Peer review of the pesticide risk assessment for the active substance metazachlor in light of confirmatory data submitted

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Abstract
The conclusions of EFSA following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State, the United Kingdom, for the pesticide active substance metazachlor are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory data regarding the groundwater exposure of metabolites and their toxicological relevance triggering an assessment. The conclusions were reached on the basis of the evaluation of the representative uses of metazachlor as a herbicide on winter and spring rapeseed and on ornamental trees and shrubs. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Concerns are identified.

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Keywords: metazachlor, peer review, confirmatory data, risk assessment, pesticide, herbicide

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Summary

Metazachlor was included in Annex I to Directive 91/414/EEC on 1 August 2009 by Commission Directive 2008/116/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. It was a specific provision of the approval that the applicant was required to submit to the European Commission further data on potential groundwater contamination from several metabolites. Indeed, conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in vulnerable zones, where appropriate. If metazachlor is classified under Directive 67/548/EEC as ‘limited evidence of a carcinogenic effect’, the Member States concerned shall request the submission of further information on the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer. Information shall be provided to the Commission within 6 months from the notification of such a classification decision.

Metazachlor was formally classified under Regulation (EC) No 1272/2008 as suspected of causing cancer (category 2, H351).

In accordance with the specific provision, the applicant, BASF SE and Feinchemie (Makhteshim Agan) submitted an updated dossier in February 2012, which was evaluated by the designated rapporteur Member State (RMS), the United Kingdom, in the form of an addendum to the draft assessment report. In compliance with guidance document SANCO 5634/2009-rev. 4.5 (European Commission, 2011), the RMS distributed the addendum to Member States, the applicant and the European Food Safety Authority (EFSA) for comments on 10 September 2013. Following the first commenting round, a revised version of the annex to the addendum was distributed for comments to Member States, the applicant and EFSA on 26 February 2016. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 8 August 2016. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table and finalised the Technical Report in August 2016 (EFSA, 2016).

Following consideration of the comments received, the European Commission requested EFSA to organise a peer review of the evaluation by RMS of the confirmatory data submitted in relation to the groundwater exposure of metabolites and their toxicological relevance triggering an assessment.

In the mammalian toxicology area, it was concluded that metabolites 479M04, 479M08 and 479M12 are not relevant up to stage 3 of step 3 of the guidance document on the assessment of the relevance of metabolites in groundwater (European Commission, 2003), while metabolites 479M09 and 479M11 are relevant should they occur in groundwater above the parametric drinking water limit of 0.1 µg/L according to environmental exposure assessment. Additionally, acceptable daily intake (ADI) values were established to perform step 5 refined risk assessments for non-relevant metabolites.

With the predicted levels in groundwater for metabolites 479M04, 479M08 and 479M12, the potential exposure of consumers to drinking water abstracted from groundwater is individually around or less than 1% of the ADI for all considered consumer groups (infant, child, adult). Therefore, total intakes from food and the drinking of groundwater considering the chronic consumer exposure scenarios are expected to be well below the established toxicological reference values also in view of the previously obtained results for consumer dietary exposure considering the representative uses of metazachlor (EFSA, 2008a).

Information to address the confirmatory data requirements for metazachlor and its soil metabolites regarding the groundwater leaching potential was submitted by the applicant. This information include new aerobic soil degradation studies for metabolites 479M04, 479M09, 479M11 and 479M12, new studies on the adsorption behaviour of metabolites 479M09, 479M11 and 479M12, new predicted environmental concentrations in groundwater (PECgw) with FOCUS groundwater modelling, third party monitoring studies, and a very comprehensive approach to refine the groundwater leaching assessment following the recommendations for the tiered approach outlined in FOCUS (2009). The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be high in geoclimatic and use situations represented by all the relevant FOCUS groundwater scenarios for all the metabolites. In contrast, in none of the 48 groundwater samples taken at four sites in the targeted monitoring study conducted in Germany, where metazachlor was applied on oilseed rape, 479M09 and 479M11 were detected. However, the number of these good quality monitoring sites is too low to conclude that the results of the higher tier groundwater monitoring data can override the lower tier FOCUS modelling results for metazachlor and its metabolites in a regulatory context.
context. Therefore, a critical area of concern was identified for potential ground water contamination by the metabolite 479M09 and 479M11 that, with the available toxicological information, have to be considered toxicologically relevant. A data gap was identified for satisfactory information on the hydrogeological characteristics of the targeted monitoring sites in France in order to properly assess the vulnerability of the selected monitoring scenarios. Finally, the new FOCUS groundwater modelling, based on the peer reviewed agreed endpoints, was repeated for winter and spring oil seed rape only. This is identified as a groundwater exposure assessment not finalised for the representative uses in ornamental trees and shrubs.
Table of contents

Abstract................................................................................................................................................... 1
Summary................................................................................................................................................. 3
Background ............................................................................................................................................. 6
The active substance and the formulated product....................................................................................... 7
Data gaps................................................................................................................................................ 14
Concerns ................................................................................................................................................. 14
1. Issues that could not be finalised ........................................................................................................ 14
2. Critical areas of concern........................................................................................................................ 14
3. Overview of the concerns identified for each representative use considered (Table 4) ....................... 15
References............................................................................................................................................... 15
Abbreviations ........................................................................................................................................... 16
Appendix A – List of end points for the active substance and the representative formulation ............... 18
Appendix B – Used compound codes ..................................................................................................... 47
Background

Metazachlor was included in Annex I to Directive 91/414/EEC\(^1\) on 1 August 2009 by Commission Directive 2008/116/EC\(^2\), and has been deemed to be approved under Regulation (EC) No 1107/2009\(^3\) in accordance with Commission Implementing Regulation (EU) No 540/2011\(^4\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^5\). The European Food Safety Authority (EFSA) previously finalised a Conclusion on this active substance (EFSA, 2008a).

It was a specific provision of the approval that the applicant was required to submit to the European Commission further data on potential groundwater contamination from several metabolites. Indeed, conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in vulnerable zones, where appropriate. If metazachlor is classified under Directive 67/548/EEC\(^6\) as ‘limited evidence of a carcinogenic effect’, the Member States concerned shall request the submission of further information on the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer. Information shall be provided to the Commission within 6 months from the notification of such a classification decision.

Metazachlor was formally classified under Regulation (EC) No 1272/2008\(^7\) as suspected of causing cancer (category 2, H351).

In accordance with the specific provision, the applicant, BASF SE and Feinchemie (Mahkteshim Agan) submitted an updated dossier in February 2012, which was evaluated by the designated rapporteur Member State (RMS), the United Kingdom, in the form of an addendum to the draft assessment report. In compliance with guidance document SANCO 5634/2009-rev.4.5 (European Commission, 2011), the RMS distributed a first version of the addendum (United Kingdom, 2013) to Member States, the applicant and EFSA for comments on 10 September 2013. Then, in compliance with guidance document SANCO 5634/2009-rev. 4.5 (European Commission, 2011), a revised version of the addendum to Member States, the applicant and EFSA was distributed for comments on 26 February 2016. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 8 August 2016. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table and finalised the Technical Report in August 2016 (EFSA, 2016).

Following consideration of the comments received, the European Commission requested EFSA to organise a peer review of the evaluation by RMS of the confirmatory data submitted in relation to the groundwater exposure of metabolites and their toxicological relevance triggering an assessment.

The addendum and the reporting table were discussed at the Pesticides Peer Review Meeting on mammalian toxicology and environmental fate in February 2017. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting reports.

A final consultation on the conclusions arising from the peer review took place with Member States via a written procedure in March–April 2017.

The conclusions laid down in this report were reached on the basis of the peer review of the RMS’s evaluation of the confirmatory data submitted on relevance groundwater metabolites and their exposure assessment. A key supporting document to this conclusion is the peer review report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review. The peer review report (EFSA, 2017) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

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1. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2. Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances. OJ L 337, 16.12.2008, p. 86–91.
3. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
4. Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
5. Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
6. Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ No 196/1, 16.8.1967, p. 234–256.
7. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.
the report of the scientific consultation with Member State experts;
the comments received on the draft EFSA conclusion.

Given the importance of the addendum to the assessment report and its annex (United Kingdom, 2013, 2016) and the peer review report, these documents are considered as background documents to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

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).
The representative formulated products for the evaluation were 'Butisan S (BAS 479 22H)', and 'Fuego', both suspension concentrates (SC) containing 500 g/L metazachlor.
The representative uses evaluated comprise foliar spraying on winter and spring rapeseed and on ornamental trees and shrubs (nursery, ornamental trees, shrubs and forest) against annual weeds and grass weeds,. Full details of the Good Agricultural Practice (GAP) can be found in the list of end points in Appendix A.

Conclusions of the evaluation

In line with the provisions of Commission Directive 2008/116/EC, the applicant has submitted further data on potential groundwater contamination from several metabolites including risk mitigation measures and monitoring programmes to verify potential groundwater contamination from the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in vulnerable zones, where appropriate. If metazachlor is classified under Directive 67/548/EEC as ‘limited evidence of a carcinogenic effect’, the Member States concerned shall request the submission of further information on the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer. Information shall be provided to the Commission within 6 months from the notification of such a classification decision. The Risk Assessment Committee of the European Chemical Agency (ECHA) in its Opinion of 8 March 2011 (ECHA, 2011) confirmed that metazachlor should be classified as suspected of causing cancer (category 2, H351) and therefore this point was further considered.

The assessment of the information was presented in a confirmatory data addendum and its annex (United Kingdom, 2013, 2016). The conclusions laid down in this report were reached on the basis of the peer review of the RMS’s evaluation of the confirmatory data submitted on the groundwater exposure of metabolites and their toxicological relevance triggering an assessment.

Mammalian toxicity

The toxicological relevance of groundwater metabolites of metazachlor was discussed during the Pesticides Peer Review Meeting 151 in February 2017.

Classification of metazachlor as Carc Cat 2, H351 ‘suspected of causing cancer’, has been adopted under Reg. (EC) No 1272/20087 (updated in its 3rd adaptation to technical progress8). Thus, an assessment of the toxicological profile of metabolites is necessary to assess whether the metabolites may share the carcinogenic potential of the parent metazachlor in accordance with the guidance document on the assessment of the relevance of metabolites in groundwater (European Commission, 2003).

During the expert Meeting 151, it was concluded that metabolites 479M04 (BH 479-4) and 479M08 (BH 479-8) are not relevant up to stage 3 of step 3 of the guidance document (European Commission, 2003) since they do not share the early events associated with the carcinogenic effects observed with the parent, metazachlor. It had been previously agreed that the metabolite 479M12 (BH 479-12) is not relevant, but 479M09 (BH 479-9) and 479M11 (BH 479-11) are relevant groundwater metabolites (EFSA, 2008a) should they occur in groundwater above the parametric drinking water limit of 0.1 μg/L according to environmental exposure assessment.

