

# 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)

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

(Authorisation)

Applicant: Bayer Crop Science Division

Submission date: 01/08/2019 (intended), 11/03/2021 (update)

MS Finalisation date: October 2021 (initial Core Assessment)

February 2022 (final Core Assessment)

Version: March 2021

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## Version history

When	What
August 2019	Original Bayer Crop Science Division submission
March 2021	<p>Bayer's updates</p> <p>Updated further to the zRMS Poland's request from 10/09/2020 and 08/02/2021 maintaining the demand for groundwater and surface water additional modelling for flupyradifuron performed with consideration of PUF (TSCF) of 0 (due to the non-acceptance of Bayer argumentation and proposal to perform only calculations with PUF (TSCF) of 0.5).</p>
October 2021	<p>Initial zRMS assessment</p> <p>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.</p>
February 2022	<p>Final report (Core Assessment updated following the commenting period)</p> <p>No additional information or assessments after the commenting period.</p>

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This part of dossier has been prepared to support the first registration of the insecticide product DLT+FPF EC 85 and summarizes the data related to the relevance of metabolites in groundwater. All data contained in this document has been evaluated for the purposes of ongoing registration. The information contained in dRR Part B10 has been accepted and considered as sufficient and appropriate for risk assessment with some amendments resulting from evaluation performed in area of Section 8.

## 10 Relevance of metabolites in groundwater

### 10.1 General information

#### Deltamethrin

The metabolite **Br<sub>2</sub>CA** 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 difluoroacetic acid (DFA) is predicted to occur in groundwater at concentrations above 0.1 µg/L (see Section 8, Chapter 8.8). 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.

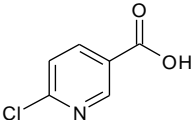
General information on metabolites with a potential for groundwater contamination is provided in **Błąd! Nie można odnaleźć źródła odwołania..** The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in 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 <sub>2</sub> CA AE F108565 RU23441		Max PEC <sub>gw</sub> Based on:	<0.001 µg/L (Tier 1, TSCF = 0, all scenarios simulated using both models and for both crops) 0.010 µg/L MACRO Chateaudun
Flupyradifurone (BYI 02960)	Difluoroacetic acid (DFA)		Max PEC <sub>gw</sub> Based on:	0.654 µg/L FOCUS PELMO 5.5.3 (Tier 2, TSCF = 0) Hamburg 0.697 µg/L (TSCF = 0.5) 0.731 µg/L (TSCF = 0) FOCUS PEARL 4.4.4 (Tier 1) Hamburg

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Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
	6-Chloronicotinic acid (6-CNA)		Max PEC <sub>gw</sub> Based on:	<0.01 µg/L (Tier 1, TSCF = 0, all scenarios simulated using both models and for both crops) <del>0.003 µg/L (TSCF = 0.5)</del> <del>0.004 µg/L (TSCF = 0)</del> <del>FOCUS PEARL 4.4.4 (Tier 1)</del> <del>Hamburg</del>

**Reviewer comments:**

Table 10.1-1 above has been amended accordingly with consideration of the results of groundwater modelling agreed by the zRMS efate expert. For details, please refer to the Core Assessment, Part B, Section 8.

## 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<sub>gw</sub> 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 **Błąd! Nie można odnaleźć źródła odwołania.** and the corresponding studies are listed in the corresponding sections.

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	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC <sub>gw</sub>	0.654 µg/L (Tier 2, TSCF = 0) <del>0.697 µg/L (TSCF = 0.5)</del> <del>0.731 µg/L (TSCF = 0)</del>
			Based on	Tier 1 FOCUS PEARL Winter OSR (annual) 30 g/ha Hamburg scenario
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 Tox. 4; STOT RE 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	acceptable (<0.75 µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*

\* N/A: not applicable

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Table 10.1-1 above has been amended accordingly with consideration of the results of groundwater modelling agreed by the zRMS efate expert. For details, please refer to the Core Assessment, Part B, Section 8.

**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<sub>gw</sub> 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 **Błąd! Nie można odnaleźć źródła odwołania..** 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 <a href="#">M-409724-02-1</a> 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 <a href="#">M-409727-02-1</a> 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 <a href="#">M-409726-02-1</a> 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).



