 4 submerged plants the geometric mean toxicity value is 40 µg a.s./L. The number of endpoints (4 submerged species) was considered not sufficient to derive a robust HC5 estimation. Some Member States use a safety factor of 4 in combination with the lower limit HC5. The experts suggested to use the endpoint of 1.67 µg a.s./L from the mesocosm study (NOAEC of 5 µg a.s./L with a safety factor of 3) in the risk assessment. A FOCUS step 4 TER calculation was presented for the use of Fuego (0.75 kg a.s./ha). The full FOCUS step 4 scenarios D1, D3, D4, D5 and the part scenario R1 (pond) resulted in a TER above the trigger if a no spray buffer zone of 5 metres was applied. The trigger was not met in the full scenarios D2, R3 and the part scenario R1 (stream). No TER calculations were presented with FOCUSstep 4 PECsw for the use of Butisan (1 kg a.s./ha). However if the regulatory endpoint of 1.67 µg a.s./L is compared to the FOCUS step 4 PECsw including a no-spray buffer zone of 10 metres than the trigger would be met in all scenarios except D2 and R3 (full scenarios). It is assumed that the use in ornamental trees and shrubs would not lead to higher concentrations of metazachlor in the aquatic environment and hence the risk assessment for oilseed rape covers also the risk from the use in ornamental trees and shrubs. The risk to aquatic organism from the metabolites 479M04, 479M06, 479M08, 479M09, 479M11, 479M12 was assessed as low. The acute and long-term TER values for earthworms were above the trigger for metazachlor and the metabolite 479M04. The long-term TER of 4.8 for metabolite 479M08 was below the trigger of 5. The NOEC used in the TER calculation was based on the highest concentration tested. Therefore the risk to earthworms was considered as addressed. Effects on reproduction of springtails (*Folsomia candida*) were tested with the two major soil metabolites 479M04, 479M08) and metazachlor formulated as “Fuego”. The TERs based on PECs from application of 1 kg metazachlor/ha in oilseed rape were markedly above the trigger of 5 indicating a low risk to other soil non-target macro-organisms. Since the $DT_{90(f)}$ of 479M04 (BH479-4) and 479M08 (BH479-8) is >365 days a litter-bag study is triggered. No effects were observed in the litter-bag study submitted by BASF. The concentrations were lower than the calculated accumulated peak PECsoil values. However the effect on soil micro organisms was <25%, the TERlt for earthworms was >5 (except for the endpoint for 479M08 from a study of MAK-FSG) and the studies with *Folsomia candida* gave an indication that the risk to soil dwelling arthropods is low. Therefore it was concluded that the risk to soil dwelling macro-organisms and organic matter breakdown is low for the representative uses of metazachlor. TERs for non-target plants based on the endpoints from glasshouse trials were below the trigger of 5. The TER is 6.05 if a no-spray buffer zone of 10 m is applied. Using the test results from the field trials then the TER is >5 for the pre-emergent exposure at 1 m distance from the treated field and the no-spray buffer zone can be reduced to 5m to achieve TERs above 5 for post-emergent exposure. In the studies with the formulation “Fuego” the lowest endpoints were observed for oat and sugar beet. The TERs were above the trigger of 5 for pre-emergent exposure at the standard distance of 1m but for the post-emergence exposure a no-spray buffer zone of 5m is required to achieve a TER > 5. The risk to non-target plants from the use in ornamental trees and shrubs is considered as covered by the risk assessment for oilseed rape. No higher drift rates are expected from the use in ornamental since the product is sprayed to reach weeds under the ornamental trees.

The risk to bees, non-target arthropods, soil non-target micro-organisms and biological methods of sewage treatment was assessed as low.

Key words: metazachlor, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, as amended by Commission Regulation (EC) No 1095/2007 regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Metazachlor is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating the United Kingdom as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, the United Kingdom submitted the report of its initial evaluation of the dossier on metazachlor, hereafter referred to as the draft assessment report, to the EFSA on 30 September 2005. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 6 October 2006 to the Member States and the main applicants BASF and Makhteshim Agan as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA and Member States identified and agreed during a written procedure in July – August 2007 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in experts' meetings in November – December 2007. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in March 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 11c (1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulations evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received;
- the resulting reporting table (rev. 1-1 of 18 September 2007)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation;
- the evaluation table (rev. 2-1 of 17 March 2008).

Given the importance of the draft assessment report including its addendum (compiled version of March 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Metazachlor is the ISO common name for 2-chloro-*N*-(pyrazol-1-ylmethyl)acet-2′,6′-xylidide (IUPAC).

Metazachlor belongs to the class of chloroacetanilide and pyrazole herbicides. Metazachlor acts as an inhibitor in the lipid biosynthesis, having effect on cell division and tissue differentiation. Metazachlor is mainly taken up via the roots, the hypocotyl, and the cotyledons of the germinating and emerging weeds. Metazachlor is used in winter and spring oilseed rape, vegetables, potato, apples and ornamentals for the pre-emergence and early post-emergence control of annual grasses and broad-leaved weeds.

The representative formulated products for the evaluation were “Butisan S” (BASF) and “Fuego” (MAK), both suspension concentrates (SC) containing 500 g/l metazachlor, registered under different trade names in Europe.

The representative uses evaluated comprise single pre- or post emergence applications with conventional tractor-mounted spraying devices to control annual weeds in winter and spring rapeseed (Butisan S), up to growth stage of BBCH 00-18, in all EU countries, at a single application at a maximum application rate of 1 kg a.s./ha, and early post emergence applications with conventional tractor-mounted spraying devices to control annual weeds and broad-leaved weeds in winter oilseed rape and ornamental trees (Northern White Cedar (*Thuja occidentalis*), Rhododendron (*Rhododendron* spp.), Privet (*Ligustrum* spp.) Lilac (*Syringa* spp.), Alder (*Alnus glutinosa*), Grey Willow (*Salix cinerea*), Sea-buckthorn (*Hippophae rhamnoides*), Norway spruce (*Picea abies*)) (Fuego), up to growth stage of BBCH 10-13, and BBCH 11-12 respectively, at a single application at a maximum application rate of 0.75 kg a.s./ha.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of metazachlor is 950 g/kg for both notifiers, which is meeting the requirements of the FAO specification 411/TC (1999) of minimum 940 g/kg.

As the two main notifiers for metazachlor did not come to an agreement for joint submission and both submitted complete dossiers, both dossiers have therefore been evaluated.
The RMS requested the applicant BASF to justify their technical specification based on more recent batch analyses data. The new data and the new specification were presented and evaluated in an addendum to vol. 4 (July 2007), discussed at the PRAPeR 36 expert meeting (November 2007).
The RMS performed an equivalence check according to the guidance document on the assessment of equivalence of technical materials (SANCO/10597/2003 rev. 7) and concluded that the MAK source of metazachlor cannot be considered equivalent to the BASF source due to the presence of a number of different impurities. A tier II assessment has been carried out and for some impurities further toxicological data were required by the RMS. The PRAPeR 39 (December 2007) expert meeting on toxicology concluded that the sources are toxicologically equivalent. Based on scientific considerations the experts concluded that a single set of reference values can be set.
As both notifiers have their own dossier, both sources can be considered as reference source.
The technical material from the BASF source contains toluene at levels below 0.01% which is considered of toxicological relevance.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of metazachlor or the respective formulations. However, the following data gaps were identified:
- information on all starting materials and process solvents (MAK source only)
- level of ethoxylation for the coformulants
- a new calculation for Henry's law constant based on the vapour pressure and water solubility (MAK source only)

The main data regarding the identity of metazachlor and its physical and chemical properties are given in appendix 1.

Adequate analytical methods based on HPLC-UV (CIPAC methods) are available for the determination of metazachlor in the technical material and in the representative formulations as well as for the determination of the respective impurities in the technical material (HPLC-UV and GC-FID).
Sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that quality control measurements of the plant protection products are possible.

The residue definition for enforcement for plants was set as the sum of metabolites 479-M04[2], 479-M08[3] and 479-M16[4]. Adequate methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant and animal origin.

A GC-MS enforcement analytical method is available to monitor residues of metabolites 479-M04, 479-M08 and 479-M16 in plant matrices, determined as 2,6 dimethyl aniline, with LOQ of 0.05 mg/kg for rape seed, wheat grain, wheat straw, cabbage and carrot. HPLC-MS/MS methods are also available allowing determination of the metabolites 479-M04, 479-M08 and 479-M16 without hydrolysis to the common moiety as in the enforcement method, serving also as a confirmatory methods, with LOQ of 0.01 mg/kg for wheat grain, wheat straw, lettuce, cauliflower, lemon and oilseed rape.

The applicability of the multi-residue method DFG S19 was tested with metazachlor only, in conclusion it cannot be used for monitoring the compounds in the residue definition.

An HPLC-MS/MS method is available to monitor residues of metazachlor, determined as 2,6 dimethylaniline, in food/feed of animal origin (milk, liver) with LOQs of 0.01 mg/kg.

Adequate methods are available (HPLC-MS/MS) to monitor metazachlor and metabolites 479M-04 and 479M-08 in soil, with LOQ of 0.01 mg/kg, and in water (drinking water, surface water) with LOQ of 0.05 µg/L. Subject to the final agreement on the hazard classification of metazachlor however, monitoring methods for metabolites 479M09, 479M11 and 479M12 would also be required.

Residues of metazachlor in air can be determined with GC-MS method with LOQ of 0.5 µg/m³

Analytical methods for the determination of residues in body fluids and tissues are not required as metazachlor is not classified as toxic or highly toxic.

2. Mammalian toxicology

Metazachlor mammalian toxicity was discussed in a meeting of experts in December 2007 (PRAPeR 39).

In the meeting, the toxicological equivalence of the two specifications was discussed. The two specifications (MAK and BASF) differ in three impurities: #2, #4 and #5 are present only in the MAK but not in the BASF specification. Furthermore, about twice as much of impurity 3# is present in the BASF specification compared to the MAK specification. Giving the absolute levels of these impurities the RMS was of the opinion that in regard to toxicological properties there should be no significant differences between the specifications. It was noted that, when looking at the studies with the a.s. there were some differences between results obtained in the tests provided by the two different notifiers. The experts noted that this might well be due to different study designs i.e. dose levels applied, animals used etc.. Overall there is strong evidence that the sources are toxicologically

[2] 479M04/BH 479-4: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide

[3] 479M08/BH 479-8/BH 479-18: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid

[4] 479M16/BH 479-21: 3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid

equivalent. Based on scientific considerations the experts concluded that a single set of reference values can be set.

As for the representativeness of batches used in toxicological studies, the RMS reported that the technical specification for BASF was changed. It was agreed that the batches tested in the tox are representative for the new specification; however, it appeared that the representativeness of the batch tested in one of the Ames test needs to be clarified by the RMS since there appeared to be an error in the addendum 4 to the DAR. After the meeting of experts, the RMS noted that in the vol. 4, listing batches used in toxicological studies, there is a minor typo regarding the batch tested in the Ames test; however, the corresponding dry-weight purity is 97.5% which is representative of the five batches (purity range 97.4-98.6%).

With regard to the impurities present in the batches used in toxicological studies, the need of further in vitro genotoxicity tests to assess the relevance of the impurities #3 (in lower level in MAK-FSG batches than in the technical specification) and #5 (in lower level in FSG batches than in the technical specification and not detected in MAK batches) was discussed by the experts.

As for impurity #5, no genotoxicity studies were available; the impurity is present in some batches tested in toxicity studies, but only in the developmental studies the level was comparable to the ones of the proposed specification. In general it was tested at lower levels than the proposed specification. However, it was concluded that there is no concern with regard to the impurity #5, since the increase in the proposed specification is limited and the chemical structure is similar to metazachlor.

The experts agreed that the notifier should provide further information, e.g. genotoxity data, for impurity #3 since the technical specification (proposed in the addendum to Vol. 4, provided by the notifier FSG) is not covered by the tox batches used.

As for applicant MAK-FSG, the need of addressing the genotoxicity of the impurities #4, #6 and #7 was highlighted. Furthermore, the experts agreed for FSG a repetition of the chromosome aberration test in human lymphocytes *in vitro* with impurity # 7 was needed since it yielded equivocal results.

2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Metazachlor is rapidly and extensively absorbed (85-95%), as well as distributed, mainly in red blood cells, for which there is limited evidence of accumulation. After extensive metabolisation, within 24 hours from administration about 80% of metazachlor is excreted in urine and bile (30-40% and 50-60%, respectively).

2.2. ACUTE TOXICITY

Metazachlor acute toxicity is low via oral, dermal and inhalation routes (LD50>2000 mg/kg and LC50>34.5 mg/l). Metazachlor is neither a skin nor an eye irritant.

BASF technical was shown to be a skin sensitiser in a Maximisation study, whereas the FSG-MAK material did not show any sensitising potential in a Buehler study. Overall, the proposal for classification as R43 (“May cause sensitisation by skin contact”) was agreed based on the results of the Maximisation study (the most sensitive method).

2.3. Short term toxicity

Liver was shown to be target organ in the three species tested (rats, mice and dogs) in subacute and subchronic tests, with increased weight and some histological findings. Rats also showed mild anaemia, in mice increased kidney weight occurred, whereas dogs showed both effects.
The relevant NOAEL in rats is 110 mg/kg bw/day and 21 mg/kg bw/day (BASF and FSG, LOAELs 330 and 137 mg/kg bw/day, respectively). Metazachlor tested with BASF technical showed a dermal NOAEL of 1000 mg/kg bw/day in a 28-day dermal study. No repeated dose inhalation studies were submitted, nor required.

2.4. Genotoxicity

Metazachlor was tested in a number of *in vitro* and *in vivo* genotoxicity studies.
Overall it was concluded that metazachlor does not have any genotoxic potential.

2.5. Long term toxicity

Increased liver and kidney weights were seen in chronic rat studies provided by both applicants; hepatic histopathology was limited in one study to adaptive effect such as hepatocellular hypertrophy, whereas in a second study ballooned hepatocytes were considered as areas of focal degeneration and therefore interpreted as an adverse effect. Renal pathology was limited to gross observations of scarring or pale, rough and cystic kidneys at high dose levels; no renal histopathology was registered.
Effects on red blood cell parameters indicative of mild anaemia were seen at high dose levels in both rat studies.
The mouse was found to be less sensitive to the chronic toxicity of metazachlor; target organs were identified as the kidney and bladder. Increased kidney weight was accompanied at high dose levels by gross findings of cortical scarring; an increased incidence of glomerulonephritis was seen in females at the top dose level in one study. Findings in the bladder were characterised by epithelial hyperplasia and nuclear enlargement; increased incidences of transitional cell tumours were also seen at 4000 ppm (578 mg/kg bw/day). Therefore, the RMS considered Metazachlor to be carcinogenic at high dose levels; a clear threshold was apparent for this effect (proposed classification Carc. cat.3, R40 "Limited evidence of a carcinogenic effect").
During the experts' meeting the issue of carcinogenicity of metazachlor was discussed.
In summary, liver adenomas and thyroid tumours occurred in the rat, while the mouse showed slight increases in bladder transitional cell tumours at high dose levels. No mechanistic studies were available in the DAR, but metazachlor had no genotoxic potential. The experts agreed that, although the mechanism for bladder tumour development is not identified, when looking at the overall genotoxicity database it appears unlikely that it involves genotoxic events.
It was noted that there were different tumour types occurring in different species and different strain also. In general high doses levels have been applied in the chronic studies and pronounced toxicity was observed at the dose levels where tumours were produced. The survival was good, and generally higher in test groups than controls. Since there was no genotoxicity and clear no-effect levels for

tumour development were seen in all tests, it was apparent that tumour development could be considered to involve a threshold mechanism.

No further information was made available by the applicant. A very clear majority of the experts including the RMS agreed to propose a classification as **Carc. Cat. 3 R40** for metazachlor.

2.6. REPRODUCTIVE TOXICITY

No evidence of reproductive toxicity was seen in a two-generation study in the rat at dose levels of up to 1000 ppm; toxicity in parental animals was limited to slight bodyweight effects in females at the top dose level. No evidence of toxicity to offspring was seen in this study. Evidence of reproductive toxicity was seen at the highest dose level of 8000 ppm in a three-generation study; reduced litter size was associated with lower numbers of corpora lutea and implantations. Parental toxicity was limited to effects on bodyweight. Reduced bodyweights and survival of offspring were seen at the top dose level in all generations and at the mid-dose level in F3 pups.

The maternal NOAEL in the rat multigeneration study was discussed by the experts.

It was noted that the effect levels from the two studies (BASF and FSG, respectively) differed. The experts agreed to set the parental NOAEL for the BASF study at 1000 ppm since the bodyweight effects observed at the highest dose were considered non relevant. The reproductive and the offspring NOAELs were set at 1000 ppm as well. It was noted also that there were no critical findings. The parental and the reproductive NOAEL of the second multigeneration study (FSG) were set at 151 and 192 mg/kg bw/day (2000 ppm), respectively. For the offspring the NOAEL was set at 20 mg/kg bw/day (200 ppm) based on reduced pup weight and survival in the F3 generation. It was added that the effects observed did not merit classification for reproductive toxicity.

It was noted that the validity of the first study (BASF) was limited since it was not a two generation study (2nd generation having almost no pregnant animals): consequently, a data gap for a multigeneration study for BASF was set. The experts agreed that this data gap does not have any influence on the present assessment as the risk assessment is driven by studies with NOAELs well below the NOAELs in the first generation of the BASF study. However, it was noted that the study per se cannot be considered acceptable due to relevant drawbacks.

No evidence of teratogenicity was seen in developmental toxicity studies in rats and rabbits. In the rat, maternal toxicity (clinical signs, reduced weight gain and food consumption) was seen at high dose levels. Foetal toxicity was limited to reduced or delayed skeletal ossification at maternally toxic dose levels in the FSG and MAK studies. The reason for the absence of similar findings in the BASF study is unclear; however it was noted that the detail of reporting in this study was limited. In the rabbit, maternal toxicity (mortality, abortion, clinical signs, reduced weight gain and food consumption) was seen at high dose levels. Evidence of foetal toxicity was limited to reduced or delayed skeletal ossification, slightly reduced foetal size and increased incidences of a small number of visceral and skeletal anomalies at maternally toxic dose levels. The absence of effects on foetal skeletal ossification in the BASF rabbit studies may be explained by the use of the less sensitive X-ray method (rather than alizarin staining) for skeletal examination. The relevant maternal NOAELs are 50 mg/kg bw/day in rat and rabbit (BASF) and 30 and 250 mg/kg bw/day in rabbit and rat, respectively (FSG); the relevant developmental NOAELs are 250 and 450 mg/kg bw/day in rabbit and rat, respectively (BASF) and 120 and 250 mg/kg bw/day in rabbit and rat, respectively (FSG).

2.7. Neurotoxicity

Metazachlor did not show any potential for acute, repeated dose or delayed neurotoxicity.

2.8. Further studies

Toxicity studies were performed on a number of metazachlor metabolites by BASF, and on the oxalic acid and sulphonic acid metabolites (479M04[5] and 479M08[6] respectively, using the BASF nomenclature) by FSG. The studies submitted did not raise any toxicological concerns.

Metabolite 479M04/BH 479-4 was found to be of low acute oral toxicity, no evidence of genotoxicity was seen in studies *in vitro* and *in vivo* and no evidence of teratogenicity was seen in a rat developmental toxicity study. Metabolite 479M08/BH 479-8/BH 479-18 was found to be of low acute oral toxicity and was not genotoxic *in vitro* or *in vivo*. Adverse effects in a 90-day study were limited to reduced kidney weights in female rats; no evidence of teratogenicity was seen in a developmental study, however there was limited evidence of foetotoxicity. Metabolite BH 479-09 (479M09)[7] was found to be of low acute oral toxicity and was not genotoxic *in vitro*.

Metabolite 479M11/BH 479-11[8] was found to be of moderate acute oral toxicity; no evidence of mutagenicity was seen in an Ames test. Metabolite BH 479-12 (479M12)[9] was found to be of low acute oral toxicity; no evidence of mutagenicity was seen in an Ames test. Metabolite 479M16/BH 479-21[10] was found to be of low acute oral toxicity and was not genotoxic *in vitro*.

The toxicological relevance of the groundwater metabolites 479M09, 479M11 and 479M12 was discussed during the meeting. Based on the available information, none of the three metabolites showed any genotoxic concern. However due to the properties of metazachlor that gave rise to the proposal for classification as Carc. Cat.3, R40 the experts considered that the metabolites with potential to contaminate groundwater should be regarded as toxicologically relevant according to the Guidance Document on the assessment of the relevance of metabolites in ground water (SANCO/221/2000); it is noted that this is dependant on the proposed classification of the parent, Carc. Cat.3 R40 being confirmed in the context of the European Chemicals Agency (ECHA) programme for classification and labelling under Directive 67/548/EEC.

If needed, the reference values of the parent would be applicable also to the metabolites.

2.9. Medical data

Neither the FSG nor the BASF health surveillance programmes in production plants have highlighted any specific health effects referable to metazachlor. A comprehensive literature search did not

[5] 479M04/BH 479-4: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide
[6] 479M08/BH 479-8/BH 479-18: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid
[7] 479M09/BH 479-09: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl acetic acid
[8] 479M11/BH 479-11: methyl *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfoxide
[9] 479M12/BH 479-12: *N*-[(2-hydroxycarbonyl-6-methyl)phenyl]-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide
[10] 479M16/BH 479-21: 3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid

identify any clinical cases, poisoning incidents or epidemiological studies related to metazachlor; however, BASF stated that skin sensitisation and eye irritation have been observed following exposure to metazachlor.

2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)

Acceptable Daily Intake (ADI)

An ADI of 0.08 mg/kg bw/day was derived for metazachlor, based on the NOAEL of 200 ppm (equivalent to 8.5 mg/kg bw/day) in the chronic rat study (FSG). Although lower NOAELs were observed in the other chronic rat studies (BASF), this is considered to be a consequence of dose spacing. The safety factor applied was 100.

Acute Reference Dose (ARfD)

The experts discussed if the effects observed merited the application of an ARfD in terms of severity and time of occurrence. The rabbit developmental study was checked to find out when the effects occurred in the study. At a dose of 150 mg /kg bw/day clinical signs occurred at days 2 and 3 of dosing with a NOAEL of 50 mg/kg bw/day. Therefore, an ARfD of 0.5 mg/kg bw was derived, based on the NOAEL of 50 mg/kg bw/day from the developmental study in rats, applying a safety factor of 100.

Acceptable Operator Exposure Level (AOEL)

A short-term systemic AOEL of 0.2 mg/kg bw/day was established, based on the relevant short term toxicity NOAEL 0.21 mg/kg bw/day in rat. An assessment factor of 100 was applied.

2.11. Dermal absorption

Dermal absorption values for the product Butisan S and Fuego were discussed by the experts.

There was a large difference between the dermal absorption values of the two representative plant protection products: in the DAR for Butisan, BASF, a 10% absorption was proposed (default), while for Fuego, FSG, 0.2% concentrate and 9% dilution were proposed (experimental study). It was noted that the default oral absorption for metazachlor would be 100. The experts agreed to use a default value for dermal absorption of 100% for "Butisan". It was acknowledged that this is a conservative approach, but it was hard to judge on the likely absorption for the dilution, based on the comparison of oral and dermal studies, as proposed.

Even though the absorption profiles indicated that absorption was almost complete within 12 to 16 hours, the experts agreed to increase the dermal absorption rate for the preparation "Fuego", since the content in the stratum corneum had not been considered in the *in vitro* test initially. The agreed values increased from 0.2 to 2% for the concentrate and from 9% to 10% for the dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

Metazachlor is intended to be used as herbicide on oilseed rape (both applicants) and on hardy ornamentals (FSG only). Maximum application rate is 1 kg a.s./ha for BASF and 0.75 kg/a.s. for FSG.

Operator exposure

Butisan

	Application method (crop)	Systemic exposure (mg/kg bw/day)	% of systemic AOEL
German model	Tractor, field crops	1.269 mg /kg bw/day 0.590 mg /kg bw/day 0.483 mg /kg bw/day 0.048 mg /kg bw/day	635 295* 241° 24§
UK POEM	Tractor, hydraulic boom and nozzles	7.634 mg/kg bw/day 3.676 mg/kg bw/day 0.751 mg/kg bw/day	3817 1838* 375°

* Gloves when handling the concentrate

° Gloves when handling the concentrate and during application

§ Gloves when handling the concentrate, coveralls and gloves during application

Fuego

	Application method (crop)	Systemic exposure (mg/kg bw/day)	% of systemic AOEL
German model	Tractor, field crops	0.054 mg /kg bw/day 0.044 mg /kg bw/day 0.036 mg /kg bw/day 0.004 mg /kg bw/day	27 22* 18° 2§
UK POEM	Tractor, hydraulic boom and nozzles	0.201 mg/kg bw/day 0.177 mg/kg bw/day 0.0311 mg/kg bw/day	100 88* 15°
UK POEM	Knapsack sprayers, low targets	0.463 mg /kg bw/day 0.432 mg /kg bw/day 0.213 mg /kg bw/day 0.085 mg /kg bw/day	232 216* 106° 42§

* Gloves when handling the concentrate

° Gloves when handling the concentrate and during application

§ Gloves when handling the concentrate, coveralls and gloves during application

In summary, the operator exposure is below the AOEL for Butisan only with the use of gloves when handling the concentrate, coveralls and gloves during application (German model); for Fuego the exposure is below the AOEL even without PPE for field application estimated with the German model, with use of gloves during mixing/loading (tractor application, UK POEM) and with the use of gloves when handling the concentrate, coveralls and gloves during application (knapsack spraying, UK POEM).

Worker exposure

Butisan

According to the German re-entry model the estimated exposure is

D = R x DFR x TC x A

D = 1 kg a.s./ha x 3 µg/cm2 x 4500 cm2/person/hour x 2 hours

The systemic worker exposure without PPE is estimated to be 0.45 mg/kg bw/day (equivalent to 225% of the systemic AOEL of 0.2 mg/kg bw/day).

EFSA notes that by applying an exposure reduction factor for the use of PPE, the exposure is expected to be below the AOEL

Fuego

According to the German re-entry model the estimated exposure is

D = R x DFR x TC x A

D = 0.75 kg a.s./ha x 3 µg/cm2 x 4500 cm2/person/hour x 2 hours

The systemic worker exposure without PPE is estimated to be 0.00675 mg/kg bw/day (equivalent to 3.4% of the systemic AOEL of 0.2 mg/kg bw/day).

Bystander exposure

Bystander exposure to both Butisan and Fuego is below the AOEL. In particular:

Butisan = 0.00883 mg/kg bw (equivalent to 4.4% of the systemic AOEL of 0.2 mg/kg bw/day).

