

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: 102000028562

Product name(s): Deltamethrin + flupyradifurone EC 85
(10+75 g/L)

Chemical active substance(s):

Deltamethrin, 10 g/L

Flupyradifurone, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(extension of use)

Applicant: Bayer Crop Science Division

Submission date: 31/08/2021

MS Finalisation date: December 2022, updated February 2023
(initial Core Assessment)

June 2023 (final Core Assessment)

Version history

When	What
31/08/2021	Original Bayer Crop Science Division submission
December 2022 updated February 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey . Not agreed or not relevant information are struck through and shaded for transparency .
June 2023	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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Reviewer summary:

This part of dossier has been submitted to support registration of the plant protection product Deltamethrin + flupyradifurone EC 85 (10+75 g/L) (DLT+FPF EC 85 / Product Code 102000028562) according art. 33 of 1107/2009. Document refers data related to the forming of metabolites in the environment (see dRR B8). Please note that for current label extension (see GAP) value Max PECgw for **flupyradifurone** metabolite **difluoroacetic acid (DFA)** has been adjusted in the dRR section B8.

Applicant decided to remove from the GAP sunflower crop for which Max PECgw has been used for risk assessment, also due to fact that zRMS do not accept calculation factor TSCF=0.5, therefore a new calculation has been done. Potential exposure to this metabolite (DFA) via ground- or drinking water has been reviewed taking into account adjusted Max PECgw values:

Tier 1:

- PECgw of 0.755 µg/L FOCUS PELMO, Tier 1, TSCF=0, Hamburg scenario, vines at 2x30 g a.s./ha at BBCH 57-81 for early application
- PECgw of 0.972 µg/L FOCUS PEARL, Tier 1, TSCF=0, Hamburg scenario, spring cereals at 2x56.25 g a.s./ha at BBCH 41-83 for late application
- PECgw of 0.846 µg/L FOCUS PELMO, Tier 1, TSCF=0, Jokioinen scenario, winter cereals at 2x56.25 g a.s./ha at BBCH 41-83 for late application

Tier2:

- PECgw of 0.881 µg/L FOCUS PEARL, Tier 2, TSCF=0, Hamburg scenario, spring cereals at 2x56.25 g a.s./ha at BBCH 41-83 for late application,
- PECgw of 0.790 µg/L, FOCUS PELMMO, Tier 2, TSCF=0, Jokioinen scenario, winter cereals at 2x56.25 g a.s./ha at BBCH 41-83 for late application

For details of calculation also explanation regarding new Max PECgw calculation please refer Section B8 of this dRR.

zRMS decided to take for the risk assessment new max PECgw values (refer Table 10.2-1 p.8 and detailed prediction see dRR B8) from Tier 2 (see above).

Note: This current dossier (2022) is for an extension of use (for details refer Vol. B0). Because the evaluation of the initial dossier submitted in October 2019 is not finished, no final Registration Report is available yet thus all data already submitted in that previous dossier is submitted again and highlighted in purple characters in the present summary part.

dRR Part B10 has been reviewed and checked its compliance with the current guidelines. Information has been considered as sufficient and appropriate for concluding.

10 Relevance of metabolites in groundwater

10.1 General information

Deltamethrin

The metabolite **Br₂CA** is not predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR core Part B section 8). **Assessment of the relevance of this metabolite** according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 **is therefore not required.**

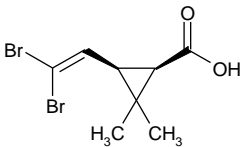
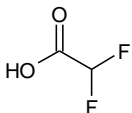
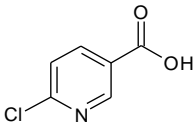
Flupyradifurone

The metabolite 6-Chloronicotinic acid (6-CNA) is not predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR core Part B section 8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

The metabolite difluoroacetic acid (DFA) is predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR core Part B section 8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore required.

General information on metabolites with a potential for groundwater contamination is provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental fate and behaviour).

Table 10.1-1: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Deltamethrin AE F032640	Br ₂ CA AE F108565 RU23441		Max PEC _{gw} Based on:	< 0.001 µg/L FOCUS PEARL & PELMO, all intended uses
Flupyradifurone (BYI 02960)	Difluoroacetic acid (DFA)		Max PEC _{gw} Based on:	1.114 0.881 µg/L^{a)} 1.033 0.790 µg/L^{b)} ^{a)} Based on PUF/TSCF = 0 FOCUS PEARL (Tier 1) Piacenza scenario Sunflower, 2x56.2 g a.s./ha, 14 d interval ^{a)} Based on FOCUS PEARL (Tier 2), TSCF=0, Hamburg scenario, spring cereals at 2x56.25 g a.s./ha at BBCH 41-83 for late application ^{b)} Based on PUF/TSCF = 0.5 FOCUS PEARL (Tier 1) Piacenza scenario Sunflower, 2x56.2 g a.s./ha, 14 d interval ^{b)} Based on FOCUS PELMMO (Tier 2), TSCF=0, Jokioinen scenario, winter cereals at 2x56.25 g a.s./ha at BBCH 41-83 for late application
	6-Chloronicotinic acid (6-CNA)		Max PEC _{gw} Based on:	0.011 µg/L ^{a)} 0.008 µg/L ^{b)} ^{a)} Based on PUF/TSCF = 0 FOCUS PELMO 5.5.3 (Tier 1) Piacenza Sunflower, 2x56.2 g a.s./ha ^{b)} Based on PUF/TSCF = 0.5

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
				FOCUS PELMO 5.5.3 (Tier 1) Piacenza Sunflower, 2×56.2 g a.s./ha

10.2 Relevance assessment of Difluoroacetic Acid

Summary:

The relevance of the groundwater metabolite difluoroacetic acid (DFA) has already been assessed and the assessment agreed at EU level (DAR 2014, EFSA Journal 2015;13(2):4020). The relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Metabolite difluoroacetic acid (DFA) is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.2-1 and the corresponding studies are listed in the corresponding sections.