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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 LD<sub>50</sub> 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 <sub>50</sub> in rats: between 300 and 2000 mg/kg	 <a href="#">M-393372-01-2</a> 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 administration; (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)	 <a href="#">M-414152-01-2</a> 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, respectively)	 <a href="#">M-424611-01-2</a> 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

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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 in drinking water is  $< 0.75 \mu\text{g/L}$  and therefore further assessment in Step 5 is not required.

#### **10.2.5 STEP 5: Refined risk assessment**

A refined risk assessment for the metabolite Difluoroacetic Acid is not required as its potential exposure in drinking water is  $< 0.75 \mu\text{g/L}$ . The potential exposure via food items is covered by the dietary risk assessment.

The chronic exposure (calculated based on the sum of flupyradifurone and DFA residues) through the diet was in maximum 17% of the ADI (see Part B, Section 7, 7.2.8.2). Hence, a long-term risk for the consumer through the diet can be excluded.

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## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

No 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	██████████	2012	[Pyridinylmethyl-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in the rat ██████████ Report No.: MEF-11/747, Edition Number: <a href="#">M-422210-01-1</a> EPA MRID No.: 48844141 Date: 2012-01-12 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.1 /02	██████████	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 <sup>14</sup> CO <sub>2</sub> ██████████ Report No.: MEF-11/276, Edition Number: <a href="#">M-409993-01-2</a> EPA MRID No.: 48844142 Date: 2011-05-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.2 /01	██████████	2011	[Furanone-4-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in the rat ██████████ Report No.: MEF-11/556, Edition Number: <a href="#">M-421499-01-1</a> EPA MRID No.: 48844143 Date: 2011-12-22 GLP/GEP: yes, unpublished	Y	Bayer

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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	██████	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 ██████ Report No.: MEF-11/275, Edition Number: <a href="#">M-409859-01-2</a> EPA MRID No.: 48844144 Date: 2011-05-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.2 /03	██████	2011	[Furanone-4-14C]BYI 02960 - Metabolism in organs and tissues of male and female rats ██████ Report No.: MEF-11/271, Edition Number: <a href="#">M-414034-02-2</a> EPA MRID No.: 48844145 Date: 2011-09-12 ...Amended: 2012-02-02 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.3 /01	██████	2011	[Ethyl-1-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in male rats ██████ Report No.: MEF-11/555, Edition Number: <a href="#">M-415647-01-1</a> EPA MRID No.: 48844146 Date: 2011-10-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.3 /02	██████	2011	[Ethyl-1-14C]BYI 02960 - Metabolism in organs and tissues of male and female rats (3 time-points) ██████ Report No.: MEF-11/270, Edition Number: <a href="#">M-415416-02-1</a> EPA MRID No.: 48844147 Date: 2011-09-29 ...Amended: 2012-02-02 GLP/GEP: yes, unpublished	Y	Bayer

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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	████████	2009	BYI 02960 - Acute toxicity in the rat after oral administration ████████████████████ Report No.: AT05287, Edition Number: <a href="#">M-349992-01-2</a> EPA MRID No.: 48844101 Date: 2009-06-08 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.2 /01	████████	2009	BYI 02960 - Acute toxicity in the rat after dermal administration ████████████████████ Report No.: AT05288, Edition Number: <a href="#">M-349995-01-2</a> EPA MRID No.: 48844104 Date: 2009-06-08 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.3 /01	████████	2010	BYI 02960 - Activity ID TXRVP033 - Acute inhalation toxicity in rats ████████████████████ Report No.: AT05727, Edition Number: <a href="#">M-362791-01-2</a> EPA MRID No.: 48844105 Date: 2010-01-07 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.4 /01	████████	2009	BYI 02960 - Acute skin irritation/corrosion on rabbits ████████████████████ Report No.: AT05342, Edition Number: <a href="#">M-353761-01-2</a> EPA MRID No.: 48844107 Date: 2009-07-08 GLP/GEP: yes, unpublished	Y	Bayer

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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 5.2.5 /01	[REDACTED]	2009	BYI 02960 - Acute eye irritation on rabbits [REDACTED] Report No.: AT05341 A, Edition Number: <a href="#">M-361319-02-2</a> EPA MRID No.: 48844106 Date: 2009-07-08 ...Amended: 2009-10-29 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.6 /01	[REDACTED]	2009	BYI 02960 - Local lymph node assay in mice (LLNA/IMDS) [REDACTED] Report No.: AT05334, Edition Number: <a href="#">M-353715-01-2</a> EPA MRID No.: 48844108 Date: 2009-06-29 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.1 /01	[REDACTED]	2007	BYI 02960 - Exploratory 28-day toxicity study in the rat by gavage [REDACTED] Report No.: SA 06075, Edition Number: <a href="#">M-283421-02-2</a> EPA MRID No.: 48844149 Date: 2007-02-02 ...Amended: 2009-02-24 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.3.1 /02	[REDACTED]	2008	BYI 02960 - Exploratory 28-day toxicity study in the rat by dietary administration [REDACTED] Report No.: SA 07047, Edition Number: <a href="#">M-297120-01-2</a> EPA MRID No.: 48844150 Date: 2008-02-01 GLP/GEP: no, unpublished	Y	Bayer