Fuego = 0.000667 mg/kg bw (equivalent to 0.33% of the systemic AOEL of 0.2 mg/kg bw/day).

3. Residues

Metazachlor was discussed by the meeting of experts in residues in December 2007 (PRAPeR 40).

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The metabolism of metazachlor has been investigated in rape seed by BASF and MAK-FSG in a way reflecting the respective representative uses. In addition, BASF submitted further studies in maize and cabbage. Metazachlor is quickly metabolised in plants.

The main degradation pathway proceeds through the initial formation of a glutathione conjugate. The glutathione conjugate is cleaved and leads after further oxidative processes to a wide range of metabolites and their glycoside conjugates. In addition to the glutathione route, loss of the chlorine atom and oxidation of the acetamide moiety leads the oxalic metabolite 479M04[11], observed in maize and cabbage, but not in rapeseed.

In rape seed the major constituent of the residue was the metabolite 479M16[12], accounting for 26 % of the TRR.

No cleavage of the phenyl and pyrazole ring systems was observed.

The metabolic pattern in plants can be considered as covered by the toxicological dossier. The glutathione metabolic pathway, which is the main route of degradation in plants, is also a major metabolic pathway in rat and the various oxidative processes in primary crops through this route were also observed in rat. Although the comparison of the nature of metabolites produced through this route shows some differences between plants and rodents, the toxicological information provided on several plant metabolites (including metabolites 479M04, 479M08[13] and 479M16) suggests that these metabolites may be considered for risk assessment of comparable toxicity to the parent compound.

[11] 479M04/BH 479-4: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)hydroxyacetamide

[12] 479M16/BH 479-21 : 3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid

[13] 479M08/BH 479-8/BH 479-18: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid

Therefore, considering the complex metabolic pattern in plant commodities, the proposed residue definitions for risk assessment and monitoring is the sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety (here after designated as 'total residues'), expressed as metazachlor. This definition allows adequate protection of consumer's health. Given that information has been provided for 3 crop groups and considering the broad coverage of the residue definition, this can be considered as valid for all crops.
For monitoring the expert meeting proposed to define the residue as the sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor. This definition covers appropriate marker compounds in cereals, oilseeds, leafy crops as well as in rotational crops.
In total more than 50 supervised residue trials have been conducted by BASF and MAK-FSG in Northern and Southern Europe, on both winter and spring oilseed rape. All these trials were analysed for total metazachlor residues. Only one trial gave a measurable residue (0.12 mg/kg) but was considered to be an outlier by the expert meeting on residues. Therefore, it was concluded that the data base is sufficient to consider that total residues of metazachlor are below a limit of quantification (LOQ) of 0.05 mg/kg in rape seed after application following the representative use.
Storage stability studies showed that residues of the parent compound in maize and rape seed are stable when stored under deep freeze conditions and analysed by the common moiety method of analysis. As parent compound has a very low contribution to total residues in rape seed, this information is of low value for ensuring the reliability of the supervised residue trials. Additional freezer storage stability data addressing the storage stability of metabolite 479M16 in oilseed rape has been submitted by FSG during the peer review and the expert concluded that this metabolite is stable under deep freeze storage conditions for up to 13 months. As this metabolite accounts for 90% of the extractable radioactivity in rape seed, this information demonstrates the reliability of the available field residue data.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Appropriate information on residues in succeeding and rotational crops has been submitted by BASF only.
The metabolic pathway in rotational crops is similar to that observed in primary crops, and involves the glutathione route and the oxidative degradation of the chloroacetamide moiety. The parent compound is not present in rotational crops. The major metabolites found are metabolites 479M04 and 479M08, although chromatographic techniques failed to separate these 2 compounds.
Field studies conducted in 1983, 2002 and 2003 indicate that under normal conditions of use of metazachlor according to the representative uses, and for short plant-back intervals (29 to 112 days), total residues of metabolites containing the 2,6-dimethyl aniline moiety are regularly present at measurable levels in foliar plant parts (lettuce, lamb's lettuce, spinach, carrot and celeriac leaves, straw, cabbage, cauliflower, leeks), while remaining in all cases but one (one radish sample at 0.06 mg/kg) below the LOQ in roots crops and in cereal grains.
No field data is available for longer plant-back intervals which would reflect the most common scenario with autumn application on winter rape.

In general the expert meeting on residues concluded that agricultural crops normally used in rotation with rape seed are not expected to show positive residue levels even after crop failure. If uses on brassicas would be supported in the future, this point would need to be revisited since rotations in brassicas are very different from rotation in rape seed.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Appropriate information on nature and magnitude of residues in livestock has been submitted by BASF only.

Livestock may be exposed residues of metazachlor through consumption of rape seed meal/press cake or of cereal straw produced in rotation with rape seed.

Livestock metabolism studies are available for goats and hens. In both animals metazachlor is extensively metabolised mainly through conjugation with gluthatione followed by further cleavage, oxidative and glucuronide conjugation processes. Additionally, hydroxylation of the pyrazole and dimethylphenyl rings was observed. The metabolic pattern in milk, eggs and edible tissues is extremely complex and consists of a mixture of very numerous compounds, but degradation products resulting from the cleavage of the dimethylphenyl or pyrazole rings were not identified. The performed studies do not suggest a possible accumulation of residual compounds.

Due to the complex metabolic pattern, the proposed residue definition for monitoring and risk assessment in animal commodities is the sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor.

An estimation of the potential livestock exposure was made considering total metazachlor residues at the LOQ level in rape seed and at the highest measured level in straw in the available field rotational crop studies. A feeding study in lactating cows indicated that this exposure level was unlikely to lead to total residues above the LOQ in any edible animal commodity, except liver where residues would reach the LOQ level (0.05 mg/kg). It was however considered that the considered exposure scenario grossly overestimated practical conditions as it was based on straw residues when cereals are sown 30 days after application.

3.3. CONSUMER RISK ASSESSMENT

Chronic and acute exposure assessments were conducted using WHO methodologies and using the WHO European diet for adult consumers and national consumption data of UK. Residue levels in rapeseed and animal commodities were considered to be at the level of the LOQ proposed as MRLs, what covers the total metazachlor residues.

No risk for the consumer is expected at short or long term resulting from the use of metazachlor according to the representative uses.

Referring to point 4.2.2, several metabolites (479M04, 479M08, 479M09, 479M11 and 479M12) show a potential for contamination of groundwater above the level of 0.75 μg /L. As indicated under point 2.8, the ADI of metazachlor should apply to these metabolites. Therefore, an additional exposure assessment through consumption of ground water used as drinking water was performed after the expert meeting by EFSA. This assessment is based on the default assumptions for water consumption laid down in the WHO Guidelines of drinking water quality and on the highest predicted

total groundwater concentration from FOCUS modelling (Piacenza scenario) for the use on rape at 1 kg/ha 1 year in 3.
For infants, toddlers and adults the estimated intakes from drinking water of the sum of the considered metabolites, expressed as metazachlor, are 0.0027 mg/kg bw/day, 0.0018 mg/kg bw/day and 0.0006 mg/kg bw/day, respectively corresponding to *ca* 3%, 2% and 1% of the ADI of metazachlor, respectively. Therefore, it can be considered that the exposure to metazachlor degradation products through consumption of drinking water does not represent a consumer health concern.

3.4. PROPOSED MRLS

Based on the results of the supervised residue trials and of the feeding studies in livestock the following MRLs are proposed:

Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor:

Rape seed : 0.05* mg/kg

Sum of metazachlor and all metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor:

Milk: 0.01* mg/kg
Other products of animal origin: 0.05* mg/kg

4. Environmental fate and behaviour

Metazachlor was discussed in the meeting of MS experts on fate and behaviour in the environment (PRAPeR 37) in December 2007, on the basis of the DAR, the addendum 5 to Vol. 3 (September 2007) and the updated list of end points (September 2007).

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Two studies on the route of degradation of metazachlor under laboratory conditions (20ºC and 40% MWHC in the dark) were available. The two soils investigated (pH 5.9 and 6.4 (in $CaCl_2$ solution); organic carbon content 1.2-2.12%; clay content 4.2-8%) were dosed with [^{14}C-phenyl]metazachlor. However, in the study submitted by FSG (Feser-Zugner, 1998) the identity of chromatographic components (except the parent compound for which an analytical standard was used) was not considered reliable. A new study to characterise/identify metabolites formed in the questionable degradation study was submitted and evaluated in addendum 5. In this case, a study performed under anaerobic conditions was used to back up the identification of the metabolites formed in the aerobic conditions by comparison of the LC-MS/MS analytical data of the two studies. The experts considered acceptable the characterisation of the metabolites and it was concluded that the FSG study can be used to evaluate the route of degradation of metazachlor in soil, with the exception of the data for quantifications of the metabolites.

Mineralisation to carbon dioxide of the phenyl ring accounted for 1.9-6.9% AR at 91 and 100 days. The formation of unextracted residues was a significant route of degradation representing 43.2% AR at 91-100 days. In the reliable study the metabolites metazachlor acid **479M04**[14] (max 16.2% AR at 91 days) and the sulfonic acid derivative **479M08**[15] (max 21.6% AR still increasing at study end) were found to be major metabolites in soil with concentrations greater than 10% AR. Metabolite 479M11[16] occurred at >5% AR on 3 consecutive time points (7.5% AR at 14d, 6.8% AR at 30d and 6.8% AR at 60d) and therefore is considered a minor non-transient metabolite. Other metabolites identified were detected in smaller amounts (479M09[17] max 5.3% AR at study end; 479M12[18] < 2.8% AR). All metabolites identified contained both ring systems (the phenyl and the pyrazol rings). Cleavage of either of the ring systems is not a significant route of breakdown.

Under anaerobic conditions, the metabolite **479M06**[19] occurred in amounts greater than 10% AR (max 8.19-18.5% AR at day 68-120). For the intended use of metazachlor applied in the autumn to oilseed rape, periods of anaerobic soil conditions will occur in practice. However, the incidence of periods when conditions would be truly anaerobic for longer than 30 days would be very rare. Therefore, it was concluded that significant formation of the metabolite 479M06 under field conditions following the intended uses would be unlikely. The new anaerobic degradation study submitted by FSG to address the identification of the degradations products under aerobic conditions did not alter the conclusions already provided in the DAR.

A laboratory soil photolysis study indicated that there was little difference between the route of degradation of metazachlor in illuminated samples compared to dark controls other than in illuminated samples mineralisation to CO_2 was more significant (4.9% AR in the light after 15 days compared to 0.45% AR in the dark). This would indicate that light energy may play a part in transforming some metabolites. Additional clarification on the reliability of the DT_{50} calculations was provided in addendum 5. It was confirmed that the UV-vis absorption spectrum for metazachlor indicates it would not be expected to undergo direct photodegradation.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Rate of degradation of metazachlor in soil under dark aerobic conditions was investigated in the same studies employed to investigate the route of degradation. Two additional studies were provided by BSF (one study with non-radio-labelled metazachlor and one study conducted in a "lysimeter soil")

[14] 479M04 = BH479-4: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide
[15] 479M08 = BH479-8: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid
[16] 479M11 = BH479-11: methyl *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl) aminocarbonylmethyl sulfoxide
[17] 479M09 = BH479-9: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl acetic acid
[18] 479M12 = BH479-12: *N*-[(2-hydroxycarbonyl-6-methyl)phenyl]-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide
[19] 479M06 = BH479-6: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)acetamide

and a second study was available from FSG. A total of 10 soils were investigated at 10-30 ºC and 40% MWHC. First order aerobic degradation rates that are considered reliable for regulatory use ranged from 3.1 to 35.8 days. After normalisation to FOCUS reference conditions (20ºC and pF2) first order DT_{50} were 5.0-25.3 days, indicating that metazachlor can be classified as low to moderate persistent.

The rate of degradation of the soil major metabolite metazachlor oxalic acid (479M04) was investigated in two of the soil metabolism studies where the parent compound was dosed, as well as in two additional laboratory studies with 4 (BASF) and 3 (FSG) soils. The range of first order (non linear regression) $DT_{50\ (20ºC\ pF2)}$ for 479M04 was 80.1-183 days in four soils, whilst in the other soils the DT_{50} calculated were always significantly longer (> 2x) the study duration (of 100-125 days) i.e. > 200-250 days. Because only one reliable DT_{50} value was available for FSG dossier, a data requirement to provide at least 2 additional reliable DT_{50} values for 479M04 was identified by the RMS in the DAR. A new aerobic soil degradation study to investigate the degradation of 479M04 was submitted by the applicant and evaluated in addendum 5. The study was performed in three sols under aerobic conditions (20ºC and 60% MWHC) with non-radio-labelled 479M04. The experts agreed on the validity of the new degradation rates (SFO DT_{50}= 22.4-50.6 days) and considered these values as appropriate for exposure assessment.
In the original DAR, the available degradation rate estimates of the soil major metabolite 479M08 were always significantly longer than twice the study designs and therefore not considered to be appropriate for regulatory use. Two new aerobic soil degradation studies were submitted and evaluated in addendum 5. Non-radio-labelled metazachlor-sulfonic acid (479M08) was applied on three soils in each study, and incubated in the dark at 20ºC and 40% MWHC (study by BASF) or 60% MWHC (study by FSG). The additional data on the rate of degradation of 479M08 were considered acceptable by the experts. Following the normalisation to FOCUS reference conditions, SFO DT_{50} values ranged from 51 to 362 days (geometric mean = 123.2 days).

Filed soil dissipation studies where parent metazachlor was applied to bare soil (1.2-1.5 kg a.s./ha) or seeded oilseed rape before emergence, representing a range of soil types and climates across the EU were carried out at 5 sites in Germany, 2 sites in Spain and a site in Sweden. In addition the metabolite 479M08 (as the sodium salt)[20] was applied as test substance (0.5 kg/ha) to bare soil at 2 sites in Germany. Soil samples at all trial sites dosed with parent metazachlor were analysed for parent metazachlor and 479M04. In the more recent trials (2003, 4 sites) 479M08 was also analysed for. At the 2 German sites where 479M08 was dosed only this substance was analysed for. At the meeting of experts the method used to determine time 0 amounts (based on concentrations in standard soil contained in Petri dishes placed in the field in order to address variability) was discussed. Although actual measured soil concentrations in the field would have been preferred by the experts, it was agreed that sufficient samples were taken at time 0 to be able to reliably estimate the initial concentration at each site. In all trials where metazachlor was applied, it disappeared fairly quickly

[20] 479M08 (as sodium salt) = 479M08 (Na salt): sodium *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonate

and showed no tendency to move into deeper layers of soil in amounts measurable by the soil methods. Metabolites 479M04 and 479M08 were also found under field conditions under measurable amounts. At least in some trials they showed a tendency to move into deeper layers of soil. After the application of the metabolite 479M08 the compound could be detected up to 1 year after application in one trial and therefore is more stable than metazachlor. Additionally it could be found in soil layers down to 75 cm and showed a tendency to move into deeper layers of soil.
Dissipation rates were calculated using residues results from all soil layers where a residue was detected, so these DT_{50} values exclude losses from the top soil layer to the deeper soil layers that contained detectable residues. First order DT_{50}s that are considered reliable for regulatory use from these studies were: 2.8-21.3 days for metazachlor (DT_{90} = 9.3-70.7; n=8), 52.8-138.7 days for 479M04 (DT_{90} = 175.3-460.5 days; n=3) and 59.7-171 days for 479M08 (DT_{90} = 198.2-567.7 days; n=3). The normalised DT_{50} values were corrected to 20ºC (except for one study in which the metabolite 479M08 was applied), but were not corrected for soil moisture content and the resulting geometric mean were 6.8 days, 56.4 days and 71.7 days for metazachlor, 479M04 and 479M08 respectively. It was considered in volume 3 of the DAR that reliable degradation/dissipation rate estimates for the major soil metabolites BH479-4 and BH479-8 were not available as FSG had no field studies and the metabolite laboratory studies they submitted (with the exception of 1 soil dosed with BH479-4) produce estimated DT50 significantly longer than the duration of their laboratory studies. Since some of the key BASF field studies and their kinetic assessment have claims for data protection, this was therefore considered a data gap for FSG. FSG subsequently submitted additional acceptable laboratory rate of degradation studies for these two metabolites and the experts considered that worst case exposure assessments could be made using just their laboratory rate of degradation studies.

As the DT_{90} of the metabolites 479M04 and 479M08 were greater than a year at some field trials sites, the level to which they may accumulate would need to be assessed if applications were to be made in consecutive years. However, the growing of continuous oilseed rape is not good agricultural practice because of pest and disease pressure build up. Therefore a consideration of accumulation for these uses is not required. However, one applicant (FSG) has notified a use in ornamental plant production and therefore an assessment of the accumulation potential for these metabolites was identified as a data gap in the DAR. As a result FSG made the same argument that was made for the proposed uses to oilseed rape with one application every 3 years. The MS experts concluded that Member States should consider whether an assessment of the accumulation potential in soil is necessary in their own Member State, and may wish to include a label phrase which specifically restricts the number of applications to one every 3 years when authorising National approvals.

PEC (Predicted Environmental Concentration) in soil were performed for the maximum proposed use rate to oilseed rape (1.0 kg as/ ha; pre-emergence) which is a worse case than the other proposed GAP to oilseed rape (0.75 kg as/ ha; early post-emergence) and to ornamentals (0.75 kg as/ ha). Calculations were based, where available, on worst case half-lives (i.e. first order kinetics) as observed either in field dissipation trials, or when field data were not available, in laboratory soil studies from all available data (i.e. both applicants dossiers). In cases, where a half-life for a metabolite was not available, just an initial PEC was calculated (metabolites BH479-6, BH479-9, BH479-11 and BH479-12). For metabolites the maximum observed amounts from laboratory soil degradation studies were used. Because of the re-evaluation of the laboratory soil aerobic degradation study of Feser-Zugner (1998), where the maximum observed formation of the metabolite 479M04 was higher (= 17.9%) than those (= 16.2%) previously considered in PECsoil calculations, new calculation for this metabolite were performed and presented in addendum 5. Although these PECs represent the worst case, it should be noted that the experts concluded that the quantification of the metabolites in the above mentioned degradation study is uncertain and therefore the maximum observed formation of 17.9% for 479M04 is not reliable.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The adsorption of parent metazachlor to soil was measured under batch conditions in different laboratory studies. The Kf values were determined for 25 soils in the range 0.65-4.4 mL/g, Kf_{oc} 53.8-220 mL/g (mean 124 mL/g, median 115.7 mL/g), 1/n (Freundlich coefficient) 0.68-1.1 (mean 1/n = 0.865, median 1/n = 0.877). In a study with further 4 soils, adsorption measured in a pre test at 1 concentration resulted in Kdoc of 29.2-73.1 (Kd 0.37-1.659 mL/g). There was no evidence of any correlation of adsorption with soil pH. If the complete adsorption database for parent metazachlor is amalgamated the mean and median Koc are 114.4 mL/g and 110 mL/g. Metazachlor can be classified as medium to high mobile in soil.

Three studies with a total of eight batch absorption/desorption experiments were available for the major metabolite 479M04. Kf values were in the range 0.008-1.57 mL/g, Kf_{oc} 1-94 mL/g (mean 24.6 mL/g, median 5.5 mL/g), 1/n (Freundlich coefficient) 0.637-1.538 (mean 1/n = 1.026, median 1/n = 1.005). In a further study performed with 3 soils, adsorption measured in a pre test at 1 concentration resulted in Kd_{oc} of 9.1-29.6 mL/g (Kd 0.135-0.145-mL/g). Again there was no evidence of any correlation of adsorption with soil pH. If the complete adsorption database for 479M04 is amalgamated the mean and median Koc are 23.05 mL/g and 9.1 mL/g.

These values for the major metabolite 479M08 determined for 8 soils were in the range Kf 0.037-0.393 mL/g, Kf_{oc} 4-78.5 mL/g (mean 19.04 mL/g, median 8 mL/g), 1/n (Freundlich coefficient) 0.727-1.117 (mean 1/n = 0.891, median 1/n = 0.831). In a further 3 soils, adsorption measured in a pre test at 1 concentration resulted in Kd_{oc} of 5.7-10.5 (Kd 0.05-0.156 mL/g). Again there was no evidence of any correlation of adsorption with soil pH. If the complete adsorption database for 479M08 is amalgamated the mean and median Koc are 16.2 mL/g and 10 mL/g.

Metabolites 479M04 and 479M08 can be classified as high to very high mobile in soil.

Investigation on the adsorption properties of the minor aerobic soil metabolite 479M06 (major anaerobic soil metabolite and minor but significant metabolite in sediment and water systems see section 4.2.1) were determined for 4 soils. Kf values were in the range 0.363-1.562 mL/g, Kf_{oc} 44-62 mL/g (mean 53.7 mL/g, median 54.5 mL/g), 1/n (Freundlich coefficient) 0.905-0.928 (mean 1/n = 0.916, median 1/n = 0.9155). Again there was no evidence of any correlation of adsorption with soil pH.

An aged column leaching study was supplied but this contributes little to our knowledge of the mobility of metazachlor and its metabolites as characterisation of the significant amounts of radioactivity present in the leachate was not carried out.

In a 2 year lysimeter study carried out in Northern Germany to BBA guidelines, (sandy loam topsoil, 1.5% organic carbon, sand subsoil) metazachlor was applied in the first year only to the soil surface as a spray 15 days after an oilseed rape crop was sown on September at a rate equivalent to 1 kg a.s./ha. The application pattern of this study was representative of the highest notified intended use and the climatic conditions were considered to represent a realistic worst case for Northern Europe. Parent metazachlor was not determinable (limit of detection 0.04 µg/L) in any leachate sample. In contrast, the concentrations of 479M04 and non identified radioactivity were high (max annual average concentration of 479M04 = 21.4 µg/L parent equivalents). There was some doubt over the characterisation of the nature of radioactive residues (other than parent metazachlor) in the original study report as it is likely some breakdown products co-eluted with the chromatographic systems used. Two leachate samples from the winter period directly following application were subsequently analysed with reference standards for all the soil metabolites identified in the soil route of degradation study. This analysis demonstrated that in these leachate samples 479M12 was present at up to 3.6 µg/L, 479M08 was up to 17.3 µg/L, 479M04 was up to 9.6 µg/L, 479M09 was up to 3.3 µg/L and 479M11 was up to 2.5 µg/L (note these concentrations are not annual averages).

A second older lysimeter study was also submitted where metazachlor was either applied in the autumn or the spring at 1.2-1.5 kg a.s./ha to oilseed rape crops. The RMS considered this study does not support the intended use patterns that have been notified, and therefore it was consider not been relied on and should be regard as supporting background information only.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Data indicate metazachlor will be stable to aqueous hydrolysis at environmentally relevant temperatures and pH.

Direct aqueous photolysis cannot occur (no absorption of light energy over wavelengths pertinent to natural sunlight).

In a ready biodegradability test, metazachlor was ‘not readily biodegradable’ under the test conditions as defined by OECD / EU directives.

Laboratory data carried out on the dissipation processes of metazachlor were available on 4 different aerobic natural sediment water systems (20ºC). Mineralisation of the phenyl ring to CO_2 was minimal (0.5-1.0% AR at 91-99 days). Formation of unextracted residues in sediment was the most significant route of dissipation (57-67% AR at day 99, repeated (3) acetonitrile extracts or 25-43% AR at 91 days, methanol/hot methanol extracts). When residue not extracted by ethyl acetate was subjected to organic carbon fractionation, the majority of the radioactivity was associated with the fulvic acid fraction (27-37% AR at day 99).

No major (>10% AR) metabolites were resolved with the chromatographic systems used from samples at any time point, either in the water or sediment extracts of all 4 natural sediment water systems. Metabolite identification was considered reliable in the 'Millstream pond' and 'Swiss Lake' systems (BASF study). In the Schaephysen and Ruckhaltebecken systems (FSG study) the identity of the metabolites was unreliable except for the single metabolite 479M04. To address the issue, the applicant provided an additional study which supports the metabolites identification with the same method used for the identification of the aerobic soil degradation products (see section 4.1.1). The identification of these metabolites was considered acceptable by the experts, but it was agreed that metabolites quantification has some uncertainty.

The most significant metabolites identified were:

1) 479M04 the concentration for which was still increasing at study termination (99 days, at 7.33-8.41% AR in water and 1.6-2.8% AR in sediment extracts);
2) 479M06 the concentration for which was still increasing at study termination (99 days, at ca. 8% AR in water and 5.1-8.0% AR in sediment extracts, except in the mill stream pond where a peak of 8.9% AR had occurred at 57 days).

All metabolites identified contained both ring systems, (both the phenyl and the pyrazol rings). Cleavage of either of the ring systems is not a significant route of breakdown.

For the DT_{50} values for whole system and parent metazachlor a one compartment model was used. Metazachlor $DissT_{50\ whole\ syst}$ for metazachlor were in the range 13.4-27.8 days and $DegT_{50\ water}$ values ranged from 48.8 days to 384 days. The multicomparment model used to evaluate the metabolism of metabolites 479M04 and 479M06 was discussed at the meeting of experts. It was agreed that although there is a high degree of uncertainty related to this approach, conservative default values (DT_{50} of 1000 days for water and sediment phases) were used in FOCUS surface water step 1 and step 2 modelling and therefore no additional calculations were required.

FOCUS surface water modelling was performed by RMS using a combination of the annex II data sets supplied by the 2 applicants in accordance with FOCUS recommendations, and therefore different input parameters were obtained to those used in the applicants submitted. PECsw were calculated for the most critical notified use pattern of 1 kg a.s./ha applied pre- and post-emergence to oilseed rape for metazachlor (up to step 3 and step 4) and for metabolites 479M04, 479M08, 479M06, 479M09, 479M11 and 479M12 (global maximum PECsw at steps 1 and 2, and global maximum PECsed at step 1). In the modelling fieldDT_{50} values were used where available (metazachlor, 479M04 and 479M08) or an arbitrary DT_{50} value of 1000 day was selected as soil degradation input parameter. FSG did not have access to field data and no assessment was made for the proposed GAP for ornamentals. Although a data gap was not noted in the original assessment in the DAR, FSG submitted a new FOCUS SW modelling study for steps 3 and 4 for parent metazachlor to address their proposed use on ornamentals (addendum 5). It was concluded that the calculations presented can only be considered to be illustrative and Member states should consider the need for a label phrase to restrict applications to ornamental crops to once in every three years to mitigate the potential for accumulation of the metazachlor metabolites.

