M-540983-02-3

Document Title

Summary of the fate and behaviour in the environment Methiocarb FS 500 (500 g/L)

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013
Document MCP
Section 9: Fate and behaviour in the environment

According to the guidance document SANCO 10181/2013

for preparing dossiers for the approval of a chemical active substance

Date

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2017-07-28	[redacted].; [redacted]; 2015; M-538609-01-1 added under CP 9.2.5. This study contains the substance data used in study [redacted]; [redacted]; 2015; M-538733-01-1	M-540983-02-1

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CP 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Methiocarb is an insecticide and repellent active substance and was included into Annex I of Directive 91/414 on 1st October 2007 (Directive 2007/5/EC).

This Supplementary Dossier contains only data which were not submitted at the time of the Annex I inclusion of methiocarb under Directive 91/414/EEC and which were therefore not evaluated during the first EU review. All data which were already submitted by Bayer CropScience (BCS) for the Annex I inclusion under Directive 91/414/EEC are contained in the DAR, its Addenda and are included in the Baseline Dossier provided by BCS. These data are only mentioned in the Supplementary Dossier for the sake of completeness and only general information (e.g. author, reference etc.) is available for these data. In order to facilitate discrimination between new data and data submitted during the Annex I inclusion process under Directive 91/414/EEC, the old data are written in grey typeface. For all new studies, detailed summaries are provided within this Supplementary Dossier.

The presented and submitted studies used different synonyms and codes for the active substance Methiocarb.

This document is submitted to support the application for renewal of the regulatory approval of the active substance methiocarb under Commission Implementing Regulation (EU) 844/2012 of 18th September 2012. This document reviews the environmental fate of the product methiocarb FS 500 G containing 500 g/L methiocarb.

Methiocarb FS 500 G is a flowable concentrate for seed treatment for maize. Methiocarb FS 500 was also one of the representative formulations during the previous EU review process of methiocarb.

Introduction

The use of methiocarb in maize in Europe was assessed according to the Good Agricultural Practice (GAP) as summarised in Table 9-1.

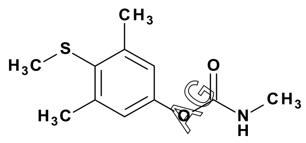
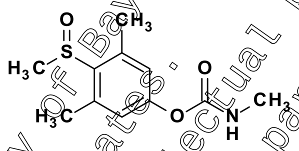
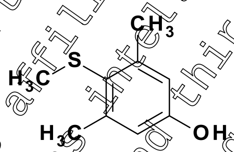
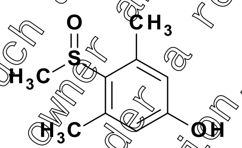
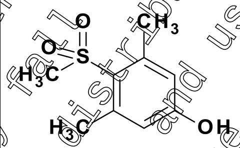
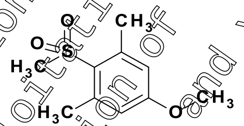
Table 9-1: Application data of methiocarb according to the use pattern in Europe

Individual crop	FOCUS crop	Rate [g a.s./ha]	Interval [days]	Plant interception [%]	BBCH stage	Amount reaching soil [g a.s./ha]
Maize	maize	1×150	-	0	0	1×150

Methiocarb and metabolites considered in the assessment

In addition to the active substance the following metabolites were addressed in this document as they were considered important due to the amounts in which they were found during the course of the environmental fate studies, or due to their specific properties. Study authors sometimes have used different names or short codes for the active substances and degradation products.

Table 9-2: Metabolites of methiocarb considered in the assessment

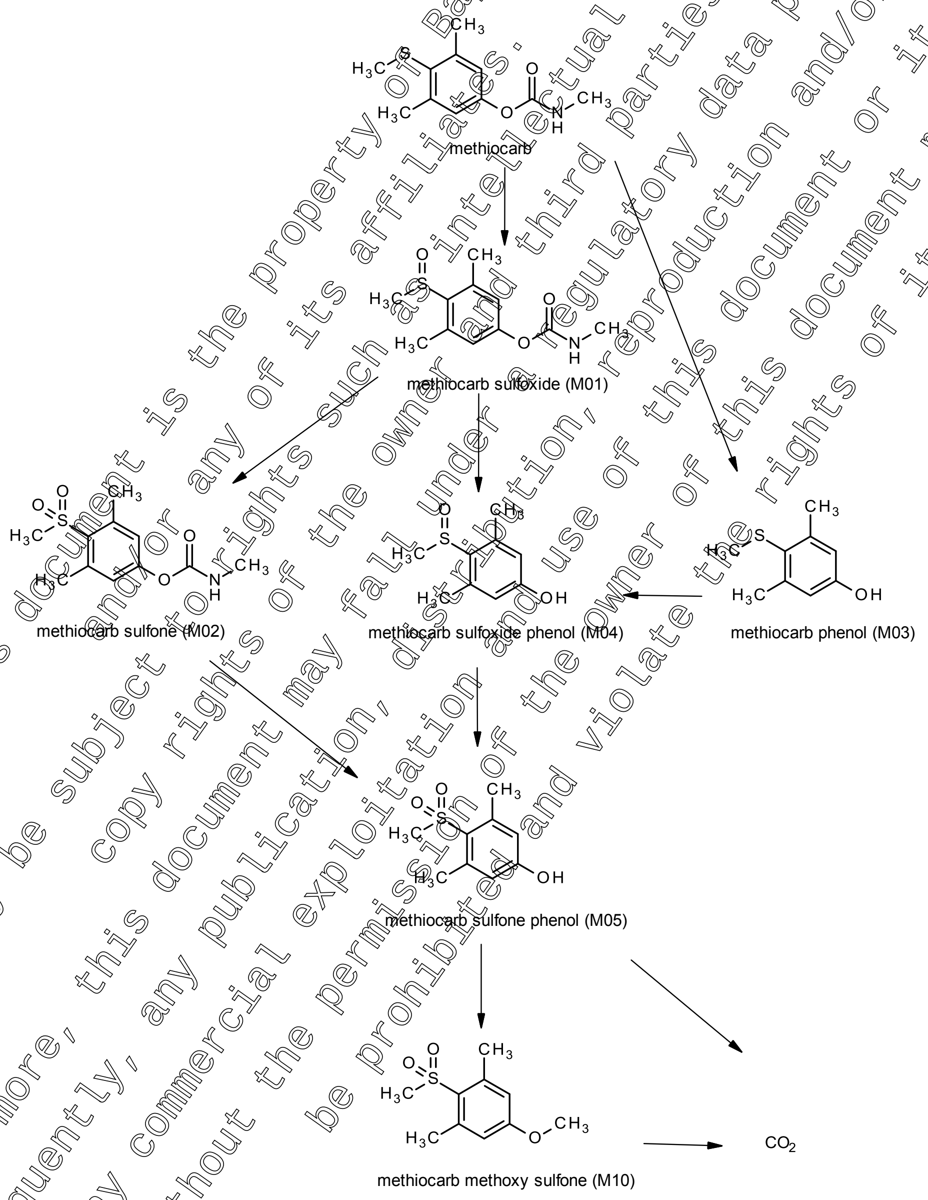
Metabolite	Molar mass	Chemical structure	Exposue assessment required due to
Methiocarb H 321	225.3		PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
Methiocarb sulfoxide (M01) AE 1371422 MSO	241.3		PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
Methiocarb phenol (M03)	168.3		$PEC_{sw/sed}$
Methiocarb sulfoxide phenol (M04) AE 1371423 MSOP	184.3		PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
Methiocarb sulfone phenol (M05) AE 1371425 MSOOP	200.3		PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
Methiocarb methoxy sulfone (M10) AE 1371424 MMS	214.3		PEC_{gw} PEC_{soil} $PEC_{sw/sed}$