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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 5.3.1 /03	[REDACTED]	2007	BYI 02960 : Preliminary 28-day toxicity study in the mouse by dietary administration [REDACTED] Report No.: SA 07013, Edition Number: <a href="#">M-294820-01-2</a> EPA MRID No.: 48844151 Date: 2007-11-23 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.3.1 /04	[REDACTED]	2008	Preliminary 28-day toxicity study in the dog by dietary administration [REDACTED] Report No.: SA07290, Edition Number: <a href="#">M-312461-01-3</a> EPA MRID No.: 48844152 Date: 2008-12-09 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.3.2 /01	[REDACTED]	2009	BYI 02960 - 90-day toxicity study in the rat by dietary administration - Amendment no.2 [REDACTED] Report No.: SA 07294, Edition Number: <a href="#">M-329048-03-2</a> EPA MRID No.: 48844111 Date: 2009-02-10 ...Amended: 2012-03-21 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.2 /02	[REDACTED]	2009	BYI 02960 - 90-day toxicity study in the mouse by dietary administration - Amendment no.2 [REDACTED] Report No.: SA 07295, Edition Number: <a href="#">M-328668-03-2</a> EPA MRID No.: 48844112 Date: 2009-02-06 ...Amended: 2012-03-22 GLP/GEP: yes, unpublished	Y	Bayer

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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 5.3.3 /01	[REDACTED]	2010	A 90-day toxicity feeding study in the beagle dog with technical grade BYi 02960 [REDACTED] Report No.: 09-S76-QQ, Edition Number: <a href="#">M-369978-01-2</a> EPA MRID No.: 48844114 Date: 2010-04-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.4 /01	[REDACTED]	2012	A chronic toxicity feeding study in the Beagle dog with technical grade BYI 02960 - Amended final report - amendment 1 [REDACTED] Report No.: 09-C76-RZ, Edition Number: <a href="#">M-425272-02-1</a> Date: 2012-02-17 ...Amended: 2013-04-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.3.7 /01	[REDACTED]	2012	A subacute dermal toxicity study in rats with BYI 02960 [REDACTED] Report No.: 11-S22-US, Edition Number: <a href="#">M-432336-01-1</a> EPA MRID No.: 48844115 Date: 2012-06-05 GLP/GEP: yes, unpublished	Y	Bayer
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: <a href="#">M-354173-01-2</a> EPA MRID No.: 48844124 Date: 2009-07-24 GLP/GEP: yes, unpublished	N	Bayer



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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 /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: <a href="#">M-420539-02-2</a> 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: <a href="#">M-359746-01-2</a> 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: <a href="#">M-359743-01-2</a> EPA MRID No.: 48844128 Date: 2009-10-29 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.4.4 /01	[REDACTED]	2009	BYI 02960 - Micronucleus-test on the male mouse [REDACTED] Report No.: AT05350, Edition Number: <a href="#">M-353785-01-2</a> EPA MRID No.: 48844134 Date: 2009-07-09 GLP/GEP: yes, unpublished	Y	Bayer

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KIIA 5.4.4 /02	██████	2011	Micronucleus assay in bone marrow cells of the mouse with BYI 02960-a.i. ██ Report No.: 1425801, Edition Number: <a href="#">M-420536-01-2</a> EPA MRID No.: 48844135 Date: 2011-11-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.5.2 /01	██████	2012	BYI 02960 - Chronic toxicity and carcinogenicity study in the Wistar rat by dietary administration ██ Report No.: SA 08337, Edition Number: <a href="#">M-428257-01-1</a> EPA MRID No.: 48844123 Date: 2012-03-05 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.5.3 /01	██████	2012	BYI 02960 - Carcinogenicity study in the C57BL/6J mouse by dietary administration ██ Report No.: SA 08338, Edition Number: <a href="#">M-425975-01-1</a> EPA MRID No.: 48844122 Date: 2012-02-24 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.1 /01	██████	2010	Technical grade BYI 02960: A dose range-finding reproductive toxicity study in the Wistar rat ██ Report No.: 09-P72-RB, Edition Number: <a href="#">M-394208-01-2</a> EPA MRID No.: 48844120 Date: 2010-11-01 GLP/GEP: yes, unpublished	Y	Bayer