For step 4 calculations spray drift input was reduced to account for the inclusion of no spray buffer zones adjacent to the water body (5m, 10m and 20m). In addition for the runoff scenarios the use of grass buffer strips to reduce input to surface water was also considered. However, the experts agreed that for runoff scenarios (R1 and R3) PECs calculated with runoff and drift mitigated buffers should not be considered for risk assessment, as harmonised approaches on a European level are currently lacking.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

FOCUS groundwater modelling was carried out using FOCUS PELMO 3.3.2 for a use pattern when metazachlor is applied at 1 kg a.s./ha, 1 year in 3 (a typical use pattern for oilseed rape that is grown in a rotation), pre-emergence to winter and spring sown oilseed rape for all the FOCUS scenarios where it is defined that oilseed rape is grown. Simulations were carried out for metazachlor and its major metabolites 479M04 and 479M08. Pesticide properties used as input were derived following FOCUS guidance and the complete batch adsorption data set available and using (normalised to 20ºC, no correction for soil moisture) first order DT_{50} and kinetic formation fractions for the identified major soil metabolites from the available field data set. At the meeting of experts it was agreed that the modelling input parameters were appropriate. The results indicated that the 80^{th} percentile annual average concentration in the leachate at 1 m depth is < 0.001 µg/L for metazachlor and minimum/maximum PECgw values of 0.76/5.00 µg/L and 1.63/8.13 µg/L for metabolites 479M04 and 479M08 respectively.

For soil metabolites 479M06, 479M09, 479M11 and 479M12 the PECgw values could not be calculated using the FOCUS groundwater models as for these minor metabolites information is not available on sorption and degradation/soil formation fraction. The PEC_{gw} values were instead estimated for these metabolites. Lysimeter results of the metabolites BH479-9, BH479-11 and BH479-12 (for which measurements > detection limits are available) were transferred to the FOCUS scenarios based on transfer factors derived from the comparison of simulated and measured concentrations of the metabolites BH479-4 and BH479-8, for which lysimeter and modelling results are available. Estimated PECgw values for FOCUS scenarios were in the range 0.31-1.72 µg/L, 0.24-1.30 µg/L and 0.34-1.88 µg/L for BH479-9, BH479-11 and BH479-12 respectively. The remaining identified soil metabolite (BH469-6) was not identified above the detection limit (0.04 µg/L) in lysimeter leachate analysed using an analytical approach that would have identified it if it had been present. It was therefore considered that this metabolite would be expected to be < 0.1 µg/L in groundwater.

A new FOCUS groundwater modelling was submitted by FSG and evaluated in addendum 5. For the reason that some deviations (the full data set soil $labDT_{50}$ was not considered, uncertain crop interception % and 1/n value for metabolites) were noted, the experts did not accept the modelling. It was also noted that the study does not cover the proposed use on ornamentals. Member states may whish to note that the applicant has indicated that applications may only be made to ornamentals once in a three year period, that growth stages for ornamental species are quoted in the GAP table and that interception may be lower at earlier growth stages. Therefore Member states should consider all of these points when considering any national product registrations. In particular Member States should consider the need for a label phrase to restrict applications to ornamental crops to once in every three years.

Monitoring data on metazachlor groundwater concentrations were available but considered to be supportive information only by the experts.

4.3. FATE AND BEHAVIOUR IN AIR

Pure (99.6%) metazachlor has a vapour pressure of 9.5×10^{-5} Pa and water solubility of 446 mg/L (both at 20ºC) resulting in a calculated Henry's Law constant of 5.9×10^{-5} $Pa.m^3.mol^{-1}$. This combination of properties indicates that volatilisation from aqueous systems / soil water is likely to be low. This is confirmed for soil by the results of studies carried out under defined conditions (4% loss to trapped volatiles within 24 hours) and in the field (of that applied 6.9% was not recovered from soil after 24 hours) where measured losses were relatively low. Losses from plant surfaces were also measured with these being 10% loss to trapped volatiles within 24 hours under controlled conditions from bush bean leaves but only 1.6% of that applied not being recovered from oilseed rape leaves after 24 hours in the field.
The small proportion of metazachlor that is lost to the upper atmosphere is expected to degrade relatively rapidly, it having an Atkinson calculated troposheric photochemical oxidative photochemical (indirect reaction with OH radicals) degradation half life of 6.5 hours assuming a hydroxyl radical concentration of 5×10^5 radicals/ cm^3. Metazachlor would therefore be unlikely to be subject to long range aerial transport. Data from open literature on metazachlor fate in air was discussed at the meeting of experts. These studies were considered as supporting information and should not be used for the risk assessment.

5. Ecotoxicology

Metazachlor was discussed in the meeting of MS experts on ecotoxicology (PRAPeR 38) in December 2007.

5.1. RISK TO TERRESTRIAL VERTEBRATES

Data were submitted from two applicants (BASF and MAK-FSG). No long-term reproduction study was submitted by MAK-FSG. The representative uses evaluated were:

1. pre- and post-emergence in oilseed rape in northern and southern Europe (BASF) at an application rate of 1 kg metazachlor/ha.
2. post emergence in winter rape and in ornamental trees and shrubs (early post emergence of weeds) at an application rate of 0.75 kg metazachlor/ha.

The acute and long-term TERs were above the Annex VI trigger for the acute and short-term risk for all standard scenarios. However the long-term TERs for insectivorous birds were below the trigger of 5.

Summary of the risk assessment for birds

Active substance: Metazachlor	1st tier TER	Proposed refinements	Conclusion of peer review
Formulation: Butisan S Scenario: Oilseed rape, winter and spring, pre-emergence			
Acute risk	IB >36.98	Not required	
Short-term risk	IB >14.89	Not required	
Long- term/ reproductive risk	IB = 2.46	RMS proposed to use the RUD of 5.1 for large insects instead of 29 for small insects. Since no vegetation is present at the time of application it is assumed that only large insects and earthworms are taken as prey. The acute, short-term and long-term TERs for earthworm eating birds exceed the Annex VI trigger indicating a low risk.	The assumption that only large insects are taken was rejected. The RMS presented a refined risk assessment based on the assumption that 40% of the diet consists of small insects to achieve a TER of 5. This was accepted by the experts as a conservative assumption for insectivorous birds feeding on a bare field.
Formulation: Butisan S Scenario: Oilseed rape, winter and spring, post-emergence			
Acute risk	IB >36.98 HB >30.25	Not required	
Short-term risk	IB >14.89 HB >14.77	Not required	
Long-term risk	IB = 2.46 HB = 4.61	Focal species: grey partridge PDspring: 0.31(crop plants), 0.31 (weed plants), 0.34 (seeds), 0.04 animal matter PD summer: 0.14(crop plants), 0.0.14 (weed plants), 0.65 (seeds), 0.16 animal matter PT = 0.125 RMS rejected grey partridge and suggested wood pigeon Lack of justification of PD – details of time of year and whether the figures are relevant for the proposed GAP Radio tracking data reflect only the occurrence of grey partridge in different habitats but information demonstrating active time spent feeding in oilseed rape is missing.	It was agreed that the risk to bird reproduction is low for the use in autumn since the application is out of the breeding season. Spring uses: Insectivorous birds: the risk assessment was covered by the one for the pre-emergence use. Herbivorous/omnivorous birds: A new risk assessment with woodpigeon (*Columba palumbus*) and skylark (*Alauda arvensis*) as focal species was presented in addendum 6. The TER value for woodpigeon was calculated as 5.3 For the skylark, refinement of PD and PT were accepted by the experts. The resulting TER value was 5.1

Active substance: Metazachlor	1st tier TER	Proposed refinements	Conclusion of peer review
Formulation: Fuego Scenario: grassland (application to ornamental trees and shrubs)			
Acute risk	IB >40.56 HB >42.68	Not required	
Short-term risk	IB >19.85 HB >17.09	Not required	
Long-term risk	IB = 3.4 HB = 5.8	No refined risk assessment was originally submitted by the applicant and a data requirement was identified by the RMS in the DAR. Refinements of RUD, PT and residue decline were suggested by MAK-FSG in the refined risk assessment for insectivorous birds and assessed in addendum 6.	The suggested refinements were not supported by data and therefore rejected by the RMS.

HB: Herbivorous bird; IB: Insectivorous bird

The risk to birds from the use of formulation Fuego in winter oilseed rape was considered to be covered by the risk assessment for the formulation Butisan S. However a potential high long-term risk was identified for herbivorous birds. Since the representative use of Fuego is only winter oilseed rape and hence out of the breeding season adverse long-term effects on reproduction are considered unlikely by the RMS.

The risk from metabolites in plants was assessed as low. The acute, short-term and long-term TERs were above the Annex VI trigger values. The assessment was based on the highest formation rates in plant tissues and 10times higher toxicity of the plant metabolites compared to metazachlor.

The long-term risk to insectivorous birds needs to be refined for the use of Fuego in ornamental trees and shrubs.

Summary of the risk assessment for mammals:

Active substance: Metazachlor	1st tier TER	Proposed refinements	Conclusion of peer review
Formulation: Butisan S Scenario: pre-emergence application to oilseed rape			
Acute risk	SIM >90.1	Not required	
Long- term/ reproductive risk	SIM = 9.6	Not required	
Formulation: Butisan S Scenario: post-emergence application to oilseed rape			
Acute risk	MHM >82.1	Not required	
Long-term risk	MHM = 13.3	Not required	
Formulation: Fuego Scenario: grassland (application to ornamental trees and shrubs)			
Acute risk	SHM >13.5	Not required	
Long-term risk	SHM = 1.9	Required, nothing proposed by the applicant	Data requirement confirmed in the expert meeting.

SHM: Small herbivorous mammal; MHM: Medium herbivorous mammal; SIM: Small insectivorous mammal

The risk to mammals from the use of Fuego in oilseed rape was considered addressed by the risk assessment for the formulation Butisan S (= higher application rate). The RMS calculated also TERs for earthworm-eating mammals. The TERs were above the Annex VI trigger values indicating a low acute and long-term risk. The long-term TER for herbivorous birds was below the trigger of 5. The potential high long-term risk to small herbivorous mammals from the use in ornamental trees and shrubs needs to be addressed. This was identified as a data gap in the expert meeting.
No risk assessment was required for secondary poisoning since the log Pow was < 3.
The risk from major plant metabolites was assessed as low.

5.2. RISK TO AQUATIC ORGANISMS

A large dataset on tests with technical and formulated metazachlor was made available by both applicants. The lowest endpoints from the whole range of studies were used for the risk assessment. Algae and higher aquatic plants were the most sensitive groups of organisms tested (EbC50 = 0.0076 mg a.s./L (algae), 0.0022 mg a.s./L (*L. gibba*), ErC50 = 0.012 mg a.s./L (algae), 0.0071 mg a.s./L (*L. gibba*) . The TERs were above the Annex VI triggers for daphnids, fish and *Chironomus riparius* with PECsw values from FOCUS step2 (Chironomus), FOCUS step2 (daphnids), FOCUS step3 (fish).
A potential high risk was indicated in the lower tier risk assessment for algae and macrophytes. Refined risk assessments based on species sensitivity distribution (SSD) and mesocosm endpoints were presented by the applicants. A NOEC (population) of 2 µg a.s./L and a NOEAEC of 5 µg a.s./L (taking recovery into account) were derived from the mesocosm study. The RMS proposed using the

NOEC with a safety factor of 1 as the regulatory endpoint considering that the most sensitive plant species (*Lemna sp.*) was present in the mesocosm study or alternatively to use the NOEAEC in combination with a safety factor. Some experts were of the opinion that a safety factor >1 should be applied to the NOEC since it is not clear whether the mesocosm represents a worst case exposure situation covering the majority of aquatic habitats in agricultural landscapes. Additional data on effects on macrophytes observed in pond and stream model ecosystems confirmed that short-term effects occur at a concentration of 5 µg a.s./L. The experts agreed using the NOEAEC of 5 µg a.s./L together with a safety factor of 3 considering that the study was well conducted and that research done by Alterra in NL gave some indication that a safety factor of 3 covers spatial and temporal effects on mesocosm study endpoints.
A new risk assessment based on the geometric mean (113.6 µg a.s./L) was submitted by BASF and included in addendum 6. It was noted in the expert meeting that the tested emergent plants were less sensitive than the submerged plants and hence should not be combined in the SSD or geomean calculation. Based on the endpoints of the 4 submerged plants the geometric mean toxicity value is 40 µg a.s./L. The number of endpoints (4 submerged species) was considered not sufficient to derive a robust HC5 estimation. In some member states a safety factor of 4 is used in combination with the lower limit HC5. The experts noted that the regulatory endpoint derived from the mesocosm study was lower than the geomean of 40 µg a.s./L. Since the mesocosm study is considered as the highest tier test it was suggested to use the endpoint of 1.67 µg a.s./L (NOAEC of 5 µg a.s./L with a safety factor of 3) in the risk assessment. The trigger was exceeded only in the FOCUS step 3 part scenarios D4(pond), D5(pond), R1(pond) but the trigger was not met in a full FOCUS step 3 scenario for the representative uses of Butisan (1 kg a.s./ha) and Fuego (0.75 kg a.s./ha). A FOCUS step 4 TER calculation was presented for the use of Fuego (0.75 kg a.s./ha). The full FOCUS step 4 scenarios D1, D3, D4, D5 and the part scenario R1 (pond) resulted in a TER above the trigger if a no spray buffer zone of 5 metres was applied.. The trigger was not met in the full scenarios D2, R3 and the part scenario R1 (stream). No TER calculations were presented with FOCUSstep 4 PECsw for the use of Butisan (1 kg a.s./ha) since the data were generated with the formulation 'Fuego' and belong to Makhetishim and FSG. However if the regulatory endpoint of 1.67 µg a.s./L is compared to the FOCUS step 4 PECsw including a no-spray buffer zone of 10 m than the trigger would be met in all scenarios except D2 and R3 (full scenarios).

It is assumed that the use in ornamental trees and shrubs would not lead to higher concentrations of metazachlor in the aquatic environment and hence the risk assessment for oilseed rape covers also the risk from the use in ornamental trees and shrubs.

The risk to aquatic organism from the metabolites 479M04, 479M06, 479M08, 479M09, 479M11, 479M12 was assessed as low.

5.3. RISK TO BEES

Technical and formulated metazachlor is of low toxicity to bees. The acute oral and contact HQ values for an application rate of 1 kg metazachlor/ha was <50 indicating a low risk to bees. The lower application rate of 0.75 kg metazachlor/ha for the uses in winter oilseed rape and ornamental trees and shrubs is also covered by the assessment for 1 kg metazachlor/ha. Overall it is concluded that the risk to bees is low for the representative uses.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The in-field and off-field HQ values for the uses in oilseed rape were <2 for the standard indicator species. Laboratory studies with *Chrysoperla carnea, Poecilus cupreus, Aleochara bilineata, Pardosa sp*. were also available. No mortality or sublethal effects of >50% were observed in the tests at an application rate of 2.5 L product/ha suggesting a low in field risk for non-target arthropods for the representative uses evaluated.

5.5. RISK TO EARTHWORMS

Both applicants submitted studies with technical and formulated metazachlor. The acute toxicity of metazachlor to earthworms is low (LC50 > 1000 mg a.s./kg soil dw). The major soil metabolites 479M04 (BH479-4) and 479M08 (BH479-8) were acutely and chronically (56-d reproduction) tested. While the metabolites were of low acute toxicity (LC50s of about 1000 mg/kg soil dw) the corresponding long-term NOECs were in the range of 1.56 – 4 mg/kg soil dw. The endpoints for metazachlor were corrected by a factor of 2 since the log Pow is >2. The log Pow of the metabolites was calculated to be <2 and hence the endpoints for the metabolites were not corrected The acute TERs for metazachlor and the major metabolites were markedly above the trigger value of 10. The trigger of 5 was breached for the metabolite 479M08 based on the lowest endpoint from a study of FSG (TER = 4.8). The TER is based on a NOEC where no effects were observed at the highest tested dose and based on the endpoint from the study of BASF the long-term TER would be 12. The experts agreed that the long-term risk to earthworms is sufficiently addressed. BASF also submitted acute toxicity studies with the minor soil metabolites 476M06, 479M011, 779M012 showing a low acute toxicity of these metabolites. The corresponding TERs were several orders of magnitude above the trigger indicating a low acute risk from the metabolites.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

The $DT_{90(f)}$ of metazachlor is <100d and therefore no information is required. The major soil metabolites 479M04 (BH479-4) and 479M08 (BH479-8) are persistent in soil (DT_{90} >365 d). Effects on reproduction of springtails (*Folsomia candida*) were tested with the two metabolites and metazachlor formulated as “Fuego”. The TERs based on PECs from application of 1 kg metazachlor/ha in oilseed rape were markedly above the trigger of 5 indicating a low risk to other soil non-target macro-organisms. Since the $DT_{90(f)}$ of 479M04 (BH479-4) and 479M08 (BH479-8) is >365 days a litter-bag study is triggered. BASF submitted a litter-bag study which was evaluated in addendum 6. No effects were observed in the study but the calculated PECsoil values for the metabolites 479M04 and 479M08 were higher than the concentrations in the test system. However the effect on soil micro organisms was <25%, the TERlt for earthworms was >5 (except for the endpoint for 479M08 from a study of MAK-FSG) and the studies with *Folsomia candida* gave an indication that the risk to soil dwelling arthropods is low. Therefore the RMS concluded that a litter-bag study is not required. The experts agreed and concluded that the risk to soil dwelling macro-organisms and organic matter breakdown is low for the representative uses of metazachlor.

5.7. Risk to soil non-target micro-organisms

No effects of >25% on soil respiration and nitrification were found at concentrations of up to 7.5 kg metazachlor/kg (about 7.5 times the proposed application rate of 1 kg/ha) indicating a low risk to soil micro-organisms for the representative uses. BASF submitted studies with the major soil metabolites 479M04 and 479M08. No effects on soil nitrification and respiration were observed up to an application rate of 1.75 kg 479M04/ha for and no effect on soil nitrification was observed at the maximum tested application rate of 1.17 mg 479M08/ha. These application rate exceed the application rates of 0.16 mg 479M04/ha and 0.25 mg 479M08/ha recalculated from the corresponding initial PECs of 0.213 mg 479M04/kg soil and 0.335 mg 479M08/kg soil. Overall it is concluded that the risk soil non-target micro organisms is considered to be low for all representative uses evaluated.

MAK-FSG did not submit studies with the metabolites 479M04 and 479M08.

5.8. Risk to other non-target-organisms (flora and fauna)

Tests on seedling emergence and vegetative vigour were submitted by BASF (3 monocotyledon and 3 dicotyledon plant species) and MAK-FSG (2 monocotyledon and 4 dicotyledon plant species). The lowest endpoints were observed for rye grass (*Lolium perenne*) and lettuce (*Lactuca sativa*) (35.1 and 45.5 mL ButisanS/ha). Field trials resulted in higher ER50 values: ER50 (post emergence) = 260 mL ButisanS/ha and ER50 (seedling emergence) = 300 mL ButisanS/ha.

TERs for Butisan S based on the endpoints from glasshouse trials are below the trigger of 5. The TER is 6.05 if a no-spray buffer zone of 10 m is applied. Using the test results from the field trials then the TER is >5 for the pre-emergent exposure at 1 m distance from the treated field and the no-spray buffer zone can be reduced to 5m to achieve TERs above 5 for post-emergent exposure.

In the studies with the formulation “Fuego” the lowest endpoints were observed for oat (*Avena sativa*) and sugar beet (*Beta vulgaris*). The TERs were above the trigger of 5 for pre-emergent exposure at the standard distance of 1m but for the post-emergence exposure a no-spray buffer zone of 5m is required to achieve a TER > 5.

The risk to non-target plants from the use in ornamental trees and shrubs is considered as covered by the risk assessment for oilseed rape. No higher drift rates are expected from the use in ornamentals since the product is sprayed to reach weeds under the ornamental trees.

5.9. Risk to biological methods of sewage treatment

The EC50 for effects on respiration of activated sewage sludge was determined as >1000 mg metazachlor/L and > 10,000 mg fuego/L, respectively. It is not expected that metazachlor would reach biological sewage treatment plants in amounts greater than 1000 mg/L if applied according to the GAP and therefore the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: metazachlor, 479M04[21] and 479M08[22]

Definitions for monitoring: metazachlor

Water

Ground water

Definitions for exposure assessment: metazachlor, 479M04, 479M08, 479M09[23], 479M11[24] and 479M12[25]

Definitions for monitoring: metazachlor, 479M04, 479M08, 479M09, 479M11 and 479M12, but inclusion of the metabolites in this definition is subject to the final agreement on the hazard classification of metazachlor.

Surface water

Definitions for risk assessment: metazachlor (water and sediment)

Definitions for monitoring: metazachlor

Air

Definitions for risk assessment: metazachlor

Definitions for monitoring: metazachlor

Food of plant origin

Definitions for risk assessment: sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor

Definitions for monitoring: sum of metabolites 479M04, 479M08 and 479M16[26], expressed as metazachlor

[21] 479M04 = BH479-4: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide

[22] 479M08 = BH479-8: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid

[23] 479M09 = BH479-9: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl acetic acid

[24] 479M11 = BH479-11: methyl *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl) aminocarbonylmethyl sulfoxide

[25] 479M12 = BH479-12: *N*-[(2-hydroxycarbonyl-6-methyl)phenyl]-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide

[26] 479M16/BH 479-21:: 3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid

Food of animal origin

Definitions for risk assessment: sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor

Definitions for monitoring: sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
metazachlor	Low to moderate persistence Single first order DT_{50lab} 6.2-25.3 days (20°C, 40% MWHC) Actual field DT_{50} 2.8-21.3 days	Low acute toxicity and low risk to earthworms, low risk to collembola and to soil micro-organisms.
479M04	Moderate to very high persistence Single first order DT_{50lab} 22.4-578 days (20°C, 40% or 50% or 60% MWHC) Actual field DT_{50} 52.8-138.7 days	Low acute toxicity and low acute and low long term risk to earthworms and collembola, low risk to soil micro-organisms.
479M08	Moderate to very high persistence Single first order DT_{50lab} 60.1-375 days (20°C, 40% or 50% or 60% MWHC) Actual field DT_{50} 59.7-171 days	Low acute toxicity and low acute risk to earthworms, the long-term TER of 4.8 was below the trigger of 5 based on data from MAK-FSG, but the long-term risk to earthworms is regarded as low since the TER is calculated with a NOEC based on the highest tested dose and the TER was above the trigger of 5 based on the NOEC from the study of BASF, the risk to collembola and soil micro-organisms is low.

Ground water

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative uses** **(at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological relevance**
metazachlor	Medium to high mobility K_{foc} 53.8-220 mL/g	FOCUS PELMO 3.3.2: no, in all scenarios Lysimeter study: no, max annual average concentrations < 0.04 µg/L	Yes	Yes	Yes
479M04	High to very high mobility K_{foc} 1-94 mL/g	FOCUS PELMO 3.3.2: yes, trigger of 0.1 µg/L exceeded in all scenarios (range: 0.76-5.00 µg/L) Lysimeter study: yes, max annual average concentrations 6.33-21.39 µg/L	No	Yes (No genotoxic concern in experimental studies. However due to properties giving rise to the proposed classification of metazachlor as Cat 3 R40, the toxicology expert meeting considered the metabolite should be regarded as toxicologically relevant. Proposed classification to be considered in the ECHA process under Directive 67/548/EEC)	No

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative uses** **(at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological relevance**
479M06 (major metabolite under anaerobic conditions)	High to very high mobility K_{foc} 44-62 mL/g	No data available, not required	No	No data available, No data required	No
479M08	High to very high mobility K_{foc} 4-78.5 mL/g	FOCUS PELMO 3.3.2: yes, trigger of 0.1 µg/L exceeded in all scenarios (range: 1.63-8.13 µg/L) Lysimeter: max concentrations in 2 leachate samples 5.8-12 µg/L	No	Yes (No genotoxic concern in experimental studies. However due to properties giving rise to the proposed classification of metazachlor as Cat 3 R40, the toxicology expert meeting considered the metabolite should be regarded as toxicologically relevant. Proposed classification to be considered in the ECHA process under Directive 67/548/EEC)	No

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
479M09	No data, arbitrary K_{oc} = 0 mL/g used for modelling purpose	Estimations with transfer factors derived from lysimeter concentrations to modelled concentrations for each FOCUS scenario (see details in section 4.2.2): yes, trigger of 0.1 µg/L exceeded in all scenarios (range: 0.31-1.72 µg/L) Lysimeter: max concentrations in 2 leachate samples 1.3-3.3 µg/L	No	Yes (No genotoxic concern in experimental studies. However due to properties giving rise to the proposed classification of metazachlor as Cat 3 R40, the toxicology expert meeting considered the metabolite should be regarded as toxicologically relevant. Proposed classification to be considered in the ECHA process under Directive 67/548/EEC)	No

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
479M11	No data, arbitrary K_{oc} = 0 mL/g used for modelling purpose	Estimations with transfer factors derived from lysimeter concentrations to modelled concentrations for each FOCUS scenario (see details in section 4.2.2): yes, trigger of 0.1 µg/L exceeded in all scenarios (range: 0.24-1.30 µg/L) Lysimeter: max concentrations in 2 leachate samples 0.8-2.5 µg/L	No	Yes (No genotoxic concern in experimental studies. However due to properties giving rise to the proposed classification of metazachlor as Cat 3 R40, the toxicology expert meeting considered the metabolite should be regarded as toxicologically relevant. Proposed classification to be considered in the ECHA process under Directive 67/548/EEC)	No

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative uses** **(at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological relevance**
479M12	No data, arbitrary K_{oc} = 0 mL/g used for modelling purpose	Estimations with transfer factors derived from lysimeter concentrations to modelled concentrations for each FOCUS scenario (see details in section 4.2.2): yes, trigger of 0.1 µg/L exceeded in all scenarios (range: 0.34-1.88 µg/L) Lysimeter: max concentrations in 2 leachate samples 0.4-3.6 µg/L	No	Yes (No genotoxic concern in experimental studies. However due to properties giving rise to the proposed classification of metazachlor as Cat 3 R40, the toxicology expert meeting considered the metabolite should be regarded as toxicologically relevant. Proposed classification to be considered in the ECHA process under Directive 67/548/EEC)	No

Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Metazachlor (water and sediment)	Very toxic to aquatic organisms (lowest endpoint observed for Lemna gibba EbC_{50} = 0.0022 mg/L).