CP 9.1 Fate and behaviour in soil

Specific studies on the preparation have not been performed. The results of laboratory studies performed with the active substance as provided in MCA Section 07 “Fate and behaviour in the environment” are also applicable for the preparation. A short summary of the data is given in the subsections below.

The proposed degradation pathway of methiocarb in soil is shown in Figure 9.1-1

Figure 9.1-1: Proposed degradation pathway of methiocarb in soil



For further information on the fate and behaviour in soil please refer to Document MCA, Section 7.1.

CP 9.1.1 Rate of degradation in soil

From the laboratory studies on the route of degradation in soil it can be concluded that methiocarb and its metabolites are well degradable in soil to the final degradation product CO_2. In parallel to mineralization, bound residues were formed. Five degradates were found and identified. Major metabolites (>10 % of the applied radioactivity) are methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05) and methiocarb methoxy sulfone (M10).
No additional metabolites as compared to the soil degradation studies performed in the dark were observed under influence of light.

CP 9.1.1.1 Laboratory studies

The rate of degradation in soil of methiocarb, methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05) and methiocarb methoxy sulfone (M10) has been determined in laboratory studies and is summarized in document MCA Section 07. The data are summarized in the Table 9.1.1.1-1and Table 9.1.1.1-2.

Table 9.1.1.1-1: Degradation parameters of methiocarb and its metabolites (normalised modelling endpoints) including normalisation. The abbreviation ff denotes formation fraction, and FC is field capacity

Compound	n	$DT50_{SFO}$ 1) [days]	$DT50_{SFO}$ (100% FC, 20°C) 1) [days]	ff 2) [-]
Methiocarb (MTC)	5	2.1	1.8	
Methiocarb sulfoxide (MSO, M01)	5	6.0	5.1	1.000 $_{MTC \rightarrow MSO}$
Methiocarb sulfoxide phenol (MSOP, M04)	4	6.8	5.9	1.000 $_{MSO \rightarrow MSOP}$
Methiocarb sulfone phenol (MSOOP, M05)	3	11.2	9.9	0.491 $_{MSOP \rightarrow MSOOP}$
Methiocarb methoxy sulfone (MMS, M10)	3	31.1	27.6	1.000 $_{MSOOP \rightarrow MMS}$

1) geometric mean of n values
2) arithmetic mean of n values
n = No of soils

Table 9.1.1.1-2: Degradation parameters of methiocarb and its metabolites (not normalised trigger endpoints)

Compound	n	DT50 1) [days]	DT90 1) [days]
Methiocarb (MTC)	5	13.7	55.8
Methiocarb sulfoxide (MSO, M01)	5	15.3	56.2
Methiocarb sulfoxide phenol (MSOP, M04)	4	16.7	55.6
Methiocarb sulfone phenol (MSOOP, M05)	3	22.7	75.4
Methiocarb methoxy sulfone (MMS, M10)	3	49.8	165.5

1) maximum of n values

The rate of degradation of methiocarb and its degradation products in anaerobic soil is not considered for the assessment for the use as seed treatment.

The rate of degradation of methiocarb by photolysis on the soil surface is not considered for the assessment for the use as seed treatment.

CP 9.1.1.2 Field studies

CP 9.1.1.2.1 Soil dissipation studies

Due to the results of the laboratory soil degradation studies demonstrating the rapid degradation of methiocarb and its major degradation products in soil, field studies were not required.

CP 9.1.1.2.2 Soil accumulation studies

The accumulation potential of methiocarb was evaluated during the Annex I Inclusion. Due to the short dissipation times, soil accumulation testing is not required for methiocarb.

CP 9.1.2 Mobility in the soil

CP 9.1.2.1 Laboratory studies

The mobility in soil of methiocarb, methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05) and methiocarb methoxy sulfone (M10) has been determined in laboratory studies and is summarized in document MCA Section 07. The data are summarised in the Table 9.1.2-1.

Table 9.1.2-1: Overall summary of adsorption constants $K_{FOC(ads)}$ in soils of methiocarb and its major degradation products

Compound	$K_{FOC(ads)}$ [a] [mL/g]
methiocarb	627
methiocarb sulfoxide (M01)	31[b)]
methiocarb sulfoxide phenol (M04)	43
methiocarb sulfone phenol (M05)	148
methiocarb methoxy sulfone (M10)	181

[a] geometric mean
[b] Koc (HPLC)

CP 9.1.2.2 Lysimeter studies

No relevant studies are included in the Baseline Dossier, as they were not required. No additional studies are submitted within this renewal of approval as this data point is addressed by modelling only.