Additionally, since triggered following the exposure assessment with regard to metabolites 479M04, 479M08 and 479M12 in line with step 4 of the guidance document (European Commission, 2003)

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7 Commission Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 179, 11.7.2012, p. 1–10.
8 Commission Regulation (EU) No 618/2012 of 10 July 2012 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 179, 11.7.2012, p. 3–10.
(see residues Section), the following acceptable daily intake (ADI) values were established to perform a step 5 refined risk assessment for non-relevant metabolites: 0.33 mg/kg body weight (bw) per day for 479M04, based on a 90-day study in mice, applying an uncertainty factor (UF) of 1,000 to account for the limited data set; 0.2 mg/kg bw per day for 479M08, based on the developmental no observed adverse effect level (NOAEL) of 195 mg/kg bw per day from a developmental toxicity study in rats, applying the same UF of 1,000 to account for the limited data set; and 0.38 mg/kg bw per day for 479M12, based on the rat, 28-day and mouse, 90-day studies, UF 1,000 applied to account for the limited data set.

Residues

With regard to the occurrence of metabolites 479M04, 479M08 and 479M12 in groundwater above the parametric drinking water limit of 0.1 µg/L using FOCUS modelling and taking into account the provisions for exposure assessments to be conducted in line with step 4 of the guidance document (European Commission, 2003), potential consumer exposure from both sources, groundwater and treated commodities has to be taken into account. Therefore, consumer intake assessments were conducted for metabolites 479M04, 479M08 and 479M12, either of which being a groundwater and plant metabolite.

At the stage of finalisation of the peer review (EFSA, 2008a), the residue definition for dietary risk assessment was proposed as the sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor for all crop categories. The proposal took into account that the toxicological information provided on several plant metabolites suggested that these metabolites could be considered in the consumer risk assessment of comparable toxicity to the parent compound. In view of the toxicological information recently assessed on metabolites 479M04 (BH 479-4), 479M08 (BH 479-8) and 479M12 (BH 479-12) (see Section mammalian toxicology), it appears that compared to the formerly proposed reference values for the metabolites the newly proposed ADI values are higher by a factor of at least 2.5 considering 479M08, a major plant metabolite in oilseed rape. However, for other plant metabolites currently also included in the risk assessment residue definition, e.g. 479M11 (BH 479-11, found > 0.01 mg/kg in rotational crops), it cannot be confirmed that they are of different toxicity compared to metazachlor. In addition, in the majority of residue trials a common moiety method was used to determine residues of compounds containing the 2,6-dimethylaniline moiety, and therefore, an amendment of the residue definition for dietary risk assessment considering the less critical toxicological reference values for metabolites 479M04, 479M08 and 479M12 is not possible with the available data and the conclusion of the peer review remains unchanged. The dietary exposure from food (representative uses) considering residues of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety using the reference values for metazachlor was < 1% ADI and < 0.1% acute reference dose (ARfD) (EFSA, 2008a).

The consumer exposure assessment with regard to groundwater potentially used as drinking water is based on the default assumptions laid down in the WHO Guidelines (WHO, 2011) for drinking water quality for (a) a 60-kg adult drinking 2 L of water per day, (b) a 10-kg child drinking 1 L of water per day and (c) a 5-kg bottle-fed infant drinking 0.75 L of water per day. With the predicted levels in groundwater, the consumer exposure for the metabolites 479M04, 479M08 and 479M12 individually is around or less than 1% ADI for all considered consumer groups. Therefore, total intakes (from food and the drinking of groundwater) considering the chronic consumer exposure scenarios are expected to be well below the established toxicological reference values.

Fate and behaviour

Metazachlor was discussed at the Pesticides Peer Review Meeting 152 in February 2017.

Information to address the confirmatory data requirements for metazachlor and its soil metabolites regarding the groundwater leaching potential was submitted by the applicant. This information include new aerobic soil degradation studies for metabolites 479M04 (BH 479-4), 479M09 (BH 479-9), 479M11 (BH 479-11) and 479M12 (BH 479-12), new studies on the adsorption behaviour of metabolites 479M09, 479M11 and 479M12, new predicted environmental concentrations in groundwater (PECgw) with FOCUS groundwater modelling, third party monitoring studies, and a very comprehensive approach to refine the groundwater leaching assessment following the recommendations for the tiered approach outlined in FOCUS (2009).

In soil laboratory incubations under aerobic conditions in the dark, metazachlor exhibits low to moderate persistence forming the major (> 10% applied radioactivity (AR)) metabolites 479M04 (max. 16.2% AR) and 479M08 (max. 21.6% AR). The persistence of these two metabolites ranged from
moderate to very high for 479M04 and medium to very high for 479M08. Metabolite 479M11 (which exhibited moderate persistence) was present at levels that trigger a groundwater exposure assessment (> 5% AR in two consecutive sampling dates, max. 7.5% AR). Other metabolites identified were detected in smaller amounts 479M09 (max. 5.3% AR, moderate persistence in soil) and 479M12 (max. 2.8% AR, medium to high persistence). Mineralisation of the phenyl ring radiolabel to carbon dioxide accounted for about 7% AR after 100 days. The formation of unextractable residues for this radiolabel accounted for 43% AR after 91–100 days. In anaerobic soil incubations, metabolite 479M06 (BH 479-6) occurred in amounts greater than 10% AR (max. 8.2–18.5% AR at day 68–120). For the intended use of metazachlor applied in the autumn to oilseed rape, periods of anaerobic 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, an environmental exposure assessment for this metabolite is not considered necessary.

Field soil dissipation studies where parent metazachlor was applied to bare soil or seeded oilseed rape before emergence were carried out at five sites in Germany, two sites in Spain and one site in Sweden. In addition, metabolite 479M08 was applied as test substance to bare soil in two sites in Germany. The persistence of metazachlor was low to moderate and showed no tendency to move into deeper layers of soil in amounts measurable by the soil methods. Metabolites 479M04 and 479M08, which exhibited moderate to medium and moderate to high persistence, respectively. These two metabolites, at least in some trials, showed a tendency to move into the deeper soil layers. After the application of metabolite 479M08 the compound could be detected up to 1 year after application in one trial. Additionally, it could be found in soil layers down to 75 cm.

Metazachlor exhibited medium high mobility in soils, while the mobility of metabolites 479M04, 479M06 and 479M08 was high to very high and the mobility of metabolites 479M09, 479M11 and 479M12 was very high. There was no evidence that the adsorption of metazachlor and of its metabolites was pH dependent. In a 2-year lysimeter study carried out in northern Germany, metazachlor was applied in the first year only to the soil surface as a spray 15 days after an oilseed rape crop was sown in September at a rate equivalent to 1 kg a.s./ha. Parent metazachlor was not determinable (limit of detection 0.04 µg/L) in any leachate sample. In contrast, the maximum annual average concentration of 479M04 was 21.4 µg/L (parent equivalents). In the leachate samples, metabolite 479M12 was present at up to 3.6 µg/L, 479M08 was up to 17.3 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).

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (2009) scenarios and the models PEARL 4.4.4 and PELMO 4.4.3 for the active substance metazachlor and the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12. It should be noted that the available simulations assume an application every third year only and used a Q10 of 2.2, which is not in line with the current EFSA (2008b) and a Walker equation coefficient of 0.7. For metazachlor, the potential for groundwater exposure from the representative uses on spring and winter oilseed rape above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all FOCUS groundwater scenarios (six scenarios for winter oilseed rape and three scenarios for spring oilseed rape). The potential for groundwater exposure by the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 was however concluded to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios (see Table 1). It should be noted that the new FOCUS groundwater modelling based on the peer reviewed agreed input parameters, did not include the representative use on ornamental trees and shrubs (considering apples as the surrogate crop to be selected for FOCUS calculations). This is identified as an issue not finalised.

In the framework of the confirmatory data assessment, a very comprehensive approach to refine the groundwater leaching assessment was submitted by the applicant. The information submitted include two targeted groundwater monitoring studies for the metabolites of metazachlor (one conducted in Germany and one in France), an assessment of the vulnerability of the monitoring sites, a vulnerability assessment for the area of intended use and, finally, the vulnerability of monitoring scenarios was compared with the vulnerability of the intended use areas. The experts’ meeting (Pesticide Peer Review Meeting 152) discussed to what extent these monitoring data should be taken into account in the groundwater risk assessment. It was acknowledged that although in the FOCUS Groundwater Guidance (2009) a list of the quality criteria for monitoring data is provided, a specific EU Guidance on the implementation of these quality criteria would be helpful in harmonising the evaluation process.

The discussion over the French targeted groundwater monitoring study was supported by the evaluation performed at the national level in France and reported by the French expert during the meeting. Of the 20 sites monitored in France, four sites were considered to have low vulnerability...
based on evidence of substance use, soil column properties and connection to groundwater/sampling location and the weather conditions. The other 16 sites were considered by the national geological experts in France to be vulnerable and associated with oilseed rape use. However, the experts noted that the reporting of the hydrogeological characteristics of the French monitoring sites provided by the applicant in the dossier was insufficient to conduct an appropriate evaluation of the data. Therefore, a data gap was identified. For the German sites (22 in total), good quality information on the hydrogeological situation was reported by the applicant. Taking into consideration the in-depth evaluation reported by the national German expert during the meeting, the experts concluded that only four locations (wells Schlammersdorf, Schoenkamp, Damm and Berge) are considered suitable regarding monitoring site quality criteria to address the groundwater exposure of metazachlor for the applied representative uses. In these hydrogeological vulnerable situations that are typical for oilseed rape cultivation in Germany, the results of the targeted groundwater monitoring study show that residues of the relevant metabolites 479M09 and 479M11 are all below limit of quantification (LOQ) (< 0.05 µg/L) at all sampling points and all points in time. In the same monitoring period, 52% of the analysed samples for metabolite 479M04 were above 0.1 µg/L, 54% of the analysed samples for metabolite 479M08 were above 0.1 µg/L and 23% of the analysed samples for metabolite 479M12 were above 0.1 µg/L.

As had been agreed previously in the context of the use of residue levels in samples taken from the saturated zone (EFSA, 2011), it was considered appropriate to compare regulatory triggers with concentrations measured in individual samples and not with the annual averages that are relevant when assessing concentrations in leachate recharge leaving the upper layers of the soil column.

A summary of the monitoring and modelling results are presented in the following bullets and in Table 1.