Compound (name and/or code)	**Ecotoxicology**
479M04 (originating in the sw and/or moving from soil)	More than 3 orders of magnitude less toxic to aquatic organisms compared to metazachlor. The risk to aquatic organisms was assessed as low.
479M06 (originating in the sw and/or moving from soil)	More than 3 orders of magnitude less toxic to aquatic organisms compared to metazachlor. The risk to aquatic organisms was assessed as low.
479M08 (originating in the sw and/or moving from soil)	More than 3 orders of magnitude less toxic to aquatic organisms compared to metazachlor. The risk to aquatic organisms was assessed as low.
479M09 (originating in the sw and/or moving from soil)	More than 3 orders of magnitude less toxic to aquatic organisms compared to metazachlor. The risk to aquatic organisms was assessed as low.
479M11 (originating in the sw and/or moving from soil)	More than 3 orders of magnitude less toxic to aquatic organisms compared to metazachlor. The risk to aquatic organisms was assessed as low.
479M12 (originating in the sw and/or moving from soil)	More than 3 orders of magnitude less toxic to aquatic organisms compared to metazachlor. The risk to aquatic organisms was assessed as low.

Air

Compound (name and/or code)	**Toxicology**
Metazachlor	Not acutely toxic via inhalation

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Information on the identity and purity of all starting materials and process solvents (MAK source only) is required. (relevant for the representative uses evaluated for Fuego, date of submission unknown, data gap identified by experts of PRAPeR 36 meeting, November 2007; refer to chapter 1)
- A new calculation for Henry's law constant based on the vapour pressure and water solubility (MAK source only) is required. (relevant for the representative uses evaluated for Fuego, date of submission unknown, data gap identified by experts of PRAPeR 36 meeting, November 2007; refer to chapter 1)
- The level of ethoxylation for the co-formulants is required. (relevant for all representative uses evaluated, data gap identified by experts of PRAPeR 36 meeting, November 2007; refer to chapter 1, data provided to the RMS, however not evaluated and not peer reviewed).
- For applicant FSG, addressing the genotoxicity of the impurities #3, #4, #6 and #7 is needed (relevant for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 39 meeting, December 2007; refer to chapter 2; after the meeting of experts it is noted that an assessment of the genotoxicity of impurity #6 is reported in the addendum to vol.4 to the DAR, September 2007).
- A valid multigeneration study for BASF is missing (gap with no influence on the overall risk assessment, relevant for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 39 meeting, December 2007; refer to chapter 2.6)
- Should the proposed classification of the parent, Carc. Cat.3 R40 be confirmed in the context of the European Chemicals Agency (ECHA) programme for classification and labelling under Directive 67/548/EEC this would, in line, with the guidance document on groundwater metabolites, require that, for those metabolites with the potential to contaminate groundwater, convincing evidence must be provided that the metabolites will not lead to the risk of carcinogenicity (A joint paper from BASF and FCS, providing a detailed review of the available data on tumour incidences in relation to classification, has been submitted to the rapporteur in March 2008 but not evaluated [in line with Regulation 1490/2002, as amended]. Further consideration of this additional information should be referred to ECHA as part of the consideration of the classification proposal.)
- For applicant MAK-FSG, metabolism studies in livestock or a robust argumentation, based on an assessment of actual livestock exposure supported by appropriate field residue data in primary and rotational crops, showing that these studies do not need to be performed (relevant representative use in winter rape, date of submission unknown; refer to chapter 3.2)
- For applicant BASF, storage stability studies for metabolite 479M16 in rape seed (relevant for all representative uses evaluated, date of submission: December 2008; refer to chapter 3.1.1)
- For applicants BASF and MAK-FSG, storage stability studies for metabolites 479M04 and 479M08 in rotational crop if a change related to the proposed label restriction related to

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

rotational crops needs to be supported by field residue trials in rotational crops (relevant for representative uses in rape seed, date of submission: December 2008 for BASF; refer to chapter 3.1.2)

- For the applicant MAK-FSG, a confined rotational crop study with the aim of determining the residue pattern and metabolic pathway in rotational crops (relevant for representative uses in rape seed, date of submission unknown; refer to chapter 3.1.2)
- For the applicant MAK-FSG, field rotational crop study with the aim of determining the residue levels in rotational crops and appropriate rotational crop management (relevant for representative uses in rape seed, date of submission unknown; refer to chapter 3.1.2)
- The long-term risk to insectivorous birds needs to be addressed. (relevant for the use of the formulation Fuego in ornamentals; no submission date proposed by the applicant MAK-FSG; refer to point 5.1.)
- The potential high long-term risk to small herbivorous mammals from the use in ornamental trees and shrubs needs to be addressed. (relevant for the use of the formulation Fuego in ornamentals; data requirement identified in the DAR and confirmed in the expert meeting; no submission date proposed by the applicant MAK-FSG; refer to point 5.1.)
- Studies on soil nitrification and respiration with the metabolites 479M04 and 479M08 (relevant for the uses of the formulation Fuego in ornamentals and oilseed rape; no submission date proposed by the applicant MAK-FSG; refer to point 5.7). Note: The studies are not required for the Annex I decision making since data were made available by BASF.

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicants which comprise single pre- or post emergence foliar spraying to control annual weeds in winter and spring rapeseed (Butisan S), up to growth stage of BBCH 00-18, in all EU countries, at a single application at a maximum application rate of 1 kg a.s./ha, and early post emergence applications with conventional tractor-mounted spraying devices to control annual weeds and broad-leaved weeds in winter oilseed rape and ornamental trees (Northern White Cedar (*Thuja occidentalis*), Rhododendron (*Rhododendron* spp.), Privet (*Ligustrum* spp.) Lilac (*Syringa* spp.), Alder (*Alnus glutinosa*), Grey Willow (*Salix cinerea*), Sea-buckthorn (*Hippophae rhamnoides*), Norway spruce (*Picea abies*)) (Fuego), up to growth stage of BBCH 10-13, and BBCH 11-12 respectively, at a single application at a maximum application rate of 0.75 kg a.s./ha.

The representative formulated product for the evaluation were “Butisan S” (BASF) and “Fuego” (MAK), both suspension concentrates (SC) containing 500 g/l metazachlor, registered under different trade names in Europe.

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Adequate analytical methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant and animal origin and environmental matrices, however subject to the final agreement on the hazard classification of metazachlor, additional analytical methods for groundwater monitoring would be required.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products are possible.

As for mammalian toxicology, metazachlor acute toxicity is low via oral, dermal and inhalation routes (LD50>2000 mg/kg and LC50>34.5 mg/l). Metazachlor is neither a skin nor an eye irritant. Metazachlor was proposed to be classified as skin sensitiser R43 "May cause sensitisation by skin contact". The relevant NOAELs for subacute and subchronic exposure in rats are 110 mg/kg bw/day and 21 mg/kg bw/day (BASF and FSG, LOAELs 330 and 137 mg/kg bw/day, respectively). Metazachlor did not show any genotoxic potential.
Liver adenomas and thyroid tumours occurred in the rat, while the mouse showed slight increases in bladder transitional cell tumours at high dose levels. Since there was no genotoxicity and clear no-effect levels for tumour development were seen in all tests, it was apparent that tumour development could be considered to involve a threshold mechanism. A classification as Carc. Cat. 3 R40 ("Limited evidence of a carcinogenic effect") was proposed. The parental NOAEL for the BASF study (limited validity) is 1000 ppm as well as the reproductive and the offspring NOAELs. The parental and the reproductive NOAELs of the FSG study are 151 and 192 mg/kg bw/day (2000 ppm), respectively. For the offspring the NOAEL is 20 mg/kg bw/day (200 ppm) based on reduced pup weight and survival in the F3 generation. No evidence of teratogenicity was seen in developmental toxicity studies in the rat and rabbit. The relevant maternal NOAELs are 50 mg/kg bw/day in rat and rabbit (BASF) and 30 and 250 mg/kg bw/day in rabbit and rat, respectively (FSG); the relevant developmental NOAELs are 250 and 450 mg/kg bw/day in rabbit and rat, respectively (BASF) and 120 and 250 mg/kg bw/day in rabbit and rat, respectively (FSG).
Metazachlor did not show any potential for acute, repeated dose or delayed neurotoxicity.
An ADI of 0.08 mg/kg bw/day was derived for metazachlor, based on the NOAEL of 8.5 mg/kg bw/day; an ARfD of 0.5 mg/kg bw was derived, based on the NOAEL of 50 mg/kg bw/day from the developmental study in rats, and the AOEL was set at 0.2 mg/kg bw/day, based on the relevant short term toxicity NOAEL 21 mg/kg bw/day in rat. The safety factor applied is 100.
The operator exposure is below the AOEL for Butisan only with the use of gloves when handling the concentrate, coveralls and gloves during application (German model); for Fuego the exposure is below the AOEL even without PPE for field application estimated with the German model, with use of gloves during mixing/loading (tractor application, UK POEM) and with the use of gloves when handling the concentrate, coveralls and gloves during application (knapsack spraying, UK POEM).
The re-entry exposure is estimated to be above the AOEL for both Butisan and below the AOEL for Fuego. Bystander exposure is below the AOEL for both plant protection products.

The metabolism of metazachlor in plant and livestock is extensive and the parent compound does not participate to the toxicological burden the consumer is exposed to. The residue definition for monitoring is proposed to include all residual compounds containing the 2,6-dimethylaniline moiety. For monitoring of plant products, 3 metabolites have been identified as valid indicator compounds: metabolites 479M04, 479M08 and 479M16.

A possible transfer of soil residues to rotational crops has been identified, but under usual rotation practices with rape seed no measurable residue level above the analytical limit of quantification is expected in food commodities from rotational crops.

There is a low exposure of livestock to residues present in feeding stuff but their transfer to edible animal commodities is not expected to reach analytically measurable levels.

No risk for the consumer has been identified resulting from short or long term dietary exposure to residues in food commodities and to metabolites contaminating groundwater resulting from the representative use of metazachlor in rape seed.

Sufficient data were available to satisfy the data requirements and characterise the fate and behaviour of metazachlor in the environment as required by the current regulatory framework. However, it should be noted that the whole assessment cover only intended uses with only one application every three years. The potential for groundwater exposure from the applied for intended uses above the parametric drinking water limit of 0.1 µg/L by parent metazachlor is concluded to be low. As for 479M04 and 479M08, FOCUS modelling results indicated that these metabolites are expected to exceed 0.75 µg/L in all the FOCUS groundwater scenarios where it is defined that oilseed rape is grown. For soil metabolites 479M09, 479M11 and 479M12 the PECgw values could not be calculated using the FOCUS groundwater models. The PEC_{gw} values were instead estimated for these metabolites on the basis of transfer factors derived from the comparison of simulated and measured concentrations of the metabolites BH479-4 and BH479-8, for which lysimeter and modelling results are available. Estimated PECgw values for FOCUS scenarios were in the range 0.31-1.72 µg/L, 0.24-1.30 µg/L and 0.34-1.88 µg/L for BH479-9, BH479-11 and BH479-12 respectively. The classification as Carc. Cat. 3 R40 ("Limited evidence of a carcinogenic effect") proposed by the expert meeting on mammalian toxicology has implications for the relevance of the metabolites with the potential to contaminate groundwater. Should the proposed classification of the parent, Carc. Cat.3 R40 be confirmed in the context of the European Chemicals Agency (ECHA) programme for classification and labelling under Directive 67/548/EEC this would, in line, with the guidance document on groundwater metabolites, require that, for those metabolites with the potential to contaminate groundwater, convincing evidence must be provided that the metabolites will not lead to the risk of carcinogenicity.

A potential high long-term risk to birds and mammals was indicated in the first-tier risk assessment. The suggested refinements were accepted by the experts for the uses of Butisan in oilseed rape. A data gap for further refinement of the risk to insectivorous birds and for herbivorous mammals was identified for the use of Fuego in ornamentals. A potential high risk to primary producers was indicated in the lower tier risk assessment. Refined risk assessments based on species sensitivity

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

distribution (SSD) and mesocosm endpoints were presented by the applicants. A new risk assessment based on the geometric mean (113.6 µg a.s./L) was submitted by BASF. It was noted in the expert meeting that the tested emergent plants were less sensitive than the submerged plants and hence should not be combined in the SSD or geomean calculation. Based on the endpoints of the 4 submerged plants the geometric mean toxicity value is 40 µg a.s./L. The number of endpoints (4 submerged species) was considered not sufficient to derive a robust HC5 estimation. Therefore it was suggested to use a safety factor of 4 in combination with the lower limit HC5. The experts suggested to use the endpoint of 1.67 µg a.s./L from the mesocosm study (NOAEC of 5 µg a.s./L with a safety factor of 3) in the risk assessment. A FOCUS step 4 TER calculation was presented for the use of Fuego (0.75 kg a.s./ha). The full FOCUS step 4 scenarios D1, D3, D4, D5 and the part scenario R1 (pond) resulted in a TER above the trigger if a no spray buffer zone of 5 metres was applied. The trigger was not met in the full scenarios D2, R3 and the part scenario R1 (stream). No TER calculations were presented with FOCUSstep 4 PECsw for the use of Butisan (1 kg a.s./ha). However if the regulatory endpoint of 1.67 µg a.s./L is compared to the FOCUS step 4 PECsw including a no-spray buffer zone of 10 metres than the trigger would be met in all scenarios except D2 and R3 (full scenarios). It is assumed that the use in ornamental trees and shrubs would not lead to higher concentrations of metazachlor in the aquatic environment and hence the risk assessment for oilseed rape covers also the risk from the use in ornamental trees and shrubs. The risk to aquatic organism from the metabolites 479M04, 479M06, 479M08, 479M09, 479M11, 479M12 was assessed as low. The acute and long-term TER values for earthworms were above the trigger for metazachlor and the metabolite 479M04. The long-term TER of 4.8 for metabolite 479M08 was below the trigger of 5. The NOEC used in the TER calculation was based on the highest concentration tested. Therefore the risk to earthworms was considered as addressed. Effects on reproduction of springtails (*Folsomia candida*) were tested with the two major soil metabolites 479M04, 479M08) and metazachlor formulated as "Fuego". The TERs based on PECs from application of 1 kg metazachlor/ha in oilseed rape were markedly above the trigger of 5 indicating a low risk to other soil non-target macro-organisms. Since the $DT_{90(f)}$ of 479M04 (BH479-4) and 479M08 (BH479-8) is >365 days a litter-bag study is triggered. However the effect on soil micro organisms was <25%, the TERlt for earthworms was >5 (except for the endpoint for 479M08 from a study of MAK-FSG) and the studies with *Folsomia candida* gave an indication that the risk to soil dwelling arthropods is low. Therefore it was concluded that the risk to soil dwelling macro-organisms and organic matter breakdown is low for the representative uses of metazachlor. TERs for non-target plants based on the endpoints from glasshouse trials were below the trigger of 5. The TER is 6.05 if a no-spray buffer zone of 10 m is applied. Using the test results from the field trials then the TER is >5 for the pre-emergent exposure at 1 m distance from the treated field and the no-spray buffer zone can be reduced to 5m to achieve TERs above 5 for post-emergent exposure. The TERs for the use of Fuego were above the trigger of 5 for pre-emergent exposure at the standard distance of 1m but for the post-emergence exposure a no-spray buffer zone of 5m is required to achieve a TER > 5. The risk to non-target plants from the use in ornamental trees and shrubs is considered as covered by the risk assessment for oilseed rape. No higher drift rates are expected from the use in ornamental since the product is sprayed to reach weeds under the ornamental trees.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Particular conditions proposed to be taken into account to manage the risk(s) identified

- Use of PPE to reduce operator exposure for Butisan.
- The available risk assessment cover intended uses applied for with only one application every three years.
- No spray buffer zones of 5 metres (use of Fuego) D1, D3, D4, D5 and the part scenario R1 (pond) resulted in a TER above the trigger (the trigger was not met in the full scenarios D2, R3 and the part scenario R1 (stream). The trigger would be met in all scenarios except D2 and R3 (full scenarios) for the use of Butisan in oilseed rape if a no-spray buffer zone of 10 metres is applied.
- An in-field no spray buffer zone of 5 metres is required to protect non-target plants in the off-field area.

Critical areas of concern

- The classification as Carc. Cat. 3 R40 ("Limited evidence of a carcinogenic effect") proposed by PRAPeR meeting to be forwarded to ECHA has a potential impact on the definition of relevant metabolites in groundwater (according to the Guidance Document on the assessment of the relevance of metabolites in ground water - SANCO/221/2000).
- The long-term risk assessment for birds and mammals needs further refinement for the use of Fuego in ornamental trees and shrubs.
- The potential to contaminate groundwater under a wide range of geoclimatic conditions has been identified for metabolites 479M04 (FOCUS GW: 0.76-5.00 µg/L), 479M08 (FOCUS GW: 1.63-8.13 µg/L), 479M09 (FOCUS GW: 0.31-1.72 µg/L), 479M11 (FOCUS GW: 0.24-1.30 µg/L) and 479M12 (FOCUS GW: 0.34-1.88 µg/L). These metabolites are currently considered relevant by experts at the PRAPeR toxicology meeting due to the proposed classification of metazachlor as Cat 3 R40.

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

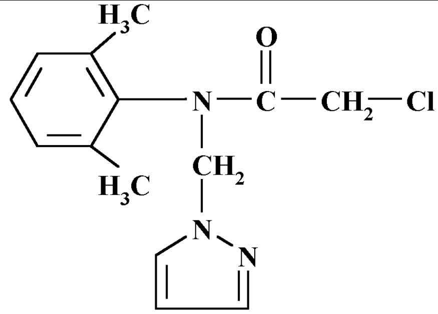
(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Metazachlor
Function (*e.g.* fungicide)	Herbicide

Rapporteur Member State	UK
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-chloro-*N*-(pyrazol-1-ylmethyl)acet-2',6'-xylidide
Chemical name (CA) ‡	2-chloro-*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)acetamide
CIPAC No ‡	411
CAS No ‡	67129-08-2
EEC No (EINECS or ELINCS) ‡	266-583-0
FAO Specification (including year of publication)‡	411/TC (1999) min. 940 g/kg
Minimum purity of the active substance as manufactured (g/kg) – BASF ‡	950g/Kg
Minimum purity of the active substance as manufactured (g/kg) – MAK-FSG ‡	950g/Kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	toluene max. 0.01%
Molecular formula ‡	$C_{14}H_{16}Cl\ N_3O$
Molecular mass ‡	277.8 g/mol
Structural formula ‡	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical and chemical properties (Annex IIA, point 2)

Melting point ‡ **BAS**	3 different crystal modifications of metazachlor which exhibit different melting points (99.6-99.9%) Recrystallised from: chloroform/hexane 80.3°C (peak 1) (no peak 2) diisopropylether 76.3°C (peak 1) 83.9°C (peak 2) cyclohexane 80.5°C (peak 1) 83.9°C (peak 2)
Melting point ‡ **MAK-FSG**	78-81°C (97%)
Boiling point ‡ **BAS**	During DSC there was no endothermic effect that is unrelated to the m.p. up to the decomposition temperature; therefore sublimation or boiling of the test substance can be excluded
Boiling point ‡ **MAK-FSG**	The active substance decomposes before boiling
Temperature of decomposition **BAS**	220°C (99.6-99.9%)
Temperature of decomposition **MAK-FSG**	238 °C (98.6%)
Appearance ‡ **BAS**	Solid partly coarse rained white powder (97.4%)
Appearance ‡ **MAK-FSG**	Light beige crystalline powder (98.5%)
Vapour pressure ‡ **BAS**	Very slightly volatile (99.6%) at 20°C 9.5 x10^{-5} Pa at 25°C 0.22 x 10^{-5} Pa
Vapour pressure ‡ **MAK-FSG**	Very slightly volatile (97%) at 20°C 8.12 x10^{-5} Pa at 25°C 0.19 x 10^{-5} Pa
Henry's law constant ‡ **BAS, MAK-FSG**	5.9 x 10^{-5} Pa m^3 mol^{-1} at 20°C
Solubility in water ‡ **BAS**	in neutral water 0.45 (99.6% g/l, at 20°C) at pH 0.3 0.71 at pH 1.3 0.45 at pH 3.8 0.43
Solubility in water ‡ **MAK-FSG**	at pH 7 0.63 (97% g/l, at 25°C) at pH 5 0.59 at pH 9 0.55 at pH 5.7 (HPLC water) 0.56

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Solubility in organic solvents ‡ **BAS**	(99.6% in g/l, at 20°C) n-heptane: < 10 toluene: > 250 dichloromethane: > 250 methanol: > 250 acetone: > 250 ethyl acetate > 250 acetonitrile > 250 n,n-dimethylformamide > 250 n-octanol 29-33 2-propanol 40-50
Solubility in organic solvents‡ **MAK-FSG**	(97.1% in g/l, at 21°C) hexane: 5 toluene: 280 1,2-dichloroethane: 657 methanol: 240 acetone: 485 ethyl acetate 359
Surface tension **BAS**	62.8 mN/m (0.1% and 1.0% w/w concentration saturated solution used) (99.6%)
Surface tension **MAK-FSG**	61.8 mN/m (0.1% w/w concentration) (97.5%)
Partition co-efficient (log P_{OW}) ‡ **BAS**	Log Pow = 2.49 at 21°C at pH 7 (99.6%)
Partition co-efficient (log P_{OW})) ‡ **MAK-FSG**	Log Pow = 2.5 at 22°C at pH 7 and pH 2.1 (97%)
Dissociation constant ‡ **BAS, MAK-FSG**	None, The test substance does not dissociate in water
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) ‡ **BAS**	neutral medium (methanol) (99.6%) $\varepsilon(Lmol^{-1}cm^{-1})$@207 nm=1.9 $x10^4$ $\varepsilon(Lmol^{-1}cm^{-1})$@265 nm=483 0 absorbance above 290 nm
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) ‡ **MAK-FSG**	neutral medium (methanol) (97%) $\varepsilon(Lmol^{-1}cm^{-1})$@214 nm=1.7 $x10^4$ $\varepsilon(Lmol^{-1}cm^{-1})$@266 nm=494 trace absorbance (well below 10) above 290 nm
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡ **BAS, MAK-FSG**	See above
Flammability ‡ **BAS**	Not highly flammable (96.6%)
Flammability ‡**MAK-FSG**	Not highly flammable (96.6-97.5%)
Explosive properties ‡ **BAS**	The applicant has proposed that the structural formula indicates the active substance incapable of explosivity with reference to UN (1999) Recommendations on the Transport of Dangerous Goods; justification acceptable, non-explosive
Explosive properties ‡ **MAK-FSG**	non-explosive (EC A14) (96.6%)
Oxidising properties ‡ **BAS, MAK-FSG**	The notifier has proposed that the structural formula indicates the active substance does not have the potential to be oxidising with reference to UN (1999) Recommendations on the Transport of Dangerous Goods

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of representative uses evaluated (*Metazachlor*)

BASF

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) (m)	Remarks:
					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 (l)		
Rapeseed, winter, spring	*South EU*	Butisan S (BAS 479 22H)	F	Annual weeds	SC	500	S P	00-09	1	Not relevant	0.17-0.5	200-600	1.0	Winter -End of January in year of harvest Spring – before 10th true leaf.	Preemergence, waiting period determined by use pattern [1]
Rapeseed, winter-, spring	*South EU*	Butisan S (BAS 479 22H)	F	Annual weeds	SC	500	S P	10-18	1	Not relevant	0.17-0.5	200-600	1.0	Winter -End of January in year of harvest Spring – before 10th true leaf.	Postemergence, waiting period determined by use pattern [1]
Rapeseed, winter, spring	*North EU*	Butisan S (BAS 479 22H)	F	Annual weeds	SC	500	S P	00-09	1	Not relevant	0.17-0.5	200-600	1.0	Winter -End of January in year of harvest Spring – before 10th true leaf.	Preemergence, waiting period determined by use pattern [1]
Rapeseed, winter-, spring	*North EU*	Butisan S (BAS 479 22H)	F	Annual weeds	SC	500	S P	10-18	1	Not relevant	0.17-0.5	200-600	1.0	Winter -End of January in year of harvest Spring – before 10th true leaf.	Posremergence, waiting period determined by use pattern [1]

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

MAK-FSG

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) (m)	Remarks:
					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 (l)		
Winter rape	GE	FUEGO	F	Grass weeds, particularly annual meadow grass, and broadleaved weeds	SC	500 g/l	Spraying	early post-emergence (BBCH 10-13)	1	not relevant	0.25	300	0.75	F	not stated [1]
Northern White Cedar (*Thuja occidentalis*), Rhododendron (*Rhododendron* spp.), Privet (*Ligustrum* spp.) Lilac (*Syringa* spp.), Alder (*Alnus glutinosa*), Grey Willow (*Salix cinerea*), Sea-buckthorn (*Hippophae rhamnoides*), Norway spruce (*Picea abies*)	GE	FUEGO	F	Grass weeds, particularly annual meadow grass, and broadleaved weeds	SC	500 g/l	Spraying	early post-emergence of the weeds (BBCH 11-12)	1	Not relevant	0.25	300	0.75	na	The available risk assessment cover intended uses applied for with only one application every three years. [1]

[1] Metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 have the potential to contaminate groundwater under a wide range of geoclimatic conditions. These metabolites are currently considered relevant by experts at the PRAPeR toxicology meeting due to the proposed classification of metazachlor as Cat 3 R40.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s). (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).** (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) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.2 Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	HPLC UV (CIPAC 411/TC/M/-) BAS HPLC UV (CIPAC 411/TC/M/-) MAK
Impurities in technical as (analytical technique)	HPLC UV (confirmation by MS) BAS GC-FID (confirmation by MS) MAK-FSG
Plant protection product (analytical technique)	HPLC UV (CIPAC 411/SC/M/-) BAS HPLC UV MAK-FSG

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	BAS: Enforcement GC-FID (or GC-MS) common moiety method for ‘total residues’ of metazachlor, 479-M04, 479-M08 & 479-M16 [determined as the 2,6-dimethylaniline moiety of metazachlor] – LOQ 0.05 mg/kg. Validated for metazaclor only in oil seed rape and cabbage (primary and ILV), wheat grain, wheat straw, carrot, leek, turnip, cauliflower and sauerkraut (primary only); validated for 479-M04, 479-M08 and 479-M16 in oil seed rape, wheat grain, wheat straw, cabbage and carrot (primary only) Confirmatory LC-MS/MS for metabolite 479M16 LOQ 0.01 mg/kg. Validated for lettuce, orange, oil seed rape, wheat grain, white cabbage (primary and ILV), Brussels spouts, curly kale and rape forage (primary only). LC-MS/MS for metabolites 479-M04 & 479-M08 LOQ 0.01 mg/kg. Validated in wheat grain, lettuce, oil seed rape (primary and ILV), wheat straw, cauliflower, lemon and apple (primary only). MAK-FSG: Enforcement GC-MS common moiety method for ‘total residues’ of metazachlor, 479-M04 & 479-M16 [determined as the 2,6-dimethylaniline moiety of metazachlor] – LOQ 0.05 mg/kg. Validated for metazachlor in oil seed rape (primary and ILV), 479-M16 in oil seed rape (primary only), M04 in cereal grain and spinach. Confirmatory LC-MS/MS for metabolites 479-M04, 479-M08 & 479M16 LOQ 0.02 mg/kg. Validated for 479-M04,