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KIIA 5.6.1 /02	[REDACTED]	2011	Technical grade BYF 02960: A two-generation reproductive toxicity study in the Wistar rat [REDACTED] Report No.: 09-R72-SA, Edition Number: <a href="#">M-417665-01-2</a> EPA MRID No.: 48844119 Date: 2011-10-17 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.10 /01	[REDACTED]	2010	BYI 02960: Developmental toxicity study in the rat by gavage [REDACTED] Report No.: SA 08347, Edition Number: <a href="#">M-363938-01-2</a> EPA MRID No.: 48844116 Date: 2010-02-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.10 /02	[REDACTED]	2012	BYI 02960 - Complementary maternal tolerability study in the pregnant Sprague-Dawley rat by gavage [REDACTED] Report No.: SA 11140, Edition Number: <a href="#">M-425810-01-2</a> EPA MRID No.: 48844118 Date: 2012-02-21 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.11 /01	[REDACTED]	2012	BYI 02960 - Developmental toxicity study in the rabbit by gavage [REDACTED] Report No.: SA 10314, Edition Number: <a href="#">M-423559-01-1</a> EPA MRID No.: 48844117 Date: 2012-01-26 GLP/GEP: yes, unpublished	Y	Bayer

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KIIA 5.7.1 /01	[REDACTED]	2011	BYI 02960 - An acute neurotoxicity study in the rat by oral administration [REDACTED] Report No.: SA 10096, Edition Number: <a href="#">M-415408-01-4</a> Date: 2011-09-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.7.4 /01	[REDACTED]	2011	BYI 02960 - A 90-day neurotoxicity study in the rat by dietary administration [REDACTED] Report No.: SA 09283, Edition Number: <a href="#">M-410022-01-2</a> EPA MRID No.: 48844139 Date: 2011-06-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.7.5 /01	[REDACTED]	2012	A developmental neurotoxicity study with technical grade BYI 02960 in Wistar rats [REDACTED] Report No.: 11-D72-UW, Edition Number: <a href="#">M-434203-01-1</a> 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: <a href="#">M-409724-02-1</a> Date: 2010-09-30 ...Amended: 2013-03-27 GLP/GEP: yes, unpublished	N	Bayer

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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: <a href="#">M-409726-01-2</a> EPA MRID No.: 48844132 Date: 2010-12-15 GLP/GEP: yes, unpublished	N	Bayer
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: <a href="#">M-409727-02-1</a> Date: 2010-12-20 ...Amended: 2013-03-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /04	████████	2010	BCS-AA56716 - Acute oral toxicity in rats - Acute toxic class method ██ Report No.: 37066 TAR, Edition Number: <a href="#">M-393372-01-2</a> EPA MRID No.: 48844102 Date: 2010-10-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /05	████████	2011	BCS-AA56716 (difluoroacetic acid): Preliminary 14-day toxicity study in the rat by dietary administration ██ Report No.: SA 10323, Edition Number: <a href="#">M-414152-01-2</a> EPA MRID No.: 48844153 Date: 2011-09-19 GLP/GEP: no, unpublished	Y	Bayer

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KIIA 5.8 /06		2012	BCS-AA56716 (Difluoroacetic acid) - 90-day toxicity study in the rat by dietary administration [REDACTED] Report No.: SA 10324, Edition Number: <a href="#">M-424611-01-2</a> 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: <a href="#">M-409728-01-2</a> EPA MRID No.: 48844127 Date: 2011-05-24 GLP/GEP: no, unpublished	N	Bayer
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: <a href="#">M-420108-01-2</a> 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: <a href="#">M-420095-01-2</a> EPA MRID No.: 48844130 Date: 2010-12-20 GLP/GEP: yes, unpublished	N	Bayer