Table 1: Results from the FOCUS modelling as well as the targeted monitoring data from Germany

|                         | Metazachlor | 479M04 | 479M08 | 479M09 |
|-------------------------|-------------|--------|--------|--------|
| **FOCUS modelling results (winter oil seed rape)** |             |        |        |        |
| Number of scenarios > 0.1 µg/L | 0/6         | 6/6    | 6/6    | 6/6    |
| Number of scenarios > 10 µg/L | 0/6         | 0/6    | 2/6    | 0/6    |
| Range (µg/L) | < 0.001     | 3.78–6.29 | 6.19–14.18 | 0.37–1.37 |
| **FOCUS modelling results (spring oil seed rape)** |             |        |        |        |
| Number of scenarios > 0.1 µg/L | 0/3         | 3/3    | 3/3    | 3/3    |
| Number of scenarios > 10 µg/L | 0/3         | 0/3    | 0/3    | 0/3    |
| Range (µg/L) | < 0.001     | 1.53–5.15 | 3.57–8.92 | 0.13–0.52 |
| **Monitoring data** |             |        |        |        |
| **Germany (targeted monitoring, 4 sites*, 48 samples)** |             |        |        |        |
| Detection > 0.1 µg/L (% of analysed samples) | n.a.        | 52%    | 54%    | 0%     |
| Max. value (µg/L) | n.a.        | 1.80   | 6.76   | < 0.05 |

|                     | 479M11 | 479M12 |
|---------------------|--------|--------|
| Number of scenarios > 0.1 µg/L | 6/6    | 6/6    |
| Number of scenarios > 10 µg/L | 0/6    | 1/6    |
| Range (µg/L) | 0.24–1.43 | 3.64–15.74 |
| **FOCUS modelling results (spring oil seed rape)** |             |        |        |        |
| Number of scenarios > 0.1 µg/L | 3/3    |        | 3/3    |        |
| Number of scenarios > 10 µg/L | 0/3    |        | 0/3    |        |
| Range (µg/L) | 0.24–0.48 | 3.04–7.78 |
| **Monitoring data** |             |        |        |        |
| **Germany (targeted monitoring, 4 sites*, 48 samples)** |             |        |        |        |
| Detection > 0.1 µg/L (% of analysed samples) | 0%     | 23%    |        |        |
| Max. value (µg/L) | < 0.05  | 0.16   |        |        |

n.a.: not analysed.
*: Only four groundwater monitoring sites in Germany were considered by the Pesticide Peer Review Meeting 152 suitable regarding monitoring site quality criteria to address the groundwater exposure of metazachlor for the applied representative uses.
479M04: The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be high in geoclimatic and use situations represented by all the relevant FOCUS groundwater scenarios and in the targeted monitoring study in Germany.

479M08: The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be high in geoclimatic and use situations represented by all the relevant FOCUS groundwater scenarios and in the targeted monitoring study in Germany. In geoclimatic conditions represented by 2/6 FOCUS groundwater scenarios for winter oilseed rape use, concentrations (80th percentile annual average recharge concentrations moving below the top 1 m) of the non-relevant metabolite 479M08 were predicted to be above 10 µg/L.

479M09: The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be:
- high in geoclimatic and use situations represented by all the relevant FOCUS groundwater scenarios.
- low in geoclimatic and use situations represented by targeted monitoring in Germany.

479M11: The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be:
- high in geoclimatic and use situations represented by all the relevant FOCUS groundwater scenarios.
- low in geoclimatic and use situations represented by targeted monitoring in Germany.

479M12: The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be:
- high in geoclimatic and use situations represented by all the relevant FOCUS groundwater scenarios.
- intermediate in geoclimatic and use situations represented by the targeted monitoring in Germany.
- in geoclimatic conditions represented by 1/6 FOCUS groundwater scenarios for winter oilseed rape use, concentrations (80th percentile annual average recharge concentrations moving below the top 1 m) of the non-relevant metabolite 479M12 were predicted to be above 10 µg/L.

The peer review concluded also that the read across from these French and German field testing sites with their periods of investigation to other regions of Europe is of limited use in this case, and that the third party monitoring data from national authority in Germany can be considered as providing only supportive information.

At the meeting of experts, it was recalled that the FOCUS groundwater guidance (2009) indicates that 90% of analyses obtained from at least 20 locations targeted to the pesticide of interest would need to be < 0.1 µg/L to demonstrate that the potential for groundwater exposure from the representative uses is low. Therefore, in the case of metazachlor, only four sites were available when consideration is made of the information provided by the applicant that could be peer reviewed by EFSA and member states experts. Overall, the experts agreed that the monitoring data have utility to describe the leaching potential of metazachlor and its metabolites. However, when considering FOCUS groundwater guidance (2009), the number of good quality monitoring sites is too low to conclude that the results of the higher tier groundwater monitoring data override the lower tier FOCUS modelling results for metazachlor and its metabolites in a regulatory context. Based on the available information in the Mammalian Toxicology Section, metabolite 479M04, 479M08 and 479M12 are considered not toxicological relevant. Metabolites 479M09 and 479M11 are relevant from the toxicological point of view as it cannot be excluded that they share the carcinogenic potential of the parent compound.
Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 2–3)

Table 2: Soil

| Compound (name and/or code) | Persistence |
|-----------------------------|-------------|
| Metazachlor                 | Low to moderate persistence |
| 479M04                      | Moderate to very high persistence |
| 479M08                      | Medium to very high persistence |
| 479M09                      | Moderate persistence |
| 479M11                      | Moderate persistence |
| 479M12                      | Medium to high persistence |

SFO: Single first-order; MWHC: maximum water-holding capacity; DT50: period required for 50% dissipation; DT90: period required for 90% dissipation.

Table 3: Groundwater

| Compound (name and/or code) | Mobility in soil | > 0.1 μg/L at 1 m depth for the representative uses(a) | Pesticidal activity | Toxicological relevance |
|-----------------------------|------------------|-----------------------------------------------------|--------------------|------------------------|
| Metazachlor                 | Medium to high mobility 53.8–220 mL/g | FOCUS: No Lysimeter: No | Yes                | Yes                   |
| 479M04                      | High to very high mobility 1–94 mL/g | FOCUS: Yes 6/6 FOCUS scenarios > 0.1 μg/L (3.78–6.29 μg/L) Lysimeter: Yes The trigger value of 0.1 μg/L was exceeded in the lysimeter study available (max. annual average concentration 21.4 μg/L) and in 52% of the samples in targeted monitoring study in Germany, concentrations up to 1.80 μg/L | No | No, up to stage 3 of step 3 of the guidance (European Commission, 2003) ADI 0.33 mg/kg bw per day |

DT50: period required for 50% dissipation; MWHC: maximum water-holding capacity; FOCUS: Field Observation Using Control Sites; Lysimeter: lysimeter study; ADI: Acceptable Daily Intake.
| Compound (name and/or code) | Mobility in soil | > 0.1 µg/L at 1 m depth for the representative uses\(^{(a)}\) | Pesticidal activity | Toxicological relevance |
|-----------------------------|------------------|--------------------------------------------------|-------------------|------------------------|
| 479M08                      | Very high mobility 4–78.5 mL/g | FOCUS: Yes 6/6 FOCUS scenarios > 0.1 µg/L (6.2–14.2 µg/L) 2/6 FOCUS scenarios > 10 µg/L for winter oilseed rape (Chateaudun and Hamburg scenarios) Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in the lysimeter study available (max. concentration in two leachate samples 5.8–12 µg/L), and in 54% of the samples in targeted monitoring study in Germany, concentrations up to 6.76 µg/L | No | No, up to stage 3 of step 3 of the guidance (European Commission, 2003) ADI 0.2 mg/kg bw per day |
| 479M09                      | Very high mobility 4.9–6.8 mL/g | FOCUS: Yes 6/6 FOCUS scenarios > 0.1 µg/L (0.37–1.37 µg/L) Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in the lysimeter study available (max. concentration in two leachate samples 1.3–3.3 µg/L) In all the 48 samples of the targeted monitoring study in Germany, concentrations < 0.1 µg/L | No | Yes, since it cannot be excluded to share the carcinogenic potential of the parent |
| 479M11                      | Very high mobility 18.1–23.5 mL/g | FOCUS: Yes 6/6 FOCUS scenarios > 0.1 µg/L (0.24–1.43 µg/L) Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in the lysimeter study available (max. concentration in two leachate samples 0.8–2.5 µg/L) In all the 48 samples of the targeted monitoring study in Germany, concentrations < 0.1 µg/L | No | Yes, since it cannot be excluded to share the carcinogenic potential of the parent |
| 479M12                      | Very high mobility 5.1–12 mL/g | FOCUS: Yes 6/6 FOCUS scenarios > 0.1 µg/L (3.38–15.74 µg/L) 1/6 FOCUS scenarios > 10 µg/L for winter oilseed rape (Chateaudun scenario) Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in the lysimeter study available (max. concentration in two leachate samples 0.4–3.6 µg/L), and in 23% of the samples in targeted monitoring study in Germany, concentrations up to 0.16 µg/L | No | No, up to stage 3 of step 3 of the guidance (European Commission, 2003) ADI 0.38 mg/kg bw per day |

\(^{(a)}\): At least one FOCUS scenario or relevant lysimeter.
Data gaps

This is a list of data gaps identified in the focussed peer review process of confirmatory data. Data gaps identified in the previously finalised EFSA conclusion on the active substance (EFSA, 2008a) that were not part of the focussed peer review process of confirmatory data remain unchanged.

- More information on the hydrological conditions of the targeted groundwater monitoring sites in France in order to perform an appropriate vulnerability assessment (relevant for all representative uses; date of submission: unknown; see Fate and Behaviour Section).
- A groundwater exposure assessment for metazachlor and its metabolites from the representative use on ornamental trees and shrubs (relevant for the representative use on ornamental trees and shrubs; date of submission: unknown; see Fate and Behaviour Section).

Concerns

1. **Issues that could not be finalised**

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1) The groundwater exposure assessment for metazachlor and its metabolites from the representative use on ornamental trees and shrubs based on the agreed peer reviewed endpoints could not be finalised.

2. **Critical areas of concern**

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to lack of information, and where the assessment performed at the lower tier level does not permit to conclude that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

2) Groundwater metabolites 479M09 and 479M11, that are considered toxicologically relevant based on the available data, are indicated to be above the parametric drinking water limit of 0.1 µg/L in vulnerable groundwater situations represented by the geoclimatic situations of all the relevant FOCUS groundwater scenarios (see mammalian toxicology and fate and behaviour Sections).

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9 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
3. Overview of the concerns identified for each representative use considered (Table 4)

Table 4: Overview of concerns

| Representative use                  | Winter oilseed rape | Spring oilseed rape | Ornamental trees and shrubs |
|-------------------------------------|---------------------|---------------------|-----------------------------|
| **Consumer risk**                   |                     |                     |                             |
| Risk identified                     |                     |                     |                             |
| Assessment not finalised            |                     |                     |                             |
| **Groundwater exposure to active substance** |                     |                     |                             |
| Legal parametric value breached    |                     |                     |                             |
| Assessment not finalised            |                     |                     |                             |
| **Groundwater exposure to metabolites** |                     |                     |                             |
| Legal parametric value breached    |                     | X^2                 |                             |
| Parametric value of 10 µg/L (a) breached | 2/6 FOCUS scenario |                     |                             |
| Assessment not finalised            |                     |                     | X^1                          |

FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use.