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	479-M08 and 479-M16 in cereal grain and oil seed rape (primary and ILV); spinach and orange pulp (primary only)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	BAS: LC-MS or LC-MS-MS common moiety method for 'total residues' of metazachlor & metabolites 479-M00, 479-M10, 479-M11 & 479-M22 [determined as the 2,6-dimethylaniline moiety of metazachlor]. Validated for metazachlor in all animal matrices. Validated for metabolites 479-M00, 479-M10, 479-M11 & 479-M22 in liver and milk only. MAK-FSG: GC-MS common moiety method for 'total residues' of metazachlor [determined as the 2,6-dimethylaniline moiety of metazachlor] Further validation of the common moiety approach required
Soil (principle of method and LOQ)	LC-MS/MS for residues of Metazachlor, 479-M04 and 479-M08. LOQ of 0.01 mg/kg.
Water (principle of method and LOQ)	BAS: LC-MS-MS metazachlor 0.05 µg/l MAK-FSG: GC-MS metazachlor 0.1 µg/l Subject to the final agreement on the hazard classification of metazachlor, the residue definition for ground water would contain also metabolites and a method would be required to monitor the metabolites, too
Air (principle of method and LOQ)	BAS: GC-ECD metazachlor 0.001 µg/l (confirmatory method required to address specificity) MAK-FSG: GC-MSD metazachlor 0.5 $\mu g/m^3$
Body fluids and tissues (principle of method and LOQ)	Not required as metazachlor is not classified as toxic or acutely toxic

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	Not classified
Active substance	None

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.3 Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Rapid absorption (Tmax 4-8 hours); extensively absorbed (85-95% based on urinary and biliary excretion.
Distribution ‡	Rapidly and extensively distributed; highest levels associated with red blood cells due to binding.
Potential for accumulation ‡	Limited evidence (blood cells)
Rate and extent of excretion ‡	Rapidly excreted (~80% within 24 hours), in urine (~30-40%) and bile (~50-60%).
Metabolism in animals ‡	Extensive metabolism by a number of routes; the initial step in the major route is formation of glutathione conjugation. No evidence of cleavage.
Toxicologically relevant compounds ‡ (animals and plants)	Parent
Toxicologically relevant compounds ‡ (environment)	Metazachlor Metabolites M4, M8, M9, M11, M12*

**based on the proposed classification of metazachlor as R40, to be discussed at the ECHA*

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	>2000 mg/kg bw	-
Rat LD_{50} dermal ‡	>2000 mg/kg bw	-
Rat LC_{50} inhalation ‡	>34.5 mg/l (nose only/4h)	-
Skin irritation ‡	Some evidence of irritation (BASF) Non-irritant (FSG).	-
Eye irritation ‡	Minimal to slight irritation.	-
Skin sensitisation ‡	Strong sensitiser (M&K; BASF) No evidence of sensitisation (OET/Buehler; FSG)	R43

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver (adaptive changes at low dose levels); red blood cell (mild anaemia) in the rat. Increased liver and kidney weights in the mouse. Liver and kidney (increased weights) and red blood cell in the dog.	
Relevant oral NOAEL ‡	90-day rat: 110 mg/kg bw/d (BASF) 90-day rat: 21 mg/kg bw/d (FGS) 90-day dog (gav): 90 mg/kg bw/d (BASF) 90-day dog : 48 mg/kg bw/d (FGS) 1-y dog: 29 mg/kg bw/d (BASF)	
Relevant dermal NOAEL ‡	1000 mg/kg bw/d (28-day rat); BASF	
Relevant inhalation NOAEL ‡	Not required	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Genotoxicity ‡ (Annex IIA, point 5.4)

	Not considered to be genotoxic.	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Liver (increased weight) and red blood cell (increased bilirubin) in the rats; bladder (epithelial hyperplasia and tumorigenicity) in the mouse.	
Relevant NOAEL ‡	2-y Rat: 3.2 mg/kg bw/d (BASF) 2-y Rat: 8.5 mg/kg bw/d (FGS) 18-monthMouse: 72 mg/kg bw/d (BASF) 18-month Mouse: 154mg/kg bw/d (FGS)	
Carcinogenicity ‡	Increased liver adenoma and thyroid tumours in rats; slight increases in bladder transitional cell tumours in the mouse at high dose levels. Lymphoplastic leukaemia in mouse.	R40

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Reduced litter size associated with lower numbers of corpora lutea and implantations at the highest dose level (FSG).	
Relevant parental NOAEL ‡	153 mg/kg bw/d (FSG)	
Relevant reproductive NOAEL ‡	192mg/kg bw/d: (FSG)	
Relevant offspring NOAEL ‡	20 mg/kg bw/d: (FSG)	

Developmental toxicity

Developmental target / critical effect ‡	Delayed skeletal ossification (rat). Reduced foetal weight and lung agenesis associated with maternal toxicity (rabbit). FSG study only. In the BASF study lower doses were applied.	
Relevant maternal NOAEL ‡	Rabbit: 50 mg/kg bw/d (BASF) Rabbit: 30 mg/kg bw/d (FSG) Rat: 50 mg/kg bw/d (BASF) Rat: 250 mg/kg bw/d (FSG)	
Relevant developmental NOAEL ‡	Rabbit: 250 mg/kg bw/d (BASF) Rabbit: 120 mg/kg bw/d (FSG) Rat: 450 mg/kg bw/d (BASF) Rat: 250 mg/kg bw/d (FSG)	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No evidence of neurotoxicity or neuropathology in standard studies.	-
Repeated neurotoxicity ‡	No evidence of neurotoxicity or neuropathology in standard studies	-
Delayed neurotoxicity ‡	No evidence of delayed neuropathy (FSG).	-

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Not provided: not required
Studies performed on metabolites or impurities ‡	Tested metabolites show comparable toxicity to metazachlor <u>479M04 / BH 479-4 / metazachlor oxalic acid</u> Rat acute oral LD50 >2000 mg/kg bw; not genotoxic in vitro or in vivo; foetal and maternal NOAELs of >1000 mg/kg bw/d (rat developmental toxicity study) <u>479M08 / BH 479-8 / metazachlor sulphonic acid</u> Rat acute oral LD50 >5000 mg/kg bw; not genotoxic in vitro or in vivo; NOAEL of 282 mg/kg bw/d (rat 90-day study); maternal NOAEL of >585 mg/kg bw/d, foetal NOAEL of 195 mg/kg bw/d (rat developmental toxicity study) <u>BH 479-9</u> Rat acute oral LD50 >2000 mg/kg bw; not genotoxic in vitro; NOAEL of >50 mg/kg bw/d (90-day rat study). ADI =0.05 mg/kg bw/d. <u>479M11 / BH 479-11</u> Rat acute oral LD50) =500-2000 mg/kg bw; negative Ames test. ADI =0.002 mg/kg bw/d. <u>BH 479-12</u> Rat acute oral LD50) >2000 mg/kg bw; negative Ames test. <u>479M16 / BH 479-21</u> Rat acute oral LD50) >2000 mg/kg bw; not genotoxic in vitro or in vivo

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Medical data ‡ (Annex IIA, point 5.9)

	No health effects identified; symptomatic treatment proposed.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.08	Rat chronic (FSG)	100
AOEL ‡	0.2	90-day rat (FSG)	100
ARfD ‡	0.5	Rat developmental (BASF, FSG)	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	'Butisan S'; 100% default 'Fuego': 2% (concentrate) and 10% (dilution), based on human *in vitro* data.

Exposure scenarios (Annex IIIA, point 7.2)

Operator

Butisan

German model	Tractor, field crops	635 295* 241° 24§
UK POEM	Tractor, hydraulic boom and nozzles	3817 1838* 375°

* Gloves when handling the concentrate

° Gloves when handling the concentrate and during application

§ Gloves when handling the concentrate, coveralls and gloves during application

Fuego

German model	Tractor, field crops	27 22* 18° 2§

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	UK POEM Tractor, hydraulic boom and nozzles	100 88* 15°
	UK POEM Knapsack sprayers, low targets	232 216* 106° 42§
	* Gloves when handling the concentrate ° Gloves when handling the concentrate and during application § Gloves when handling the concentrate, coveralls and gloves during application	
Worker	Estimates based on the German worker re-entry model and using published transfer coefficient data predict that the supported use of 'Butisan S' will result in a level of exposure to metazachlor equivalent to 225% of the systemic AOEL for an unprotected worker inspecting a treated crop. Similar estimates predict that the supported use of 'Fuego' will result in a level of exposure to metazachlor equivalent to 3.4% of the systemic AOEL for an unprotected worker.	
Bystanders	Estimates based on published field study measurements predict that the supported use of 'Butisan S' will result in a level of exposure to metazachlor equivalent to 4.4% of the systemic AOEL for an unprotected bystander. Similar estimates predict that the supported use of 'Fuego' will result in a level of exposure to metazachlor equivalent to 0.33% of the systemic AOEL for an unprotecetd bystander.	

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Substance classified	R43 'May cause sensitisation by skin contact'. Carc. Cat. 3 R40 Possible .

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.4 Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Leafy crops (white cabbage); pulses/oilseeds (oilseed rape); cereals (maize) (BAS) Pulses/Oilseeds (oilseed rape) (MAK-FSG)
Rotational crops	Leafy crops (lettuce); root crop (radish); cereals (wheat) (BAS)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not applicable
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Sum of metabolites 479M04,479M08 and 479M16 expressed as metazachlor
Plant residue definition for risk assessment	Metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor.
Conversion factor (monitoring to risk assessment)	Not applicable (as long as total residues are below the LOQ)

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goats and laying hens (BASF)
Time needed to reach a plateau concentration in milk and eggs	No residues observed in milk above 0.01 mg/kg
Animal residue definition for monitoring	Metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor.
Animal residue definition for risk assessment	Metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor.
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No (based on Pow for metazachlor); Pow not known for metabolites. Residues were low in fat (<0.05 mg/kg) for all doses in the animal feeding study.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

	A potential transfer of soil residues to rotational crops has been identified, but under usual rotation practices with rape seed no measurable residue level above the analytical limit of quantification is expected in food commodities from rotational crops.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

	The stability of metazachlor and its metabolite 479 M16 were demonstrated in oil seed rape for periods of up to 13 months, (MAK-FSG)

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3) (BASF only)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	*	No	No
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Unknown as practical exposure level of ruminant is unknown	no	no
	Feeding studies (dairy cows, 0.021 mg/kg bw/d, BASF) Residue levels in matrices : mg/kg		
Muscle	<0.05		
Liver	0.06		
Kidney	<0.05		
Fat	<0.05		
Milk	<0.01		
Eggs		Insignificant based on metabolism data (BAS)	

*Unknown (as no data is available on actual residue level in straw from cereal sown under practical conditions of crop rotation), but most probably significantly less than 0.022 mg/kg bw/d, corresponding to 0.11 mg/kg diet as received (value calculated on the basis of residues present in straw from cereal sown 30 days after application of metazachlor.

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Oilseed rape	Total 19 (12 N, 7 S) (BAS GAP)	All <0.05 'total residues of metazachlor'	Residues determined using common moiety approach involving determination as 2,6-dimethylaniline Further data on storage stability and validation of the analytical method are required (fortification using metabolite 479M16 is required)	0.05*	0.05	<0.05
Oilseed rape	Total 9 (7 N, 2 S) (MAK-FSG GAP)	All <0.05 'total residues of metazachlor'	Residues determined using common moiety approach involving determination as 2,6-dimethylaniline Further data on storage stability and validation of the analytical method are required	0.05*	0.05	<0.05

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.08 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	< 1%
TMDI (% ADI) according to national (to be specified) diets	See NEDI calculations
IEDI (WHO European Diet) (% ADI)	See TMDI calculation
NEDI (specify diet) (% ADI)	<1% (UK diet)
Factors included in IEDI and NEDI	none
ARfD	0.5 mg/kg bw/day
IESTI (% ARfD)	UK diet used
NESTI (% ARfD) according to national (to be specified) large portion consumption data	UK NESTI below 0.1 % of the ARfD in adult population
Factors included in IESTI and NESTI	none

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Data on processing (BAS) do not enable processing factors to be proposed (no further studies are required as 'total residues' of metazachlor in oilseed rape are<0.05 mg/kg.)				

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Oilseed rape grain	Sum of metabolites 479M04,479M08 and 479M16 expressed as metazachlor: 0.05* mg/kg
Milk	sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor: 0.01* mg/kg
Other products of animal origin	sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor: 0.05* mg/kg

* Indicates that the MRL is set at the level of analytical limit of quantification.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.5 Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡ (BASF/ FSG)	1.9% AR at 91 days,-6.9% AR at 100 days (phenyl label) n=2
Non-extractable residues after 100 days ‡ (BASF/ FSG)	43.2%AR at 91 and 100 days (phenyl label) n=2
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum) (BASF/ FSG)	Major (>10%AR) BH 479-4[27] max 16.2% AR at 91 days BH 479-8[28] max 21.6% AR at study end (181 days) Minor (<10% AR) BH 479-9[29] max 5.3% AR at study end (181 days) BH 479-11[30] max 7.5%AR at day 14 (6.8% AR at 30d and 6.8% AR at 60d) BH 479-12[31], BH 497-7 max < 2.8%AR (phenyl label) n=2

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days (BASF/ FSG)	Max 0.16 – 2.41%AR at 120 - 123 days (study end; n=2)
Non-extractable residues after 100 days (BASF/ FSG)	Max 58.6 - 62%AR at study end (120-123 days; n=2)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) (BASF/ FSG)	BH 479-6[32] max 8.19 - 18.5%AR at day 68 – 120 (study end) (phenyl label) n=2

[27] BH479-4 = 479M04 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)oxalamide)
[28] BH479-8 = 479M08 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid)
[29] BH479-9 = 479M09 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl acetic acid)
[30] BH479-11 = 479M11 (methyl N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl) aminocarbonylmethyl sulfoxide)
[31] BH479-12 = 479M12 (N-[(2-hydroxycarbonyl-6-methyl)phenyl]-N-(1H-pyrazol-1-ylmethyl)oxalamide)
[32] BH479-6 = 479M06 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)acetamide)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Parent metazachlor is stable to soil photolysis, however evidence that soil metabolites were more readily mineralised under light conditions (4.5% AR as CO_2 compared to 0.45% AR as CO_2 in the dark) (phenyl label) n=1

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡ (BASF/ FSG)

Parent	Aerobic conditions						
Soil type	X[33]	pH	t. ^{o}C / % MWHC	DT_{50} /DT_{90} †(d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Li 35b - loamy sand$		6.4	20 / 40	13.6/ 45.2	11.9	0.99	SFO (MCM)
LUFA 2.2 - loamy sand		5.7	20 / 40	25.3/ 84.0	25.3	0.98	SFO (MCM)
Limb'hof, Li 10 - sandy loam		6.7	20 / 40	8/ 26.6	5.8	0.994	SFO (MCM)
Bruch Ost - sandy clay loam		7.2	20 / 40	10.3/ 34.2	8.2	0.997	SFO (MCM)
Speyerer Wald – loamy sand		5.7	20 / 40	12.5/ 41.5	10.7	0.985	SFO
Bruch West – sandy clay loam*		7.2	10 / 40	19.7/ 65.4	7.2	0.998	SFO (MCM)
		7.2	20 / 40	6.2/ 20.6	5.0	0.99	SFO (MCM)
		7.2	30 / 40	3.1/ 10.3	5.5	0.993	SFO (MCM)
Speyer 2.2 – loamy sand		5.9	20 / 40	7.2/ 23.9	7.2	0.999	SFO
Speyer 2.1 - sand		6.0	*Ca.* 20 / 40	17.6/ 58.4	17.2	0.941	SFO
Eigenboden – sandy silt loam		6.6	*Ca.* 20 / 40	21.9/ 72.7	15.7	0.803	SFO
Speyer 2.3 – sandy loam*		6.0	*Ca.* 20 / 40	10.9/ 36.2	9.8	0.871	SFO
		6.0	10 / 40	35.8/ 118.9	14.7	0.977	SFO
Geometric mean/median					10.8/ 11.3		

MCM = multi compartment model
* All DT50 values from study averaged prior to inclusion in overall geomean calculation.
†DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single first order kinetics
$ For this soil (Li 35b) the metabolite BF 479-11 had an experimental half life of 41.3 days, resulting in a half life ref of 36.2 days

[33] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

479M04	Aerobic conditions (BASF/ FSG)							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} ‡ (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
*†Li 35b - loamy sand		6.4	20 / 40	578/ 1919	0.169	507	0.99	SFO (MCM)
LUFA 2.2 - loamy sand		5.7	20 / 40	Uncertain value RSD too high			0.98	SFO (MCM)
Limb'hof, Li 10 - sandy loam		6.7	20 / 40	Uncertain value RSD too high			0.994	SFO (MCM)
Bruch Ost - sandy clay loam		7.2	20 / 40	102.8/ 341.3	0.158	82.3	0.997	SFO (MCM)
Bruch West – sandy clay loam*		7.2	20 / 40	90.1/ 299.1	0.200	72.1	0.999	SFO (MCM)
		7.2	30 / 40	59.3/ 196.9	0.276	104.4	0.993	SFO (MCM)
Bruch West – sandy clay loam*		7.2	10 / 40	277.3/ 920.6	N/A	93.7	0.92	SFO
		7.2	20 / 40	70.7/ 234.7	N/A	52.6	0.97	SFO
		7.2	30 / 40	47.5/ 157.7	N/A	77.7	0.99	SFO
Bruch Ost – clayey loam		7.6	20 / 40	Uncertain values with poor data fit			0.62	SFO
LUFA 2.2 – loamy sand		6.0	20 / 40	Uncertain values with poor data fit			0.36	SFO
Limb'hof, Li 10 – loamy sand		6.4	20 / 40	161.2/ 535.2	N/A	108.6	0.90	SFO
†Speyer 2.1 – sand		5.7	20 / 50	296/ 983	N/A	286	0.978	SFO
Speyer 2.2 – loamy sand		6.0	20 / 50	Poor data fit			0.539	SFO
Speyer 2.3 – sandy loam		7.6	20 / 50	214/ 710.5	N/A	183	0.956	SFO
Speyer 2.3 – sandy loam		6.5	20 / 60	43.3/ 143.9	N/A	39.0	0.9837	SFO
Speyer 3A - loam		7.0	20 / 60	22.4/ 74.5	N/A	19.2	0.9704	SFO
Speyer 5M – sandy loam		7.1	20 / 60	50.6/ 168.1	N/A	48.83	0.9668	SFO
Geometric mean/median‡						89.9/ 82.3		

MCM = multi compartment model
* All DT50 values from study averaged prior to inclusion in overall geomean calculation.
† DT50 longer than twice the study length
‡DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single first order kinetics

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

479M08	Aerobic conditions (BASF/ FSG)							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} ‡ (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
†Speyer 2.2 – loamy sand		5.7	20 / 40	331/ 1100	N/A	331	0.7234	SFO
Speyer 3A - loam		7.1	20 / 40	60.15/ 199.7	N/A	51.01	0.971	SFO
PTRL – clay loam		6.8	20 / 40	180/ 597.6	N/A	133.2	0.9220	SFO
†Speyer 2.1 – sand		5.7	20 / 50	375	N/A	362	0.769	SFO
Speyer 2.2 – loamy sand		6.0	20 / 50	Poor data fit			0.066	SFO
Speyer 2.3 – sandy loam		7.6	20 / 50	Poor data fit			0.697	SFO
Speyer 2.3 – sandy loam		6.5	20 / 60	105.8/ 351.5	N/A	95.33	0.9667	SFO
Speyer 3A - loam		7.0	20 / 60	60.8/ 202.0	N/A	52.11	0.9875	SFO
Speyer 5M – sandy loam		7.1	20 / 60	110.2/ 366.1	N/A	106.3	0.9600	SFO
Geometric mean/median‡						123.2/ 106.3		

† DT50 longer than twice the study length
‡DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single first order kinetics

Field studies ‡ (BASF)

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d)‡ actual	St. (r^2)	DT_{50} (d) Norm.*	Method of calculation
Sandy loam	Bothkamp (DE)		6.5	0 – 25	15.0	49.8	0.959	9.8	SFO (MCM)
Slightly loamy sand	Havixbeck (DE)		6.5	0 - 25	7.3	24.2	0.994	5.1	SFO (MCM)
Sandy silty loam	Lippetal-Brockhausen (DE)		6.7	0 – 25	12.2	40.5	0.995	7.5	SFO (MCM)
Sandy loam	Niederhofen (DE)		6.1	0 – 10	12.4	41.2	0.999	8.4	SFO (MCM)
Sand	Utrera (ES)		6.5	0 – 10	2.8	9.3	0.992	2.0	SFO (MCM)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Field studies ‡ (BASF)

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d)‡ actual	St. (r^2)	DT_{50} (d) Norm.*	Method of calculation
Loamy sand	Manzanilla (ES)		7.5	0 – 25	8.2	27.2	0.974	6.4	SFO (MCM)
Silty sand	Grossharrie (DE)		6.0	0 - 10	10.9	36.2	0.983	8.4	SFO (MCM)
Loamy sand	Bjärred (SE)		6.1	0 - 50	21.3	70.7	0.924	14.4	SFO (MCM)
Geometric mean/median					9.8/ 11.5			6.8/ 8.0	

* Normalised DT50 values were corrected to 20 °C, but were not corrected for soil moisture content.
‡DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single first order kinetics

479M04	Aerobic conditions (BASF)								
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) ‡ actual	St. (r2)	DT_{50} (d) Norm.*	Method of calculation
Slightly loamy sand	Havixbeck (DE)		6.5	0 – 37	138.7	460.5	0.994	54.6	SFO (MCM)
Sandy loam	Niederhofen (DE)		6.1	0 - 10	52.8	175.3	0.999	49.9	SFO (MCM)
Silty sand	Grossharrie (DE)		6.0	0 - 50	65.8	218.5	0.983	66	SFO (MCM)
Geometric mean/median					78.4/ 65.8			56.4/ 54.6	

* Normalised DT50 values were corrected to 20 °C, but were not corrected for soil moisture content.
‡DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single first order kinetics

479M08	Aerobic conditions (BASF)								
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) ‡ actual	St. (r2)	DT_{50} (d) Norm.*	Method of calculatio n
Loamy sand	Meckenheim (DE)		5.3	0 - 75	171	567.7	0.768	116.4	SFO
Silty sandy loam	Lippetal-Brockhausen (DE)		6.4	0 - 50	59.7	198.2	0.933	43.4	SFO

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

479M08	Aerobic conditions (BASF)								
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) ‡ actual	St. (r2)	DT_{50} (d) Norm.*	Method of calculation
Silty sand	Grossharrie (DE)		6.0	0 - 50	108.8	361.2	0.983	NC	SFO (MCM)
Geometric mean/median					103.6/ 108.8			71.1/ 79.9	

NC = not calculated
* Normalised DT50 values were corrected to 20 °C, but were not corrected for soil moisture content.
‡DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single first order kinetics

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Accumulation of parent metazachlor will not occur. For the critical notified uses on oilseed rape grown in rotation according to good agricultural practice, and on ornamental trees and shrubs with one application per crop with the crops grown for at least three years, one application will occur every 3 years and soil accumulation of metabolites will not occur. When used in consecutive years accumulation of the metabolites 479M04 and 479M08 is possible.

Laboratory studies ‡

Parent	Anaerobic conditions (BASF/ FSG)						
Soil type	X[34]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Li35b – sandy loam		6.5	20 / flooded soil	25/ 83	N/A	0.995	SFO
German standard soil 2.2 – Sandy Loam		5.8	20 / flooded soil	11.6/ 38.5	N/A	0.994	SFO
Geometric mean				17.0			

[34] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡ (BASF/ FSG)								
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	r^2
Pfungstadt - Loam	0.58	7.3	-	-	0.48368	83.4	0.848	0.9879
Neuhofen – Loamy sand	2.66	7.2	-	-	2.2026	82.8	0.798	0.9958
LUFA - Sand	0.51	7.0	-	-	0.3699	72.5	0.877	0.9955
Speyer 2.1 - Sand	0.56	6.0	0.37	66.1	-	-	-	-
Speyer 2.2 – Loamy sand	2.27	6.1	1.659	73.1	-	-	-	-
Speyer 2.3 – Sandy loam	1.18	6.6	0.560	47.4	-	-	-	-
Agroplan – sandy silt	1.75	6.0	0.511	29.2	-	-	-	-
Borstel – Silty sand	1.29	6.3	-	-	1.251	97.0	0.91	0.9985
Rendzina Soest – Loamy silt	4.10	7.5	-	-	2.656	64.8	0.93	0.9999
LUFA 2.2 – Loamy sand	2.30	5.7	-	-	1.787	77.7	0.94	0.9996
LUFA 2.3 – Sandy loam	1.20	6.5	-	-	0.646	53.8	0.93	0.9970
1 – Clay loam	1.4	6.8	-	-	2.2	157.1	0.7	NR
2 – Clay loam	1.2	7.2	-	-	2	166.7	0.72	NR
3 – Loam	1.9	6	-	-	3.3	173.7	0.82	NR
4 – Clay	2	7	-	-	4.4	220.0	0.68	NR
5 – Sandy clay loam	0.7	7.3	-	-	0.81	115.7	1.2	NR
6 – Sandy clay loam	1.4	7.4	-	-	1.1	78.6	1.1	NR
7 – Clay loam	1.7	7.3	-	-	1.5	88.2	0.75	NR
8 – Sandy clay loam	2.2	6.5	-	-	3.1	140.9	0.88	NR
9 – Sandy Clay loam	1.3	6.6	-	-	2	153.8	0.89	NR
10 – Clay loam	1.5	6.8	-	-	3.1	206.7	0.74	NR
11 – Silty clay loam	1.2	5	-	-	1.5	125.0	1.0	NR
12 – sandy loam	2.4	6.4	-	-	2.7	112.5	0.79	NR
13 – Sandy clay loam	2	6.4	-	-	2.2	110.0	0.70	NR
14 – Clay loam	1.4	6.4	-	-	2.1	150.0	0.76	NR
15 – Clay	2.2	6.8	-	-	2.4	109.1	1.0	NR
16 – Sandy clay loam	2.2	6.6	-	-	3.8	172.7	0.79	NR
17 – Sandy loam	0.6	6.3	-	-	0.89	148.3	0.95	NR
18 – Sandy clay loam	1.5	6.6	-	-	2.1	140.0	0.91	NR
Median*					-	110	0.877	-

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

pH dependence, Yes or No	No

NR = not reported
*Median Koc value was derived from combined set of Kfoc and Kdoc values (therefore n=29). Averaging Kdoc and Kfoc values is acceptable in this specific case because the values are similar and 1/n is close to 1. For 1/n value, n = 25.