CP 9.1.2.3 Field leaching studies

A field leaching study is not regarded as necessary.

CP 9.1.3 Estimation of concentrations in soil

New calculations on the studies presented in Document MCA, Section 7, Fate and behavior in the environment were performed to consider the most recent guidance documents for exposure calculations. Previously submitted [redacted].; 2002; M-051384-02-1 is therefore obsolete.

Calculations of predicted environmental concentrations in soil (PEC_{soil}) are presented below.

Predicted environmental concentrations in soil (PEC_{soil})

Report:	KCP 9.1.3/02[redacted].,;[redacted]; 2015; M-538737-01-1
Title:	Methiocarb (MTC) and metabolites: PECsoil EUR - Use in maize in Europe
Report No.:	EnSa-15-0699
Document No.:	M-538737-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials:
The predicted environmental concentrations in soil (PEC_{soil}) of methiocarb and its metabolites methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05) and methiocarb methoxy sulfone (M10) were calculated based on a simple first tier approach using a Microsoft® Excel spreadsheet. A bulk density of 1.5 kg/L and a soil mixing depth of 5 cm was used as recommended by FOCUS (1997)[1] and EU Commission (1995[2], 2000[3]).

The use of methiocarb in maize in Europe was assessed according to the Good Agricultural Practice (GAP) as summarized in Table 9.1.3-1.

Table 9.1.3-1: Application data of methiocarb according to the use pattern in Europe

Individual crop	FOCUS crop	Rate [g a.s./ha]	Interval [days]	Plant interception [%]	BBCH stage	Amount reaching soil [g a.s./ha]
Maize	maize	1×150	-	0	0	1×150

The calculations were based on the maximum intended application rate together with the maximum intended number of applications per season and (for multi-application sequences) the minimum interval between the applications. Crop interception was taken into account according to the BBCH growth stage, as recommended by FOCUS (2014[4]).

For metabolites, the (pseudo) application rate is calculated based on the maximum amount of the metabolite observed in soil degradation studies and the molar mass correction as summarized in Table 9.1.3-2

[1] FOCUS, 1997: Soil persistence models and EU registration. Final report of the work off the Soil Modelling Work group of FOCUS
[2] EU Commission, 1995: Directive 95/36/EC of 14 July 1995, amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market
[3] EU Commission, 2000: Guidance Document on Persistence in Soil (Working Document) 9188/VI/97 rev 8.
[4] FOCUS, 2014: Generic Guidance for FOCUS Groundwater Scenarios, Version 2.2

Table 9.1.3-2: Calculation of metabolite application rates (# = application number)

Compound		Methiocarb	Methiocarb sulfoxide	Methiocarb sulfoxide phenol	Methiocarb sulfone phenol	Methiocarb methoxy sulfone
Crop / rate	#	[g a.s./ha]	[g/ha]	[g/ha]	[g/ha]	[g/ha]
Maize, 1×150 g a.s./ha	1	150	94.46	43.93	26.4	18.83

Substance Specific Parameters:
PEC_{soil} calculations were based on the compound specific input parameters as summarized in Table 9.1.3-3.

Table 9.1.3-3: Key substance specific input parameters of methiocarb and its metabolites

Compound	DT_{50} [days]	Max occur. in soil [%]	Molar mass [g/mol]	Molar mass correction factor
Methiocarb	[a]	100	225.3	1
Methiocarb Sulfoxide	15.3	58.8	241.3	1.071
Methiocarb Sulfoxide Phenol	16.7	35.8	184.3	0.818
Methiocarb Sulfone Phenol	22.7	19.8	200.3	0.889
Methiocarb Methoxy Sulfone	49.8	13.2	214.3	0.9512

[a] Persistence endpoints from bi-phasic degradation (DFOP) with max. DT90 of 55.8 days and parameters g = 0.926, k1 = 0.0562 1/day, k2 = 0.00393 1/day

Findings:
The maximum PEC_{soil} values for methiocarb and its major degradation product are summarised in Table 9.1.3-4. Detailed PEC_{soil} and $TWAC_{soil}$ values for the individual uses are listed in Table 9.1.3-5 and Table 9.1.3-6.

Table 9.1.3-4: Maximum PEC_{soil} of methiocarb and its metabolites for the uses assessed

	Methiocarb	Methiocarb sulfoxide	Methiocarb sulfoxide phenol	Methiocarb sulfone phenol	Methiocarb methoxy sulfone
Use pattern	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]
Maize, 1×150 g a.s./ha	0.200	0.126	0.059	0.035	0.025

Table 9.1.3-5: PEC_{soil} of methiocarb and its metabolites

		Methiocarb	Methiocarb sulfoxide	Methiocarb sulfoxide phenol	Methiocarb sulfone phenol	Methiocarb methoxy sulfone
Days after maximum		PEC_{soil} [mg/kg]	PEC_{soil} [mg/kg]	PEC_{soil} [mg/kg]	PEC_{soil} [mg/kg]	PEC_{soil} [mg/kg]
Initial	0	0.200	0.126	0.059	0.035	0.025
Short term	1	0.190	0.120	0.056	0.034	0.025
	2	0.181	0.115	0.054	0.033	0.024
	4	0.163	0.105	0.050	0.031	0.024
Long term	7	0.140	0.092	0.044	0.028	0.023
	14	0.098	0.067	0.033	0.023	0.021
	21	0.069	0.049	0.024	0.019	0.019
	28	0.049	0.035	0.018	0.015	0.017
	42	0.024	0.019	0.010	0.010	0.014
	50	0.016	0.013	0.007	0.008	0.013
	100	0.001	0.001	<0.001	0.002	0.006