Columns are grey if no safe use can be identified. The superscript numbers relate to the numbered points indicated in Sections 1 and 2 under the Concerns Section.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

References

ECHA (European Chemicals Agency), 2011. Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of metazachlor. [ECHA/RAC/CLH-O-000001586-69-01/F]. Adopted in 8 March 2011.

EFSA (European Food Safety Authority), 2008a. Conclusion regarding the peer review of the pesticide risk assessment of the active substance metazachlor. EFSA Journal 2008;6(7):145r, 125 pp. https://doi.org/10.2903/j.efsa.2008.145r

EFSA (European Food Safety Authority), 2008b. Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. EFSA Journal 2008;6(1):622, 32pp. https://doi.org/10.2903/j.efsa.2008.622

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance acetochlor. EFSA Journal 2011;9(5):2143, 109 pp. https://doi.org/10.2903/j.efsa.2011.2143

EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for metazachlor in light of confirmatory data. EFSA Supporting Publication 2016;13(9):EN-1086, 62 pp. https://doi.org/10.2903/sp.efsa.2016.EN-1086

EFSA (European Food Safety Authority), 2017. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance metazachlor. Available online: www.efsa.europa.eu

European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.

European Commission, 2011. Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC. SANCO 5634/2009-rev. 4.5.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2009. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 1, 604 pp, as outlined in Generic guidance for tier 1 FOCUS groundwater assessment, v. 2.0, January 2011.

United Kingdom, 2013. Addendum to the assessment report on metazachlor confirmatory data. September 2013 revised in November 2013. Available online: www.efsa.europa.eu

United Kingdom, 2016. Technical Annex to the Addendum to the assessment report on metazachlor confirmatory data, September 2013 revised in November 2013, in June 2014 and in August 2016. Available online: www.efsa.europa.eu

WHO (World Health Organisation), 2011. WHO Guidelines for drinking-water quality. 4th Edition, ISBN 978 92 4 154815 1, 541 pp.
Abbreviations

1/n slope of Freundlich isotherm
a.s. active substance
ADI acceptable daily intake
AOEL acceptable operator exposure level
AR applied radioactivity
ARfD acute reference dose
bw body weight
CAS Chemical Abstracts Service
CIPAC Collaborative International Pesticides Analytical Council Limited
DSC differential scanning calorimetry
DT50 period required for 50% dissipation (define method of estimation)
DT90 period required for 90% dissipation (define method of estimation)
ECD electron capture detector
ECH A European Chemicals Agency
EEC European Economic Community
EINECS European Inventory of Existing Commercial Chemical Substances
ELINCS European List of New Chemical Substances
FAO Food and Agriculture Organization of the United Nations
FID flame ionisation detector
FOCUS Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP Good Agricultural Practice
GC gas chromatography
GCPF Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
HPLC high-pressure liquid chromatography or high-performance liquid chromatography
HPLC–MS high-pressure liquid chromatography–mass spectrometry
ILV independent laboratory validation
ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry
Koc organic carbon linear adsorption coefficient
Kfoc Freundlich organic carbon adsorption coefficient
LC liquid chromatography
LC50 lethal concentration, median
LC–MS liquid chromatography–mass spectrometry
LC–MS/MS liquid chromatography with tandem mass spectrometry
LD50 lethal dose, median; dosis letalis media
LOAEL lowest observable adverse effect level
LOQ limit of quantification (determination)
M&K Maximisation test of Magnusson & Kligman
MS mass spectrometry
MSD mass selective detector
MWHC maximum water-holding capacity
NOAEL no observed adverse effect level
OECD Organisation for Economic Co-operation and Development
OM organic matter content
PEC predicted environmental concentration
PECair predicted environmental concentration in air
PECgw predicted environmental concentration in groundwater
PECsed predicted environmental concentration in sediment
PECsoil predicted environmental concentration in soil
PECsw predicted environmental concentration in surface water
PHI preharvest interval
Pwood partition coefficient between n-octanol and water
r2 coefficient of determination
RMS rapporteur Member State
| Abbreviation | Definition |
|--------------|------------|
| SC           | suspension concentrate |
| SFO          | single first-order |
| SMILES       | simplified molecular-input line-entry system |
| t<sub>1/2</sub> | half-life (define method of estimation) |
| TSH          | thyroid-stimulating hormone (thyrotropin) |
| UV           | ultraviolet |
| w/w          | weight per unit weight |
| WHO          | World Health Organization |
## Appendix A – List of end points for the active substance and the representative formulation

### 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)-\(N\)-(1H-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 ‡** | 950 g/Kg |
| **Minimum purity of the active substance as manufactured (g/kg) – MAK-FSG ‡** | 950 g/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_{3}O |
| **Molecular mass ‡** | 277.8 g/mol |

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

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![Structural formula](image)
### Physical and chemical properties (Annex IIA, point 2)

| Property                      | Annex IIA | MAK-FSG |
|-------------------------------|-----------|---------|
| **Melting point**             | ± BAS     |         |
| Three 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 x 10⁻⁵ Pa | | |
| at 25°C 0.22 x 10⁻⁵ Pa | | |
| **Vapour pressure**           | ± MAK-FSG |         |
| Very slightly volatile (97%)  | | |
| at 20°C 8.12 x 10⁻⁵ Pa | | |
| at 25°C 0.19 x 10⁻⁵ Pa | | |
| **Henry’s law constant**      | ± BAS, MAK-FSG | 5.9 x 10⁻⁵ Pa m³/mol 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      |         |
| **Solubility in organic solvents** | ± BAS  | (99.6% in g/l, at 20°C) |
| Heptane:                      | < 10      |         |
| Toluene:                      | > 250     |         |
| Dichloromethane:              | > 250     |         |
| Methanol:                     | > 250     |         |
| Acetone:                      | > 250     |         |
| Ethyl acetate:                | > 250     |         |
| Acetonitrile:                 | > 250     |         |
| N,N-Dimethylformamide         | > 250     |         |
| 1-Octanol:                    | 29–33     |         |
| 2-Propanol:                   | 40–50     |         |
Solubility in organic solvents† MAK-FSG

(97.1% in g/l, at 21°C)

| Solvent          | Solubility (g/l) |
|------------------|------------------|
| 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 \( P_{ow} = 2.49 \) at 21°C at pH 7 (99.6%)

Partition co-efficient (log \( P_{ow} \)) † MAK-FSG

Log \( P_{ow} = 2.5 \) 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 \( \varepsilon \) at wavelength) † BAS

Neutral medium (methanol) (99.6%)

\( \varepsilon (L/mol \ cm) @ 207 \) nm = \( 1.9 \times 10^4 \)

\( \varepsilon (L/mol \ cm) @ 265 \) nm = 483

0 absorbance above 290 nm

UV/VIS absorption (max.) (if absorption > 290 nm state \( \varepsilon \) at wavelength) † MAK-FSG

Neutral medium (methanol) (97%)

\( \varepsilon (L/mol \ cm) @ 214 \) nm = \( 1.7 \times 10^3 \)

\( \varepsilon (L/mol \ cm) @ 266 \) nm = 494

Trace absorbance (well below 10) above 290 nm

Quantum yield of direct phototransformation in water at \( \sum > 290 \) nm † BAS, MAK-FSG

See above

Flammability † BAS, MAK-FSG

Not highly flammable (96.6%)

Explosive properties † BAS, MAK-FSG

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

Non-explosive (EC A14) (96.6%)

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

Oxidising properties † BAS, MAK-FSG

See above

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## Summary of representative uses evaluated (Metazachlor)

| Crop and/or situation | Member State or Country | Product name | FG or I | Pests or group of pests controlled | Formulation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|--------------|---------|-----------------------------------|-------------|------------|-------------------------------|----------|---------|
| **BASF**              |                         |              |         |                                   |             |            |                               |          |         |
| Rapeseed, winter, spring | South EU                | Butisan S (BAS 479 22H) | F       | Annual weeds                     | SC          | 500        | SP               | 00–09     | 1       |
|                       |                         |              |         |                                   |             |            |                               |          |         |
|                        |                         |              |         |                                   |             |            |                               |          |         |
| Rapeseed, winter, spring | South EU                | Butisan S (BAS 479 22H) | F       | Annual weeds                     | SC          | 500        | SP               | 10–18     | 1       |
|                       |                         |              |         |                                   |             |            |                               |          |         |
|                        |                         |              |         |                                   |             |            |                               |          |         |
| Rapeseed, winter, spring | North EU               | Butisan S (BAS 479 22H) | F       | Annual weeds                     | SC          | 500        | SP               | 00–09     | 1       |
|                       |                         |              |         |                                   |             |            |                               |          |         |
|                        |                         |              |         |                                   |             |            |                               |          |         |
| Rapeseed, winter, spring | North EU               | Butisan S (BAS 479 22H) | F       | Annual weeds                     | SC          | 500        | SP               | 10–18     | 1       |
|                       |                         |              |         |                                   |             |            |                               |          |         |
|                        |                         |              |         |                                   |             |            |                               |          |         |
| **MAK-FSG**           |                         |              |         |                                   |             |            |                               |          |         |
| Winter rape           | GE                      | FUEGO        | F       | Grass weeds, particularly annual meadow grass, and broadleaved weeds | SC          | 500        | Spraying          | Early post-emergence (BBCH 10-13) | 1       |
|                       |                         |              |         |                                   |             |            |                               |          |         |
|                        |                         |              |         |                                   |             |            |                               |          |         |

Remarks: Pre-emergence, waiting period determined by use pattern [1]
| **Crop and/or situation**\(^{(a)}\) | **Member State or Country** | **Product name** | **FG or I\(^{(b)}\)** | **Pests or group of pests controlled\(^{(c)}\)** | **Formulation** | **Application** | **Application rate per treatment** | **PHI (days)\(^{(l)}\)** | **Remarks\(^{(m)}\)** |
|---|---|---|---|---|---|---|---|---|---|
| Northern White Cedar (*Thuja occidentalis*), Rhododendron (*Rhododendron* spp.), privet (*Ligustrum* 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 | Spraying | Early post-emergence of the weeds (BBCH 11–12) | 1 | Not relevant | 0.25 | 300 | 0.75 | na |

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\(^{(a)}\) 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 sucking 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 and type of equipment used must be indicated.

\(^{(i)}\) Method, e.g. high-volume spraying, low-volume spraying, spreading, dusting, drench.

\(^{(j)}\) Method, e.g. high-volume spraying, low-volume spraying, spreading, dusting, drench.

\(^{(k)}\) Method, e.g. high-volume spraying, low-volume spraying, spreading, dusting, drench.

\(^{(l)}\) 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.

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[1] Metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 have the potential to contaminate groundwater under a wide range of geoclimatic conditions. Metazachlor classification has been decided by RAC as Carc.Cat 2 (adopted in 3rd ATP). 479M04, 479M08/18 and 479M12 are considered 'non-relevant' in relation to carcinogenicity and in relation to general toxicity. Metabolites 479M09 and 479M11 are likely to possess the liver carcinogenic potential of the parent compound and are similar to the parent in relation to toxicity in general.

*: 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 sucking 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 and 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. fluoroxypry). **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): Method, e.g. high-volume spraying, low-volume spraying, spreading, dusting, drench.

\(\) (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.
### Methods of Analysis

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

| Component                      | Technique                  | Agency                              |
|-------------------------------|----------------------------|-------------------------------------|
| Technical as                  | HPLC-UV (CIPAC 411/TC/M/-) | BAS                                 |
| Impurities in technical as    | HPLC-UV (CIPAC 411/TC/M/-) | MAK                                 |
| Plant protection product       | HPLC-UV (CIPAC 411/SC/M/-) | BAS                                 |
|                              | HPLC-UV MAK-FSG             |                                     |

#### Analytical methods for residues (Annex IIA, point 4.2)

| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | BAS:                                                                 | MAK-FSG:                                                                 |
|------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------------|
| 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 metazachlor 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) | 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 metabolite 479M16 LOQ 0.01 mg/kg. Validated for lettuce, orange, oil seed rape, wheat grain, white cabbage (primary and ILV), Brussels sprouts, 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) | LC–MS/MS for metabolites 479-M04, 479-M08 & 479M16 LOQ 0.02 mg/kg. Validated for 479-M04, 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:                                                                 | MAK-FSG:                                                                 |
|------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------------|
| 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 μg/m³ |
| 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)**

| Active substance | Not classified |
| Body fluids and tissues | None |
### Impact on Human and Animal Health

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

| Parameter                                      | Description                                                                                   |
|------------------------------------------------|---------------------------------------------------------------------------------------------|
| Rate and extent of oral absorption ‡           | Rapid absorption ($T_{\text{max}}$ 4–8 h); 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 h), 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 ‡          | Metazachlor                                                                                  |
| (animals and plants)                          | Metabolites 479M09 (BH 479-9) and 479M11 (BH 479-11)                                       |
| Toxicologically relevant compounds ‡          | Metazachlor                                                                                  |
| (environment)                                 | Metabolites 479M04 (BH 479-4), 479M08 (BH 479-8) and 479M12 (BH 479-12)                     |
| Toxicologically non-relevant compounds ‡      |                                                                                              |
| (environment)                                 |                                                                                              |

**Acute toxicity (Annex IIA, point 5.2)**

| Parameter                                      | Description                                                                                   |
|------------------------------------------------|---------------------------------------------------------------------------------------------|
| Rat LD$_{50}$ oral ‡                          | $> 2,000 \text{mg/kg bw}$                                                                  |
| Rat LD$_{50}$ dermal ‡                        | $> 2,000 \text{mg/kg bw}$                                                                  |
| Rat LC$_{50}$ inhalation ‡                    | $> 34.5 \text{mg/L (nose only/4 h)}$                                                         |
| 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)**

| Parameter                                      | Description                                                                                   |
|------------------------------------------------|---------------------------------------------------------------------------------------------|
| 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 per day (BASF), 90-day rat: 21 mg/kg bw per day (FGS), 90-day dog (gav): 90 mg/kg bw per day (BASF), 90-day dog: 48 mg/kg bw per day (FGS), 1-year dog: 29 mg/kg bw per day (BASF) |
| Relevant dermal NOAEL ‡                       | 1000 mg/kg bw per day (28-day rat); BASF                                                    |
| Relevant inhalation NOAEL ‡                   | Not required                                                                                 |
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-year rat: 3.2 mg/kg bw per day (BASF)
2-year rat: 8.5 mg/kg bw per day (FGS)
18-month mouse: 72 mg/kg bw per day (BASF)
18-month mouse: 154 mg/kg bw per day (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 per day (FSG)

Relevant reproductive NOAEL ‡
192 mg/kg bw per day (FSG)

Relevant offspring NOAEL ‡
20 mg/kg bw per day (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 per day (BASF)
Rabbit: 30 mg/kg bw per day (FGS)
Rat: 50 mg/kg bw per day (BASF)
Rat: 250 mg/kg bw per day (FGS)

Relevant developmental NOAEL ‡
Rabbit: 250 mg/kg bw per day (BASF)
Rabbit: 120 mg/kg bw per day (FGS)
Rat: 450 mg/kg bw per day (BASF)
Rat: 250 mg/kg bw per day (FGS)
### Neurotoxicity (Annex IIA, point 5.7)

| Neurotoxicity Type          | Description                                                                 | Result          |
|-----------------------------|-----------------------------------------------------------------------------|-----------------|
| 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 ‡

Numerous mechanistic studies in rats (Wistar) and mice (CD-1 and C57BL/6J) investigating both the liver and the kidney have been conducted.

Liver:
In Wistar rats, subacute dietary exposure to metazachlor at 500 mg/kg bw per day caused ↑ liver weight; marked cytochrome P450 enzyme induction, typical of a CAR activator (Cyp2b1 and Cyp2b2 inducer; similar to that caused by phenobarbital given at approx 35 mg/kg bw per day); centrilobular hypertrophy; and hepatocyte proliferation (with similar time-course to that produced by phenobarbital). There was no evidence of peroxisome proliferation.

In the mouse (both CD-1 and C57BL/6J), subacute dietary exposure to metazachlor at 1,400–1,900 mg/kg bw per day caused ↑ liver weight and some cytochrome P450 enzyme induction, typical of a CAR activator.

A clear and definite mode of action for the liver tumours caused by metazachlor in Wistar rats has not been established; however, there is overwhelming evidence that short-term exposure to metazachlor causes liver hypertrophy and cytochrome P450 2B1 and 2B2 enzyme induction in rats. Although it is still unclear how these early events lead to tumour formation, they seem to be a pre-requisite of metazachlor-induced rat liver carcinogenicity.

Kidneys:
In CD-1 and C57BL/6J mice, subacute dietary exposure to metazachlor at 700–1,900 mg/kg bw per day caused a small ↑ in kidney weight and limited cytochrome P450 enzyme induction. However, even with longer durations of treatment (up to 91 days), there was no evidence of kidney toxicity or significant replicative response of the tubular cells. One study in CD-1 mice reported changes in urinary parameters indicative of tubular and glomerular damage in males. However, as these effects were transient (seen after 3 days of treatment but not after 13 days of treatment) and were not corroborated by the pathology findings of several other studies, it is most likely they were unrelated to treatment.

In Wistar rats, subacute dietary exposure to metazachlor at 500 mg/kg bw per day caused ↑ kidney weight and limited cytochrome P450 enzyme induction.
In summary, a mode of action for the kidney tumours caused by metazachlor in CD-1 mice has not been established; however, there is clear evidence that short-term exposure to metazachlor does not cause any pathology or hyperplastic response in mouse kidney.

Studies performed on metabolites or impurities ‡

| Metabolites 479M04, 479M08 and 479M12 are ‘non-relevant’ up to stage 3 of step 3 according to the guidance document on the assessment of the relevance of metabolites in groundwater (GD). Metabolites 479M09 and 479M11 are likely to possess the liver carcinogenic potential of the parent compound and are similar to the parent in relation to toxicity in general, they are therefore considered relevant according to the GD. |
|---|

479M04/BH 479-4/metazachlor oxalic acid

| Rat acute oral LD50 > 2,200 mg/kg bw; not genotoxic in vitro or in vivo in a standard battery (in vitro gene mutation in bacteria and mammalian cells, clastogenicity and in vivo MN test) |
|---|

| Rat developmental toxicity study: developmental and maternal NOAELs of > 1,000 mg/kg bw per day (highest dose tested) |
|---|

| Dietary 28-day study in Wistar rats with 14-day enzyme induction satellite group: no effects on liver, kidney or liver enzyme induction (P450 2B1 and 2B2) up to 1,128/1,174 mg/kg bw per day; slight haematology effects in top-dose females; NOAEL = 469 mg/kg bw per day |
|---|

| Dietary 28-day study in CD-1 mice: no effects on kidney up to 1,005/1,595 mg/kg bw per day; liver effects (hypertrophy in males, ↓ tot bilirubin in males and ↓ cholesterol in females) at the top dose; NOAEL = 348 mg/kg bw per day |
|---|

| Dietary 90-day S-Phase (kidney) study in CD-1 male mice: no effects on kidney weight, histopathology and cell proliferation of proximal tubules up to 328 mg/kg bw per day for 90 days. |
|---|

| ADI = 0.33 mg/kg bw per day, based on the 90-day study in mice, UF 1,000 to account for the limited data set |
|---|

479M08/BH 479-8/metazachlor sulfonic acid

| Rat acute oral LD50 > 5,000 mg/kg bw; not genotoxic in vitro or in vivo in a standard battery (in vitro gene mutation in bacteria and mammalian cells, clastogenicity and in vivo MN test) |
|---|

| 90-day, rat: NOAEL of 382 mg/kg bw per day, for reduced absolute and relative kidney weight in females |
|---|

| Rat developmental toxicity study: maternal NOAEL > 585 mg/kg bw per day, developmental NOAEL 195 mg/kg bw per day based on the ↑ incidence of post-implantation loss and late resorptions. |
|---|
| 479M09/BH 479-9 | Dietary 28-day study in CD-1 mice: no effects on kidney weight or pathology up to 986/1,361 mg/kg bw per day; decreased body weight gains and signs of anaemia in top-dose females; NOAEL = 538 mg/kg bw per day  
Dietary 90-day S-Phase (kidney) study in CD-1 male mice: no effects on kidney wt, histopathology and cell proliferation of proximal tubules up to 398 mg/kg bw per day for 90 days.  
ADI = 0.2 mg/kg bw per day, based on the developmental NOAEL of 195 mg/kg bw per day from the developmental toxicity study in rats, 1,000 UF to account for the limited data set  
Rat acute oral LD₅₀ > 2,000 mg/kg bw; not genotoxic in vitro (in vitro gene mutation in bacteria and mammalian cells, clastogenicity)  
90-day, rat: NOAEL > 50 mg/kg bw per day (the highest dose tested)  
Dietary 28-day study in Wistar rats with 14-day enzyme induction satellite group: At 1,947 mg/kg bw per day (for 14 days in females), significant liver enzyme induction (P450 2B1 and 2B2); liver weight and histopathology not performed as mortality and body wt loss occurred at this dose. At lower dose of 439 mg/kg bw per day, no effects on liver or kidney, but effects on body wt and haemo-concentration in males; NOAEL = 127 mg/kg bw per day |
| 479M11/BH 479-11 | Rat acute oral LD₅₀ = 500–2000 mg/kg bw  
Not genotoxic in vitro (gene mutation tests in bacteria and mammalian cells, clastogenicity tests)  
Dietary 28-day study in Wistar rats with 14-day enzyme induction satellite group: effects on body weight, haematology and clinical-chem parameters (prothrombin time, cholesterol, triglycerides, tot bilirubin, globulins), liver (weight and hypertrophy) and thyroid (weight, follicular cell hypertrophy and increased TSH); marked liver enzyme induction response (P450 2B1 and 2B2) in females at 2,735 mg/kg bw per day for 14 days; LOAEL = 143 mg/kg bw per day  
Dietary 90-day study in Wistar rats: effects on body weight, haematology and clin-chem parameters (prothrombin time, cholesterol, triglycerides, tot bilirubin, globulins, glucose, calcium), liver (weight, hypertrophy and fatty changes) and thyroid (weight and follicular cell hypertrophy in males); NOAEL = 9.8 mg/kg bw per day |
Medical data ‡ (Annex IIA, point 5.9)

No health effects identified; symptomatic treatment proposed

Summary (Annex IIA, point 5.10)

| Parameter | Value | Study Details |
|-----------|-------|---------------|
| ADI ‡     | 0.08  | Rat chronic (FSG) |
| AOEL ‡    | 0.2   | 90-day rat (FSG) |
| ARfD ‡    | 0.5   | Rat developmental (BASF, FSG) |

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 | Model | Equipment | Exposure |
|----------|-------|-----------|----------|
| **Butisan** | German model | Tractor, field crops | 635 |
| | | | 295* |
| | | | 241° |
| | | | 24§ |
| | UK POEM | Tractor, hydraulic boom and nozzles | 3,817 |
| | | | 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§ |
| | 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 unprotected bystander.
Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

| Substance classified |
|----------------------|
| Metazachlor |
| Harmonised classification - Annex VI of Regulation (EC) No 1272/20087 (updated in its 3rd adaptation to technical progress8) |
| Skin Sens. 1B 'may cause an allergic skin reaction’ Carc. 2 'suspected of causing cancer’(ECHA, 2011) |
| R43 'May cause sensitisation by skin contact’ Carc. Cat. 3 R40 Possible (EFSA, 2008) |

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 479-411 max 16.2% AR at 91 days |
| BH 479-812 max 21.6% AR at study end (181 days) |
| Minor (< 10% AR) |
| BH 479-913 max 5.3% AR at study end (181 days) |
| BH 479-1114 max 7.5%AR at day 14 (6.8% AR at 30 days and 6.8% AR at 60 days) |
| BH 479-1215 , BH 497-7 max < 2.8%AR (phenyl label) n = 2 |

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10 It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
11 BH479-4 = 479M04 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)oxalamide).
12 BH479-8 = 479M08 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)aminocarboxymethylsulfonic acid).
13 H479-9 = 479M09 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)aminocarboxymethylsulfonyl acetic acid).
14 BH479-11 = 479M11 (methyl N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl) aminocarboxymethyl sulfoxide).
15 BH479-12 = 479M12 (N’-[2-hydroxycarbonyl-6-methyl]phenyl)-N-(1H-pyrazol-1-ylmethyl)oxalamide).
Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days
(BASF/FSG)

Non-extractable residues after 100 days
(BASF/FSG)

Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)
(BASF/FSG)

Max 0.16–2.41% AR at 120–123 days (study end; n = 2)

Max 58.6–62% AR at study end (120–123 days; n = 2)

BH 479-616 max 8.19–18.5% AR at day 68–120
(study end) (phenyl label) n = 2

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 CO₂ compared to 0.45% AR as CO₂ 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          | Soil type               | pH | t °C/% MWHC | DT50/DT90(a) (days) | DT50 (days) 20°C pF 2/10 kPa | St. (r²) | Method of calculation |
|-----------------|-------------------------|----|-------------|---------------------|----------------------------|---------|----------------------|
| Li 35b – loamy sand(b) | 6.4 20/40 | 13.6/45.2 | 11.9 | 0.99 | SFO (MCM) |
| LUF A 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 | | | |

MWHC: maximum water-holding capacity; DT₅₀: period required for 50% dissipation; DT₉₀: period required for 90% dissipation; SFO: single first-order; MCM: multicompartment model.

*: All DT₅₀ values from study averaged prior to inclusion in overall geometric mean calculation.

(a): DT₅₀ values calculated by multiplying DT₅₀ values by 3.32 since DT₅₀ values are calculated using single first-order kinetics.

(b): 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.

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16 BH479-6 = 479M06 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)acetamide).
### 479M04

**Aerobic conditions (BASF/FSG)**

| Soil type                      | pH   | t °C/% MWHC | DT50/DT90 (b) (days) | f. f. kdp/kf | DT50 (days) 20°C pF 2/10 kPa | St. (r²) | Method of calculation |
|--------------------------------|------|-------------|----------------------|--------------|----------------------------|----------|----------------------|
| *(a)* 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)           |
| Bruch West – sandy clay loam*  | 7.2  | 30/40       | 59.3/196.9           | 0.276        | 104.4                      | 0.993    | SFO (MCM)           |
| 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 (MCM)           |
| *(a)* Speyer 2.1 – sand        | 5.7  | 20/50       | 296/983              | N/A          | 286                        | 0.978    | SFO (MCM)           |
| Speyer 2.2 – loamy sand        | 6.0  | 20/50       | Poor data fit        |              |                            |          | SFO (MCM)           |
| Speyer 2.3 – sandy loam        | 7.6  | 20/50       | 214/710.5            | N/A          | 183                        | 0.956    | SFO (MCM)           |
| Speyer 2.3 – sandy loam        | 6.5  | 20/60       | 43.3/143.9           | N/A          | 39.0                       | 0.9837   | SFO (MCM)           |
| Speyer 3A – loam               | 7.0  | 20/60       | 22.4/74.5            | N/A          | 19.2                       | 0.9704   | SFO (MCM)           |
| Speyer 5M – sandy loam         | 7.1  | 20/60       | 50.6/161.1           | N/A          | 48.83                      | 0.9668   | SFO (MCM)           |
| LUFA 2.2 – loamy sand(d)       | 6.2  | 20/40       | 249/827              | N/A          | 189.8                      | –(c)     | SFO (MCM)           |
| LUFA 3A – loam(d)              | 7.8  | 20/40       | 53.4/178             | N/A          | 30.3                       | –(c)     | SFO (MCM)           |
| Li 10 – loamy sand(d)          | 7.0  | 20/40       | 126.5/420            | N/A          | 104.8                      | –(c)     | SFO (MCM)           |
| Geometric mean/median(b)       |      |             |                      |              |                            |          | SFO (MCM)           |
|                                |      |             |                      |              |                            |          |                     |

**MWHC:** maximum water-holding capacity; **DT50:** period required for 50% dissipation; **DT90:** period required for 90% dissipation; **SFO:** single first-order; **MCM:** multicompartment model.

*(a): DT50 longer than twice the study length.
*(b): DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single first-order kinetics.
*(c): x2 values were 3.2% (LUFA 2.2 soil), 8.7% (LUFA 3A soil), and 5.1% (Li 10 soil).
*(d): Metabolite dosed study.

### 479M08

**Aerobic conditions (BASF/FSG)**

| Soil type                      | pH   | t °C/% MWHC | DT50/DT90 (b) (days) | f. f. kdp/kf | DT50 (days) 20°C pF 2/10 kPa | St. (r²) | Method of calculation |
|--------------------------------|------|-------------|----------------------|--------------|----------------------------|----------|----------------------|
| *(a)* 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                  |
| *(a)* Speyer 2.1 – sand        | 5.7  | 20/50       | 375/> 1,000          | 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(b)       |      |             |                      |              |                            |          | SFO                  |
|                                |      |             |                      |              |                            |          |                     |

**MWHC:** maximum water-holding capacity; **DT50:** period required for 50% dissipation; **DT90:** period required for 90% dissipation; **SFO:** single first-order.

*(a): DT50 longer than twice the study length.
*(b): DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single first-order kinetics.

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### Aerobic conditions (BASF)

| Soil type                  | pH  | T (°C)/% | DT$_{50}$/DT$_{90}$ (days) | DT$_{50}$ (days) 20°C | $\chi^2$ (%) | Method of calculation |
|----------------------------|-----|----------|----------------------------|------------------------|--------------|-----------------------|
| LUFA 2.2 – loamy sand      | 6.2 | 20/40    | 19.0/63                    | 16.4                   | 4.0          | SFO                   |
| LUFA 5M – sandy loam       | 7.9 | 20/40    | 39.0/129                   | 25.9                   | 3.0          | SFO                   |
| Li 10 – loamy sand         | 7.0 | 20/40    | 13.8/45.9                  | 11.4*                  | 11.9         | DFOP                  |

MWHC: maximum water-holding capacity; DT$_{50}$: period required for 50% dissipation; DT$_{90}$: period required for 90% dissipation; SFO: single first-order.

*: Back calculated from overall DT$_{90}$ value according to FOCUS kinetics guidance.

### Geometric mean

16.9

### Aerobic conditions (BASF)

| Soil type                  | pH  | T (°C)/% | DT$_{50}$/DT$_{90}$ (days) | DT$_{50}$ (days) 20°C | $\chi^2$ (%) | Method of calculation |
|----------------------------|-----|----------|----------------------------|------------------------|--------------|-----------------------|
| LUFA 2.2 – loamy sand($^{(c)}$) | 6.2 | 20/40    | 52.4/174                   | 39.9*                  | 9.6          | FOMC                  |
| LUFA 3A – loam($^{(c)}$)    | 7.8 | 20/40    | 28.4/94.3                  | 16.1*                  | 4.5          | DFOP                  |
| Li 10 – loamy sand($^{(c)}$) | 7.0 | 20/40    | 21.0/69.8                  | 17.4*                  | 7.6          | DFOP                  |

MWHC: maximum water-holding capacity; DT$_{50}$: period required for 50% dissipation; DT$_{90}$: period required for 90% dissipation; SFO: single first-order.

*: Back calculated from overall DT$_{90}$ value according to FOCUS kinetics.

(b): Value from parent applied study (see footnote to parent data table).

(c): Metabolite dosed study.

### Metabolite dosed study

| Soil type                  | pH  | T (°C)/% | DT$_{50}$/DT$_{90}$ (days) | DT$_{50}$ (days) 20°C | $\chi^2$ (%) | Method of calculation |
|----------------------------|-----|----------|----------------------------|------------------------|--------------|-----------------------|
| LUFA 2.2 – loamy sand      | 6.2 | 20/40    | 63/210                     | 54.3                   | 6.2          | SFO                   |
| LUFA 5M – sandy loam       | 7.9 | 20/40    | 140/465                    | 93.0                   | 4.0          | SFO                   |
| Li 10 – loamy sand         | 7.0 | 20/40    | 148/492                    | 122.5                  | 7.0          | SFO                   |

MWHC: maximum water-holding capacity; DT$_{50}$: period required for 50% dissipation; DT$_{90}$: period required for 90% dissipation; SFO: single first-order.

Geometric mean

85.2
## Field studies*(a) (BASF)

| Soil type (indicate if bare or cropped soil was used) | Location (country or USA state) | pH | Depth (cm) | DT<sub>50</sub> (days) | DT<sub>90</sub> (days)<sup>(a)</sup> | St. (r<sup>2</sup>) | DT<sub>50</sub> (days) 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) |
| sandy | Utrera (ES) | 6.5 | 0–10 | 2.8 | 9.3 | 0.992 | 2.0 | SFO (MCM) |
| Sandy loam | Niederhofen (DE) | 6.1 | 0–10 | 12.4 | 41.2 | 0.999 | 8.4 | 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) |
| 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) |

**DT<sub>50</sub>:** period required for 50% dissipation; **DT<sub>90</sub>:** period required for 90% dissipation; **SFO:** single first-order; **MCM:** multicompartment model.

*(a): DT<sub>90</sub> values calculated by multiplying DT<sub>50</sub> values by 3.32 since DT<sub>50</sub> values are calculated using single first-order kinetics.

### Geometric mean/median

| | 9.8/11.5 | 6.8/8.0 |

### 479M04 Aerobic conditions (BASF)

| Soil type | Location | pH | Depth (cm) | DT<sub>50</sub> (days) | DT<sub>90</sub> (days)<sup>(a)</sup> | St. (r<sup>2</sup>) | DT<sub>50</sub> (days) Norm.* | Method of calculation |
|---|---|---|---|---|---|---|---|---|
| Slightly loamy sand | Meckenheim (DE) | 5.3 | 0–75 | 171 | 567.7 | 0.768 | 116.4 | SFO |
| Sandy loam | Lippetal-Brockhausen (DE) | 6.4 | 0–50 | 59.7 | 198.2 | 0.933 | 43.4 | SFO |
| Silty sand | Grossharrie (DE) | 6.0 | 0–50 | 108.8 | 361.2 | 0.983 | NC | SFO (MCM) |

**DT<sub>50</sub>:** period required for 50% dissipation; **DT<sub>90</sub>:** period required for 90% dissipation; **SFO:** single first-order; **MCM:** multicompartment model; **NC:** not calculated.

*(a): DT<sub>90</sub> values calculated by multiplying DT<sub>50</sub> values by 3.32 since DT<sub>50</sub> values are calculated using single first-order kinetics.

### Geometric mean/median

| | 103.6/108.8 | 71.1/79.9 |

**DT<sub>50</sub>:** period required for 50% dissipation; **DT<sub>90</sub>:** period required for 90% dissipation; **SFO:** single first-order; **MCM:** multicompartment model; **NC:** not calculated.

*(a): DT<sub>90</sub> values calculated by multiplying DT<sub>50</sub> values by 3.32 since DT<sub>50</sub> 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 ‡

| Soil type                     | pH     | t °C/% MWHC | DT50/DT90 (days) | DT50 (days) 20°C pF 2/10 kPa | St. (r²) | Method of calculation |
|-------------------------------|--------|-------------|-----------------|-----------------------------|---------|----------------------|
| Li 35b – 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                 |

MWHC: maximum water-holding capacity; DT50: period required for 50% dissipation; DT90: period required for 90% dissipation; SFO: single first-order.

### Soil adsorption/desorption (Annex IIA, point 7.1.2)

| Soil Type                      | OC %  | Soil pH | Kd (mL/g) | Koc (mL/g) | Kf (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|-------------------------------|-------|---------|-----------|------------|-----------|-------------|------|-----|
| Pfungstadt – loam             | 0.58  | 7.3     | –         | –          | –         | –           | –    | –   |
| Neuhofen – loamy sand         | 2.66  | 7.2     | –         | –          | –         | –           | –    | –   |
| LUFA – sand                   | 0.51  | 7.0     | –         | –          | –         | –           | –    | –   |
| 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 | 0.9885 |
| 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   |     |
| Soil Type                  | OC % | Soil pH | Kd (mL/g) | Koc (mL/g) | Kf (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|---------------------------|------|---------|-----------|------------|-----------|-------------|------|-----|
| 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       | –    | –   |

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.

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| Soil type                  | OC % | Soil pH | Kd (mL/g) | Koc (mL/g) | Kf (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|---------------------------|------|---------|-----------|------------|-----------|-------------|------|-----|
| 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 1/n value, n = 8.

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| Soil type                  | OC % | Soil pH | Kd (mL/g) | Koc (mL/g) | Kf (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|---------------------------|------|---------|-----------|------------|-----------|-------------|------|-----|
| 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|
| 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       | –         | –           | –    | –   |
### 479M08 (BASF/FSG)

| Soil Type                  | OC % | Soil pH | Kd (mL/g) | Koc (mL/g) | Kr (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|----------------------------|------|---------|-----------|------------|----------|-------------|-----|-----|
| BBA 2.3 – silty sand       | 0.76 | 7.0     | 0.043     | 5.7        | –        | –           | –   | –   |
| Median*                   |      |         |           |            |          |             |     |     |
| 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) | Kr (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|----------------------------|------|---------|-----------|------------|----------|-------------|-----|-----|
| LUFA 2.1 – sand            | 0.7  | 5.8     | –         | 0.636      | 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                     |      |         |           |            |          |             |     |     |
| pH dependence (yes or no) |      |         |           |            |          |             | No  |     |

### 479M09 (BASF)

| Soil Type                  | OC % | Soil pH (CaCl₂) | Kd (mL/g) | Koc (mL/g) | Kr (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|----------------------------|------|-----------------|-----------|------------|----------|-------------|-----|-----|
| La Gironda – silt clay loam| 3.84 | 7.5             | –         | 0.188      | 4.9      | 0.891       | 0.9841 |
| LUFA 2.2 – loamy sand      | 1.72 | 5.7             | –         | 0.099      | 5.8      | 0.965       | 0.9808 |
| Li 10 – loamy sand         | 0.73 | 6.0             | –         | 0.050      | 6.8      | 0.826       | 0.9925 |
| Arithmetic mean            | 0.112| 5.8             |           | 0.112      | 5.8      | 0.897       | –   |
| pH dependence (yes or no) |      |                 |           |            |          |             | No  |     |

### 479M11 (BASF)

| Soil Type                  | OC % | Soil pH (CaCl₂) | Kd (mL/g) | Koc (mL/g) | Kr (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|----------------------------|------|-----------------|-----------|------------|----------|-------------|-----|-----|
| LUFA 2.2 – loamy sand      | 1.84 | 5.6             | –         | 0.367      | 20.0     | 1.005       | 0.9726 |
| LUFA 3A – loam             | 3.15 | 7.0             | –         | 0.571      | 18.1     | 0.698       | 0.9624 |
| Li 10 – loamy sand         | 0.91 | 6.4             | –         | 0.214      | 23.5     | 0.873       | 0.9435 |
| Arithmetic mean            | 0.384| 20.5            |           | 0.384      | 20.5     | 0.859       | –   |
| pH dependence (yes or no) |      |                 |           |            |          |             | No  |     |

### 479M12 (BASF)

| Soil Type                  | OC % | Soil pH (CaCl₂) | Kd (mL/g) | Koc (mL/g) | Kr (mL/g) | Kfoc (mL/g) | 1/n | r²  |
|----------------------------|------|-----------------|-----------|------------|----------|-------------|-----|-----|
| La Gironda – silt clay loam| 3.84 | 7.5             | –         | 0.197      | 5.1      | 0.997       | 0.9781 |
| LUFA 2.2 – loamy sand      | 1.72 | 5.7             | –         | 0.167      | 9.7      | 0.927       | 0.9808 |
| Li 10 – loamy sand         | 0.73 | 6.0             | –         | 0.087      | 12.0     | 0.962       | 0.9919 |
| Arithmetic mean            | 0.150| 8.9             |           | 0.150      | 8.9      | 0.963       | –   |
| 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 (days):** 60 days and 300 days
- **Time period (days):** 45 days
- **Eluation (mm):** 542 mm

**Analysis of soil residues post ageing (soil residues pre-leaching):**
- 39.9% AR for 60-day experiment
- 41.0% AR for 300-day experiment

**Nature of radioactivity in soil not characterised**

**Leachate:**
- 54.5% AR for 60-day experiment
- 51.5% AR for 300-day experiment

**Nature of radioactivity in leachate not characterised**

### 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:** 4/9/1990
- **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:** 1,000 g a.s./ha
- **Average annual rainfall (mm):** 730 mm year 1
- **Average annual leachate volume:** 321 mm (44%) year 1

**% radioactivity in leachate (maximum/year):**
- 45.61 μg/L year 1
- Metazachlor < limit of detection (0.04 μg/L)
- 479M01 < limit of detection (0.04 μg/L)
- 479M04 = 21.39 μg/L year 1, 6.33 μg/L year 2
- 479M05 < limit of detection (0.04 μg/L)

**Not identified radioactivity:**
- 21.7 μg/L year 1, 15.5 μg/L year 2
- Still not identified radioactivity 1.4–2.3 μg/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 (0.04 μg/L)

**Maximum concentrations in two leachate samples were also determined (not annual averages) but identified other components originally not identified**

**Amount of radioactivity in the soils at the end of the study = 4.2% AR; minor amounts as parent, remainder unidentified**
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)): FOCUS PEARL 4.4.4 and FOCUS PELMO 4.4.3 for the following components: Metazachlor, 479M04, 479M08, 479M09, 479M11, and 479M12

Scenarios (list of names): autumn application: Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza, Porto
spring application: Jokioinen, Okehampton, Porto

Crop: autumn and spring oilseed rape

Application rate

Application rate: 1,000 g/ha
No. of applications: 1 year in 3 pre-emergence (no crop interception)
Time of application (month or season): 7 days pre-emergence application modelled (no crop interception). Applications to autumn and spring oilseed rape modelled

Groundwater modelling input parameters

| Parameter                        | Units | Metazachlor | 479M04 | 479M08 | 479M09 | 479M11 | 479M12 |
|----------------------------------|-------|-------------|--------|--------|--------|--------|--------|
| Physicochemical parameters      |       |             |        |        |        |        |        |
| Molecular weight                | g/mol | 277.75      | 273.29 | 323.37 | 349.41 | 305.4  | 303.27 |
| Water solubility (20°C)         | mg/L  | 450         |        |        |        |        |        |
| Saturated vapour pressure (20°C)| Pa    | 9.6 × 10⁻⁵  |        |        |        |        |        |
|                                 |       |             |        |        |        |        |        |
| DegT₅₀, soil (normalised to 20°C)| d    | 6.8ᶜ       | 56.4ᶜ  | 116.4ᶜ | 16.9ᵈ  | 25.2ᵈ  | 85.2ᵈ  |
| Arhenius activation energy      | KJ/mol | 54.12      |        |        |        |        |        |
| Exponent of moisture correction function | – | 0.7       |        |        |        |        |        |
| Q₁₀ factor                      | –     | 2.2*        |        |        |        |        |        |
| Sorption parameters             |       |             |        |        |        |        |        |
| Kₒₒc                           | mL/g  | 110         | 9.1    | 10     | 5.8    | 20.5   | 8.9    |
| Kₒₚₐₚ                          | mL/g  | 63.8        | 5.3    | 5.8    | 3.4    | 11.9   | 5.2    |
| Freundlich exponent (1/n)       | –     | 0.877       | 1.000  | 0.831  | 0.897  | 0.859  | 0.963  |
| Crop related parameters         |       |             |        |        |        |        |        |
| Crop uptake factor              | –     | 0.5         |        |        |        |        |        |

(a): No measured value available, therefore, a conservative default value for leaching was used.
(b): No measured value available, therefore, the default value of the model was used.
(c): From field study data (normalised DT₅₀ values were corrected to 20°C, but were not corrected for soil moisture content). For metabolite 479M08, the longest field DT₅₀ value was used for modelling in the EFSA conclusion. It is the longer of two field study values available and it is noted that the formation and decline of this metabolite does not impact on any other metabolite PECGW value in the modelling. It was decided not to change the endpoint from that used for groundwater modelling in the EFSA conclusion.
(d): From laboratory study data.
(e): Default value.