479M04 ‡ (BASF/ FSG)								
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	r^2
LUFA 2.1 – Sand	0.7	5.8	-	-	0.014	2	1.058	0.9365
LUFA 2.2 – Sand/ Loamy sand	2.5	5.8	-	-	0.053	2	0.983	0.9976
LUFA 2.3 – Sandy loam	1.0	6.8	-	-	0.024	2	1.027	0.9914
Limburgerhof Bruch West – Sandy loam	1.5	7.5	-	-	0.008	1	0.745	0.7528
Limburgerhof Bruch Ost – Sandy loam	3.1	7.0	-	-	0.5602	18	0.6369	0.9437
LUFA 2.1 – Sand	0.7	6.1	-	-	0.659	94	1.538	0.9855
LUFA 2.2 –Loamy sand	2.29	6.0	-	-	1.5702	69	1.439	0.9764
LUFA 2.3 – Sandy loam	1.34	6.9	-	-	0.1181	9	0.7799	0.9485
BBA 2.1 – Sand	0.49	5.7	0.145	29.6	-	-	-	-
BBA 2.2 – Silty sand	1.48	6.0	0.135	9.1	-	-	-	-
BBA 2.3 – Silty sand	0.76	7.0	0.136	17.9	-	-	-	-
Median*					-	9.1	1.0	-
pH dependence (yes or no)			No					

*Median Koc value was derived from combined set of Kfoc and Kdoc values (therefore n=11). Averaging Kdoc and Kfoc values is acceptable in this specific case because the values are similar and 1/n is close to 1. For the 1/n value, n = 8.

479M08 ‡ (BASF/ FSG)								
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	r^2
LUFA 2.1 – Sand	0.7	5.8	-	-	0.037	5	0.811	0.9934
LUFA 2.2 – Sand/ Loamy sand	2.5	5.8	-	-	0.129	5	0.904	0.9996
LUFA 2.3 – Sandy loam	1.0	6.8	-	-	0.058	6	0.806	0.9945
Limburgerhof Bruch West – Sandy loam	1.5	7.5	-	-	0.063	4	0.833	0.9942
Limburgerhof Bruch Ost – Clay loam	0.5	5.8	-	-	0.3927	78.5	0.727	0.9804
LUFA 2.1 – Loamy Sand	2.4	6.0	-	-	0.3674	15.3	1.117	0.9957

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

LUFA 2.2 –Sandy loam	1.1	6.5	-	-	0.3130	28.5	0.829	0.9815
LUFA 2.3 – Sandy loam	3.27	7.8	-	-	0.3263	10.0	1.103	0.9771
BBA 2.1 – Sand	0.49	5.7	0.05	10.2	-	-	-	-
BBA 2.2 – Silty sand	1.48	6.0	0.156	10.5	-	-	-	-
BBA 2.3 – Silty sand	0.76	7.0	0.043	5.7	-	-	-	-
Median*					-	10	0.831	-
pH dependence (yes or no)			No					

*Median Koc value was derived from combined set of Kfoc and Kdoc values (therefore n=11). Averaging Kdoc and Kfoc values is acceptable in this specific case because the values are similar and 1/n is close to 1. For the 1/n value, n = 8.

479M06 ‡ (BASF)								
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	r^2
LUFA 2.1 – Sand	0.7	5.8			0.363	52	0.924	0.9998
LUFA 2.2 – Sand/ Loamy sand	2.5	5.8			1.562	62	0.928	0.9998
LUFA 2.3 – Sandy loam	1.0	6.8			0.575	57	0.907	0.9999
Limburgerhof Bruch West – Sandy loam	1.5	7.5			0.666	44	0.905	1.0
Median					-	54	0.92	-
pH dependence (yes or no)			No					

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Aged residues column leaching ‡ (BASF)	Aged for (d): 60 d and 300 d Time period (d): 45 d Eluation (mm): 542 mm
	Analysis of soil residues post ageing (soil residues pre-leaching):39.9 % AR for 60 d experiment 41.0 % AR for 300 d experiment. Nature of radioactivity in soil not characterised.
	Leachate: 54.5 % AR for 60d experiment. 51.51 % AR for 300 d experiment. Nature of radioactivity in leachate not characterised.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Lysimeter/ field leaching studies ‡ (BASF)	Location: North Rhine-Westphalia, Germany. Study type (e.g.lysimeter, field): Lysimeter study Soil properties: texture, pH = 5.7 , OC= 1.5 % , MWHC = Not reported Dates of application : 04/09/1990 Crop : Oilseed rape Interception estimated: Growth stage and interception not reported, but application made 15 days after sowing and seedlings had just emerged. Number of applications: 1 application in the first year Duration: 2 years Application rate: 1000 g as/ ha Average annual rainfall (mm): 730 mm year 1 Average annual leachate volume: 321mm (44%) year 1 % radioactivity in leachate (maximum/year): 45.61 µg/l year 1. Maximum annual average concentrations: Metazachlor <limit of detection (0.04µg/l) 479M01 <limit of detection (0.04µg/l) 479M04 - 21.39µg/l year 1, 6.33 µg/l year 2 479M05 <limit of detection (0.04µg/l) Not identified radioactivity 21.7 µg/l year 1, 15.5 µg/l year 2 Maximum concentrations in 2 leachate samples were also determined (not annual averages) but identified other components originally not identified Still not identified radioactivity 1.4-2.3µg/l. 479M12, 0.4-3.6 µg/l 479M08, 5.8-12 µg/l 479M04, 3.3-9.6 µg/l 479M09, 1.3-3.3 µg/l 479M11, 0.8-2.5 µg/l 479M06, < limit of detection (0.04µg/l) Amount of radioactivity in the soils at the end of the study = 4.2 % AR; minor amounts as parent, remainder unidentified

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 21.3 days Kinetics: SFO Field or Lab: representative worst case from field studies.
Application data	Crop: oilseed rape Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: Pre-emergence therefore no crop interception Number of applications: 1 Application rate(s): 1000 g as/ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		1.333		-	
Short term	24h	1.291	1.312	-	-
	2d	1.249	1.291	-	-
	4d	1.171	1.250	-	-
Long term	7d	1.062	1.192	-	-
	28d	0.536	0.875	-	-
	50d	0.262	0.658	-	-
	100d	0.051	0.394	-	-
Plateau concentration		Accumulation of parent metazachlor will not occur.			

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite 479M04 Method of calculation	Molecular weight relative to the parent: 0.984 Observed molar formation: 17.9 %* DT_{50} (d): 139 days Kinetics: SFO Field or Lab: representative worst case from field studies.
Application data	Application rate assumed: 1000 g as/ha

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.235		-	
Short term 24h	0.234	0.234	-	-
2d	0.232	0.234	-	-
4d	0.230	0.232	-	-
Long term 7d	0.227	0.231	-	-
28d	0.204	0.219	-	-
50d	0.183	0.208	-	-
100d	0.142	0.185	-	-
Plateau concentration	For the critical notified uses on oilseed rape grown in rotation according to good agricultural practice, and on ornamental trees and shrubs with one application per crop with the crops grown for at least three years, one application will occur every 3 years and soil accumulation of metabolites will not occur. When used in consecutive years accumulation of the metabolites 479M04 is possible.			

*max formation fraction observed in the aerobic degradation study, which was not considered reliable for quantification of the metabolites. Reliable value should be 16.2%.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite 479M08 Method of calculation	Molecular weight relative to the parent: 1.164 Molar formation fraction: 21.6 % DT_{50} (d): 171 days Kinetics: SFO Field or Lab: representative worst case from field studies.
Application data	Application rate assumed: 1000 g as/ha

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.335		-	
Short term 24h	0.334	0.335	-	-
2d	0.333	0.334	-	-
4d	0.330	0.333	-	-
Long term 7d	0.326	0.331	-	-
28d	0.299	0.317	-	-
50d	0.274	0.304	-	-
100d	0.224	0.276	-	-
Plateau concentration	For the critical notified uses on oilseed rape grown in rotation according to good agricultural practice, and on ornamental trees and shrubs with one application per crop with the crops grown for at least three years, one application will occur every 3 years and soil accumulation of metabolites will not occur. When used in consecutive years accumulation of the metabolites 479M08 is possible.			

Metabolite 479M09, 479M06 and 479M12 Method of calculation	Molecular weights relative to the parent: 479M09 1.258 479M06 0.876 479M12 1.092 Observed molar formation %: 479M09 5.3 % 479M06 18.49 % 479M12 8.29 % Initial PECs values only were calculated as no soil DT50 values are available.
Application rate	1x1000 g as/ ha pre emergence (no crop interception)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

		479M09		479M06		479M12	
	DAT	$PEC_{s,act}$	$PEC_{s,twa}$	$PEC_{s,act}$	$PEC_{s,twa}$	$PEC_{s,act}$	$PEC_{s,twa}$
	[d]	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]
Initial	0	0.089	---	0.216	---	0.121	---

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH4______:Stable to hydrolysis at 20-25ºC (BASF/ FSG) pH5______: Stable to hydrolysis at 20-25ºC (BASF)
	pH7______: Stable to hydrolysis at 20-25ºC (BASF/ FSG)
	pH9______: Stable to hydrolysis at 20-25ºC (BASF/ FSG)
Photolytic degradation of active substance and metabolites above 10 % ‡ (BASF/ FSG)	Stable to direct aqueous photolysis
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data submitted or required
Readily biodegradable ‡ (yes/no) (BASF)	No

Degradation in water / sediment

Parent	Distribution (Max. sed 10.87 – 19.76 % after 3 -15d)									
Water / sediment system	pH water phase	pH sed	t. °C	$DissT_{50}$-$DissT_{90}$ whole sys.	St. (r^2)	$DegT_{50}$-$DegT_{90}$ water	St. (r^2)	$DissT_{50}$-$DissT_{90}$ sed	St. (r^2)	Method of calculation
Millstream Pond (BASF)	7.9	7.1	20	13.4 / 44.4*	0.998	144/ 480	0.997	3.0/ 8.0	0.997	SFO (MCM)
Swiss lake (BASF)	6.7	5.5	20	23.0/ 76.5*	0.987	133/ 443	0.987	3.8/ 12.7	0.987	SFO (MCM)
Schaephysen Pond (FSG)	7.6	6.9	20	16.1/ 53.6*	0.999	48.8/ 162	0.992	5.9/ 19.7	0.992	SFO (MCM)
Rückhaltebecken river reservoir (FSG)	7.1	7.0	20	27.8/ 92.4*	0.992	384/ 1276	0.992	6.8/ 22.7	0.992	SFO (MCM)
Geometric mean				19.3		137.6		4.6		-

*significant unextracted sediment residues formed
MCM = multi-compartment model

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

479M04	Distribution (max in water 3.25 – 8.41 after 99 - 121 d (all study end). Max. sed 1.19 – 2.79 % after 91 - 121 d (study end))									
Water / sediment system	pH water phase	pH sed	t. ^{o}C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Millstream Pond[@] (BASF)	7.9	7.1	20	-	-	-*	-*	-	-	-
Swiss lake[@] (BASF)	6.7	5.5	20	-	-	-*	-*	-	-	-
Schaephysen Pond (FSG)	7.6	6.9	20	-	-	-*	-*	-	-	-
Rückhaltebecken river reservoir (FSG)	7.1	7.0	20	-	-	-*	-*	-	-	-
Geometric mean			-	-		_		-		-

479M06	Distribution (eg max in water *7.91 – 8.06* after 99 d (study end). Max. sed 5.07 – 8.87 % after *57 - 99* d (study end))									
Water / sediment system	pH water phase	pH sed	t. ^{o}C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Millstream Pond[@] (BASF)	7.9	7.1	20	-	-	45.4/ 150.8	0.997	-	-	SFO (MCM)
Swiss lake[@] (BASF)	6.7	5.5	20	-	-	27.1/ 90.0	0.987	-	-	SFO (MCM)
Geometric mean			-	-		35.1		-		-

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Millstream Pond (BASF)	7.9	7.1	0.95 (day 99)	67.10 (day 99)	67.10 (day 99)
Swiss lake (BASF)	6.7	5.5	0.72 (day 99)	57.22 (day 99)	57.22 (day 99)
Schaephysen Pond (FSG)	7.6	6.9	0.8 (day 121)	43.3 (day 91)	41.8 (day 121)
Rückhaltebecken river reservoir (FSG)	7.1	7.0	1.3 (day 121)	24.9 (day 91)	21.1 (day 121)

@ uncertain DT50/ DT90 values as partitioning rate constants in and out of sediment had low statistical significance
* DT50/ DT90 values not calculated as concentrations still increasing at study termination.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 277.7 Water solubility (mg/L): 450 K_{OC} (L/kg): 110 (median) DT_{50} soil (d): 6.8 days (geomean field, normalised to 20 °C but not corrected for soil moisture. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): (geomean from sediment water studies) DT50 whole system (d): 19.3 DT_{50} water (d): 137.6 DT_{50} sediment (d): 4.6 Crop interception (%): 0 % (worst-case pre-emergence application)
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH 1.1, MACRO 4.4.2, PRZM 1.1.1, TOXSWA 1.1.1. Vapour pressure: 9.6×10^{-5} Pa Kom/ Koc: 110 L/ Kg 1/n: 0.877 Crop interception: In addition post-emergence GAP for applications up to GS 18 was considered; crop interception is calculated following actual application date is calculated by PAT.
Parameters used in FOCUSsw step 4 (if performed)	Runoff reduction due to grassed buffer strip and spray drift reduction due to drift buffer zones. Buffer strip and buffer zone distances of 5 m, 10 m and 20 m considered.
Application rate	Crop: winter and spring oilseed rape Crop interception: 0 % (worst-case pre-emergence application) Number of applications: 1 Interval (d): N/A Application rate(s): 1000 g as/ha Application window: 30 days

FOCUS STEP 1 – Global maximum PECsw metazachlor = 300 µg/l
Global maximum PECsed metazachlor = 320µg/kg

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
*Southern EU	0 h	85.3		90.1	
	24 h	84.4	84.8	80.3	85.2
	2 d	82.5	84.1	78.5	82.3
	4 d	78.9	82.4	75.0	79.5
	7 d	73.7	79.8	70.1	76.5
	14 d	63.0	74.0	59.9	70.7
	21 d	53.8	68.8	51.1	65.6
	28 d	45.9	64.0	43.7	61.0
	42 d	33.5	55.8	31.9	53.2
	50 d	28.0	51.8	26.6	49.3
	100 d	9.1	34.3	8.6	32.7

* Northern Europe was less critical hence results were not reported.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Step 3 + 4 level: Predicted initial concentrations** PEC$_{sw,}$ (global max. concentration) **of metazachlor in different water bodies for FOCUS surface water scenarios following application to winter or spring oilseed rape (STEP 3 and STEP 4 considering buffer zones for mitigating drift).

Location	Crop	Type of water body / pre or post emergence application timing	Step 3 FOCUS standard (edge of field)	Step 4 Buffer distance (mitigating spray drift): 5 m	10 m	20 m
			Global maximum PEC$_{sw,}$ [µg/L]			
D1	Spring oilseed rape	Ditch / pre	6.464	1.826	1.016	0.576
		Ditch / post	**6.646**	**1.972**	**1.156**	**0.713**
		Stream / pre	5.076	1.894	1.035	**0.568**
		Stream / post	**5.609**	**2.050**	**1.087**	0.565
D2	Winter oilseed rape	Ditch / pre	7.262	7.253	7.251	7.250
		Ditch / post	**33.914**	**33.913**	**33.913**	**33.913**
		Stream / pre	5.719	4.893	4.893	4.893
		Stream / post	**21.44**	**21.44**	**21.44**	**21.44**
D3	Winter oilseed rape	Ditch / pre	**6.387**	**1.732**	**0.918**	0.378
		Ditch / post	6.361	1.724	0.915	**0.475**
D3	Spring oilseed rape	Ditch / pre&post	6.338	1.718	0.911	0.474
D4	Winter oilseed rape	Pond / pre	0.227	0.198	0.145	0.107
		Pond / post	**0.867**	**0.856**	**0.837**	**0.821**
		Stream / pre	5.481	2.002	1.062	0.522
		Stream / post	5.481	2.002	**1.492**	**1.492**
D4	Spring oilseed rape	Pond / pre	0.219	**0.190**	**0.137**	**0.092**
		Pond / post	0.219	0.189	0.136	0.091
		Stream / pre	4.926	1.800	0.955	0.497
		Stream / post	**5.254**	**1.919**	**1.018**	**0.529**
D5	Winter oilseed rape	Pond / pre	0.226	0.197	0.143	0.098
		Pond / post	**0.256**	**0.256**	**0.256**	**0.256**
		Stream / pre&post	5.913	2.160	1.146	0.595
D5	Spring oilseed rape	Pond / pre&post	0.219	0.189	0.136	0.091
		Stream / pre	4.895	1.788	0.949	0.493
		Stream / post	**4.967**	**1.815**	**0.963**	**0.500**
R1	Winter oilseed rape	Pond / pre&post	0.219	0.189	0.136	0.091
		Stream / pre	4.191	1.531	0.812	0.422
		Stream / post	4.191	1.531	**1.183**	**1.183**
R1	Spring oilseed rape	Pond / pre	0.265	0.244[%]	0.206[%]	0.174[%]
		Pond / post	**0.273**	**0.252**[%]	**0.214**[%]	**0.182**[%]
		Stream / pre	4.174	2.511[#]	2.511[#]	2.511[#]
		Stream / post	4.174	**2.702**[#]	**2.702**[#]	**2.702**[#]
R3	Winter oilseed rape	Stream / pre	7.439	7.439[#]	7.439[#]	7.439[#]
		Stream / post	**20.454**	**20.454**[#]	**20.454**[#]	**20.454**[#]

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

[§] drainage entry responsible for global max. concentration, therefore no reduction by considering spray drift buffer zones
[#] runoff entry responsible for global max. concentration, therefore no reduction by considering spray drift buffer zones
[%] spray drift and runoff entry governing global max. concentration

Step 3 + 4 level: Predicted initial concentrations** PECsw (2 day Time weighted average) **of metazachlor in different water bodies for FOCUS surface water scenarios following application to winter or spring oilseed rape (STEP 3 and STEP 4 considering buffer zones for mitigating drift).

Location	**Crop**	**Type of water body / pre or post emergence application timing**	**Step 3**	**Step 4 Buffer distance (mitigating spray drift)**		
			FOCUS standard (edge of field)	**5 m**	**10 m**	**20 m**
			2 day time weighted average $PEC_{sw,}$[µg/L]			
D1	Spring oilseed rape	Ditch / pre	5.016	1.431	0.806	0.468
		Ditch / post	**6.355**	**1.882**	**1.103**	**0.680**
		Stream / pre	0.230	0.132	0.132	0.132
		Stream / post	**2.544**	**0.929**	**0.493**	**0.371**
D2	Winter oilseed rape	Ditch / pre	6.143	2.872	2.872	2.872
		Ditch / post	**19.061**	**19.060**	**19.060**	**19.060**
		Stream / pre	5.466	1.998	1.391	1.391
		Stream / post	**10.610**	**10.610**	**10.610**	**10.610**
D3	Winter oilseed rape	Ditch / pre	**5.629**	**1.552**	**0.806**	0.331
		Ditch / post	4.530	1.225	0.649	**0.337**
D3	Spring oilseed rape	Ditch / pre	3.088	0.836	0.443	0.230
		Ditch / post	**3.292**	**0.891**	**0.472**	**0.245**
D4	Winter oilseed rape	Pond / pre	0.222	0.194	0.142	0.107
		Pond / post	**0.866**	**0.856**	**0.836**	**0.820**
		Stream / pre	0.808	0.295	0.156	0.121
		Stream / post	**1.324**	**1.324**	**1.324**	**1.324**
D4	Spring oilseed rape	Pond / pre	**0.215**	**0.186**	**0.134**	**0.090**
		Pond / post	0.214	0.185	0.133	0.089
		Stream / pre	0.142	0.052	0.028	0.015
		Stream / post	**0.306**	**0.110**	**0.058**	**0.030**
D5	Winter oilseed rape	Pond / pre	0.221	0.193	0.141	0.096
		Pond / post	**0.256**	**0.256**	**0.256**	**0.256**
		Stream / pre	1.153	0.421	0.223	0.116
		Stream / post	**1.154**	0.421	**0.350**	**0.350**
D5	Spring oilseed rape	Pond / pre	0.213	0.185	0.133	0.089
		Pond / post	**0.214**	0.185	0.133	0.089
		Stream / pre	0.085	0.031	0.016	0.009
		Stream / post	**0.093**	**0.034**	**0.018**	0.009
R1	Winter oilseed rape	Pond / pre	0.213	0.184	0.133	0.088
		Pond / post	0.213	**0.185**	0.133	**0.089**
		Stream / pre	**0.445**	**0.163**	0.086	0.045
		Stream / post	0.444	0.162	**0.143**	**0.143**
R1	Spring oilseed rape	Pond / pre	0.261	0.240[%]	0.203[%]	0.171[%]
		Pond / post	**0.269**	**0.248**[%]	**0.211**[%]	**0.179**[%]
		Stream / pre	0.680	0.680[#]	0.680[#]	0.680[#]
		Stream / post	**0.732**	**0.732**[#]	**0.732**[#]	**0.732**[#]
R3	Winter oilseed rape	Stream / pre	2.373	2.373[#]	2.373[#]	2.373[#]
		Stream / post	**8.672**	**8.672**[#]	**8.672**[#]	**8.672**[#]

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

§ drainage entry responsible for global max. concentration, therefore no reduction by considering spray drift buffer zones
# runoff entry responsible for global max. concentration, therefore no reduction by considering spray drift buffer zones
% spray drift and runoff entry governing global max. concentration

Step 3 + 4 level: Predicted initial concentrations** PECsw, (7 day Time weighted average) **of metazachlor in different water bodies for FOCUS surface water scenarios following application to winter or spring oilseed rape (STEP 3 and STEP 4 considering buffer zones for mitigating drift).

Location	**Crop**	**Type of water body / pre or post emergence application timing**	**Step 3** FOCUS standard (edge of field)	**Step 4** Buffer distance (mitigating spray drift): 5 m	10 m	20 m
			7 day time weighted average PEC_{sw},[µg/L]			
D1	Spring oilseed rape	Ditch / pre	2.114	0.648	0.392	0.253
		Ditch / post	**6.029**	**1.773**	**1.033**	**0.633**
		Stream / pre	0.125	0.125	0.125	0.125
		Stream / post	**0.736**	**0.350**	**0.350**	**0.350**
D2	Winter oilseed rape	Ditch / pre	5.842	2.218	2.217	2.217
		Ditch / post	**13.480**	**13.477**	**13.476**	**13.476**
		Stream / pre	5.197	1.894	1.111	1.111
		Stream / post	**7.153**	**7.153**	**7.153**	**7.153**
D3	Winter oilseed rape	Ditch / pre	**3.440**	**0.929**	**0.492**	**0.202**
		Ditch / post	1.549	0.419	0.222	0.115
D3	Spring oilseed rape	Ditch / pre	0.908	0.246	0.130	0.068
		Ditch / post	**0.975**	**0.264**	**0.140**	**0.073**
D4	Winter oilseed rape	Pond / pre	0.215	0.187	0.137	0.106
		Pond / post	**0.861**	**0.850**	**0.831**	**0.814**
		Stream / pre	0.231	0.106	0.106	0.106
		Stream / post	**1.110**	**1.110**	**1.110**	**1.110**
D4	Spring oilseed rape	Pond / pre	**0.208**	**0.180**	0.129	**0.087**
		Pond / post	0.207	0.179	0.129	0.086
		Stream / pre	0.041	0.016	0.009	0.005
		Stream / post	**0.086**	**0.031**	**0.017**	**0.009**
D5	Winter oilseed rape	Pond / pre	0.214	0.187	0.136	0.093
		Pond / post	**0.253**	**0.253**	**0.253**	**0.253**
		Stream / pre	0.330	0.121	0.064	0.039
		Stream / post	0.330	**0.234**	**0.234**	**0.234**
D5	Spring oilseed rape	Pond / pre	0.205	0.178	0.128	0.085
		Pond / post	**0.206**	0.178	0.128	**0.086**
		Stream / pre	0.024	0.009	0.005	0.002
		Stream / post	**0.026**	**0.010**	0.005	**0.003**
R1	Winter oilseed rape	Pond / pre	0.204	0.177	0.127	0.085
		Post / post	**0.205**	0.177	0.127	0.085
		Stream / pre	0.127	0.046	0.025	0.013
		Stream / post	0.127	0.046	**0.041**	**0.041**
R1	Spring oilseed rape	Pond / pre	0.253	0.233[%]	0.196[%]	0.166[%]
		Pond / post	**0.261**	**0.241**[%]	**0.204**[%]	**0.174**[%]
		Stream / pre	0.213	0.213[#]	0.213[#]	0.213[#]
		Stream / post	**0.233**	**0.233**[#]	**0.233**[#]	**0.233**[#]
R3	Winter oilseed rape	Stream / pre	0.778	0.778[#]	0.778[#]	0.778[#]
		Stream / post	**2.571**	**2.571**[#]	**2.571**[#]	**2.571**[#]

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

§ drainage entry responsible for global max. concentration, therefore no reduction by considering spray drift buffer zones
# runoff entry responsible for global max. concentration, therefore no reduction by considering spray drift buffer zones
% spray drift and runoff entry governing global max. concentration

Metabolite 479M04 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 273.3 Water solubility (mg/L): 1000 (arbitary high value as measured data not available or necessary) Koc/Kom (L/kg): 9.1 (median) DT_{50} soil (d): 57 days (Geomean field DT50. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): (arbitary high value as measured data not available or necessary) DT_{50} whole system (d): 1000 Crop interception (%): 0%. Worst case pre-emergence treatment to oilseed rape only was performed at Steps 1 and 2. Maximum occurrence observed (% molar basis with respect to the parent): Soil: 16.2 % Whole system water/ sediment: 13.3 %
Application rate	Crop: oilseed rape Number of applications: 1 Interval (d): N/A Application rate(s): 1000 g as/ha Application window: 30 days
Main routes of entry	Spray drift and run-off/ drainage

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite 479M08 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 323.4 Water solubility (mg/L): 1000 (arbitary high value as measured data not available or necessary) Koc/Kom (L/kg): 10.0 (median) DT_{50} soil (d): 116.4 days (longest field DT50. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): (arbitary high value as measured data not available or necessary) DT_{50} whole system (d): 1000 Crop interception (%): 0%. Worst case pre-emergence treatment to oilseed rape only was performed at Steps 1 and 2. Maximum occurrence observed (% molar basis with respect to the parent): Soil: 21.6 % Whole system water/ sediment: 0.01 % (not detected, so arbitrary low value selected)
Application rate	Crop: oilseed rape Number of applications: 1 Interval (d): N/A Application rate(s): 1000 g as/ha Application window: 30 days
Main routes of entry	Spray drift and run-off/ drainage

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite 479M06 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 243.3 Water solubility (mg/L): 1000 (arbitary high value as measured data not available or necessary) Koc/Kom (L/kg): 54 (median) DT_{50} soil (d): 1000 days (arbitary high value as measured data not available or necessary) DT_{50} water/sediment system (d; geomean) DT_{50} whole system (d): 35.1 Crop interception (%): 0%. Worst case pre-emergence treatment to oilseed rape only was performed at Steps 1 and 2. Maximum occurrence observed (% molar basis with respect to the parent): Soil: 0.01 % (not detected; arbitrary low value selected) Whole system water/ sediment: 16.45 %
Application rate	Crop: oilseed rape Number of applications: 1 Interval (d): N/A Application rate(s): 1000 g as/ha Application window: 30 days
Main routes of entry	Spray drift and run-off/ drainage

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite 479M09, 479M11, 479M12 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 479M09: 349.4 479M11: 305.4 479M12: 303.3 Water solubility (mg/L): 1000 (arbitary high value as measured data not available or necessary) Koc/Kom (L/kg): 0 (arbitary low value as measured data not available or necessary) DT_{50} soil (d): 1000 days (arbitary high value as measured data not available or necessary) DT_{50} water/sediment system (d): (arbitary high value as measured data not available or necessary) DT_{50} whole system (d): 1000 Crop interception (%): 0%. Worst case pre-emergence treatment to oilseed rape only was performed at Steps 1 and 2. Maximum occurrence observed (% molar basis with respect to the parent): Soil: 479M09: 5.3 % 479M11: 7.5 % 479M12: 8.29 % Whole system water/ sediment: 0.01 % (not detected; arbitrary low value selected)
Application rate	Crop: oilseed rape Number of applications: 1 Interval (d): N/A Application rate(s): 1000 g as/ha Application window: 30 days
Main routes of entry	Spray drift and run-off/ drainage

Step 1
The global maximum PECsw were 53.7µg/l (479M04), 82.7µg/l (479M08), 1.3µg/l (479M06) 22.2µg/l (479M09), 27.5µg/l (479M11), 30.2µg/l (479M12).