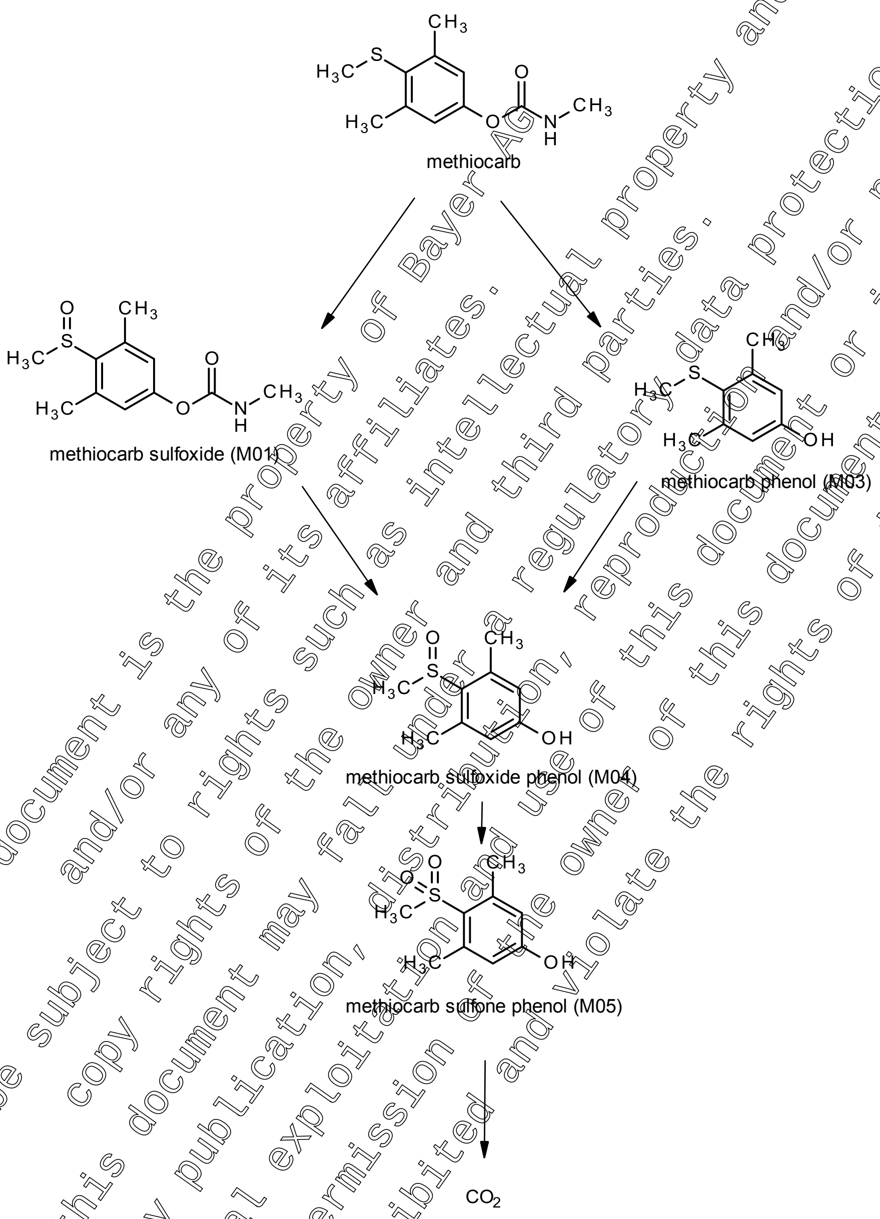
Table 9.1.3-6: $TWAC_{soil}$ of methiocarb and its metabolites

		Methiocarb	Methiocarb sulfoxide	Methiocarb sulfoxide phenol	Methiocarb sulfone phenol	Methiocarb methoxy sulfone
Weighting period		$TWAC_{soil}$ [mg/kg]	$TWAC_{soil}$ [mg/kg]	$TWAC_{soil}$ [mg/kg]	TWACsoil [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	---	---	---	---	---
Short term	1	0.195	0.123	0.057	0.035	0.025
	2	0.190	0.120	0.056	0.034	0.025
	4	0.181	0.115	0.054	0.033	0.024
Long term	7	0.168	0.108	0.051	0.032	0.024
	14	0.143	0.093	0.044	0.029	0.023
	21	0.123	0.081	0.039	0.026	0.022
	28	0.107	0.071	0.035	0.024	0.021
	42	0.083	0.056	0.028	0.020	0.019
	50	0.073	0.050	0.025	0.018	0.018
	100	0.039	0.028	0.014	0.011	0.014

CP 9.2 Fate and behaviour in water and sediment

The proposed degradation pathway of methiocarb in water and sediment is shown in Figure 9.2-1

Figure 9.2-1: Proposed degradation pathway of methiocarb in water and sediment



For further information on the fate and behaviour in water and sediment please refer to Document MCA, Section 7.2.

CP 9.2.1 Aerobic mineralisation in surface water

For information on aerobic mineralisation in surface water studies please refer to Document MCA, Section 7.2.2.2.

CP 9.2.2 Water/sediment study

For information on water/sediment studies please refer to Document MCA, Section 7.2.2.3.

CP 9.2.3 Irradiated water/sediment study

For information on irradiated water/sediment studies please refer to Document MCA, Section 7.2.2.4.

CP 9.2.4 Estimation of concentrations in groundwater

CP 9.2.4.1 Calculation of concentrations in groundwater

New calculations on the studies presented in Document MCA, Section 7 "Fate and behavior in the environment" were performed to consider the most recent guidance documents for exposure calculations. Previously submitted [redacted].; 2002; M-044043-02-1 is therefore obsolete.
Calculations of predicted environmental concentrations in groundwater (PEC_{gw}) are presented below.

Predicted environmental concentrations in soil (PEC_{gw})

Report:	KCP 9.2.4.1/02 [redacted] A; [redacted]; 2015; M-538740-01-1
Title:	Methiocarb (MTC) and metabolites: PECgw FOCUS PEARL, PELMO EUR - Use in maize in Europe
Report No.:	EnSa-15-0697
Document No.:	M-538740-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials:
Predicted environmental concentrations of the active substance methiocarb and its metabolites methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05) and methiocarb methoxy sulfone (M10) in groundwater recharge (PECgw) were calculated for the use in Europe, using the simulation models FOCUS PEARL 4.4.4 and FOCUS-PELMO (version 5.5.3). PECgw were evaluated as the 80^{th} percentile of the mean annual leachate concentration at 1 m soil depth. Model parameters and scenarios consisting of weather, soil, and crop data were used as proposed by FOCUS (2009, 2014).

The use of methiocarb in maize in Europe was assessed according to the Good Agricultural Practice (GAP) as summarized in Table 9.2.4-1.

Table 9.2.4-1: Application data of methiocarb according to the use pattern in Europe

Individual crop	FOCUS crop	Rate [g a.s./ha]	Interval [days]	Plant interception [%]	BBCH stage	Amount reaching soil [g a.s./ha]
Maize	maize	1×150	-	0	0	1×150.000

The calculations were (where applicable) based on the maximum intended application rate together with the maximum intended number of applications per season and the minimum interval between two applications (where applicable).
Application dates for the simulation runs were defined following the crop event dates of the respective crop and scenario (Table 9.2.4-2) as given by FOCUS (2009, 2014). Crop interception was taken into account according to the BBCH growth stage, as recommended by FOCUS (2014).
Since methiocarb is intended to be used as seed treatment, the applications were at planting for the designated scenarios by FOCUS (2000, 2014). In FOCUS PEARL, the application depth was set to 3 cm.

Table 9.2.4-2: **First application dates and related information for methiocarb as used for the simulation runs; offset is relevant only for relative application dates**

Individual crop	Maize
Repeat Interval for App. Events	Every Year
Application Technique	Incorp. [3 cm]
Absolute / Relative to	Planting
Scenario	**1st App. Date (Julian day) Offset**
[redacted]	20 Apr (110) 0
[redacted]	20 Apr (110) 0
[redacted]	- - -
[redacted]	20 Apr (110) 0
[redacted]	07 May (127) 0
[redacted]	30 Apr (120) 0
[redacted]	20 Apr (110) 0
[redacted]	28 Feb (59) 0
[redacted]	01 Apr (91) 0

Substance Specific Parameters:

Substance parameters used as input parameters in the simulations are summarized in Table 9.2.4-3. Detailed information about the formation fractions and degradation rates is given in Table 9.2.4-4.

Table 9.2.4-3: Compound input parameters for methiocarb and its metabolites

Parameter	Unit	Methiocarb	Methiocarb Sulfoxide	Methiocarb Sulfoxide Phenol	Methiocarb Sulfone Phenol	Methiocarb Methoxy Sulfone
Common						
Molar Mass	[g/mol]	225.3	241.3	184.3	200.3	214.3
Solubility	[mg/L]	27.0	6620	1800	16400	1209
Vapour Pressure	[Pa]	1.50E-05	7.00E-04	2.60E-03	1.10E-03	1.23E-02
Freundlich Exponent		0.830	1.000	0.900	0.880	0.850
Plant Uptake Factor		0.35	0.49	0.65	0.76	0.78
Walker Exponent		0.7	0.7	0.7	0.7	0.7
PEARL Parameters						
Substance Code		MTC	MSO	MSOP	MSOOP	MMS
DT50	[days]	1.8	5.1	5.9	9.9	27.6
Molar Activ. Energy	[kJ/mol]	65.4	65.4	65.4	65.4	65.4
Kom	[mL/g]	364.0	18.0	25.0	69.0	105.0
Kf	[mL/g]	-	-	-	-	-
PELMO Parameters						
Substance Code		AS	A1	B1	C1	D1
Rate Constant	[1/day]	0.38508	0.13591	0.11750	0.07002	0.02511
Q10		2.58	2.58	2.58	2.58	2.58
Koc	[mL/g]	627.0	31.0	43.0	118.0	181.0

Table 9.2.4-4: Degradation pathway related parameters for methiocarb and its metabolites

Degradation fraction from → to (FOCUS PEARL)	1 MTC -> MSO 1 MSO -> MSOP 0.491 MSOP -> MSOOP 1 MSOOP -> MMS
Degradation rate from → to (FOCUS PELMO)	0.3850820 Active Substance -> A1 0.1359110 A1 -> B1 0.0577000 B1 -> C1 0.0598000 B1 -> <BR/CO2 0.0700150 C1 -> D1 0.0251140 D1 -> <BR/CO2

Findings:

PEC_{gw} were evaluated as the 80[th] percentile of the mean annual leachate concentration at 1 m soil depth. PEC_{gw} values for methiocarb and its metabolites are given in the Table 9.2.4-5 and Table 9.2.4-6.

Table 9.2.4-5: FOCUS PEARL PECgw results of methiocarb and its metabolites in µg/L (Maize, 1×150 g a.s./ha, 0% interception)

Scenario	Methiocarb	Methiocarb Sulfoxide	Methiocarb Sulfoxide Phenol	Methiocarb Sulfone Phenol	Methiocarb Methoxy Sulfone
[redacted]	<0.001	<0.001	<0.001	<0.001	<0.001
[redacted]	<0.001	<0.001	<0.001	<0.001	0.001
[redacted]	<0.001	<0.001	0.001	<0.001	0.001
[redacted]	<0.001	0.001	0.003	0.001	0.003
[redacted]	<0.001	<0.001	<0.001	<0.001	0.001
[redacted]	<0.001	<0.001	<0.001	<0.001	<0.001
[redacted]	<0.001	<0.001	<0.001	<0.001	<0.001
[redacted]	<0.001	<0.001	<0.001	<0.001	<0.001

Table 9.2.4-6: FOCUS PELMO PECgw results of methiocarb and its metabolites in µg/L (Maize, 1×150 g a.s./ha, 0% interception)

Scenario	Methiocarb	Methiocarb Sulfoxide	Methiocarb Sulfoxide Phenol	Methiocarb Sulfone Phenol	Methiocarb Methoxy Sulfone
[redacted]	<0.001	<0.001	<0.001	<0.001	<0.001
[redacted]	<0.001	<0.001	<0.001	<0.001	0.001
[redacted]	<0.001	0.001	0.001	<0.001	0.001
[redacted]	<0.001	0.002	0.003	0.001	0.002
[redacted]	<0.001	<0.001	<0.001	<0.001	0.002
[redacted]	<0.001	<0.001	<0.001	<0.001	<0.001
[redacted]	<0.001	<0.001	<0.001	<0.001	<0.001
[redacted]	<0.001	<0.001	<0.001	<0.001	<0.001

Report:	KCP 9.2.4.1/03 [redacted], L.; [redacted]; 2015; M-538742-01-1
Title:	Methiocarb (MTC) and metabolites: PECgw FOCUS MACRO EUR - Use in maize in Europe
Report No.:	EnSa-15-0700
Document No.:	M-538742-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials:

Predicted environmental concentrations in groundwater recharge (PEC_{gw}) of methiocarb, methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05) and methiocarb methoxy sulfone (M10) were calculated for the use in Europe, using the simulation model FOCUS MACRO 5.5.4. PEC_{gw} were evaluated as the 80th percentile of the mean annual average concentrations over 20 years (considering a six year warm-up period) in the percolate at 1 m depth. Groundwater scenarios were used as proposed by FOCUS (2009, 2014).

The use of methiocarb in maize in Europe was assessed according to the Good Agricultural Practice (GAP) as summarized in Table 9.2.4-1 (see above).

The calculations were (where applicable) based on the maximum intended application rate together with the maximum intended number of applications per season and the minimum interval between two applications (where applicable).
Application dates for the simulation runs were defined following the crop event dates of the respective crop and scenario (Table 9.2.4-7) as given by FOCUS (2009[5], 2014b[6]). Crop interception was taken into account according to the BBCH growth stage, as recommended by FOCUS (2014a[7]).
Since methiocarb is intended to be used as seed treatment, the applications were at planting for the designated scenarios.

Table 9.2.4-7: First application dates and related information for methiocarb as used for the simulation runs; offset is relevant only for relative application dates

Individual crop	Maize
Repeat Interval for App. Events Absolute	Every Year Planting
Scenario	1st App. Date (Julian day)
[redacted]	20 Apr (110)

The FOCUS model MACRO 5.5.4 is restricted to the simulation of one parent active substance and one consecutive metabolite. It is not foreseen in the GUI to simulate the degradation of metabolites as it is required for the metabolic scheme of methiocarb. Therefore the consecutive metabolites were calculated as parent substance with metabolite application rates (Table 9.2.4-9) considering the maximum occurrence in soil and the molar mass correction (Table 9.2.4-8).

Table 9.2.4-8: Summary of properties for metabolite rate calculation

		Methiocarb	Methiocarb sulfoxide	Methiocarb sulfoxide phenol	Methiocarb sulfone phenol	Methiocarb methoxy sulfone
Molar mass	[g/mol]	225.3	241.3	184.3	200.3	214.3
Corr. factor		1	1.071	0.818	0.889	0.9512
Max occ. in soil	%	100	58.8	35.8	19.8	13.2

[5] FOCUS (2009) Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU: Report of the FOCUS Ground Water Work Group
EC Document Reference: Sanco/13144/2010 version 1, 604 pp.
[6] FOCUS, 2014b: Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU: The Final Report of the Ground Water Work Group of FOCUS
EC Document Reference: Sanco/13144/2010 version 3, 613 pp.
[7] FOCUS, 2014a: Generic Guidance for Tier 1 FOCUS Groundwater Assessments, Version 2.2

Table 9.2.4-9: Calculation of metabolite application rates (# = application number)

Compound		Methiocarb	Methiocarb sulfoxide phenol	Methiocarb sulfone phenol	Methiocarb methoxy sulfone
Crop / rate	#	[g a.s./ha]	[g/ha]	[g/ha]	[g/ha]
Maize, 1×150 g a.s./ha	1	150	43.93	26.4	18.83

Substance Specific Parameters:

PEC_{gw} calculations were based on the compound specific input parameters as summarized in Table 9.2.4-10.

Table 9.2.4-10: Compound input parameters for methiocarb and its metabolites

Parameter	Unit	Methiocarb	Methiocarb Sulfoxide	Methiocarb Sulfoxide Phenol	Methiocarb Sulfone Phenol	Methiocarb Methoxy Sulfone
Common						
Molar Mass	[g/mol]	225.3	241.3	184.3	200.3	214.3
Vapour Pressure	[Pa]	1.50E-05	7.00E-04	2.60E-03	1.06E-03	1.23E-02
Freundlich Exponent		0.830	1.000	0.900	0.880	0.850
Plant Uptake Factor		0.35	0.49	0.65	0.76	0.78
Walker Exponent [a]		0.49	0.49	0.49	0.49	0.49
Substance Code		MTC	MSO	MSOP	MSOOP	MMS
DT50soil	[days]	1.8	5.1	5.9	9.9	27.6
Metabolite Conversion Factor (*fconvert*)[b]		-	1.071	-	-	-
Q10[c]		0.0948	0.0948	0.0948	0.0948	0.0948
Koc	[mL/g]	627	31.0	43	118	181

[a] as proposed for MACRO 5.5.3 and later versions

[b] metabolite formation in MACRO is based on molar masses M and formation fraction: fconvert = Mmetab / Mparent * formation fraction

[c] corresponding MACRO parameter tresp = 0.0948

Findings:

PEC_{gw} were evaluated as the 80[th] percentile of the mean annual leachate concentration at 1 m soil depth. PEC_{gw} values for methiocarb and its metabolites are given in the Table 9.2.4-11.

Table 9.2.4-11: FOCUS MACRO PECgw results of methiocarb and its metabolites in µg/L for the use assessed for the scenario [redacted]

Use Pattern	Methiocarb	Methiocarb Sulfoxide	Methiocarb Sulfoxide Phenol	Methiocarb Sulfone Phenol	Methiocarb Methoxy Sulfone
Maize, 1×150 g a.s./ha	<0.001	<0.001	<0.001	<0.001	<0.001

Conclusion:

There are no concerns for groundwater from the active substance methiocarb and its metabolite in accordance with the use pattern for the current formulation.

CP 9.2.4.2 Additional field tests

No additional field studies were performed due to low PEC_{gw} values calculated (see Section CP 9.2.4.1)

CP 9.2.5 Estimation of concentrations in surface water and sediment

New calculations were performed, to reflect findings from new studies presented in Document MCA, Section 7, Fate and behavior in the environment. In addition these calculations consider the most recent guidance documents for exposure calculations. Previously submitted [redacted].; 2002; M-049954-02-1 is therefore obsolete.
Calculations of predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) are presented below.

Predicted environmental concentrations in soil (PEC_{sw})

Predicted environmental concentrations in soil (PEC_{sed})

PEC_{sw} modelling approach

Calculation of PEC values for the active substance according to FOCUS

$FOCUS_{sw}$ is a four step tiered approach:
Step 1: All inputs are considered as a single loading to the water body and a worst-case PEC_{sw} and PEC_{sed} is calculated (most conservative step).
Step 2: Individual loadings into the water body from different entry routes according to the number of applications are considered. Scenarios are also considered for Northern and Southern Europe separately but no specific crop scenarios are defined.
Step 3: An exposure assessment using realistic worst-case scenarios is performed. The scenarios are representative for agricultural conditions in Europe and consider weather, soil, crop and different water-bodies. Simulations use the models PRZM, MACRO and TOXSWA.
Step 4: PEC values are refined by considering mitigation measures according to the FOCUS Landscape and Mitigation Factors, i.e. drift reduction or vegetated filter strips, which intercept runoff water and eroded sediment prior to entry into surface water.

Derivation of kinetic modelling input values is presented in Document MCA, Section 7.2.

Report:	KCP 9.2.5/02 [redacted]; 2015; M-538733-01-1
Title:	Methiocarb (MTC) and metabolites: PECsw,sed FOCUS EUR - Use in maize in Europe
Report No.:	EnSa-15-0698
Document No.:	M-538733-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

General substance data as used in [redacted]; 2015; M-538733-01-1 are documented in [redacted]; 2015; M-538609-01-1.

Report:	KCP 9.2.5/03 [redacted] A; [redacted]; 2015; M-538609-01-1
Title:	Methiocarb (MTC) PECsw EUR - Modelling core info document for standard FOCUS STEP 1-2 and STEP 3-4 surface water exposure assessment in Europe
Report No.:	EnSa-15-0651
Document No.:	M-538609-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials:

Predicted environmental concentrations of the active substance methiocarb and its metabolites methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05), methiocarb methoxy sulfone (M10) and methiocarb phenol (M03) in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for the use in Europe, employing the tiered FOCUS Surface Water (SW) approach (FOCUS 2001, 2014). All relevant entry routes of a compound into surface water (principally a combination of spray drift and runoff/erosion or drain flow) were considered in these calculations.

The use of the insecticide methiocarb in maize was assessed according to the Good Agricultural Practice (GAP) in Europe. Detailed application parameters are presented in Table 9.2.5-1.

Table 9.2.5-1: General and FOCUS-specific data on the use pattern of methiocarb in Europe

Crop	BBCH stage	Interval [days]	Rate [g a.s./ha]	FOCUS crop (crop group)	Season	Crop cover
Maize	0	-	1 × 150	no drift (incorp or seed treatment) (arable crops)	Mar - May	no interception

For methiocarb and methiocarb sulfoxide (M01) FOCUS Step 3 values were calculated in addition to FOCUS Step 1 and Step 2 values.

PECsw and PECsed values were calculated using the following tools:
FOCUS STEPS 1+2 version 3.2
FOCUS SWASH 3.1, including
PRZM 3.21b connected to PRZM in FOCUS 2.6 (shell)
FOCUS MACRO 5.5.4 (shell)
FOCUS TOXSWA 2.6 (shell)

Compound specific input data are summarised below in Table 9.2.5-2.

Table 9.2.5-2: Substance parameters used for methiocarb and its metabolites at Steps 1-2 level

Parameter	Unit	Methiocarb	Methiocarb sulfoxide	Methiocarb sulfoxide phenol	Methiocarb sulfone phenole	Methiocarb methoxy sulfone	Methiocarb phenol
Molar Mass	g/mol	225.3	241.3	184.3	200.3	214.3	168.3
Water Solubility	mg/L	27	6620	1800	16400	1209	433.8
Koc	mL/g	627	31	43	118	181	0
Degradation							
Soil	days	1.8	5.1	5.9	9.9	27.6	1000
Total System	days	5.8	1000	35.7	1000	1000	72.3

Water	days	5.8	1000	35.7	1000	1000	72.3
Sediment	days	5.8	1000	35.7	1000	1000	72.3
Max Occurrence							
Water / Sediment	%	100/37.1	1.0E-8	40.2	6.5	1.0E-8	19.1
Soil	%	100	58.8	35.8	19.8	13.2	1.0E-8

Substance parameters which were used for the calculations at the Step 3 level are summarised in Table 9.5.2-3.

Table 9.5.2-3: Substance parameters used for methiocarb and its metabolite methiocarb sulfoxide at Step 3 level

Parameter	Unit	Methiocarb	Methiocarb sulfoxide
Company Code		H 321	AE 1371422
SWASH Code		MTC	MSO
General Parameters			
Molar Mass	g/mol	225.3	241.3
Water Solubility	mg/L	27.0	6620.0
Vapour Pressure	Pa	1.5E-05	7.0E-04
Plant Uptake Factor		0.35	0.0
Wash-Off Factor PRZM	1/cm	0.5	0.5
Wash-Off Factor MACRO	1/mm	0.05	0.05
Sorption			
Koc	mL/g	627	31
Freundlich Exponent		0.83	1.00
Degradation			
Soil	days	1.8	5.1
Form. Frac. PRZM	molar basis	-	1.000
Form. Frac. MACRO	mass basis	-	1.071
Water	days	5.8	1.0
Sediment	days	1000	1000
Walker Exponent		0.7	0.7
Effect of Temperature			
Activation Energy	J/mol	65400	65400
Exponent	1/K	0.095	0.095
Q10		2.58	2.58

In FOCUS Step 3, the application date for each scenario is determined by the Pesticide Application Timer (PAT), which is part of the FOCUS SW Scenarios. The user may only define an application time window. The actual application date is then set by the PAT in such a way that there are at least 10 mm of rainfall in the first 10 days after application, and at the same time less than 2 mm of rain per day in a five day period around the date of application. If no such date can be found within the application time window, the above rules are step-wise relaxed. Information on application dates can be found in Table 9.2.5-4.

Table 9.2.5-4: Application dates of methiocarb for the FOCUS Step 3 calculations (Emg. stands for the emergence date)

Parameter	Maize
PAT start date rel./absolute	Emg., -10 days
Appl. method (appl. type)	soil incorp. (3 cm) (CAM 8)
No of appl.	1
PAT window range	30
Appl. interval	1

Application Details	PAT Start Date (Julian Day)	Appl. Date
D3 (1st)	25-Apr (115)	04-May
D3 (2nd)	- -	-
D4 (1st)	30-Apr (120)	30-May
D5 (1st)	30-Apr (120)	11-May
D6 (1st)	10-Apr (100)	10-Apr
R1 (1st)	23-Apr (113)	26-Apr
R2 (1st)	21-Apr (111)	22-Apr
R3 (1st)	21-Apr (111)	22-Apr
R4 (1st)	31-Mar (90)	07-Apr

Findings:

The PEC values were calculated employing the "STEPS 1-2 in FOCUS" calculator.

Table 9.2.5-5 and Table 9.2.5-6 provide a summary of the overall results of PECsw and PEC_{sed} FOCUS Step 1-2 calculations for methiocarb and its metabolites methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05). methiocarb methoxy sulfone (M10) and methiocarb phenol (M03).

Table 9.2.5-5: Summary of the maximum PECsw values in µg/L of methiocarb and its metabolites (FOCUS Steps 1-2)

Crop	Scenario	Methiocarb	Methiocarb sulfoxide	Methiocarb sulfoxide phenol	Methiocarb sulfone phenole	Methiocarb methoxy sulfone	Methiocarb phenol
Maize 1 × 150 g a.s./ha	Step 1	27.23	30.24	29.40	10.10	5.06	7.13
	Step 2						
	N-EU Single	1.17	3.51	2.40	1.26	0.91	0.31
	S-EU Single	2.33	7.02	4.80	2.51	1.83	0.61

Table 9.2.5-6: Summary of the maximum PECsed values in µg/kg of methiocarb and its metabolites (FOCUS Steps 1-2)

Crop	Scenario	Methiocarb	Methiocarb sulfoxide	Methiocarb sulfoxide phenol	Methiocarb sulfone phenole	Methiocarb methoxy sulfone	Methiocarb phenol
Maize 1 × 150 g a.s./ha	Step 1	170.75	9.37	12.64	11.92	9.15	<0.001
	Step 2						
	N-EU Single	7.32	1.09	1.04	1.48	1.66	<0.001
	S-EU Single	14.64	2.18	2.08	2.97	3.31	<0.001

Step 3 calculations were conducted for methiocarb and its metabolite methiocarb sulfoxide (M01). The reported PEC_{sw} and PEC_{sed} values represent loadings via all relevant entry routes.
The maximum PECsw and PEC_{sed} values for the relevant scenarios are summarized in Table 9.2.5-7 and Table 9.2.5-8 together with the dominant entry path.

Maize, 1 × 150 g/ha

Table 9.2.5-7: PECsw and PECsed values of methiocarb in maize for all calculated scenarios according to FOCUS SW Step 3; letters S, D, and R before correspond to the dominant entry path – spray drift, drainage, and runoff

Scenario	Single Application		
	Entry route	PECsw [µg/L]	PECsed [µg/kg]
D3 (ditch, 1st)	D	<0.001	<0.001
D4 (pond, 1st)	D	<0.001	<0.001
D4 (stream, 1st)	D	<0.001	<0.001
D5 (pond, 1st)	D	<0.001	<0.001
D5 (stream, 1st)	D	<0.001	<0.001
D6 (ditch, 1st)	D	<0.001	<0.001
R1 (pond, 1st)	R	<0.001	<0.001
R1 (stream, 1st)	R	<0.001	<0.001
R2 (stream, 1st)	R	<0.001	<0.001
R3 (stream, 1st)	R	<0.001	<0.001
R4 (stream, 1st)	R	<0.001	<0.001

Table 9.2.5-8: PECsw and PECsed values of metabolite methiocarb sulfoxide in maize for all calculated scenarios according to FOCUS SW Step 3

Scenario	Single Application	
	PECsw [µg/L]	PECsed [µg/kg]
D3 (ditch, 1st)	<0.001	<0.001
D4 (pond, 1st)	<0.001	<0.001
D4 (stream, 1st)	<0.001	<0.001
D5 (pond, 1st)	<0.001	<0.001
D5 (stream, 1st)	<0.001	<0.001
D6 (ditch, 1st)	<0.001	<0.001
R1 (pond, 1st)	<0.001	<0.001
R1 (stream, 1st)	<0.001	<0.001
R2 (stream, 1st)	<0.001	<0.001
R3 (stream, 1st)	<0.001	<0.001
R4 (stream, 1st)	<0.001	<0.001

CP 9.3 Fate and behaviour in air

For information on the fate and behaviour in air please refer to MCA Section 7, data point 7.3.

CP 9.3.1 Route and rate of degradation in air and transport via air

Predicted environmental concentrations from airborne transport

Based on the information on vapour pressure and the volatility of methiocarb, it is not expected that this compound will be significantly volatilised. In addition, even if it were emitted into the atmosphere, the calculated photochemical oxidative degradation half-life of 13.8 hours indicates that it is unlikely to be subject to long-range transport. The relevant residue for quantitation in air is the parent compound only.

CP 9.4 Estimation of concentrations for other routes of exposure

There are no other routes of exposure if the product is used according to good agricultural practice. Therefore, no further estimations are considered necessary.