*: It should be noted that a proper normalisation of the DT₅₀ values should be based on the new agreed Q₁₀ value of 2.58 in accordance with EFSA (2008a) and a Walker equation coefficient of 0.7.
**PEC\textsubscript{gw} – FOCUS modelling results**

**FOCUS PEARL 4.4.4**

| Scenario          | PEC\textsubscript{gw} (µg/L) | Metazachlor | 479M04 | 479M08 | 479M09 | 479M11 | 479M12 |
|-------------------|-------------------------------|-------------|-------|-------|-------|-------|-------|
| **Winter oilseed rape** |                               |             |       |       |       |       |       |
| Châteaudun        | < 0.001                       | 5.190       | 14.177| 0.401 | 0.292 | 15.742|
| Hamburg           | < 0.001                       | 6.292       | 10.108| 1.327 | 1.209 | 6.644 |
| Kremsmünster      | < 0.001                       | 3.984       | 7.567 | 0.516 | 0.562 | 5.365 |
| Okehampton        | < 0.001                       | 3.601       | 6.194 | 0.662 | 0.871 | 3.640 |
| Piacenza          | < 0.001                       | 4.046       | 7.184 | 0.886 | 1.056 | 4.686 |
| Porto             | < 0.001                       | 3.714       | 6.801 | 0.731 | 0.822 | 4.008 |
| **Spring oilseed rape** |                               |             |       |       |       |       |       |
| Jokioinen         | < 0.001                       | 5.149       | 8.917 | 0.413 | 0.220 | 7.775 |
| Okehampton        | < 0.001                       | 2.702       | 5.238 | 0.233 | 0.375 | 3.958 |
| Porto             | < 0.001                       | 1.534       | 3.568 | 0.080 | 0.110 | 3.043 |

**Results: FOCUS PELMO 4.4.3**

| Scenario          | PEC\textsubscript{gw} (µg/L) | Metazachlor | 479M04 | 479M08 | 479M09 | 479M11 | 479M12 |
|-------------------|-------------------------------|-------------|-------|-------|-------|-------|-------|
| **Winter oilseed rape** |                               |             |       |       |       |       |       |
| Châteaudun        | < 0.001                       | 4.956       | 12.450| 0.373 | 0.237 | 12.929|
| Hamburg           | < 0.001                       | 6.293       | 10.649| 1.366 | 1.247 | 6.250 |
| Kremsmünster      | < 0.001                       | 4.837       | 8.448 | 0.719 | 0.663 | 6.247 |
| Okehampton        | < 0.001                       | 4.037       | 6.572 | 0.811 | 0.998 | 3.379 |
| Piacenza          | < 0.001                       | 5.434       | 8.518 | 1.280 | 1.433 | 5.189 |
| Porto             | < 0.001                       | 3.777       | 6.319 | 0.898 | 1.316 | 3.412 |
| **Spring oilseed rape** |                               |             |       |       |       |       |       |
| Jokioinen         | < 0.001                       | 4.969       | 8.397 | 0.515 | 0.274 | 7.403 |
| Okehampton        | < 0.001                       | 2.765       | 5.397 | 0.318 | 0.475 | 3.664 |
| Porto             | < 0.001                       | 1.736       | 3.747 | 0.128 | 0.239 | 2.815 |

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A data gap is identified for PEC\textsubscript{gw} calculations for the representative uses on nursery, ornamental trees, shrubs and forests

Residues requiring further assessment

| Soil | 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)

| 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 30–205 m. no detections of metazachlor or 479M04 (detection limit quoted as 0.05 μg/L). |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                  | General German federal state monitoring for metazachlor only. 1998 3498 sites no detection, 4 sites < 0.1 μg/L 3 sites 0.1–1 μg/L. |
|                                                  | German Rheinlan-Pfalz state monitoring for parent metazachlor: 1985, 1987 & 1988 all concentrations < 0.02 μg/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 > 0.1 μg/L. |
1. LAWA working group (Bund/Länder-Arbeitsgemeinschaft Wasser):
   Metazachlor (1990–2008):
   Findings > 0.1 μg/L at a very low frequency of 0.03–0.07 % of all sampling points analysed.
   Metabolites (2006–2008)
   Findings reported in concentration classes.
   Metabolites BH 479-4 and BH 479-8 detected in a significant number of samples > 0.1 μg/L (max. < 3 μg/L and < 10 μg/L, respectively)
   Metabolites BH 479-9, BH 479-11 and BH 479-12 never detected above 0.1 μg/L

2. Federal State of Baden-Württemberg (Germany)
   Metazachlor: < LOQ to 0.19 μg/L (one detection above 0.1 μg/L)
   BH 479-4 < LOQ to 1.47 μg/L
   BH 479-8 < LOQ to 3.7 μg/L
   BH 479-9 < LOQ to < 0.05 μg/L
   BH 479-11 < LOQ to < 0.05 μg/L
   BH 479-12 < LOQ to 0.09 μg/L

3. Federal State of Baden-Württemberg (Germany)
   Metazachlor: < LOQ to 0.3 μg/L (two detection above 0.1 μg/L)
   BH 479-4 < LOQ to 1.0 μg/L
   BH 479-8 < LOQ to 3.7 μg/L
   BH 479-9 < LOQ to 0.07 μg/L
   BH 479-11 < LOQ
   BH 479-12 < LOQ to 0.15 μg/L

Targeted monitoring was carried out in Germany and France for metabolites 479M04, 479M08, 479M09, 479M11, and 479M12

Reported concentrations:

|               | Detection > 0.1 μg/L (% of analysed samples) | Max value (μg/L) |
|---------------|---------------------------------------------|-----------------|
| 479M04        | 52%                                         | 1.8             |
| 479M08        | 54%                                         | 6.76            |
| 479M09        | 0%                                          | < 0.05          |
| 479M11        | 0%                                          | < 0.05          |
| 479M12        | 23%                                         | 0.16            |

* Only four groundwater monitoring sites in Germany were considered by the Pesticide Peer Review Meeting 152 suitable regarding monitoring site quality criteria
France (from 2010) *

| Metabolite | Concentration range (μg/L) |
|------------|-----------------------------|
| 479M04     | < LOQ to 1.19               |
| 479M08     | < LOQ to 4.42               |
| 479M09     | < LOQ to 0.09               |
| 479M11     | < LOQ                       |
| 479M12     | < LOQ to 0.19               |

France (from 2011) *

| Metabolite | Concentration range (μg/L) |
|------------|-----------------------------|
| 479M04     | < LOQ to 3.60               |
| 479M08     | < LOQ to 5.10               |
| 479M09     | < LOQ to 0.28<sup>3</sup>   |
| 479M11     | < LOQ                       |
| 479M12     | < LOQ to 0.63               |

* The experts of the Pesticide Peer Review Meeting 152 agreed that the information on the hydrogeological data of the targeted monitoring sites in France was insufficient in the documentation provided by the applicant that could be peer reviewed by the Member States experts. This is identified as a data gap.

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 biodegradable
### Appendix B – Used compound codes

| Code/trivial name(a) | Chemical name/SMILES notation | Structural formula |
|----------------------|-------------------------------|--------------------|
| 479M04 BH 479-4      | [(2,6-Dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino][(oxo)acetic acid O=C(N(Cn1cccn1)c2c(C)ccccc2C)C(=O)O] | ![Structure](image1) |
| 479M08 BH 479-8      | 2-[(2,6-Dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonic acid O=C(CS(C)=O)O(N(Cn1cccn1)c2c(C)ccccc2C) | ![Structure](image2) |
| 479M18 BH 479-18     | Sodium 2-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonate [Na+]O=C(CS([O-])=O)O(N(Cn1cccn1)c2c(C)ccccc2C) | ![Structure](image3) |
| 479M09 BH 479-9      | (2-[(2,6-Dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino]-2-oxoethyl)sulfanyl acetic acid O=C(CS(C)=O)CC(=O)O(N(Cn1cccn1)c2c(C)ccccc2C) | ![Structure](image4) |
| 479M11 BH 479-11     | N-(2,6-Dimethylphenyl)-2-(methylsulfinyl)-N-(1H-pyrazol-1-ylmethyl)acetamide O=C(CS(C)=O)N(Cn1cccn1)c2c(C)ccccc2C | ![Structure](image5) |
| Code/trivial name<sup>(a)</sup> | Chemical name/SMILES notation | Structural formula |
|-------------------------------|--------------------------------|--------------------|
| **479M12**<br> BH 479-12      | 3-Methyl-2-[oxalo-(1H-pyrazol-1-ylmethyl) amino]benzoic acid<br> O=C(N(Cn1cccn1)c2c(C)cccc2C(-O)O)C (-O)O | ![Structural formula](image) |
| **479M16**<br> M16            | 3-[(2,6-Dimethylphenyl)-(1H-pyrazol-1-ylmethyl)amino]-2-oxoethyl sulfanyl)-2-hydroxypropanoic acid<br> O=C(CS(-O)CC(O)(-O)O)N(Cn1cccn1)c2c(C)cccc2C | ![Structural formula](image) |
| **479M06**<br> M06 BH s479-6  | \( N\)-(2,6-Dimethylphenyl)-\( N\)-(1H-pyrazol-1-ylmethyl) acetamide<br> O=C(C)N(Cn1cccn1)c2c(C)cccc2C | ![Structural formula](image) |

SMILES: simplified molecular-input line-entry system.

(a): The metabolite name in bold is the name used in the conclusion.