The global maximum PEC sediment were 4.9µg/kg (479M04), 8.3µg/kg (479M08), 0.67µg/kg (479M06) <0.005µg/kg (479M09, 479M11, 479M12).

Step 2
The global maximum PECsw were 21.2µg/l (479M04), 32.3µg/l (479M08), 1.33µg/l (479M06) 8.87µg/l (479M09), 10.97µg/l (479M11), 12.04µg/l (479M12).

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used (with version control no.(s)): FOCUSPELMO 3.3.2 for parent metazachlor, 479M04 and 479M08. For other metabolites (479M09, 479M11 and 479M12) lysimeter study results of 479M04 and 479M08 compared to modelled results of 479M04 and 479M08. Transfer factors derived for lysimeter concentrations to modelled concentrations. Maximum transfer factor applied to each metabolite (479M09, 479M11 and 479M12) and a pseudo modelled PECgw value calculated. Scenarios (list of names): autumn application: Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza, Porto spring application: Jokioinen, Okehampton, Porto Crop: autumn and spring oilseed rape Parent Geometric mean $DT_{50field}$ 6.8 d (normalisation to 20 °C; no correction for soil moisture). Parent K_{OC} (median): 110 ml/ g, $^1/_n$= 0.88. 479M04 Geometric mean $DT_{50field}$ 57 d 479M04 K_{OC} (median): 9.1 ml/ g, $^1/_n$= 1.0. 479M04 kinetic formation fraction: 0.1 479M08 Maximum $DT_{50field}$ 116 d 479M08 K_{OC} (median): 10 ml/ g, $^1/_n$= 0.83 479M08 kinetic formation fraction: 0.112
Application rate	Application rate: 1000 g/ha. No. of applications: 1 year in 3 pre-emergence (no crop interception) Time of application (month or season): Worst case pre-emergence application modelled (no crop interception). Applications to autumn and spring oilseed rape modelled.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PEC(gw) - FOCUS modelling results

	Scenario	Parent (µg/l)	Metabolite (µg/l) 479M04	479M08	479M09	479M11	479M12
PELMO3.3.2 /autumn oilseed rape	Châteaudun	< 0.001	3.69	6.95	1.33	1.01	1.45
	Hamburg	< 0.001	4.59	7.08	1.58	1.19	1.72
	Kremsmünster	< 0.001	3.11	5.33	1.07	0.81	1.17
	Okehampton	< 0.001	3.19	5.09	1.10	0.83	1.20
	Piacenza	< 0.001	5.00	8.13	1.72	1.30	1.88
	Porto	< 0.001	2.07	3.23	0.71	0.54	0.78
PELMO3.3.2 /spring oilseed	Jokioinen	< 0.001	3.94	6.95	1.35	1.03	1.48
	Okehampton	< 0.001	2.41	4.85	0.92	0.70	1.01
	Porto	< 0.001	0.76	1.63	0.31	0.24	0.34

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied-compound has no absorption at wavelengths in the UV/VIS spectrum.
Quantum yield of direct phototransformation	0- compound has no absorption at wavelengths in the UV/VIS spectrum.
Photochemical oxidative degradation in air ‡	Half life of 6.5 hours derived by the Atkinson method of calculation assuming a conservative atmospheric hydroxyl radical concentration of $5x10^5$ radicals/ cm^3
Volatilisation ‡	from plant surfaces: ‡ controlled conditions BBA guideline 10% loss after 24 hours from bush bean leaves. Field conditions 1.6% loss after 24 hours from oilseed rape leaves.
	from soil: ‡ controlled conditions BBA guideline 4% loss after 24 hours (trapped volatiles). Field conditions 6.9% of applied radioactivity was not recovered after 24 hours.
Metabolites	No data submitted or required

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

$PEC_{(a)}$

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: metazachlor and 479M04 and 479M08 were the major (>10% Applied) components of the residue. Exposure / risk assessments were also completed for the minor (<10% Applied) soil metabolites 479M09, 479M11 and 479M12. Surface Water: Water parent metazachlor and 479M04 were the major (>10% Applied) components of the residue identified in aerobic sediment water studies. Exposure / risk assessments were also completed for the minor (<10% Applied) metabolites 479M06, 479M08, 479M09, 479M11 and 479M12 originating in the surface water body and / or moving from soil. Sediment: metazachlor Ground water: metazachlor and the metabolites 479M04, 479M08, 479M09, 479M11, 479M12 Air: metazachlor

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data submitted probably not available
Surface water (indicate location and type of study)	General German federal state monitoring for metazachlor only (LAWA report). From 1992-1996 2373 determinations for metazachlor made from potentially up to 151 sampling locations of flowing water. The maximum concentration reported was 0.32µg/l. Other information on metazachlor groundwater concentrations from German government monitoring 1989-1993 was also provided but in reports that amalgamated results from surface water monitoring and it is unclear which detections were in groundwater and which in surface water. The proportion of samples with detections >0.1µg/l was low 22/6252.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Ground water (indicate location and type of study)	Targeted monitoring with information of extent of use in oilseed rape growing areas of Schleswig-Holstein in Germany. 32 wells sampled depths 30-205m. no detections of metazachlor or 479M04 (detection limit quoted as 0.05µg/l). General German federal state monitoring for metazachlor only. 1998 3498 sites no detection, 4 sites<0.1µg/l 3 sites 0.1-1µg/l. German Rheinlan-Pfalz state monitoring for parent metazachlor: 1985, 1987&1988 all concentrations<0.02µg/l (no information on use history around the monitored wells or number of wells/samples was available). Other information on metazachlor groundwater concentrations from German government monitoring 1989-1993 was also provided but in reports that amalgamated results from surface water monitoring and it is unclear which detections were in groundwater and which in surface water. The proportion of samples with detections is low with an even smaller proportion having concentrations>0.1µg/l.
Air (indicate location and type of study)	Two publicly available scientific papers have been submitted which detail monitoring of pesticides, including metazachlor, in rainwater in Europe or Belgium. Either concentrations in wet deposition or total deposition have been reported. It is considered that the reported concentrations are comparable as amounts deposited by dry deposition are small when compared to those deposited by wet deposition. The first paper summarises several rainwater monitoring studies from locations throughout Europe, three of which analysed for metazachlor. Results for one of those studies were not presented. Of the results presented from the remaining two studies 6 samples out of 73 displayed detectable concentrations, with a maximum concentration of 134 ng/ L in one study. The second study displayed a frequency of detection of 0/40. The second paper described a monitoring study at up to 8 locations in Belgium from 1997 – 2001. Metazachlor was monitored for specifically in 1998, 2000 and 2001. It was not detected at all in 1998 or 2001. In 2000 it had an average annual

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	concentration of 0.2 ng/ L (mean of all sample locations; calculated by dividing total annual deposition by total annual precipitation at each individual site. A mean was then taken for values at each individual site) a maximum concentration of 49 ng/ L and a frequency of detection of 1 %.

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Possibly a candidate for R53 as metazachlor is not readily biodegradeable.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.6 Effects on non target species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Coturnix coturnix japonica *Colinus virginianus*[2]	metazachlor	Acute	LD_{50} >2000 mg a.s./kg bw (MAK-FSG and BASF)	-
Coturnix coturnix japonica	metazachlor	Short-term	LDD_{50} >449 mg a.s./kg bw/day[1] (MAK-FSG)	LC_{50} >5000 mg a.s./kg feed
Colinus virginianus	metazachlor	Long-term	NOEL: 76.5 mg a.s./kg bw/day (BASF)[3]	NOEC: 1000 mg a.s./kg feed
Mammals ‡				
Rat	metazachlor	Acute	LD_{50} **>2000** mg a.s./kg bw (MAK-FSG)	-
Rat	Metabolite 479M16	Acute	LD_{50} >2000 mg/kg bw (BASF)[4]	-
Rat	Metabolite 479M8 (Na salt)	Acute	LD_{50} >5000 mg/kg bw (BASF)[4]	-
Rat	Metabolite 479M04 (BH 479-4)	Acute	LD_{50} >2200 mg/kg bw (BASF)[4]	-
Rat	metazachlor	Long-term	NOAEL: 79 mg a.s./kg bw/day (BASF)	NOAEC: 1000 mg a.s./kg feed
Additional higher tier studies ‡				
None submitted.				

[1] LDD_{50}: Lethal Dietary Dose.
[2] Both species, *Coturnix coturnix japonica* (MAK-FSG) and *Colinus virginianus* (BASF), gave exactly the same endpoint.
[3] Avian reproduction study submitted by BASF, MAK-FSG do not have an equivalent study.

[4] BASF data, MAK-FSG have not supplied an equivalent study and therefore the data cannot be used to support approval for MAK-FSG.

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Single application of 1 kg a.s./ha pre-emergent application of metazachlor to winter and spring sown oilseed rape (represented by 'leafy crops' scenario)

Indicator species/Category		Time scale	ETE mg a.s./kg bw/day	TER	Annex VI Trigger
Tier 1 (Birds)					
Insectivorous bird		Acute	54.08	>36.98	10
Insectivorous bird		Short-term	30.16	>14.89	10
Insectivorous bird[1]		Long-term	30.16	**2.5**	5
Higher tier refinement (Birds)					
Insectivorous bird	100 % large insects[2]	Long-term	5.3[3]	14.4	5
Insectivorous bird	40% small insects 60% large insects[2]	Long-term	15.2[3]	5	5
Tier 1 (Mammals)					
Insectivorous mammals		Acute	22.2	>90.1	10
Insectivorous mammals		Long-term	8.1	9.6	5

TERs highlighted in **bold** are less than the respective Annex VI trigger value
[1] First tier risk assessment for small insectivorous bird assumes a diet consisting of 100% small insects which have an RUD value of 29 mg a.s./kg food item.
[2] Given that the proposed use of metazachlor is as a pre-emergent or early post emergent herbicide the RMS considers that there will be predominately larger ground dwelling arthropods present. The RMS therefore assumed a diet of 100% large insects (RUD for large insects is 5.1 mg a.s./kg food item). An acceptable long-term TER is also achieved from a diet consisting of 40% small insects and 60% large insects.
[3] FIR/bw value used for calculation of refined ETE was 1.04 (Table 2, of SANCO/4145).

Single application of 1 kg a.s./ha post-emergent application of metazachlor to winter and spring sown oilseed rape (represented by 'leafy crops' scenario)

Indicator species/Category	Time scale	Refinement	ETE mg a.s./kg bw/day	TER	Annex VI Trigger
Tier 1 (Birds)					
Insectivorous bird	Acute	-	54.08	>36.98	10
Medium herbivorous bird	Acute	-	66.12	>30.25	10
Insectivorous bird	Short-term	-	30.16	>14.89	10
Medium herbivorous bird	Short-term	-	30.40	>14.77	10
Insectivorous bird	Long-term	-	30.16[1]	**2.46**	5
Medium herbivorous bird	Long-term	-	16.11	**4.7**	5
Higher tier refinement (Birds)					
Insectivorous bird	Long-term	Assuming a diet of 100 % large insects[2]	5.3[3]	14.4	5
Insectivorous bird	Long-term	Assuming a diet of 40% small insects 60% large insects[2]	15.2[3]	5.0	5
Woodpigeon (focal species for a medium herbivorous bird)	Long-term	Revised FIR/bw of 0.68 for a 490 g woodpigeon	14.42	5.3	5
Skylark (focal species for a smaller birds which consume oilseed rape foliage)	Long-term	Revised estimated PD values: 60% oilseed rape foliage, 20% weed seeds and 20% large insects. PT value of 0.8	15.04	5.1	5
Tier 1 (Mammals)					
Medium herbivorous mammal	Acute	-	24.36	>82.1	10
Medium herbivorous mammal	Long-term	-	5.94	13.3	5

TERs highlighted in **bold** are less than the respective Annex VI trigger value
[1] First tier risk assessment for small insectivorous bird assumes a diet consisting of 100% small insects which have an RUD value of 29 mg a.s./kg food item.
[2] Given that the proposed use of metazachlor is as a pre-emergent or early post emergent herbicide the RMS considers that there will be predominately larger ground dwelling arthropods present. The

RMS therefore assumed a diet of 100% large insects (RUD for large insects is 5.1 mg a.s./kg food item). An acceptable long-term TER is also achieved from a diet consisting of 40% small insects and 60% large insects.
[3] FIR/bw value used for calculation of refined ETE was 1.04 (Table 2, of SANCO/4145).

Single application of 0.75 kg a.s./ha application to ornamental trees and shrubs (represented by 'grassland' scenario)

Indicator species/Category	Time scale	ETE mg a.s./kg bw/day	TER	Annex VI Trigger
Tier 1 (Birds)				
Insectivorous bird	Acute	40.56	>49.31	10
Large herbivorous bird	Acute	46.86	>42.68	10
Insectivorous bird	Short-term	22.62	>19.85	10
Medium herbivorous bird	Short-term	25.08	>17.09	10
Insectivorous bird	Long-term	22.62	**3.4**[2]	5
Large herbivorous bird	Long-term	13.29	5.8	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	148.04	>13.5	10
Small herbivorous mammal	Long-term	41.99	**1.9**[3]	5

TERs highlighted in **bold** are less than the respective Annex VI trigger value
[2] No suitable refinement provided by the Notifier and therefore the risk to insectivorous birds is unresolved.
[3] No suitable refinement provided by the Notifier and therefore the risk small herbivorous mammals is unresolved.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	metazachlor	96 hr (static)	Mortality, LC_{50}	8.5 (BASF)
Oncorhynchus mykiss	metazachlor	28 d (flow-through)	Growth NOEC	2.15 (BASF)
Oncorhynchus mykiss	Fuego	96 hr (flow-through)	Mortality, EC_{50}	4.61 (MAK-FSG) (10.4 mg product/l)
Oncorhynchus mykiss	BAS 479 22H	28 d (flow-through)	Growth NOEC	1.39 (BASF) (3.16 mg product/l)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Oncorhynchus mykiss	479M04 (BH479-4)	96 hr (static)	Mortality, LC_{50}	>100 (BASF)[2]
Oncorhynchus mykiss	479M08 (BH479-8)	96 hr (static)	Mortality, LC_{50}	>93.8 (BASF)[2]
Oncorhynchus mykiss	479M09 (BH479-9)	96 hr (static)	Mortality, LC_{50}	>100 (BASF)[2]
Oncorhynchus mykiss	479M011 (BH479-11)	96 hr (static)	Mortality, LC_{50}	>100 (BASF)[2]
Oncorhynchus mykiss	479M012 (BH479-12)	96 hr (static)	Mortality, LC_{50}	>100 (BASF)[2]
Aquatic invertebrate				
Daphnia magna	metazachlor	48 h (static)	Mortality, EC_{50}	33.0 (MAK-FSG)
Daphnia magna	metazachlor	21 d (static)	Reproduction, NOEC	0.1 (MAK-FSG) 6.25 (BASF)
Daphnia magna	Fuego	48 h (static)	Mortality, EC_{50}	29.7 (MAK-FSG) (67 mg product/l)
Daphnia magna	479M04 (BH479-4)	48 h (static)	Mortality, EC_{50}	>100 (BASF)[2]
Daphnia magna	479M06 (BH479-6)	48 h (static)	Mortality, EC_{50}	84.7 (BASF)[2]
Daphnia magna	479M08 (BH479-8) tested as 479M08 (BH479-8) (Na salt) (BH479-18)	48 h (static)	Mortality, EC_{50}	>93.8 (BASF)[2]
Daphnia magna	479M09 (BH479-9)	48 h (static)	Mortality, EC_{50}	>100 (BASF)[2]
Daphnia magna	479M011 (BH479-11)	48 h (static)	Mortality, EC_{50}	>100 (BASF)[2]
Daphnia magna	479M012 (BH479-12)	48 h (static)	Mortality, EC_{50}	27.7 (BASF)[2]
Sediment dwelling organisms				
Chironomus riparius	metazachlor	28 d (static)	NOEC	9.8 (7.93 mg a.s./kg dw sediment) (MAK-FSG)[3]
Algae				
Pseudokirchneriella subcapitata	metazachlor	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0162 0.0318 (BASF)[2]
Scenedesmus subcapitatus	metazachlor	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0088 0.031 (MAK-FSG)[3]

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Pseudokirchneriella subcapitata	BAS 479 22H	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0076 (0.0172 mg prodcut/L) 0.012 (0.027 mg prodcut/L) (BASF)[2]
Scenedesmus subcapitatus	Fuego	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0279 (0.063 mg product/L) 0.0488 (0.11 mg product/L) (MAK-FSG)[3]
Anabena flos-aquae	metazachlor	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	25.2 32 (BASF)[2]
Navicula pelliculosa	metazachlor	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	13.7 72.5 (MAK-FSG)[3]
Pseudokirchneriella subcapitata	479M04 (BH479-4)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	10.6 25.7 (BASF)
Pseudokirchneriella subcapitata	479M06 (BH479-6)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	26.0 49.9 (MAK-FSG)[3]
Pseudokirchneriella subcapitata	479M08 (BH479-8)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>91.9 >91.9 (MAK-FSG)
Pseudokirchneriella subcapitata	479M09 (BH479-9)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	17.0 45.3 (MAK-FSG)
Pseudokirchneriella subcapitata	479M011 (BH479-11)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100 >100 (BASF and MAK-FSG)
Pseudokirchneriella subcapitata	479M012 (BH479-12)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	81.1 89.4 (MAK-FSG)
Higher plant				
Lemna gibba	metazachlor	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0023 0.0071 (MAK-FSG)
Lemna gibba	BAS 479 22H	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0022 0.014 (BASF)
Lemna gibba	metazachlor	7d + sediment	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0064 0.0208 (BASF) [2]

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Higher aquatic plants macrophytes (range)	BAS 479 22H	11,12 or 14 d (species dependent)	Geometric mean of wet weight EC50:	The geometric mean value should be based only on the submerged plant species (BASF) [2]
Lemna minor	479M04 (BH479-4)	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100 >100 (MAK-FSG)
Lemna gibba	479M06 (BH479-6)	7 d (static)	Biomass: E_bC_{50}	34.4 (BASF)
Lemna minor	479M06 (BH479-6)	7 d (static)	Growth rate: E_rC_{50}	76.1 (MAK-FSG)
Lemna minor	479M08 (BH479-8)	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 91.9 > 91.9 (MAK-FSG)[3]
Lemna minor	479M09 (BH479-9)	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	77.6 144 (MAK-FSG)[3]
Lemna minor	479M011 (BH479-11)	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>400 >400 (MAK-FSG)[3]
Lemna minor	479M012 (BH479-12)	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100 >100 (MAK-FSG)[3]
Microcosm or mesocosm tests				
The NOAEAC is 5.0 µg a.s./L (with an uncertainty factor of 3) thus the regulatory acceptable concentration from this mesocosm is 5/3 = 1.67 µg a.s./L.				

[2] BASF data, MAK-FSG have not supplied an equivalent study and therefore the data cannot be used to support approval for MAK-FSG.
[3] MAK-FSG data, BASF have not supplied an equivalent study and therefore the data cannot be used to support approval for BASF.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step1

Pre and post emergence winter and spring oilseed rape, 1.0 kg a.s./ha

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
metazachlor	Fish	4.61	Acute	0.3		**15.3**	100
metazachlor	Fish	1.39	Chronic	0.3		**4.6**	10
'Fuego' formulation	Aquatic invertebrates	29.7	Acute	0.3		**99**	100
metazachlor	Aquatic invertebrates	33.0	Acute	0.3		110	10

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
metazachlor	Aquatic invertebrates	0.1	Chronic	0.3		**0.33**	10
metazachlor	Algae	0.0076	Chronic	0.3		**0.025**	10
metazachlor	Higher plants	0.0022	Chronic	0.3		**0.007**	10
metazachlor	Sediment-dwelling[1] organisms	9.8	Chronic	0.3		32.7	10
479M04 (BH479-4)	Fish	>100	Acute	0.0537		>1862	100
479M04 (BH479-4)	Aquatic invertebrate	>100	Acute	0.0537		>1862	100
479M04 (BH479-4)	Algae	10.6	Chronic	0.0537		197	10
479M04 (BH479-4)	Higher plants	>100	Chronic	0.0537		>1862	10
479M06 (BH479-6)	Aquatic invertebrate	84.7	Acute	0.0013		65154	100
479M06 (BH479-6)	Algae	26.0	Chronic	0.0013		20000	10
479M06 (BH479-6)	Higher plants	34.4	Chronic	0.0013		26462	10
479M08[2] (Na salt) (BH479-18)	Fish	>93.8	Acute	0.0827		>1134	100
479M08[2] (Na salt) (BH479-18)	Aquatic invertebrate	>93.8	Acute	0.0827		>1134	100
479M08[2] (Na salt) (BH479-18)	Algae	>91.9	Chronic	0.0827		>1111	10
479M08[2] (Na salt) (BH479-18)	Higher plants	>91.9	Chronic	0.0827		>1111	10
479M09 (BH479-9)	Fish	>100	Acute	0.0222		>4505	100
479M09 (BH479-9)	Aquatic invertebrate	>100	Acute	0.0222		>4505	100
479M09 (BH479-9)	Algae	17.0	Chronic	0.0222		766	10
479M09 (BH479-9)	Higher plants	77.6	Chronic	0.0222		3495	10

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
479M11 (BH479-11)	Fish	>100	Acute	0.0275		>3636	100
479M11 (BH479	Aquatic invertebrate	>100	Acute	0.0275		>3636	100
479M11 (BH479	Algae	>100	Chronic	0.0275		>3636	100
479M11 (BH479	Higher plants	>400	Chronic	0.0275		14545	10
479M12 (BH479-12)	Fish	>100	Acute	0.0302		>3311	100
479M12 (BH479	Aquatic invertebrate	27.7	Acute	0.0302		917	100
479M12 (BH479	Algae	81.1	Chronic	0.0302		2685	10
479M12 (BH479	Higher plants	> 100	Chronic	0.0302		3311	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value
[1] Based on PEC_{sw}
[2] Studies were conducted with BH 479-18, the sodium salt of 479M08 (BH479-8). The results are calculated to 479M08 (BH479-8) being >100 mg/L for BH479-18 (factor used 0.933 based on molecular weight).

FOCUS Step 2

Pre and post emergence winter and spring oilseed rape, 1.0 kg a.s./ha

Test substance	N/S[1]	Organism[2]	Toxicity end point (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger
metazachlor		Fish	4.61	Acute	0.0853	**54**	100
metazachlor		Fish	1.39	Chronic	0.0853	16.3	10
'Fuego' formulation		Aquatic invertebrates	29.7	Acute	0.0853	348	100
metazachlor		Aquatic invertebrates	0.1	Chronic	0.0853	**1.17**	10
metazachlor		Algae	EbC50:0.0076 ErC50:0.012	Chronic	0.0853	**0.089** **0.141**	10
metazachlor		Higher plants[5]	EbC50:0.0022 ErC50:0.0071	Chronic	0.0853	**0.026** **0.083**	10

[1] indicate whether Northern of Southern
[2] Groups which fail at Step 1.
[3] Maximum values have been used.