Table 10.2-1: Summary of the relevance assessment for Difluoroacetic Acid

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	1.114 0.881 µg/L ^{a)} 1.033 0.790 µg/L ^{b)}
			Based on	^{a)} Based on PUF/TSCF=0 FOCUS PEARL (Tier 1) Piacenza scenario Sunflower, 2x56.2 g a.s./ha; 14 d interval ^{a)} Based on FOCUS PEARL (Tier 2), TSCF=0, Hamburg scenario, spring cereals at 2x56.25 g a.s./ha at BBCH 41-83 for late application ^{b)} Based on PUF/TSCF=0.5 FOCUS PEARL (Tier 1) Piacenza scenario Sunflower, 2x56.2 g a.s./ha; 14 d interval ^{b)} Based on FOCUS PELMMO (Tier 2), TSCF=0, Jokioinen scenario, winter cereals at 2x56.25 g a.s./ha at BBCH 41-83 for late application
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	
			Classification of parent	Acute toxicity: Category 4 Specific target organ toxicity - re- peated exposure: Category 2
			Classification of metabolite	No classification
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable (>0.75 µg/L)
	STEP 5		Refined risk assessment	Acceptable
			Predicted exposure (% of ADI)	Intake by means of drinking water: <10% of ADI Maximum intake by means of food of plant (primary and rotational) and animal origin: 69% (assuming all residues consist of DFA)
			ADI based on	0.064 mg a.s./kg bw/day 2-generation reproductive toxicity study in rats, safety factor of 100; EFSA, 2015 (ADI of parent flupyradifurone)

10.2.1 STEP 1: Exclusion of degradation products of no concern

Difluoroacetic acid (DFA) does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.2.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for difluoroacetic acid were performed (see Part B, Section 8, chapter 8.8.2). The uses for which concentrations of difluoroacetic acid were considered to exceed 0.1 µg/L are listed in Table 10.2-1. Details are given in Part B, Section 8, chapter 8.8.2.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

The biological activity of difluoroacetic acid does not have comparable target activity as the parent active compound as stated in the DAR (2014) Chapter B.9.9.2 (Study IIA, 8.14.1/01). Difluoroacetic acid is considered not relevant and is further evaluated in Stage 2.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

The genotoxic and clastogenic potential of metabolite DFA was investigated in a battery of in vitro tests:

Summary of genotoxicity studies conducted with DFA (difluoroacetic acid, BCS-AA56716):

Study	Dose	Result	Reference
Bacterial reverse mutation assay (OECD 471; S. typhimurium strains TA1535, TA1537, TA98, TA100 and TA102)	Experiment I: 3-5000 µg/plate (+/- S9-mix) Experiment II: 33-5000 µg/plate (+/- S9-mix)	Non-mutagenic without and with S9 mix	Sokolowski A.; 2013 M-409724-02-1 Part B, Section 6, 6.4.1; EFSA, 2015
<i>In vitro</i> mammalian cells: gene mutation assay (OECD 476 ; Chinese hamster V79 cells/HPRT)	60-960 µg/mL (+/- S9-mix; 4 hours) 120-960 µg/mL (+S9-mix; 4 hours) 30-960 µg/mL (-S9-mix; 24 hours)	Non-mutagenic without and with S9 mix	Wollny, H. E.; 2013 M-409727-02-1 Part B, Section 6, 6.4.1; EFSA, 2015
<i>In vitro</i> mammalian cells: chromosome aberration test (OECD 473 ; Chinese hamster V79 cells)	3.8-960 µg/mL (+/- S9-mix, 4 hours) 60-960 µg/mL (+/- S9-mix; 18 hours)	Non clastogenic for mammalian cells in vitro	Bohnenberger, S.; 2013 M-409726-02-1 Part B, Section 6, 6.4.1; EFSA, 2015

No indication of mutagenic effects was found in the Ames test with five strains of *Salmonella typhimurium*. In addition, DFA did neither induce structural chromosome aberrations in V79 lung cells (Chinese hamster cell line), nor gene mutations at the HPRT locus in V79 lung cells. In conclusion, metabolite DFA is considered to be non-mutagenic – with and without metabolic activation (+/- S9-mix).

Metabolite DFA is considered not relevant and is further evaluated in Stage 3. The genotoxicity studies are summarized in Part B, Section 6, chapter 6.4 and were already evaluated at EU level (EFSA Journal 2015;13(2):4020).

10.2.3.3 STEP 3, Stage 3: screening for toxicity

DFA is a rat metabolite, which accounted for approx. 6% of the administered dose in the urine, as shown in a rat ADME study. In a rat study on metabolism in organs and tissues – which was conducted at a later point in time - DFA was the dominating metabolite in the 24-hours samples of plasma, organs and tissues (accounting for more than 50% of the radioactivity) indicating that DFA is formed quickly and distributed within the whole body. Thus, it is a metabolite which is systemically available and contributes to the toxicity effects of parent flupyradifurone. Nevertheless, the toxicological properties of DFA were investigated in a series of tests.

The acute oral toxicity of DFA was investigated in a rat study. The oral LD₅₀ was found to be between 300 and 2000 mg/kg in rats. For parent flupyradifurone, mortalities were also reported at 2000 mg/kg but none at 300 mg/kg. Thus, DFA shows a similar acute toxicity as flupyradifurone.

Study	Dose	Result	Reference
Acute toxicity in the rats "Acute toxic class method" (OECD 423)	300-2000 mg/kg	oral LD ₅₀ in rats: between 300 and 2000 mg/kg	xxx M-393372-01-2 Part B, Section 6, 6.4.1 ; EFSA, 2015

Furthermore, the DFA toxicity profile was investigated in the rat following repeated dietary administration for 14 and 90 days.

Study	Dose	Result	Reference
Preliminary 14-day toxicity study in the rat (dietary ad- ministration; (no OECD guideline specified, no GLP)	500, 2000 and 8000 ppm (males: 48, 187 and 745 mg/kg bw; females: 51, 201 and 800 mg/kg bw/day)	NOAEL: 500 ppm (51 mg/kg bw/day)	xxx M-414152-01-2 Part B, Section 6, 6.4.1 ; EFSA, 2015
90-day toxicity study in the rat (dietary administration; OECD 408)	200, 1000 and 6000 ppm	NOAEL: 200 ppm (12.7-15.6 mg/kg bw/day for female and male rats, respec- tively)	xxx 2012 M-424611-01-2 Part B, Section 6, 6.4.1 ; EFSA, 2015

In a 14-day repeat dietary administration range finding study in the rat, the most significant findings were decreased mean glucose concentration in both sexes; an increase in urea concentration was observed in females only (not statistically significant). These few changes were considered not to be adverse in view of their isolated occurrence and in absence of associated histological findings.

In a 90-day rat study, DFA was administered in the diet to Wistar rats (10/sex/group) at concentrations of 200, 1000 and 6000 ppm. Lower mean glucose concentrations, lower total bilirubin and slightly higher mean urea concentrations were observed in both sexes at all doses. At 6000 and 1000 ppm dose levels, mean body weight, overall body weight gain and food consumption were reduced in both sexes. Lower hemoglobin concentration and lower mean corpuscular volume were observed in females, together with lower mean corpuscular hemoglobin and lower hematocrit, and higher ketone levels were noted in both sexes. A few black foci were also noted in the glandular part of the stomach in both sexes (including one control female), in correlation with a few cases of focal glandular erosion/necrosis observed at the microscopic examination. The minor changes noted in the clinical chemistry determination at the low dose are considered not to be adverse effects of the test substance as they do not represent any functional impairment in the test organism. Therefore, the dose level of 200 ppm (equating to 12.7 and 15.6 mg/kg body weight/day in males and females, respectively) was considered to be a No Observed Adverse Effect Level (NOAEL) in the rat. When the NOAEL is expressed in flupyradifurone (BYI 02960) equivalents, it equates to 38 and 47 mg/kg/day in males and females, respectively. Therefore, difluoroacetic acid was not more toxic than flupyradifurone (BYI 02960) after subchronic administration to the rat. The metabolic changes observed with DFA are also observed with flupyradifurone. The decrease in glucose was reversible and appeared to be adaptive as it was no longer significant during the second part of the rat carcinogenicity study.

The toxicity studies are summarized in Part B, Section 6, chapter 6.4 and were already evaluated at EU level (EFSA Journal 2015;13(2):4020). Metabolite DFA is considered not relevant and is further evaluated in Step 4.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

The potential exposure to difluoroacetic acid is > 0.75 µg/L but <10 µg/L. A further assessment in Step 5 is required.

10.2.5 STEP 5: Refined risk assessment

Diffuoroacetic acid has a PEC_{gw} between 0.75 $\mu\text{g/L}$ and 10 $\mu\text{g/L}$. A refined assessment of the potential toxicological significance including the selected ADI is presented here.

Proposed residue definitions in plant and livestock matrices:

Plant matrices:

The only residues of flupyradifurone that were consistently observed at significant levels across all primary and succeeding crops were the parent compound flupyradifurone and its metabolite DFA. These two compounds were the constituents of the residue definition for risk assessment (expressed as their sum, in flupyradifurone equivalents).

For monitoring/enforcement, two separate residue definitions were proposed: First, parent compound flupyradifurone (expressed as flupyradifurone) and second, metabolite DFA (expressed as DFA).

Livestock matrices:

On the basis of the results of the feeding studies conducted in poultry and cattle, it has been shown that parent flupyradifurone and its metabolite DFA were by far the predominant compounds detected. Considering these results in combination with those from livestock metabolism studies, parent compound flupyradifurone and its metabolite DFA (expressed as their sum, in flupyradifurone equivalents) are the proposed constituents of the residue definitions for risk assessment in animal matrices. As for plant two separate residue definitions were proposed for monitoring/enforcement: Flupyradifurone expressed as flupyradifurone and DFA expressed as DFA.

Thus DFA is a major plant and livestock metabolite and is always included in the dietary risk assessments. Since the toxicological profiles of parent flupyradifurone and metabolite DFA are similar (with DFA being of comparable toxicity), the endpoints derived for flupyradifurone will effectively cover DFA toxicity and the risk assessments can be conducted with the endpoints derived for the parent compound:

ADI = 0.064 mg a.s./kg bw/day

ARfD = 0.15 mg a.s./kg bw/day

Risk assessment: Consumer exposure via ground-or drinking water

The exposure of consumers to metabolite DFA via drinking water is assessed based on the following assumptions which lead to a conservative approach:

- The reference values for parent flupyradifurone can be used (ADI of 0.064 mg/kg bw/day and ARfD of 0.15 mg/kg bw/day).
- The potential groundwater contamination was estimated to be ~~1.033~~ 0.881 $\mu\text{g/L}$ for DFA and is thus in the range between 0.75-10 $\mu\text{g/L}$. The upper limit of 10 $\mu\text{g/L}$ will be used for the risk assessment, although this concentration will never be reached.
- An intake of
 - 0.75 L water/day is assumed for a 5 kg bottle-fed infant
 - 1 L water/day is assumed for a 10 kg child
 - 2 L water/day is assumed for European adults with an average body weight of 60 kg

Because the groundwater concentrations are compared to toxicological reference values expressed in flupyradifurone equivalents, also the concentration of DFA in ground- or drinking water must be expressed in parent equivalents.

Metabolite	Estimated concentration in groundwater [µg DFA/L]	Estimated concentration in groundwater [µg BYI 02960 equiv./L]
DFA	10	30

Molar mass flupyradifurone (BYI 02960): 288.68 g/mol

Molar mass DFA: 96.03 g/mol

Intake of DFA via ground- or drinking water:

Bottle-fed infant (5 kg): $30 \mu\text{g/L} \times 0.75 \text{ L} / 5 \text{ kg} = 4.5 \mu\text{g/kg}$

Child (10 kg): $30 \mu\text{g/L} \times 1 \text{ L} / 10 \text{ kg} = 3.0 \mu\text{g/kg}$

Adults (60 kg): $30 \mu\text{g/L} \times 2 \text{ L} / 60 \text{ kg} = 1.0 \mu\text{g/kg}$

Metabolite	Intake scenario	Intake [µg BYI 02960 equiv./kg bw]	Usage of ADI [%]	Usage of ARfD [%]
DFA	bottle-fed infant	4.5	7.0	3.0
	child	3.0	4.7	2.0
	adult	1.0	1.6	1.1

The intake of metabolite DFA via drinking water is very limited. Even when using the very conservative approach which assumes a groundwater concentration of 10 µg DFA/L, the ADI and ARfD usage values are well below 10%.

The chronic exposure (calculated based on the sum of flupyradifurone and DFA residues) through the diet was in maximum 69% of the ADI (see Part B, Section 7, 7.2.8.2). Hence, a long-term risk for the consumer (through the diet and drinking water) can be excluded.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

No new data submitted.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.1.1 /01	xxx	2012	[Pyridinylmethyl-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in the rat xxx Report No.: MEF-11/747, Edition Number: <u>M-422210-01-1</u> EPA MRID No.: 48844141 Date: 2012-01-12 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.1 /02	xxx	2011	Quantitative whole body autoradiography of [pyridinylmethyl-14C]BYI 02960 in male and female rats: Distribution of total radioactivity and elimination from blood, organs and tissues after single oral administration including determination of radioactivity in the excreta and exhaled 14CO2 xxx Report No.: MEF-11/276, Edition Number: <u>M-409993-01-2</u> EPA MRID No.: 48844142 Date: 2011-05-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.2 /01	xxx	2011	[Furanone-4-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in the rat xxx Report No.: MEF-11/556, Edition Number: <u>M-421499-01-1</u> EPA MRID No.: 48844143 Date: 2011-12-22 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.1.2 /02	xxx	2011	Quantitative whole body autoradiography of [furanone-4-14C]BYI 02960 in male and female rats: Distribution of total radioactivity and elimination from blood, organs and tissues after single oral administration including determination of radioactivity in the excreta and exhaled 14CO2 xxx Report No.: MEF-11/275, Edition Number: <u>M-409859-01-2</u> EPA MRID No.: 48844144 Date: 2011-05-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.2 /03	xxx	2011	[Furanone-4-14C]BYI 02960 - Metabolism in organs and tissues of male and female rats xxx Report No.: MEF-11/271, Edition Number: <u>M-414034-02-2</u> EPA MRID No.: 48844145 Date: 2011-09-12 ...Amended: 2012-02-02 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.3 /01	xxx	2011	[Ethyl-1-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in male rats xxx Report No.: MEF-11/555, Edition Number: <u>M-415647-01-1</u> EPA MRID No.: 48844146 Date: 2011-10-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.3 /02	xxx	2011	[Ethyl-1-14C]BYI 02960 - Metabolism in organs and tissues of male and female rats (3 time-points) xxx Report No.: MEF-11/270, Edition Number: <u>M-415416-02-1</u> EPA MRID No.: 48844147 Date: 2011-09-29 ...Amended: 2012-02-02 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.2.1 /01	xxx	2009	BYI 02960 - Acute toxicity in the rat after oral administration xxx Report No.: AT05287, Edition Number: <u>M-349992-01-2</u> EPA MRID No.: 48844101 Date: 2009-06-08 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.2 /01	xxx	2009	BYI 02960 - Acute toxicity in the rat after dermal administration xxx Report No.: AT05288, Edition Number: <u>M-349995-01-2</u> EPA MRID No.: 48844104 Date: 2009-06-08 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.3 /01	xxx	2010	BYI 02960 - Activity ID TXRVP033 - Acute inhalation toxicity in rats xxx Report No.: AT05727, Edition Number: <u>M-362791-01-2</u> EPA MRID No.: 48844105 Date: 2010-01-07 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.4 /01	xxx	2009	BYI 02960 - Acute skin irritation/corrosion on rabbits xxx Report No.: AT05342, Edition Number: <u>M-353761-01-2</u> EPA MRID No.: 48844107 Date: 2009-07-08 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.5 /01	xxx	2009	BYI 02960 - Acute eye irritation on rabbits xxx Report No.: AT05341 A, Edition Number: <u>M-361319-02-2</u> EPA MRID No.: 48844106 Date: 2009-07-08 ...Amended: 2009-10-29 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.2.6 /01	xxx	2009	BYI 02960 - Local lymph node assay in mice (LLNA/IMDS) xxx Report No.: AT05334, Edition Number: <u>M-353715-01-2</u> EPA MRID No.: 48844108 Date: 2009-06-29 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.1 /01	xxx	2007	BYI 02960 - Exploratory 28-day toxicity study in the rat by gavage xxx Report No.: SA 06075, Edition Number: <u>M-283421-02-2</u> EPA MRID No.: 48844149 Date: 2007-02-02 ...Amended: 2009-02-24 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.3.1 /02	xxx	2008	BYI 02960 - Exploratory 28-day toxicity study in the rat by dietary administration xxx Report No.: SA 07047, Edition Number: <u>M-297120-01-2</u> EPA MRID No.: 48844150 Date: 2008-02-01 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.3.1 /03	xxx	2007	BYI 02960 : Preliminary 28-day toxicity study in the mouse by dietary administration xxx Report No.: SA 07013, Edition Number: <u>M-294820-01-2</u> EPA MRID No.: 48844151 Date: 2007-11-23 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.3.1 /04	xxx	2008	Preliminary 28-day toxicity study in the dog by dietary administration xxx Report No.: SA07290, Edition Number: <u>M-312461-01-3</u> EPA MRID No.: 48844152 Date: 2008-12-09 GLP/GEP: no, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.3.2 /01	xxx	2009	BYI 02960 - 90-day toxicity study in the rat by dietary administration - Amendment no.2 xxx Report No.: SA 07294, Edition Number: <u>M-329048-03-2</u> EPA MRID No.: 48844111 Date: 2009-02-10 ...Amended: 2012-03-21 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.2 /02	xxx	2009	BYI 02960 - 90-day toxicity study in the mouse by dietary administration - Amendment no.2 xxx Report No.: SA 07295, Edition Number: <u>M-328668-03-2</u> EPA MRID No.: 48844112 Date: 2009-02-06 ...Amended: 2012-03-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.3 /01	xxx	2010	A 90-day toxicity feeding study in the beagle dog with technical grade BYi 02960 xxx Report No.: 09-S76-QQ, Edition Number: <u>M-369978-01-2</u> EPA MRID No.: 48844114 Date: 2010-04-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.4 /01	xxx	2012	A chronic toxicity feeding study in the Beagle dog with technical grade BYI 02960 - Amended final report - amendment 1 xxx Report No.: 09-C76-RZ, Edition Number: <u>M-425272-02-1</u> Date: 2012-02-17 ...Amended: 2013-04-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.7 /01	xxx	2012	A subacute dermal toxicity study in rats with BYI 02960 Xenometrics, LLC, Stilwell, KS, USA xxx Edition Number: <u>M-432336-01-1</u> EPA MRID No.: 48844115 Date: 2012-06-05 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.4.1 /01	Herbold, B.	2009	BYI 02960 (tested as BYI 02960 technical) (project: BYI 02960) - Salmonella/microsome test plate incorporation and preincubation method Bayer Schering Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05387, Edition Number: <u>M-354173-01-2</u> EPA MRID No.: 48844124 Date: 2009-07-24 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.4.1 /02	Sokolowski, A.	2011	1st amendment to report Salmonella typhimurium reverse mutation assay with BYI 02960 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1425802, Edition Number: <u>M-420539-02-2</u> EPA MRID No.: 48844125 Date: 2011-09-23 ...Amended: 2011-10-17 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.4.2 /01	Thum, M.	2009	BYI 02960 (tested as BYI 02960 technical) - In vitro chromosome aberration test with chinese hamster V79 cells Bayer Schering Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05626, Edition Number: <u>M-359746-01-2</u> EPA MRID No.: 48844131 Date: 2009-11-11 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.4.3 /01	Entian, G.	2009	BYI 02960 (tested as BYI 02960 technical) (project: BYI 02960) - V79/HPRT test in vitro for the detection of induced forward mutations Bayer Schering Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05625, Edition Number: <u>M-359743-01-2</u> EPA MRID No.: 48844128 Date: 2009-10-29 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.4.4 /01	xxx	2009	BYI 02960 - Micronucleus-test on the male mouse xxx Report No.: AT05350, Edition Number: <u>M-353785-01-2</u> EPA MRID No.: 48844134 Date: 2009-07-09 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.4.4 /02	xxx	2011	Micronucleus assay in bone marrow cells of the mouse with BYI 02960-a.i. xxx Report No.: 1425801, Edition Number: <u>M-420536-01-2</u> EPA MRID No.: 48844135 Date: 2011-11-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.5.2 /01	xxx	2012	BYI 02960 - Chronic toxicity and carcinogenicity study in the Wistar rat by dietary administration xxx Report No.: SA 08337, Edition Number: <u>M-428257-01-1</u> EPA MRID No.: 48844123 Date: 2012-03-05 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.5.3 /01	xxx	2012	BYI 02960 - Carcinogenicity study in the C57BL/6J mouse by dietary administration xxx Report No.: SA 08338, Edition Number: <u>M-425975-01-1</u> EPA MRID No.: 48844122 Date: 2012-02-24 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.1 /01	xxx	2010	Technical grade BYI 02960: A dose range-finding reproductive toxicity study in the Wistar rat xxx Report No.: 09-P72-RB, Edition Number: <u>M-394208-01-2</u> EPA MRID No.: 48844120 Date: 2010-11-01 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.6.1 /02	xxx	2011	Technical grade BYF 02960: A two-generation reproductive toxicity study in the Wistar rat xxx Report No.: 09-R72-SA, Edition Number: <u>M-417665-01-2</u> EPA MRID No.: 48844119 Date: 2011-10-17 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.10 /01	xxx	2010	BYI 02960: Developmental toxicity study in the rat by gavage xxx Report No.: SA 08347, Edition Number: <u>M-363938-01-2</u> EPA MRID No.: 48844116 Date: 2010-02-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.10 /02	xxx	2012	BYI 02960 - Complementary maternal tolerability study in the pregnant Sprague-Dawley rat by gavage xxx Report No.: SA 11140, Edition Number: <u>M-425810-01-2</u> EPA MRID No.: 48844118 Date: 2012-02-21 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.11 /01	xxx	2012	BYI 02960 - Developmental toxicity study in the rabbit by gavage xxx Report No.: SA 10314, Edition Number: <u>M-423559-01-1</u> EPA MRID No.: 48844117 Date: 2012-01-26 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.7.1 /01	xxx	2011	BYI 02960 - An acute neurotoxicity study in the rat by oral administration xxx Report No.: SA 10096, Edition Number: <u>M-415408-01-4</u> Date: 2011-09-30 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.7.4 /01	xxx	2011	BYI 02960 - A 90-day neurotoxicity study in the rat by dietary administration xxx Report No.: SA 09283, Edition Number: <u>M-410022-01-2</u> EPA MRID No.: 48844139 Date: 2011-06-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.7.5 /01	xxx	2012	A developmental neurotoxicity study with technical grade BYI 02960 in Wistar rats xxx Report No.: 11-D72-UW, Edition Number: <u>M-434203-01-1</u> EPA MRID No.: 48844140 Date: 2012-07-09 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /01	Sokolowski, A.	2010	First amendment to report - Salmonella typhimurium reverse mutation assay with BCS-AA56716 (metabolite of BYI 02960) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1351101, Edition Number: <u>M-409724-02-1</u> Date: 2010-09-30 ...Amended: 2013-03-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /02	Hall, C.	2010	BCS-AA56716 (metabolite of BYI 02960) - In vitro chromosome aberration test in Chinese hamster V79 cells Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1351103, Edition Number: <u>M-409726-01-2</u> EPA MRID No.: 48844132 Date: 2010-12-15 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /03	Wollny, H. E.	2010	First amendment to report - BCS-AA56716 (metabolite of BYI 02960) - Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1351102, Edition Number: <u>M-409727-02-1</u> Date: 2010-12-20 ...Amended: 2013-03-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /04	xxx	2010	BCS-AA56716 - Acute oral toxicity in rats - Acute toxic class method xxx Report No.: 37066 TAR, Edition Number: <u>M-393372-01-2</u> EPA MRID No.: 48844102 Date: 2010-10-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /05	xxx	2011	BCS-AA56716 (difluoroacetic acid): Preliminary 14-day toxicity study in the rat by dietary administration xxx Report No.: SA 10323, Edition Number: <u>M-414152-01-2</u> EPA MRID No.: 48844153 Date: 2011-09-19 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.8 /06	xxx	2012	BCS-AA56716 (Difluoroacetic acid) - 90-day toxicity study in the rat by dietary administration xxx Report No.: SA 10324, Edition Number: <u>M-424611-01-2</u> EPA MRID No.: 48844113 Date: 2012-02-02 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /07	Sokolowski, A.	2011	Salmonella typhimurium reverse mutation assay with BYI 02960-difluoroethyl-amino-furanone (metabolite of byi-02960) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1399701, Edition Number: <u>M-409728-01-2</u> EPA MRID No.: 48844127 Date: 2011-05-24 GLP/GEP: no, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /08	Hall, C.	2010	BYI 02960-difluoroethyl-amino-furanone (metabolite of BYI 02960) - In vitro chromosome aberration test in Chinese hamster V79 cells Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1399703, Edition Number: <u>M-420108-01-2</u> EPA MRID No.: 48844133 Date: 2010-10-07 GLP/GEP: no, unpublished	N	Bayer
KIIA 5.8 /09	Hall, C.	2010	BYI 0960-difluoroethyl-amino-furanone (metabolite of BYI 02960) - Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1399702, Edition Number: <u>M-420095-01-2</u> EPA MRID No.: 48844130 Date: 2010-12-20 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /10	xxx	2011	Micronucleus assay in bone marrow cells of the mouse with BYI 02960-difluoroethyl-aminofuranone (metabolite of BYI 02960) xxx Report No.: <u>M-420540-01-2</u> , Edition Number: <u>M-420540-01-2</u> EPA MRID No.: 48844136 Date: 2011-11-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /11	xxx	2011	In vivo unscheduled DNA synthesis in rat hepatocytes with BYI 02960-difluoroethyl-amino-furanone (metabolite of BYI 02960) xxx Report No.: 1421402, Edition Number: <u>M-420111-01-2</u> EPA MRID No.: 48844137 Date: 2011-10-26 GLP/GEP: no, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /12	xxx	2011	BYI-02960-difluoroethyl-amino-furanone acute oral toxicity in rats acute toxic class method xxx Report No.: 37503 TAR, Edition Number: <u>M-409674-01-2</u> EPA MRID No.: 48844103 Date: 2011-05-19 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /13	xxx	2012	BYI 02960-difluoroethyl aminofuranone: A 14-day dose range finding toxicity/palatability study in rats xxx Report No.: 11/116-100PE, Edition Number: <u>M-426158-01-2</u> EPA MRID No.: 48844109 Date: 2012-02-24 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /14	xxx	2012	BYI 02960-difluoroethyl aminofuranone: A 28-day dietary toxicity study in wistar rats xxx Report No.: 11/116-100P, Edition Number: <u>M-426136-01-2</u> EPA MRID No.: 48844110 Date: 2012-02-29 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /15	Nobuo, M.; Yukihiro, K.	1997	Reverse mutation study on bacteria IM-0 Nippon Soda Co., Ltd., Odawara Reseach Center, Japan Nippon Soda, Report No.: G-949, Report includes Trial Nos.: 9862 Edition Number: <u>M-195904-01-2</u> EPA MRID No.: 44988432 Date: 1997-09-30 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /16	xxx	1997	Acute oral toxicity study in rats IM-0 xxx Report No.: G-0887, Report includes Trial Nos.: 3662 Edition Number: <u>M-195899-01-2</u> EPA MRID No.: 44988421 Date: 1997-09-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /17	xxx	1997	Thirteen-week dietary subchronic toxicity study in rats IM-0 xxx Report No.: G-0889, Report includes Trial Nos.: 0259 Edition Number: <u>M-195901-01-2</u> EPA MRID No.: 44988427 Date: 1997-11-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /18	Yukihiro, K.	1997	Reverse mutation study on bacteria IC-0 Report No.: G-942, Report includes Trial Nos.: 9854 Edition Number: <u>M-195932-01-2</u> EPA MRID No.: 44988502 Date: 1997-09-30 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /19	xxx	1997	Acute oral toxicity study in rats IC-0 xxx Report No.: G-0941, Report includes Trial Nos.: 3686 Edition Number: <u>M-195930-01-2</u> EPA MRID No.: 44988420 Date: 1997-09-30 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.10 /01	xxx	2010	BYI 02960 - Biokinetic in the plasma of rats following 7 days exposure through the diet xxx Report No.: SA 09334, Edition Number: <u>M-385777-01-2</u> EPA MRID No.: 48844154 Date: 2010-07-08 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.10 /02	xxx	2011	BYI 02960: 28-day immunotoxicity study in the female wistar rat by dietary administration xxx Report No.: SA 10353, Edition Number: <u>M-414754-01-2</u> EPA MRID No.: 48844148 Date: 2011-09-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 7.1.1 /01	Menke, U.	2011	[Pyridinylmethyl-14C]BYI 02960: Aerobic soil metabolism/degradation and time-dependent sorption in soils Bayer CropScience, Report No.: MEF-07/334, Edition Number: <u>M-414615-01-2</u> EPA MRID No.: 48843674 Date: 2011-08-05 GLP/GEP: yes, unpublished ...also filed: KIIA 7.2.1 /01 ...also filed: KIIA 7.4.1 /03	N	Bayer
KIIA 7.1.1 /02	Menke, U.; Unold, M.	2011	[Furanone-4-14C]BYI 02960: Aerobic soil metabolism/degradation Bayer CropScience, Report No.: MEF-10/804, Edition Number: <u>M-411625-01-2</u> EPA MRID No.: 48843676 Date: 2011-07-28 GLP/GEP: yes, unpublished ...also filed: KIIA 7.2.1 /02	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.1.1 /03	Ripperger, R. J.	2011	[Furanone-4-14C]BYI 02960: Aerobic soil metabolism in two US soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP037-2, Edition Number: <u>M-405497-03-1</u> EPA MRID No.: 48843677 Date: 2011-01-14 ...Amended: 2012-01-05 GLP/GEP: yes, unpublished ...also filed: KIIA 7.2.1 /03	N	Bayer
KIIA 7.1.1 /04	Menke, U.; Unold, M.	2011	[Ethyl-1-14C]BYI 02960: Aerobic soil metabolism Bayer CropScience, Report No.: MEF-10/858, Edition Number: <u>M-414981-01-1</u> EPA MRID No.: 48843679 Date: 2011-09-08 GLP/GEP: yes, unpublished ...also filed: KIIA 7.2.1 /04	N	Bayer
KIIA 7.1.1 /05	Menke, U.; Unold, M.	2011	[Pyridine-2,6-14C]BYI 02960: Aerobic soil metabolism Bayer CropScience, Report No.: MEF-10/880, Edition Number: <u>M-411693-01-2</u> EPA MRID No.: 48843681 Date: 2011-07-28 GLP/GEP: yes, unpublished ...also filed: KIIA 7.2.1 /05	N	Bayer
KIIA 7.1.1 /06	Shepherd, J. J.	2011	[Pyridine-2,6-14C]BYI 02960: Aerobic soil metabolism in two US soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP038-1, Edition Number: <u>M-413425-02-1</u> EPA MRID No.: 48843682 Date: 2011-09-06 ...Amended: 2012-01-05 GLP/GEP: yes, unpublished ...also filed: KIIA 7.2.1 /06 ...also filed: KIIA 7.2.3 /04	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.1.2 /01	Menke, U.; Unold, M.	2012	[Furanone-4-14C] and [Ethyl-1-14C] and [Pyridine-2,6-14C]BYI 02960: Anaerobic Soil Metabolism Bayer CropScience, Report No.: MEF-11/514, Edition Number: <u>M-421504-01-2</u> EPA MRID No.: 48843686 Date: 2012-01-03 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.1.2 /02	Mislankar, S. G.; Woodard, D.	2012	[Pyridine-2,6-14C]BYI 02960: Anaerobic soil metabolism Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERV094, Edition Number: <u>M-421993-01-1</u> Date: 2012-01-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.1.2 /03	Woodard, D.	2012	[Pyridine-2,6-14C]BYI 02960: Anaerobic soil metabolism in Springfield, Nebraska (USA) soil Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERV006, Edition Number: <u>M-424987-01-1</u> Date: 2012-02-14 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.1.3 /01	Menke, U.; Unold, M.	2011	[Pyridinylmethyl-14C]BYI 02960 and [furanone-4-14C]BYI 02960: Phototransformation on soil Bayer CropScience, Report No.: MEF-10/351, Edition Number: <u>M-405776-01-2</u> EPA MRID No.: 48843672 Date: 2011-03-24 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.2.1 /01	Menke, U.	2011	[Pyridinylmethyl-14C]BYI 02960: Aerobic soil metabolism/degradation and time-dependent sorption in soils Bayer CropScience, Report No.: MEF-07/334, Edition Number: <u>M-414615-01-2</u> EPA MRID No.: 48843674 Date: 2011-08-05 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /01 ...also filed: KIIA 7.4.1 /03	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.2.1 /02	Menke, U.; Unold, M.	2011	[Furanone-4-14C]BYI 02960: Aerobic soil metabolism/degradation Bayer CropScience, Report No.: MEF-10/804, Edition Number: <u>M-411625-01-2</u> EPA MRID No.: 48843676 Date: 2011-07-28 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /02	N	Bayer
KIIA 7.2.1 /03	Ripperger, R. J.	2011	[Furanone-4-14C]BYI 02960: Aerobic soil metabolism in two US soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP037-2, Edition Number: <u>M-405497-03-1</u> EPA MRID No.: 48843677 Date: 2011-01-14 ...Amended: 2012-01-05 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /03	N	Bayer
KIIA 7.2.1 /04	Menke, U.; Unold, M.	2011	[Ethyl-1-14C]BYI 02960: Aerobic soil metabolism Bayer CropScience, Report No.: MEF-10/858, Edition Number: <u>M-414981-01-1</u> EPA MRID No.: 48843679 Date: 2011-09-08 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /04	N	Bayer
KIIA 7.2.1 /05	Menke, U.; Unold, M.	2011	[Pyridine-2,6-14C]BYI 02960: Aerobic soil metabolism Bayer CropScience, Report No.: MEF-10/880, Edition Number: <u>M-411693-01-2</u> EPA MRID No.: 48843681 Date: 2011-07-28 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /05	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.2.1 /06	Shepherd, J. J.	2011	[Pyridine-2,6-14C]BYI 02960: Aerobic soil metabolism in two US soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP038-1, Edition Number: <u>M-413425-02-1</u> EPA MRID No.: 48843682 Date: 2011-09-06 ...Amended: 2012-01-05 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /06 ...also filed: KIIA 7.2.3 /04	N	Bayer
KIIA 7.2.3 /01	Lowden, P.; Oddy, A. M.; Jones, M. K.	1997	Rate of degradation of the acid metabolite, (14C)-IC-O in three soils NI-25 Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C007660, Edition Number: <u>M-196378-01-1</u> Date: 1997-08-14 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.2.3 /04	Shepherd, J. J.	2011	[Pyridine-2,6-14C]BYI 02960: Aerobic soil metabolism in two US soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP038-1, Edition Number: <u>M-413425-02-1</u> EPA MRID No.: 48843682 Date: 2011-09-06 ...Amended: 2012-01-05 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /06 ...also filed: KIIA 7.2.1 /06	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.3.1 /01	Heinemann, O.	2011	Determination of the residues of BYI 02960 in/on soil after spraying of BYI 02960 SL 200 in the field in Germany, Italy, Spain and the United Kingdom Bayer CropScience, Report No.: 09-2702, Report includes Trial Nos.: 09-2702-01 09-2702-02 09-2702-03 09-2702-05 09-2702-06 09-2702-07 Edition Number: <u>M-414245-01-1</u> Date: 2011-09-13 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.4.1 /01	Menke, U.; Telscher, M.	2008	[Pyridinylmethyl-14C]BYI 02960: Adsorption to and desorption from soils Bayer CropScience, Report No.: MEF-08/261, Edition Number: <u>M-327492-01-2</u> EPA MRID No.: 48843662 Date: 2008-12-17 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.4.1 /02	Stroeck, K.	2010	[Pyridinylmethyl-14C]BYI 02960: Adsorption/desorption on two soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP017, Edition Number: <u>M-363541-01-1</u> EPA MRID No.: 48843663 Date: 2010-01-29 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.4.1 /03	Menke, U.	2011	[Pyridinylmethyl-14C]BYI 02960: Aerobic soil metabolism/degradation and time-dependent sorption in soils Bayer CropScience, Report No.: MEF-07/334, Edition Number: <u>M-414615-01-2</u> EPA MRID No.: 48843674 Date: 2011-08-05 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /01 ...also filed: KIIA 7.2.1 /01	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.4.2 /01	Liu, A. C.	1997	Soil adsorption/desorption study 6-chloronicotinic acid (Acetamiprid metabolite) Rhone-Poulenc Ag Company, RTP, NC, USA Bayer CropScience, Report No.: C007666, Edition Number: <u>M-196394-01-1</u> Date: 1997-09-15 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.4.2 /02	Menke, U.; Unold, M.	2011	[1-14C]BYI 02960-DFA (BCS-AB60481): Adsorption to and desorption from five soils Bayer CropScience, Report No.: MEF-10/538, Edition Number: <u>M-413836-01-2</u> EPA MRID No.: 48843665 Date: 2011-08-26 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.4.3 /01	de Souza, T. J. T.	2012	Amendment no 001 to final report - Mobility of [Pyridine-2,6-14C]-BYI 02960 in Brazilian soils - Soil columns leaching method Bioensaios Analises e Consultoria Ambiental S/C Ltda., Viamao, Brazil Bayer CropScience, Report No.: 2301-LIX-344-11, Edition Number: <u>M-424966-02-2</u> Date: 2012-02-08 ...Amended: 2012-06-05 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.4.9 /01	Smeykal, H.	2008	BYI 02960, pure substance: Vapour pressure - Final report Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20080615.01, Edition Number: <u>M-309853-01-1</u> Date: 2008-10-10 GLP/GEP: yes, unpublished ...also filed: KIIA 2.3.1 /01	N	Bayer
KIIA 7.5 /01	Mislankar, S.; Woodard, D.	2011	BYI-02960: Hydrolytic degradation Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERV019, Edition Number: <u>M-398952-01-1</u> Date: 2011-01-07 GLP/GEP: yes, unpublished ...also filed: KIIA 2.9.1 /01	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.6 /01	Hall, L. R.	2011	Phototransformation of [14C]BYI 02960 in aqueous pH 7 buffer - amended report Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP042-1, Edition Number: <u>M-418426-02-1</u> Date: 2011-11-28 ...Amended: 2012-03-05 GLP/GEP: yes, unpublished ...also filed: KIIA 2.9.2 /01 ...also filed: KIIA 2.9.4 /01	N	Bayer
KIIA 7.6 /02	Heinemann, O.	2011	BYI 02960: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water Bayer CropScience, Report No.: MEF-11/554, Edition Number: <u>M-414756-01-2</u> EPA MRID No.: 48843668 Date: 2011-09-26 GLP/GEP: yes, unpublished ...also filed: KIIA 2.9.3 /01 ...also filed: KIIA 2.9.4 /02	N	Bayer
KIIA 7.6 /03	Hall, L. R.	2011	Phototransformation of [14C]BYI 02960 in natural water Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP020, Edition Number: <u>M-415368-01-1</u> Date: 2011-08-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.8.2 /01	Xu, T.	2012	[Pyridine-2,6-14C]BYI 02960: Anaerobic aquatic metabolism in two water/sediment systems Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP027, Edition Number: <u>M-422616-01-1</u> Date: 2012-01-17 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.8.3 /01	Hellpointner, E.; Unold, M.	2012	[Pyridine-2,6-14C]BYI 02960: Aerobic aquatic metabolism Bayer CropScience, Report No.: MEF-11/907, Edition Number: <u>M-422359-01-1</u> EPA MRID No.: 48843690 Date: 2012-01-12 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.8.3 /02	Unold, M.; Menke, U.	2012	[Furanone-4-14C] and [ethyl-1-14C]BYI 02960: Aerobic aquatic metabolism Bayer CropScience, Report No.: MEF-10/730, Edition Number: <u>M-426504-01-1</u> EPA MRID No.: 48843692 Date: 2012-02-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.8.3 /03	Hellpointner, E.; Unold, M.	2012	[1-14C]BYI 02960-DFA (BCS-AB60481): Aerobic aquatic degradation Bayer CropScience, Report No.: <u>M-422371-01-1</u> , Edition Number: <u>M-422371-01-1</u> EPA MRID No.: 48843691 Date: 2012-01-12 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.8.3 /04	Bruns, E.	2012	Fate of BYI 02960 (tech.) in outdoor microcosm ponds simulating actual exposure conditions in agricultural use Bayer CropScience, Report No.: EBRVP109, Edition Number: <u>M-427167-01-1</u> Date: 2012-03-20 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /01	Bogdoll, B.; Strunk, B.	2011	BCS-CC98193 (BYI 02960-DFEAF): Water solubility at pH 5, pH 7 and pH 9 (flask method) Bayer CropScience, Report No.: PA11/018, Edition Number: <u>M-415753-01-1</u> Date: 2011-10-04 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /02	Wiche, A.; Ziemer, F.	2011	BCS-CR74729 (BYI 02960-succinamide): Water solubility at pH 5, pH 7 and pH 9 (flask method) Bayer CropScience, Report No.: PA11/078, Edition Number: <u>M-416651-01-1</u> Date: 2011-11-04 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.13 /03	Ziemer, F.; Strunk, B.	2011	BCS-CU93236 (BYI 02960-azabicyclosuccinamide Na-salt): Water solubility at pH 5, pH 7 and pH 9 (flask method) Bayer CropScience, Report No.: PA11/094, Edition Number: <u>M-417069-01-1</u> Date: 2011-11-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /04	Bogdoll, B.; Strunk, B.	2011	Difluoroacetic acid (BCS-AA56716): Miscibility with distilled water and solubility in water in a pH range of 1.6 to 13 Bayer CropScience, Report No.: PA10/042, Edition Number: <u>M-418554-01-1</u> Date: 2011-11-29 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /05	Kenji, M.	2001	Solubility of IC-0 in water Nisso Chemical Analysis Serv. Co., Ltd., Japan Nippon Soda, Report No.: C016679, Edition Number: <u>M-202871-01-1</u> Date: 2001-09-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /06	Eyrich, U.; Ziemer, F.	2011	BCS-CR74729 (BYI 02960-succinamide): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer CropScience, Report No.: PA11/079, Edition Number: <u>M-416883-01-1</u> Date: 2011-11-04 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /07	Eyrich, U.; Ziemer, F.	2011	BCS-CU93236 (BYI 02960-azabicyclosuccinamide Na-salt): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer CropScience, Report No.: PA11/093, Edition Number: <u>M-416656-01-1</u> Date: 2011-11-04 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.13 /08	Eyrich, U.; Ziemer, F.	2011	Difluoroacetic acid (BCS-AA56716): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer CropScience, Report No.: PA10/043, Edition Number: <u>M-416624-01-1</u> Date: 2011-11-04 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /09	Shirou, H.	2001	Partition coefficient (n-octanol/water) of IC-0 Nisso Chemical Analysis Serv. Co., Ltd., Japan Nippon Soda, Report No.: C017442, Edition Number: <u>M-204285-01-1</u> Date: 2001-11-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /10	Wiche, A.; Bogdoll, B.	2011	BCS-CC98193 (BYI 02960-DFEAF): Dissociation constant in water Bayer CropScience, Report No.: PA11/021, Edition Number: <u>M-415757-01-1</u> Date: 2011-10-04 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /11	Winkler, S.	2011	Difluoro acetic acid (BCS-AA56716): Determination of the dissociation constant in water Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20100366.02, Edition Number: <u>M-418626-01-1</u> Date: 2011-11-18 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /12	Kenji, M.	2001	Dissociation constant of IC-0 Nisso Chemical Analysis Serv. Co., Ltd., Japan Nippon Soda, Report No.: C016811, Edition Number: <u>M-203097-01-1</u> Date: 2001-10-17 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 7.13 /13	Dornhagen, J.	2011	BCS-CC98193 (BYI 02960-DFEAF): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110091.01, Edition Number: <u>M-420457-01-1</u> Date: 2011-11-07 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.13 /14	Smeykal, H.	2011	Difluoroacetic acid (BCS-AA56716): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20100366.01, Edition Number: <u>M-418553-01-1</u> Date: 2011-11-24 GLP/GEP: yes, unpublished	N	Bayer

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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Appendix 2 Additional information

No additional information.