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KIIA 5.8 /10	██████	2011	Micronucleus assay in bone marrow cells of the mouse with BYI 02960-difluoroethyl-aminofuranone (metabolite of BYI 02960) ██ Report No.: <a href="#">M-420540-01-2</a> , Edition Number: <a href="#">M-420540-01-2</a> EPA MRID No.: 48844136 Date: 2011-11-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /11	██████	2011	In vivo unscheduled DNA synthesis in rat hepatocytes with BYI 02960-difluoroethyl-amino-furanone (metabolite of BYI 02960) ██ Report No.: 1421402, Edition Number: <a href="#">M-420111-01-2</a> EPA MRID No.: 48844137 Date: 2011-10-26 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.8 /12	██████	2011	BYI-02960-difluoroethyl-amino-furanone acute oral toxicity in rats acute toxic class method ██ Report No.: 37503 TAR, Edition Number: <a href="#">M-409674-01-2</a> EPA MRID No.: 48844103 Date: 2011-05-19 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /13	██████████	2012	BYI 02960-difluoroethyl aminofuranone: A 14-day dose range finding toxicity/palatability study in rats ██ Report No.: 11/116-100PE, Edition Number: <a href="#">M-426158-01-2</a> EPA MRID No.: 48844109 Date: 2012-02-24 GLP/GEP: yes, unpublished	Y	Bayer

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KIIA 5.8 /14	[REDACTED]	2012	BYI 02960-difluoroethyl aminofuranone: A 28-day dietary toxicity study in wistar rats [REDACTED] Report No.: 11/116-100P, Edition Number: <a href="#">M-426136-01-2</a> 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: <a href="#">M-195904-01-2</a> EPA MRID No.: 44988432 Date: 1997-09-30 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /16	[REDACTED]	1997	Acute oral toxicity study in rats IM-0 [REDACTED] Report No.: G-0887, Report includes Trial Nos.: 3662 Edition Number: <a href="#">M-195899-01-2</a> EPA MRID No.: 44988421 Date: 1997-09-30 GLP/GEP: yes, unpublished	Y	Bayer



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KIIA 5.8 /17	[REDACTED]	1997	Thirteen-week dietary subchronic toxicity study in rats IM-0 [REDACTED] Report No.: G-0889, Report includes Trial Nos.: 0259 Edition Number: <a href="#">M-195901-01-2</a> EPA MRID No.: 44988427 Date: 1997-11-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /18	Nobuo, M.; Yukihiro, K.	1997	Reverse mutation study on bacteria IC-0 Nippon Soda Co., Ltd., Odawara Reseach Center, Japan Nippon Soda, Report No.: G-942, Report includes Trial Nos.: 9854 Edition Number: <a href="#">M-195932-01-2</a> EPA MRID No.: 44988502 Date: 1997-09-30 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /19	[REDACTED]	1997	Acute oral toxicity study in rats IC-0 [REDACTED] Report No.: G-0941, Report includes Trial Nos.: 3686 Edition Number: <a href="#">M-195930-01-2</a> EPA MRID No.: 44988420 Date: 1997-09-30 GLP/GEP: yes, unpublished	Y	Bayer

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KIIA 5.10 /01	[REDACTED]	2010	BYI 02960 - Biokinetic in the plasma of rats following 7 days exposure through the diet [REDACTED] Report No.: SA 09334, Edition Number: <a href="#">M-385777-01-2</a> EPA MRID No.: 48844154 Date: 2010-07-08 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.10 /02	[REDACTED]	2011	BYI 02960: 28-day immunotoxicity study in the female wistar rat by dietary administration [REDACTED] Report No.: SA 10353, Edition Number: <a href="#">M-414754-01-2</a> 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: <a href="#">M-414615-01-2</a> 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: <a href="#">M-411625-01-2</a> EPA MRID No.: 48843676 Date: 2011-07-28 GLP/GEP: yes, unpublished ...also filed: KIIA 7.2.1 /02	N	Bayer

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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.: MERV037-2, Edition Number: <a href="#">M-405497-03-1</a> 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: <a href="#">M-414981-01-1</a> 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: <a href="#">M-411693-01-2</a> 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.: MERV038-1, Edition Number: <a href="#">M-413425-02-1</a> 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

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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: <a href="#">M-421504-01-2</a> 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-2,614C]BYI 02960: Anaerobic soil metabolism Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERV094, Edition Number: <a href="#">M-421993-01-1</a> Date: 2012-01-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 7.1.2 /03	Woodard, D.	2012	[Pyridine-2,614C]BYI 02960: Anaerobic soil metabolism in Springfield, Nebraska (USA) soil Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERV006, Edition Number: <a href="#">M-424987-01-1</a> 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: <a href="#">M-405776-01-2</a> 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: <a href="#">M-414615-01-2</a> 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

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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: <a href="#">M-411625-01-2</a> 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.: MERV037-2, Edition Number: <a href="#">M-405497-03-1</a> 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: <a href="#">M-414981-01-1</a> 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: <a href="#">M-411693-01-2</a> EPA MRID No.: 48843681 Date: 2011-07-28 GLP/GEP: yes, unpublished ...also filed: KIIA 7.1.1 /05	N	Bayer

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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: <a href="#">M-413425-02-1</a> 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 Rhône-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C007660, Edition Number: <a href="#">M-196378-01-1</a> 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: <a href="#">M-413425-02-1</a> 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

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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: <a href="#">M-414245-01-1</a> 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: <a href="#">M-327492-01-2</a> 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: <a href="#">M-363541-01-1</a> EPA MRID No.: 48843663 Date: 2010-01-29 GLP/GEP: yes, unpublished	N	Bayer

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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: <a href="#">M-414615-01-2</a> 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
KIIA 7.4.2 /01	Liu, A. C.	1997	Soil adsorption/desorption study 6-chloronicotinic acid (Acetamiprid metabolite) Rhône-Poulenc Ag Company, RTP, NC, USA Bayer CropScience, Report No.: C007666, Edition Number: <a href="#">M-196394-01-1</a> 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: <a href="#">M-413836-01-2</a> 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., Viamão, Brazil Bayer CropScience, Report No.: 2301-LIX-344-11, Edition Number: <a href="#">M-424966-02-2</a> Date: 2012-02-08 ...Amended: 2012-06-05 GLP/GEP: yes, unpublished	N	Bayer



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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: <a href="#">M-309853-01-1</a> 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.: MERVP019, Edition Number: <a href="#">M-398952-01-1</a> Date: 2011-01-07 GLP/GEP: yes, unpublished ...also filed: KIIA 2.9.1 /01	N	Bayer
KIIA 7.6 /01	Hall, L. R.	2011	Phototransformation of [ <sup>14</sup> C]BYI 02960 in aqueous pH 7 buffer - amended report Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP042-1, Edition Number: <a href="#">M-418426-02-1</a> 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: <a href="#">M-414756-01-2</a> 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

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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.: MERV020, Edition Number: <a href="#">M-415368-01-1</a> 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.: MERV027, Edition Number: <a href="#">M-422616-01-1</a> Date: 2012-01-17 GLP/GEP: yes, unpublished	N	Bayer
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: <a href="#">M-422359-01-1</a> 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: <a href="#">M-426504-01-1</a> 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.: <a href="#">M-422371-01-1</a> , Edition Number: <a href="#">M-422371-01-1</a> EPA MRID No.: 48843691 Date: 2012-01-12 GLP/GEP: yes, unpublished	N	Bayer

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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: <a href="#">M-427167-01-1</a> 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: <a href="#">M-415753-01-1</a> 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: <a href="#">M-416651-01-1</a> Date: 2011-11-04 GLP/GEP: yes, unpublished	N	Bayer
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: <a href="#">M-417069-01-1</a> 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: <a href="#">M-418554-01-1</a> Date: 2011-11-29 GLP/GEP: yes, unpublished	N	Bayer

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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 /05	Kenji, M.	2001	Solubility of IC-0 in water Nisso Chemical Analysis Serv. Co., Ltd., Japan Nippon Soda, Report No.: C016679, Edition Number: <a href="#">M-202871-01-1</a> 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: <a href="#">M-416883-01-1</a> 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: <a href="#">M-416656-01-1</a> Date: 2011-11-04 GLP/GEP: yes, unpublished	N	Bayer
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: <a href="#">M-416624-01-1</a> 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: <a href="#">M-204285-01-1</a> Date: 2001-11-16 GLP/GEP: yes, unpublished	N	Bayer

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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: <a href="#">M-415757-01-1</a> 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: <a href="#">M-418626-01-1</a> 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: <a href="#">M-203097-01-1</a> Date: 2001-10-17 GLP/GEP: yes, unpublished	N	Bayer
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: <a href="#">M-420457-01-1</a> 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: <a href="#">M-418553-01-1</a> Date: 2011-11-24 GLP/GEP: yes, unpublished	N	Bayer

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**List of data relied on not submitted by the applicant but necessary for evaluation**

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

No additional information.