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Pre and post emergence winter and spring oilseed rape, 1.0 kg a.s./ha

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC[1]	TER	Annex VI trigger
metazachlor	Worst case		Fish	Acute	4610	0.0339	135988.0	100
metazachlor	D1	Ditch	Invertebrates	Chronic	100	6.464	15.47	10
metazachlor	D1	Stream	Invertebrates	Chronic	100	5.609	17.83	10
metazachlor	D2	Ditch	Invertebrates	Chronic	100	33.914	**2.95**	10
metazachlor	D2	Stream	Invertebrates	Chronic	100	21.44	**4.66**	10
metazachlor	D3	Ditch[W]	Invertebrates	Chronic	100	6.387	15.66	10
metazachlor	D4	Pond [W]	Invertebrates	Chronic	100	0.867	115.34	10
metazachlor	D4	Stream[W]	Invertebrates	Chronic	100	5.481	18.24	10
metazachlor	D5	Pond[W]	Invertebrates	Chronic	100	0.256	390.63	10
metazachlor	D5	Stream[W]	Invertebrates	Chronic	100	5.913	16.91	10
metazachlor	R1	Stream[W]	Invertebrates	Chronic	100	4.191	23.86	10
metazachlor	R1	Pond[S]	Invertebrates	Chronic	100	0.273	366.30	10
metazachlor	R3	Stream	Invertebrates	Chronic	100	20.454	**4.89**	10
metazachlor	D1	Ditch	Algae		7.6	6.464	**1.18**	10
metazachlor	D1	Stream	Algae		7.6	5.609	**1.35**	10
metazachlor	D2	Ditch	Algae		7.6	33.914	**0.22**	10
metazachlor	D2	Stream	Algae		7.6	21.44	**0.35**	10
metazachlor	D3	Ditch[W]	Algae		7.6	6.387	**1.19**	10
metazachlor	D4	Pond [W]	Algae		7.6	0.867	**8.77**	10
metazachlor	D4	Stream[W]	Algae		7.6	5.481	**1.39**	10
metazachlor	D5	Pond[W]	Algae		7.6	0.256	29.69	10
metazachlor	D5	Stream[W]	Algae		7.6	5.913	**1.29**	10
metazachlor	R1	Stream[W]	Algae		7.6	4.191	**1.81**	10
metazachlor	R1	Pond[S]	Algae		7.6	0.273	27.84	10
metazachlor	R3	Stream	Algae		7.6	20.454	**0.37**	10
metazachlor	D1	Ditch	Macrophytes		2.2	6.464	**0.34**	10
metazachlor	D1	Stream	Macrophytes		2.2	5.609	**0.39**	10
metazachlor	D2	Ditch	Macrophytes		2.2	33.914	**0.06**	10
metazachlor	D2	Stream	Macrophytes		2.2	21.44	**0.10**	10
metazachlor	D3	Ditch[W]	Macrophytes		2.2	6.387	**0.34**	10
metazachlor	D4	Pond [W]	Macrophytes		2.2	0.867	**2.54**	10
metazachlor	D4	Stream[W]	Macrophytes		2.2	5.481	**0.40**	10
metazachlor	D5	Pond[W]	Macrophytes		2.2	0.256	**8.59**	10
metazachlor	D5	Stream[W]	Macrophytes		2.2	5.913	**0.37**	10
metazachlor	R1	Stream[W]	Macrophytes		2.2	4.191	**0.52**	10
metazachlor	R1	Pond[S]	Macrophytes		2.2	0.273	**8.06**	10
metazachlor	R3	Stream	Macrophytes		2.2	20.454	**0.11**	10

[W] Winter oilseed rape worst case
[S] Spring oilseed rape worst case
Where winter or spring oil seed rape is not indicated only one crop uses that scenario (D1 spring only, D2, R3 winter only)
[1] Maximum PEC_{sw}
[2] Geometric mean of 9 species of aquatic macrophytes (BASF data)
Figures in **bold** are below the trigger value

Pre and post emergence winter and spring oilseed rape, 0.75 kg a.s./ha

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)*	PEC[1]	TER	Proposed trigger
metazachlor	D1	Ditch	Mesocosm		1.67	4.901	**0.34**	1
metazachlor	D1	Stream	Mesocosm		1.67	4.207	**0.40**	1
metazachlor	D2	Ditch	Mesocosm		1.67	23.505	**0.07**	1
metazachlor	D2	Stream	Mesocosm		1.67	14.852	**0.11**	1
metazachlor	D3	Ditch[W]	Mesocosm		1.67	4.773	**0.35**	1
metazachlor	D4	Pond [W]	Mesocosm		1.67	0.659	2.53	1
metazachlor	D4	Stream[W]	Mesocosm		1.67	4.111	**0.41**	1
metazachlor	D5	Pond[W]	Mesocosm		1.67	0.173	9.65	1
metazachlor	D5	Stream[W]	Mesocosm		1.67	4.435	**0.38**	1
metazachlor	R1	Stream[W]	Mesocosm		1.67	3.143	**0.53**	1
metazachlor	R1	Pond[S]	Mesocosm		1.67	0.207	8.07	1
metazachlor	R3	Stream	Mesocosm		1.67	15.321	**0.11**	1

[W] Winter oilseed rape worst case
[S] Spring oilseed rape worst case
Where winter or spring oil seed rape is not indicated only one crop uses that scenario (D1 spring only, D2, R3 winter only)
[1] Maximum PEC_{sw} (µg/L)
Figures in **bold** are below the trigger value
* NB. The proposed trigger value already includes an uncertainty factor of 3 on the NOEAEC of 5.0 (regulatory acceptable concentration 5/3 = 1.67 µg/L)

FOCUS Step 4

Pre and post emergence winter and spring oilseed rape, 1.0 kg a.s./ha

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
D1	Ditch	Algae		7.6	10 m	1.156	**6.57**	10
D1	Stream	Algae		7.6	10 m	1.087	**6.99**	10
D2	Ditch	Algae		7.6	10 m	33.913	**0.22**	10
D2	Stream	Algae		7.6	10 m	21.44	**0.35**	10
D3	Ditch [W]	Algae		7.6	10 m	0.918	**8.28**	10
D4	Pond [W]	Algae		7.6	10 m	0.837	**9.08**	10
D4	Stream [W]	Algae		7.6	10 m	1.492	**5.09**	10
D5	Pond [W]	Algae		7.6	10 m	0.256	29.69	10
D5	Stream [W]	Algae		7.6	10 m	1.146	**6.63**	10
R1	Pond [W]	Algae		7.6	10 m	0.136	55.88	10
R1	Stream [W]	Algae		7.6	10 m	1.183	**6.42**	10
R1	Pond [S]	Algae		7.6	10 m grass[2]	0.021	361.90	10
R1	Pond [S]	Algae		7.6	10 m	0.214	35.51	10
R1	Stream [S]	Algae		7.6	10 m grass[2]	0.27	28.15	10
R1	Stream [S]	Algae		7.6	10 m	2.702	**2.81**	10
R3	Stream	Algae		7.6	10 m grass[2]	2.045	**3.72**	10
R3	Stream	Algae		7.6	10 m	20.454	**0.37**	10
D1	Ditch	Algae		7.6	20 m	0.713	10.66	10
D1	Stream	Algae		7.6	20 m	0.568	13.38	10
D2	Ditch	Algae		7.6	20 m	33.913	**0.22**	10

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
D2	Stream	Algae		7.6	20 m	21.44	**0.35**	10
D3	Ditch [W]	Algae		7.6	20 m	0.475	16.00	10
D4	Pond [W]	Algae		7.6	20 m	0.821	**9.26**	10
D4	Stream [W]	Algae		7.6	20 m	1.492	**5.09**	10
D5	Pond [W]	Algae		7.6	20 m	0.256	29.69	10
D5	Stream [W]	Algae		7.6	20 m	0.595	12.77	10
R1	Pond [W]	Algae		7.6	20 m	0.091	83.52	10
R1	Stream [W]	Algae		7.6	20 m	1.183	**6.42**	10
R1	Pond [S]	Algae		7.6	20 m grass[2]	0.002	3800	10
R1	Pond [S]	Algae		7.6	20 m	0.182	41.76	10
R1	Stream [S]	Algae		7.6	20 m grass[2]	0.027	281.48	10
R1	Stream [S]	Algae		7.6	20 m	2.702	**2.81**	10
R3	Stream	Algae		7.6	20 m grass[2]	0.204	37.25	10
R3	Stream	Algae		7.6	20 m	20.454	**0.37**	10

[W] Winter oilseed rape worst case
[S] Spring oilseed rape worst case
Where winter or spring oil seed rape is not indicated only one crop uses that scenario (D1 spring only, D2, R3 winter only)
[1] Maximum PEC_{sw}
[2]Grass refers to a grass buffer strip to mitigate against run off
Figures in **bold** are below the trigger value

Pre and post emergence winter and spring oilseed rape, 0.75 kg a.s./ha

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
D1	Ditch	Mesocosm		1.67	5 m	1.393	1.20	1
D1	Stream	Mesocosm		1.67	5 m	1.537	1.09	1
D2	Ditch	Mesocosm		1.67	5 m	23.505	**0.07**	1
D2	Stream	Mesocosm		1.67	5 m	14.852	**0.11**	1
D3	Ditch[W]	Mesocosm		1.67	5 m	1.293	1.29	1
D4	Pond [W]	Mesocosm		1.67	5 m	0.652	2.56	1
D4	Stream[W]	Mesocosm		1.67	5 m	1.502	1.11	1
D5	Pond[W]	Mesocosm		1.67	5 m	0.151	11.06	1
D5	Stream[W]	Mesocosm		1.67	5 m	1.62	1.03	1
R1	Pond[S]	Mesocosm		1.67	5 m	0.192	8.70	1
R1	Stream[W]	Mesocosm		1.67	5 m	2.088	**0.80**	1
R3	Stream	Mesocosm		1.67	5 m	15.321	**0.11**	1
D1	Ditch	Mesocosm		1.67	10 m	0.78	2.14	1
D1	Stream	Mesocosm		1.67	10 m	0.815	2.05	1
D2	Ditch	Mesocosm		1.67	10 m	23.505	**0.07**	1
D2	Stream	Mesocosm		1.67	10 m	14.852	**0.11**	1
D3	Ditch[W]	Mesocosm		1.67	10 m	0.686	2.43	1
D4	Pond [W]	Mesocosm		1.67	10 m	0.637	2.62	1
D4	Stream[W]	Mesocosm		1.67	10 m	1.129	1.48	1
D5	Pond[W]	Mesocosm		1.67	10 m	0.111	15.05	1
D5	Stream[W]	Mesocosm		1.67	10 m	0.859	1.94	1
R1	Pond[S]	Mesocosm		1.67	10 m	0.163	10.25	1

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
R1	Stream[W]	Mesocosm		1.67	10 m	2.088	**0.80**	1
R3	Stream	Mesocosm		1.67	10 m	15.321	**0.11**	1

[W] Winter oilseed rape worst case
[S] Spring oilseed rape worst case
Where winter or spring oil seed rape is not indicated only one crop uses that scenario (D1 spring only, D2, R3 winter only)
[1] Maximum PEC_{sw} (µg/L)
[2]Grass refers to a grass buffer strip to mitigate against run off
Figures in **bold** are below the trigger value
* NB. The proposed trigger value already includes an uncertainty factor of 3 on the NOEAEC of 5.0 (regulatory acceptable concentration 5/3 = 1.67 µg/L)

Where winter or spring oil seed rape is not indicated only one crop uses that scenario (D1 spring only, D2, R3 winter only)
[1] Maximum PEC_{sw} (µg/L)
[2]Grass refers to a grass buffer strip to mitigate against run off
Figures in **bold** are below the trigger value
* NB. The proposed trigger value already includes an uncertainty factor of 3 on the NOEAEC of 5.0 (regulatory acceptable concentration 5/3 = 1.67 µg/L)

Bioconcentration

LogPow/Kow Metazachlor: 2.49 479M04 (BH479-4): 0.56 479M08 (BH479-8): 0.83

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	**Acute oral toxicity (LD_{50} µg/bee)**	**Acute contact toxicity (LD_{50} µg/bee)**
Metazachlor ‡	>72.19 µg a.s./bee (BASF)[1]	>100 µg a.s./bee (BASF)[1]
'BAS 479 22 H'	>92.12 µg a.s./bee (BASF)	>100 µg a.s./bee (BASF)
'Fuego'	>155.5 µg a.s./bee (MAK-FSG)	>200.2 µg a.s./bee (MAK-FSG)
Field or semi-field tests		
Not required		

[1] MAK-FSG has not supplied an equivalent study with metazachlor and therefore this data cannot be used to support approval for MAK-FSG. This is discussed further in Section B.9.4.5 of the DAR.

Hazard quotients for honey bees (Annex IIIA, point 10.4)

'BAS 479 22 H': Single application of 2.0 L formulation/ha (1 kg a.s./ka metazachlor) to oilseed rape

Test substance	Route	Hazard quotient	Annex VI Trigger
Metazachlor	Contact	<10	50
Metazachlor	oral	<13.85	50
'BAS 479 22 H'	Contact	<10.86	50
'BAS 479 22 H'	oral	<10	50

'Fuego': Proposed for use as a single application of 1.5 L formulation/ha (0.75 kg a.s./ka metazachlor) to oilseed rape and ornamental trees and shrubs
(The following hazard quotients are calculated for a 1 kg a.s./ha application, in line with that presented in the DAR)

Test substance	Route	Hazard quotient	Annex VI Trigger
'Fuego'	Contact	<6.4[1]	50
'Fuego'	oral	<4.9[1]	50

[1] Hazard quotients calculated for a 1 kg a.s./ha application as presented in Section B.9.4.4 of the DAR

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	LR_{50}
Typhlodromus pyri ‡	'BAS 479 22 H'	Mortality	>7.5 L formulation/ha
Aphidius rhopalosiphi ‡	'BAS 479 22 H'	Mortality	>7.5 L formulation/ha
Typhlodromus pyri ‡	'Fuego'[1]	Mortality	>2.5 L formulation/ha
Aphidius rhopalosiphi ‡	'Fuego'[1]	Mortality	>2.5 L formulation/ha

[1] LR_{50} for 'Fuego' derived from limit test

'BAS 479 22 H': Single application of 2.0 L formulation/ha (1 kg a.s./ka metazachlor) to oilseed rape

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
'BAS 479 22 H'	*Typhlodromus pyri*	>7.5 L formulation/ha	<0.27	<0.007	2
'BAS 479 22 H'	*Aphidius rhopalosiphi*	>7.5 L formulation/ha	<0.27	<0.007	2

[1] Distance of 1 m from the crop: 2.77% drift.

'Fuego': Proposed for use as a single application of 1.5 L formulation/ha (0.75 kg a.s./ka metazachlor) to oilseed rape and ornamental trees and shrubs
(The following hazard quotients are calculated for a 1 kg a.s./ha application, in line with that presented in the DAR)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
'Fuego'	*Typhlodromus pyri*	>2.5 L formulation/ha	<0.8	<0.02	2
'Fuego'	*Aphidius rhopalosiphi*	>2.5 L formulation/ha	<0.8	<0.02	2

[1] Distance of 1 m from the crop: 2.77% drift

Further laboratory and extended laboratory studies ‡
'BAS 479 22 H': 500 g metazachlor/L SC (suspension concentrate) formulation
'Fuego': 500 g metazachlor/L SC (suspension concentrate) formulation

Species	Life stage	Test substance, substrate and duration	Dose	End point	% effect[2]	Trigger value
Chrysoperla carnea	larvae	'BAS 479 22 H' Glass plate	2.5 L formulation/ha	Fertility	-18.0% (BASF)	50 %[1]
Aleochara bilineata	adult	'BAS 479 22 H' Quartz sand	2.5 L formulation/ha	Reproduction	-8.1% (BASF)	50 %[1]
Pardosa spp.	adult	'BAS 479 22 H' Quartz sand	2.5 L formulation/ha	Feeding	-14% (BASF)	50 %[1]
Poecilus cupreus	adult	'Fuego' Quartz sand	2.5 L formulation/ha	Feeding	-10.5% (MAK-FSG)	50 %[1]
Pardosa spp.	Sub-adult	'Fuego' Quartz sand	2.5 L formulation/ha	Feeding	17.5% (MAK-FSG)	50%[1]
Chrysoperla carnea	larvae	'Fuego' Glass plate	2.5 L formulation/ha	Reproduction	35.9% (MAK-FSG)	50%[1]

[1] ESCORT 2 trigger value.
[2] Negative values indicates a positive effect compared to the control

Field or semi-field tests
Not required.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
	a.s. ‡	Acute 14 days	LC50corr > 500 mg a.s./kg soil BASF
	'BAS 479 22 H'	Acute	LC50corr > 250 mg a.s./kg soil BASF
	'Fuego'	Acute	LC50corr = 219.5 mg a.s./kg soil MAK-FSG
	479M04 (BH479-4)	Acute	LC50 > 1000 mg/kg soil BASF*
		Chronic	NOEC = 3.5 BASF NOEC = 2.31 MAK-FSG
	479M08 (BH479-8)	Acute	LC50 > 933.5 BASF*
	tested as BH479-18, results expressed as BH479-8)	Chronic	NOEC = 4.0 BASF NOEC = 1.56 MAK-FSG
	479M06 (BH479-6)	Acute	LC50 > 1000 mg/kg soil BASF*
	479M08 (BH479-9)	Acute	LC50 >1000 mg/kg soil BASF*
	479M08 (BH479-11)	Acute	LC50 >1000 mg/kg soil BASF*
	479M08 (BH479-12)	Acute	LC50 >1000 mg/kg soil BASF*
*No acute study submitted by MAK-FSG, however case made which concluded an acceptable risk from the proposed uses.			
Other soil macro-organisms			
Collembola			
Folsomia candida	'Fuego' ‡	Chronic	NOEC: 1000 mg formulation/kg soil Equivalent to NOEC of 410.0 mg a.s./kg soil $NOEC_{CORR}$: 205.0 mg a.s./kg soil (MAK-FSG)
Folsomia candida	Metabolite 479M04 (BH 479-4)	Chronic	NOEC: 125.0 mg metabolite/kg soil[4] (BASF)
Folsomia candida	Metabolite 479M08 (BH 479-8)	Chronic	NOEC: 465.2 mg metabolite/kg soil[3, 4] (MAK-FSG)
Soil micro-organisms			
Nitrogen mineralisation	BAS 479 14H (minor change to BAS 479 22H)	-	Less than 25% effect by day 28 at 15 L formulation/ha (equivalent to 8.45 mg a.s/ha) (BASF(

Test organism	Test substance	Time scale	End point[1]
	'Fuego'	-	Less than 25% effect by day 28 at 12.5 L formulation/ha (equivalent to 8.45 mg a.s/ha) (MAK-FSG)
	Metabolite 479M04 (BH 479-4)	-	Less than 25% effect by day 28 at 1.75 kg metabolite/ha (BASF)[5]
	Metabolite 479M08 (BH 479-8)	-	Less than 25% effect by day 28 at 1.17 kg metabolite/ha (BASF)[5]
Carbon mineralisation	BAS 479 14H (minor change to BAS 479 22H):	-	Less than 25% effect by day 28 at 15 L formulation/ha (equivalent to 7.5 mg a.s/ha) (BASF)[5]
	'Fuego'	-	Less than 25% effect by day 28 at 12.5 L formulation/ha (equivalent to 8.45 mg a.s/ha) (MAK-FSG)
	Metabolite 479M04 (BH 479-4)	-	Less than 25% effect by day 28 at 1.75 kg metabolite/ha (BASF)[5]
	Metabolite 479M08 (BH 479-8)	-	Less than 25% effect by day 28 at 1.17 kg metabolite/ha (BASF)[5]
Field studies[2]			
Indicate if not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies
[3] 479M08 was actually tested as the sodium salt and so the NOEC derived from this study has been reduced by a factor of 0.933 to account for loss of the sodium ion
[4] The log P_{ow} of metabolites 479M04 (BH 479-4) and 479M08 (BH 479-8) are less than 2 and therefore no correction factor is required.
[5] MAK-FSG have not submitted an equivalent soil micro-organsim stud with metabolites 479M04 (BH 479-4) and 479M08 (BH 479-8) and therefore these studies cannot be used to support approval for MAK-FSG products. Please see Section B.9.8.2.2 of the Ecotox addendum for further details.

Toxicity/exposure ratios for soil organisms

Single application of 1 kg a.s./ha post-emergent application of metazachlor to winter and spring sown oilseed rape

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	a.s. ‡	Acute	1.333	> 375	10
	'BAS 479 22 H'	Acute		> 188	10
	'Fuego'	Acute		165	5
	479M04 (BH479-4)	Acute	0.235	> 4695	10
		Chronic		16^{BASF}/ $11^{MAK-FSG}$	10
	479M08 (BH479-8) tested as BH479-18, results expressed as BH479-8)	Acute	0.335	> 2786	10
		Chronic	0.335	12^{BASF}/ $4.8^{MAK-FSG}$	10
			0.251 [3]	6.2	
	479M06 (BH479-6)	Acute	0.216	> 4630	5
	479M08 (BH479-9)	Acute	0.089	> 11236	5
	479M08 (BH479-11)	Acute	0.100	> 10000	5
	479M08 (BH479-12)	Acute	0.121	> 8265	5
Other soil macro-organisms					
Folsomia candida	Metazachlor applied as 'Fuego' ‡	Chronic	1.333 mg a.s./kg soil[1]	153.8	5
Folsomia candida	Metabolite 479M04 (BH 479-4)	Chronic	0.213 mg/kg soil[2]	587	5
Folsomia candida	Metabolite 479M08 (BH 479-8)	Chronic	0.335 mg/kg soil[2]	1363.6	5

[1] Initial soil PEC following a 1 kg a.s./ha application to pre-emergent oilseed rape
[2] Initial soil PEC for metabolites following a 1 kg a.s./ha application to pre-emergent oilseed rape
[3] Initial soil PEC for metabolite following at 0.75 kg a.s./ha application post-emergence use (not taking into account any interception)

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required as ER_{50} data are provided.

Laboratory dose response tests 'BAS 479 22 H': 2.0 L formulation/ha to oilseed rape

Most sensitive species	Test substance	ER_{50} vegetative vigour mL formulation/ha	ER_{50} Seedling emergence mL formulation/ha	Exposure[3]	TER	Trigger
Lettuce (most sensitive pre-emergent)[1] Glass house study	'BAS 479 22 H'	-	35.1 mL formulation/ha (BASF)	Distance of 1 m, 2.77% drift. PEC: 55.4 mL formulation/ha	**0.63**	5
				Distance of 5 m, 0.57% drift. PEC: 11.4 mL	**3.1**	5

Most sensitive species	Test substance	ER_{50} vegetative vigour mL formulation/ha	ER_{50} Seedling emergence mL formulation/ha	Exposure[3]	TER	Trigger
				formulation/ha		
				Distance of 10 m, 0.29% drift. PEC: 5.8 mL formulation/ha	6.05	5
Rye grass (most sensitive post emergent)[2] Glasshouse study	'BAS 479 22 H'	219.1 mL formulation/ha (BASF)	-	Distance of 1 m, 2.77% drift. PEC: 55.4 mL formulation/ha	**4.0**	5
				Distance of 5 m, 0.57% drift. PEC: 11.4 mL formulation/ha	19.2	

[1] Derived from glasshouse seedling emergence study (6 monocots and 6 dicots tested).
[2] Derived from glasshouse vegetation and vigour study (6 monocots and 6 dicots tested).
[3] Calculated using Rautman *et al.* (2001) revised spray drift values (SANCO/10329).
TERs highlighted in **bold** are less than the respective Annex VI trigger value

Field data for 'BAS 479 22 H': 2.0 L formulation/ha to oilseed rape

Most sensitive species	Test substance	ER_{50} vegetative vigour mL formulation/ha	ER_{50} Seedling emergence mL formulation/ha	Exposure[3]	TER	Trigger
Lettuce (most sensitive pre-emergent)[1] Field data	'BAS 479 22 H'	-	>300 mL formulation/ha (BASF)	Distance of 1 m, 2.77% drift. PEC: 55.4 mL formulation/ha	>5.4	5
Lettuce (most sensitive post emergent)[2] Field data	'BAS 479 22 H'	260 mL formulation/ha (BASF)	-	Distance of 1 m, 2.77% drift. PEC: 55.4 mL formulation/ha	**4.7**	5
				Distance of 5 m, 0.57% drift. PEC: 11.4 mL formulation/ha	22.9	-

[1] Derived from field data for seedling emergence.
[2] Derived from field data for vegetation and vigour study.
[3] Calculated using Rautman *et al.* (2001) revised spray drift values (SANCO/10329).
TERs highlighted in **bold** are less than the respective Annex VI trigger value

Laboratory dose response tests 'Fuego': 1.5 L formulation/ha to oilseed rape and ornamental trees and shrubs

Most sensitive species	Test substance	ER_{50} vegetative vigour mL formulation/ha	ER_{50} Seedling emergence mL formulation/ha	Exposure[3, 4]	TER	Trigger
Sugar beet (most sensitive pre-emergent)[1] Glass house study	'Fuego'	-	210 mL formulation/ha (MAK-FSG)	Distance of 1 m, 2.77% drift. PEC: 41.55 mL formulation/ha	5.1	5
Oat (most sensitive post emergent)[2] Glasshouse study	'Fuego'	120 mL formulation/ha (MAK-FSG)	-	Distance of 1 m, 2.77% drift. PEC: 41.55 mL formulation/ha	**2.88**	5
				Distance of 5 m, 0.57% drift. PEC: 8.55 mL formulation/ha	14.0	

[1] Derived from glasshouse seedling emergence study.
[2] Derived from glasshouse vegetation and vigour study.
[3] Calculated using Rautman *et al.* (2001) revised spray drift values (SANCO/10329).
[4] As discussed in Section B.9.9.3.2 of the ecotox addendum, the RMS considers that the non-target plant risk assessment presented for 'Fuego' used on oilseed rape is also applicable for the proposed use on ornamental trees and shrubs, as the application will be made to the base of the trees and shrubs and not in to the canopy.
TERs highlighted in **bold** are less than the respective Annex VI trigger value

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	EC_{50} >1000 mg metazachlor/L

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	metazachlor
water	metazachlor
sediment	metazachlor
groundwater	metazachlor

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	N, R50, R53

	RMS/peer review proposal
Preparation (both BAS 479 22H and Fuego)	N, R50, R53

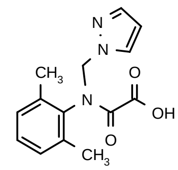
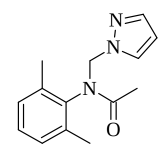
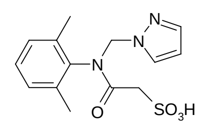
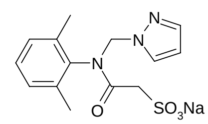
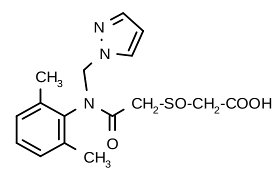
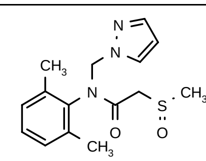
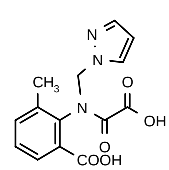
APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high performance liquid chromatography – mass spectrometry
HPLC-MS/MS	high performance liquid chromatography – tandem mass spectrometry
ISO	International Organisation for Standardisation

IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
µg	microgram
mL	millilitre
mN	milli-Newton
mol	Mol
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
Pa	Pascal
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between n-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue

TC	technical material
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV/VIS	Ultraviolet/visibil
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
479M04/BH 479-4	*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide	
479M06 BH479-6	*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)acetamide	
479M08/BH 479-8/BH 479-18	*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid sodium *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonate	 
479M09/BH 479-09	*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl acetic acid	
479M11/BH 479-11	methyl *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfoxide	
479M12/BH 479-12	*N*-[(2-hydroxycarbonyl-6-methyl)phenyl]-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide	
479M16/BH 479-21	3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid